

1 Title: To amend the Federal Food, Drug, and Cosmetic Act to establish a time-limited  
2 conditional approval pathway, subject to specific obligations, for certain drugs and biological  
3 products, and for other purposes.  
4  
5

6 Be it enacted by the Senate and House of Representatives of the United States of America in  
7 Congress assembled,

## 8 SECTION 1. SHORT TITLE.

9 This Act may be cited as the “Promising Pathway Act 2.0”.

## 10 SEC. 2. CONDITIONAL APPROVAL OF NEW HUMAN 11 DRUGS FOR INDIVIDUALS WITH RARE, PROGRESSIVE, 12 AND SERIOUS DISEASES.

13 (a) In General.—Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21  
14 U.S.C. 351 et seq.) is amended by adding at the end of the following:

### 15 “SEC. 524C. CONDITIONAL APPROVAL OF HUMAN 16 DRUGS FOR INDIVIDUALS WITH RARE, PROGRESSIVE, 17 AND SERIOUS DISEASES.

18 “(a) Conditional Approval; Priority Review; Other Designations.—

19 “(1) IN GENERAL.—The sponsor of a drug may file with the Secretary an application for  
20 conditional approval of an eligible drug described in subsection (b). The Secretary shall  
21 approve or deny such application in accordance with subsection (c).

22 “(2) PRIORITY REVIEW.—The Secretary shall give priority review to an application for  
23 conditional approval of an eligible drug described in subsection (b).

24 “(3) OTHER DESIGNATIONS.—If a drug that is granted conditional approval under this  
25 section is eligible for a special designation by the Secretary under this Act, including as a  
26 drug for a rare disease or condition under section 526, all applicable benefits of such other  
27 designation shall be available for use under such conditional approval, including any tax  
28 credits and waiving of fees under chapter VII.

29 “(4) OTHER PROGRAMS.—A sponsor of a drug seeking conditional approval of such drug  
30 under this section may also seek designation, exclusivity, or approval, as applicable, of such  
31 drug under other applicable provisions of this Act or the Public Health Service Act, subject  
32 to the requirements of such provisions.

33 “(b) Eligibility.—

34 “(1) IN GENERAL.—A drug may be eligible for conditional approval under this section if  
35 such drug is intended to treat a disease or condition that is—

36 “(A) rapidly progressive, terminal, and has substantial unmet medical need, as  
37 determined by the Secretary; or

1 “(B) a rare disease or condition (as defined in section 526(a)(2)) that results in a  
2 substantially shortened lifespan, substantial reduction in quality of life, or other  
3 substantial adverse health effects, as determined by the Secretary.

4 “(2) EXCLUSION FROM ELIGIBILITY.—A drug that is intended to treat or respond to a  
5 material threat identified by the Secretary of Homeland Security under section 319F–  
6 2(c)(2)(A)(ii) shall not be eligible for conditional approval under this section.

7 “(c) Standard of Review for Conditional Approval.—

8 “(1) REQUIREMENTS.—The Secretary shall only approve an application for conditional  
9 approval of a drug under this section if—

10 “(A) the Secretary determines that—

11 “(i)(I) evidence of safety for the drug has been established by—

12 “(aa) the completion of a phase 1 clinical investigation of the drug (as  
13 described in section 312.21 of title 21, Code of Federal Regulations (or  
14 successor regulations)); or

15 “(bb) another demonstration of safety, as determined appropriate by the  
16 Secretary; and

17 “(II) evidence of effectiveness in treating a given indication (which indication  
18 is congruent with the eligibility requirements of subsection (b)), as established by  
19 an ongoing or completed phase 2 clinical investigation of the drug (as described  
20 in section 312.21 of title 21, Code of Federal Regulations (or successor  
21 regulations)); or

22 “(ii) in the case of a drug that is intended to treat a terminal pediatric rare  
23 disease or condition (as defined in section 526(a)(2)) that does not predominately  
24 affect adults—

25 “(I) evidence of safety for the drug has been established in accordance  
26 with clause (i)(I); and

27 “(II) the drug shows preliminary evidence of clinical effectiveness based  
28 upon studies in animal models; and

29 “(B) the sponsor has provided a written affirmation of the sponsor’s intent to pursue  
30 under section 505 of this Act or section 351 of the Public Health Service Act approval  
31 of the drug, which affirmation shall include a justification and a plan for pursuing such  
32 approval.

33 “(2) ROLLING, REAL-TIME REVIEW.—

34 “(A) IN GENERAL.—If the Secretary determines, after preliminary evaluation of data  
35 submitted by the sponsor, that a drug may meet the standard for conditional approval,  
36 the sponsor may submit portions of an application for conditional approval of a drug  
37 under this section for evaluation by the Secretary before the sponsor submits a  
38 complete application, which submission shall include—

39 “(i) a schedule for submission of information necessary to make the application  
40 complete; and

1 “(ii) a payment of any fee that may be required under section 736.

2 “(B) REVIEW.—The Secretary—

3 “(i) shall evaluate each application submitted under subparagraph (A) to assess  
4 whether such application is complete or ready to be filed; and

5 “(ii) may commence review of portions of such application for approval.

6 “(3) USE OF REAL-WORLD EVIDENCE.—

7 “(A) IN GENERAL.—The Secretary shall allow the use of real world evidence (as  
8 defined in section 505F(b)), including real world data used to generate real world  
9 evidence, and of external sources of data, including prospective or retrospective natural  
10 history data, to support an application for conditional approval under this section.

11 “(B) DATA INTEGRITY REQUIREMENTS.—In using evidence described in  
12 subparagraph (A) to support an application for conditional approval under this section,  
13 the sponsor shall consider the guidance of the Food and Drug Administration entitled  
14 ‘Data Standards for Drug and Biological Product Submissions Containing Real-World  
15 Data’ and dated December 2023 (or successor guidance).

16 “(d) FDA Authority to Withdraw Conditional Approval.—

17 “(1) IN GENERAL.—The Secretary may withdraw the conditional approval of a drug under  
18 this section if—

19 “(A) after adequate review of appropriate safety data, including data from an  
20 observational registry established under subsection (g), the Secretary determines that  
21 such data no longer supports conditional approval;

22 “(B) the Secretary determines that the application for conditional approval submitted  
23 under subsection (a)(1) contained an untrue statement of material fact; or

24 “(C) the Secretary determines that the drug is no longer eligible under subsection  
25 (b).

26 “(2) FDA EXAMINATION AUTHORITY.—

27 “(A) IN GENERAL.—For purposes determining whether to withdraw the conditional  
28 approval of a drug under paragraph (1), the Secretary may—

29 “(i) review any available clinical data made available through clinical trials or  
30 an observational registry under subsection (g), applicable to such drug; and

31 “(ii) determine whether the sponsor of such drug is in violation of a  
32 requirement established under paragraph (3) or (4) of section 505(o) or section  
33 505–1 with respect to the drug.

34 “(B) TRANSPARENCY.—

35 “(i) IN GENERAL.—The Secretary may require drug sponsors and observational  
36 registries under subsection (g) to submit the data described in subparagraph (A)  
37 for the purposes of the review under that subparagraph.

38 “(ii) FINES.—The Secretary may levy fines on sponsors and observational  
39 registries that do not comply with a request for data under clause (i) within such

1 reasonable timeframe as is established by the Secretary.

2 “(3) EFFECT OF WITHDRAWAL.—

3 “(A) AVAILABILITY TO NEW PATIENTS.—

4 “(i) IN GENERAL.—If a conditional approval is withdrawn under this subsection,  
5 the sponsor may not make the drug available to any new patients, but may  
6 continue to make such drug available to patients who started taking the drug prior  
7 to the date of withdrawal.

8 “(ii) EFFECT.—Nothing in this subparagraph shall be construed to require—

9 “(I) a patient to continue taking a conditionally approved drug if such  
10 patient decides to stop taking such drug; or

11 “(II) the sponsor to ensure such drug continues to be manufactured after  
12 the date of withdrawal.

13 “(B) CIVIL MONETARY PENALTY.—Any sponsor who makes available to new  
14 patients a drug for which conditional approval has been withdrawn under this  
15 subsection shall be subject to such civil monetary penalty as is determined by the  
16 Secretary.

17 “(4) WITHDRAWAL NOTICE.—Upon determining to withdraw the conditional approval of  
18 a drug under paragraph (1), the Secretary shall submit written notice to the sponsor of such  
19 drug and such withdrawal shall be effective on the date that is 14 days after the date of such  
20 submission of notice.

21 “(5) APPEALS.—Not later than 180 days after the date of enactment of the Promising  
22 Pathway Act 2.0, the Secretary, by rule, shall establish a process by which a sponsor of a  
23 drug for which conditional approval was withdrawn under paragraph (1) may appeal such  
24 withdrawal.

25 “(6) AUTOMATIC WITHDRAWAL.—

26 “(A) IN GENERAL.—If the sponsor of a drug that receives conditional approval under  
27 this section does not submit an application for renewal of such conditional approval  
28 under subsection (f)(2) by the deadline under that subsection, such conditional  
29 approval shall automatically be withdrawn in accordance with paragraph (3) on the  
30 date on which such conditional approval expires.

31 “(B) MARKETING REQUIREMENT.—If any drug that receives conditional approval  
32 under this section is not brought to market within 1 year of the date on which the  
33 conditional approval is granted, such conditional approval, along with any benefits  
34 described in subsection (a)(3), shall automatically be withdrawn in accordance with  
35 paragraph (3) on such date.

36 “(C) NO RIGHT TO APPEAL; EFFECT OF AUTOMATIC WITHDRAWAL.—

37 “(i) IN GENERAL.—A sponsor shall not have the right to appeal an automatic  
38 withdrawal under this paragraph.

39 “(ii) EFFECT.—The Secretary shall have no means or power to prevent an  
40 automatic withdrawal under this paragraph from occurring.

1 “(e) Labeling; Review of Materials.—

2 “(1) IN GENERAL.—Sponsors may not make available to patients a drug conditionally  
3 approved under this section, unless—

4 “(A) all labeling and advertising of such drug contains the statement ‘conditionally  
5 approved for a limited population’ in a prominent manner and adjacent to, and not  
6 more prominent than—

7 “(i) the proprietary name of such drug, if any; or

8 “(ii) if there is no proprietary name, the established name of such drug, if any,  
9 as defined in section 502(e)(3), or, in the case of a drug that is a biological  
10 product, the proper name, as defined by regulation; and

11 “(B) the prescribing information for the drug required by section 201.57 of title 21,  
12 Code of Federal Regulations (or any successor regulation) includes the following  
13 statement: ‘This drug is conditionally approved for use in a limited and specific  
14 population. This drug has not received full approval by the Food and Drug  
15 Administration. Conditional approval of this drug may be withdrawn at short notice.’.

16 “(2) SUBMISSION.—Not later than 45 days before such materials are distributed, all  
17 promotional, educational, and marketing materials for such drug shall be submitted to the  
18 Secretary for review.

19 “(3) PUBLIC LIST.—The Secretary shall maintain a list of all drugs conditionally approved  
20 under this section on a publicly accessible website. Such website shall briefly describe what  
21 each conditionally approved drugs is and list the 1 or more diseases or conditions for which  
22 the drug is indicated.

23 “(f) Renewal of Conditional Approval; Requirement to Bring Drug to Market.—

24 “(1) DURATION; RENEWALS.—The conditional approval for a drug under this section is  
25 effective for a 2-year period. The sponsor may request renewal of such conditional approval  
26 for up to 3 subsequent 2-year periods. Conditional approval with respect to a drug shall not  
27 exceed a total of 8 years from the initial date the drug was granted conditional approval.

28 “(2) APPLICATIONS FOR RENEWAL OF CONDITIONAL APPROVAL.—

29 “(A) IN GENERAL.—Except as provided in subparagraph (C), the sponsor of a drug  
30 seeking a renewal of conditional approval for such drug under this subsection shall  
31 submit to the Secretary, not later than 180 days before the date on which such  
32 conditional approval expires, an application that contains the applicable information  
33 described in paragraph (3) in a standardized format determined by the Secretary.

34 “(B) PROCESS FOR GRANTING RENEWALS.—Not later than 180 days after the date of  
35 enactment of the Promising Pathway Act 2.0, the Secretary, by rule, shall establish the  
36 process for granting a renewal under this subsection.

37 “(C) EXEMPTION FOR SMALL POPULATION DISEASES.—

38 “(i) IN GENERAL.—The Secretary shall exempt from the requirements of  
39 subparagraph (A) and paragraph (3) an application for a renewal of conditional  
40 approval for a drug under this subsection if the Secretary determines that the

1 population affected by the disease or condition that the drug is intended to treat  
2 does not support additional preliminary evidence of effectiveness (as defined in  
3 paragraph (3)(D)).

4 “(ii) APPLICATION FOR EXEMPTION.—Sponsors may submit an application for  
5 exemption under this subparagraph not later than 180 days before the date on  
6 which the conditional approval expires.

7 “(iii) APPLICATION PROCESS.—Not later than 180 days after the date of  
8 enactment of the Promising Pathway Act 2.0, the Secretary shall establish a  
9 standardized application process for purposes of this subparagraph.

10 “(iv) DEADLINE.—The Secretary shall approve or deny an application under  
11 this subparagraph before the date on which the conditional approval expires.

12 “(v) APPEALS.—Not later than 180 days after the date of enactment of the  
13 Promising Pathway Act 2.0, the Secretary shall establish process under which a  
14 sponsor may appeal a denial of an application under this subparagraph.

15 “(3) ADDITIONAL PRELIMINARY EVIDENCE OF EFFECTIVENESS.—The information  
16 described in this paragraph is the following:

17 “(A) FOR THE FIRST APPROVAL RENEWAL.—With respect to an application under  
18 paragraph (2) for the first renewal of conditional approval for a drug under this  
19 subsection, additional preliminary evidence of effectiveness of the drug, as compared  
20 to the evidence provided in the initial application for conditional approval for the drug  
21 under subsection (c).

22 “(B) FOR THE SECOND APPROVAL RENEWAL.—With respect to an application under  
23 paragraph (2) for the second renewal of conditional approval for a drug under this  
24 subsection, additional preliminary evidence of effectiveness of the drug, as compared  
25 to the evidence provided in the renewal application described in subparagraph (A).

26 “(C) FOR THE FINAL APPROVAL RENEWAL.—With respect to an application under  
27 paragraph (2) for the third renewal of conditional approval for a drug under this  
28 subsection, a written affirmation from the head of the drug’s review division of the  
29 Office of New Drugs or the Office of Therapeutic Products asserting that a third  
30 renewal is necessary—

31 “(i) for patients who have benefitted from such drug to retain access to such  
32 drug; and

33 “(ii) to generate additional preliminary evidence of effectiveness for the  
34 purposes of attaining approval under section 505 of this Act or section 351 of the  
35 Public Health Service Act.

36 “(D) DEFINITION.—In this paragraph, the term ‘preliminary evidence of  
37 effectiveness’ means—

38 “(i) clinical evidence generated by an ongoing or completed clinical trial  
39 conducted in accordance with section 11.22 of title 42, Code of Federal  
40 Regulations (or successor regulations);

41 “(ii) real-world evidence (as defined in section 505F(b)); or

1 “(iii) evidence from an observational registry under subsection (g).

2 “(4) DENIAL OF RENEWAL ON THE BASIS OF DATA FRAUD.—The Secretary may deny the  
3 application for renewal of conditional approval for a drug under this subsection if the  
4 Secretary, in conducting a review under subsection (d)(2), finds that the evidence provided  
5 in such application under subparagraph (A) or (B) of paragraph (3) was fraudulently  
6 manipulated by the applicable observational registry and that such application substantially  
7 relies on such data.

8 “(g) Observational Registries.—

9 “(1) ESTABLISHMENT.—

10 “(A) IN GENERAL.—Subject to subparagraph (C), the sponsor of a drug conditionally  
11 approved under this section shall establish an observational registry, for patients who  
12 are or will be treated with such drug, that pertains to the disease or condition that the  
13 drug is intended to treat.

14 “(B) REGISTRIES.—In establishing an observational registry for a drug under  
15 subparagraph (A), the sponsor may—

16 “(i) establish a new observational registry;

17 “(ii) use an existing observational registry that pertains to the disease or  
18 condition such drug is intended to treat;

19 “(iii) combine 1 or more existing observational registries that pertain to the  
20 disease or condition such drug is intended to treat with a new observational  
21 registry; or

22 “(iv) combine 2 or more existing observational registries that pertain to the  
23 disease or condition such drug is intended to treat.

24 “(C) APPROVAL OF REGISTRY AND RIGHT TO APPEAL.—Not later than 180 days after  
25 the date of enactment of the Promising Pathway Act 2.0, the Secretary shall  
26 establish—

27 “(i) a process to approve or deny the establishment of an observational registry  
28 under subparagraph (A); and

29 “(ii) a process for sponsors that received such a denial to appeal the denial.

30 “(2) REQUIREMENT FOR PATIENTS TO ENROLL IN OBSERVATIONAL REGISTRY.—

31 “(A) IN GENERAL.—A drug conditionally approved under this section shall not be  
32 made available to a patient unless such patient is enrolled in the applicable  
33 observational registry described in paragraph (1).

34 “(B) INFORMED CONSENT.—

35 “(i) IN GENERAL.—Prior to enrolling in an observational registry under  
36 subparagraph (A), a patient shall provide informed consent in accordance with  
37 clause (ii).

38 “(ii) APPLICATION OF CERTAIN REQUIREMENTS.—The requirements for  
39 informed consent under part 50 of subchapter A of chapter I of title 21, Code of

1 Federal Regulations (or successor regulations), shall apply to enrollment an  
2 observational registry under this paragraph.

3 “(3) SUBMISSION OF PATIENT DATA.—

4 “(A) IN GENERAL.—The sponsor of a drug conditionally approved under this section  
5 shall be responsible for obtaining and submitting patient data to the applicable  
6 observational registry described in paragraph (1).

7 “(B) SUBMISSION STANDARDS.—Not later than 180 days after date of enactment of  
8 the Promising Pathway Act 2.0, the Secretary shall establish data submission standards  
9 for sponsors to comply with for purposes of subparagraph (A) to ensure that registry  
10 data is consistent and clinically informed.

11 “(4) REQUIREMENTS FOR REGISTRIES.—An observational registry described in paragraph  
12 (1) for a drug conditionally approved under this section may be operated by the sponsor of  
13 such drug or, at the sponsor’s discretion, a third party, for-profit organization, or nonprofit  
14 organization.

15 “(5) RISK AND BENEFIT DATA.—

16 “(A) IN GENERAL.—The sponsor of a drug conditionally approved under this section  
17 shall submit relevant risk and benefit data to the applicable observational registry  
18 described in paragraph (1).

19 “(B) ONLINE PORTAL.—The Secretary shall operate an online portal on an existing  
20 website of the Secretary for sponsors to submit data described in subparagraph (A).

21 “(6) ACCESSIBILITY.—

22 “(A) IN GENERAL.—An observational registry described in paragraph (1) shall—

23 “(i) not later than 30 days after receipt of a request, provide patients (or their  
24 designated representatives) with access to such patient’s personal registry  
25 information; and

26 “(ii) provide approved researchers and medical professionals access to de-  
27 identified and aggregated data from the registry for the purposes of indication-  
28 and disease-specific and translational research into conditions and diseases  
29 relating to the disease or condition that the drug tracked by the observational  
30 registry is intended to treat.

31 “(B) APPROVED RESEARCHERS AND MEDICAL PROFESSIONALS.—Not later than 180  
32 days after the date of enactment of the Promising Pathway Act 2.0, the Secretary, by  
33 rule, shall establish a process for approving researchers and medical professionals for  
34 purposes of subparagraph (A)(ii).

35 “(7) EFFECT.—Nothing in this section shall be construed to modify or limit the  
36 Secretary’s authority to require for a drug conditionally approved under this section any  
37 type of postapproval study under any other provision of law, including sections 505(o)(3),  
38 505B, and 506.

39 “(h) Pursuit of a Different Indication.—

40 “(1) IN GENERAL.—In the case of a drug conditionally approved under this section for



1 which such approval was withdrawn under subsection (d), expired under subsection (f)(1),  
2 or was denied for renewal under subsection (f)(4), not later than 2 years after the date of  
3 withdrawal, expiration, or denial, as applicable, the sponsor of such drug shall have the  
4 opportunity to petition the Secretary to receive conditional approval of such drug, in  
5 accordance with this section, for a different indication.

6 “(2) PROCESS.—Not later than 180 days after the date of enactment of the Promising  
7 Pathway Act 2.0, the Secretary shall establish a process for petitions under paragraph (1).

8 “(i) Transition to Other Forms of Approval.—

9 “(1) IN GENERAL.—A drug that receives conditional approval under this section may be  
10 granted approval under section 505 of this Act or section 351 of the Public Health Service  
11 Act during the period in which such conditional approval is in effect. Effective on the date  
12 on which approval for such drug is granted under section 505 of this Act or section 351 of  
13 the Public Health Service Act, such conditional approval shall be automatically withdrawn  
14 in accordance with subsection (d)(3).

15 “(2) CONSIDERATION OF CERTAIN EVIDENCE.—In determining whether to approve under  
16 section 505 of this Act or section 351 of the Public Health Service Act a drug that has  
17 received conditional approval under this section, the Secretary may consider evidence from  
18 the observational registry for the drug under subsection (g).

19 “(j) Informed Consent.—

20 “(1) IN GENERAL.—Prior to being prescribed a drug conditionally approved under this  
21 section, a patient shall provide informed consent in accordance with paragraph (2).

22 “(2) APPLICATION OF CERTAIN REQUIREMENTS.—The requirements for informed consent  
23 under part 50 of subchapter A of chapter I of title 21, Code of Federal Regulations (or  
24 successor regulations), shall apply to drugs conditionally approved under this section.

25 “(3) OBSERVATIONAL REGISTRIES.—An observational registry established for a drug in  
26 accordance with subsection (g) may obtain, and maintain records of, informed consent of a  
27 patient on behalf of the drug sponsor, in accordance with paragraph (2).

28 “(4) COMMON RULE.—Drugs conditionally approved under this section shall comply with  
29 subpart A of part 46 of title 45, Code of Federal Regulations (commonly known as the  
30 ‘Common Rule’) (or successor regulations), if applicable.

31 “(k) Limitation on Liability.—With respect to any claim under State law relating to a drug  
32 made available pursuant to a grant of conditional approval under this section, no liability shall lie  
33 against a sponsor or manufacturer of the drug, or any health care provider who prescribes or  
34 administers the drug, absent intentional wrongdoing.

35 “(l) Report to Congress.—

36 “(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Promising  
37 Pathway Act 2.0, and once every 2 years thereafter, the Secretary, in collaboration with  
38 drug sponsors, shall submit a report to Congress on all drugs granted conditional approval  
39 under this section. Such report shall include—

40 “(A) an estimated number of patients treated with each such drug, and the number of  
41 patients tracked in an observational registry under subsection (g) with respect to each

1 such drug, if applicable;

2 “(B) a discussion, at an aggregate level, of the types and amounts of data obtained  
3 through observational registries under subsection (g), such as patient treatments and  
4 uses, length of use, side effects encountered, relevant biomarkers, scan results, cause of  
5 death and how long the patient lived, and adverse drug effects;

6 “(C) a list of all such drugs for which an application for approval under this section,  
7 or an application for an extension of conditional approval under this section, has been  
8 submitted; and

9 “(D) the number of all applications granted and denied conditional approval under  
10 this section.

11 “(2) SPONSOR PARTICIPATION.—Not later than 180 days before the date on which the  
12 Secretary submits a report under paragraph (1), the sponsor of a drug conditionally  
13 approved under this section shall provide to the Secretary the information described in  
14 subparagraphs (A) and (B) of paragraph (1), as applicable.

15 “(3) NOTICE AUTHORITY.—The Secretary may notify sponsors of drugs conditionally  
16 approved under this section and observational registries under subsection (g) as necessary to  
17 complete a report under paragraph (1).”.

18 (b) Conforming Amendment.—Section 505(a) of the Federal Food, Drug, and Cosmetic Act  
19 (21 U.S.C. 355(a)) is amended by inserting “, or there is in effect a conditional approval under  
20 section 524C with respect to such drug” before the period.

21 (c) Reimbursement.—

22 (1) PRIVATE HEALTH INSURERS.—Section 2719A of the Public Health Service Act (42  
23 U.S.C. 300gg–19a) is amended by adding at the end the following:

24 “(f) Coverage of Certain Drugs.—A group health plan or health insurance issuer offering  
25 group or individual health insurance coverage shall provide coverage for, and shall not impose  
26 any cost sharing requirements for, drugs conditionally approved under section 524C of the  
27 Federal Food, Drug, and Cosmetic Act for patients who have the disease or condition the drug is  
28 intended to treat.”.

29 (2) FEDERAL HEALTH CARE PROGRAMS.—The requirement under subsection (f) of section  
30 2719A of the Public Health Service Act (as added by paragraph (1)) shall apply with respect  
31 to coverage determinations under a Federal health care program (as defined in section  
32 1128B(f) of the Social Security Act (42 U.S.C. 1320a–7b(f))) in the same manner such  
33 requirement applies under such subsection (f).

34 (3) CONFORMING AMENDMENT.—Section 1927(k)(2)(A)(i) of the Social Security Act (42  
35 U.S.C. 1396r–8(k)(2)(A)(i)) is amended—

36 (A) by striking “or which” and inserting “, which”; and

37 (B) by inserting “, or which is conditionally approved under section 524C of such  
38 Act” before the semicolon.  
39