

1 (b) IMPROVING STATE AND LOCAL PUBLIC HEALTH
2 SECURITY.—Effective on October 1, 2011, section 319C–
3 1 of the Public Health Service Act (42 U.S.C. 247d–3a)
4 is amended—

5 (1) in subsection (f)—

6 (A) in paragraph (2), by inserting “and”
7 at the end;

8 (B) in paragraph (3), by striking “; and”
9 and inserting a period; and

10 (C) by striking paragraph (4);

11 (2) by striking subsection (h); and

12 (3) in subsection (i)—

13 (A) in paragraph (1)—

14 (i) by amending subparagraph (A) to
15 read as follows:

16 “(A) IN GENERAL.—For the purpose of
17 carrying out this section, there is authorized to
18 be appropriated \$632,900,000 for each of fiscal
19 years 2012 through 2016.”; and

20 (ii) by striking subparagraph (B); and

21 (B) in subparagraphs (C) and (D) of para-
22 graph (3), by striking “(1)(A)(i)(I)” each place
23 it appears and inserting “(1)(A)”.

24 (c) PARTNERSHIPS FOR STATE AND REGIONAL HOS-
25 PITAL PREPAREDNESS TO IMPROVE SURGE CAPACITY.—

1 Paragraph (1) of section 319C–2(j) of the Public Health
2 Service Act (42 U.S.C. 247d–3b(j)) is amended to read
3 as follows:

4 “(1) IN GENERAL.—For purposes of carrying
5 out this section, there is authorized to be appro-
6 priated \$378,000,000 for each of fiscal years 2012
7 through 2016.”.

8 (d) CDC PROGRAMS FOR COMBATING PUBLIC
9 HEALTH THREATS.—Section 319D of the Public Health
10 Service Act (42 U.S.C. 247d–4) is amended—

11 (1) by striking subsection (c); and

12 (2) in subsection (g), by striking “such sums as
13 may be necessary in each of fiscal years 2007
14 through 2011” and inserting “\$160,121,000 for
15 each of fiscal years 2012 through 2016”.

16 (e) DENTAL EMERGENCY RESPONDERS: PUBLIC
17 HEALTH AND MEDICAL RESPONSE.—

18 (1) ALL-HAZARDS PUBLIC HEALTH AND MED-
19 ICAL RESPONSE CURRICULA AND TRAINING.—Sec-
20 tion 319F(a)(5)(B) of the Public Health Service Act
21 (42 U.S.C. 247d–6(a)(5)(B)) is amended by striking
22 “public health or medical” and inserting “public
23 health, medical, or dental”.

1 (2) NATIONAL HEALTH SECURITY STRATEGY.—
2 Section 2802(b)(3) of the Public Health Service Act
3 (42 U.S.C. 300hh–1(b)(3)) is amended—

4 (A) in the matter preceding subparagraph
5 (A), by inserting “and which may include den-
6 tal health facilities” after “mental health facili-
7 ties”; and

8 (B) in subparagraph (D), by inserting
9 “(which may include such dental health as-
10 sets)” after “medical assets”.

11 (f) PROCUREMENT OF COUNTERMEASURES.—

12 (1) CONTRACT TERMS.—Clause (ii) of section
13 319F–2(c)(7)(C) of the Public Health Service Act
14 (42 U.S.C. 247d–6b(c)(7)(C)) is amended by adding
15 at the end the following:

16 “(X) GOVERNMENT PURPOSE.—
17 The contract shall provide a clear
18 statement of defined Government pur-
19 pose limited to uses related to a secu-
20 rity countermeasure, as defined in
21 paragraph (1)(B).”.

22 (2) REAUTHORIZATION OF THE SPECIAL RE-
23 SERVE FUND.—Section 319F–2 of the Public Health
24 Service Act (42 U.S.C. 247d–6b) is amended—

25 (A) in subsection (c)—

1 (i) by striking “special reserve fund
2 under paragraph (10)” each place it ap-
3 pears and inserting “special reserve fund
4 as defined in subsection (g)(5)”; and

5 (ii) by striking paragraphs (9) and
6 (10); and

7 (B) by adding at the end the following:

8 “(g) SPECIAL RESERVE FUND.—

9 “(1) AUTHORIZATION OF APPROPRIATIONS.—In
10 addition to amounts appropriated to the special re-
11 serve fund prior to the date of the enactment of this
12 subsection, there is authorized to be appropriated,
13 for the procurement of security countermeasures
14 under subsection (c) and for carrying out section
15 319L (relating to the Biomedical Advanced Research
16 and Development Authority), \$2,800,000,000 for the
17 period of fiscal years 2014 through 2018. Amounts
18 appropriated pursuant to the preceding sentence are
19 authorized to remain available until September 30,
20 2019.

21 “(2) NOTICE OF INSUFFICIENT FUNDS.—Not
22 later than 15 days after any date on which the Sec-
23 retary determines that the amount of funds in the
24 special reserve fund available for procurement is less
25 than \$1,500,000,000, the Secretary shall submit to

1 the relevant committees of Congress a report detail-
2 ing the amount of such funds available for procure-
3 ment and the impact such funding will have—

4 “(A) in meeting the security counter-
5 measure needs identified under this section; and

6 “(B) on the annual Countermeasure Imple-
7 mentation Plan under section 2811(d).

8 “(3) USE OF SPECIAL RESERVE FUND FOR AD-
9 VANCED RESEARCH AND DEVELOPMENT.—The Sec-
10 retary may utilize not more than 30 percent of the
11 amounts authorized to be appropriated under para-
12 graph (1) to carry out section 319L (related to the
13 Biomedical Advanced Research and Development
14 Authority). Amounts authorized to be appropriated
15 under this subsection to carry out section 319L are
16 in addition to amounts otherwise authorized to be
17 appropriated to carry out such section.

18 “(4) RESTRICTIONS ON USE OF FUNDS.—
19 Amounts in the special reserve fund shall not be
20 used to pay—

21 “(A) costs other than payments made by
22 the Secretary to a vendor for advanced develop-
23 ment (under section 319L) or for procurement
24 of a security countermeasure under subsection
25 (c)(7); and

1 “(B) any administrative expenses, includ-
2 ing salaries.

3 “(5) DEFINITION.—In this section, the term
4 ‘special reserve fund’ means the ‘Biodefense Coun-
5 termeasures’ appropriations account, any appropria-
6 tion made available pursuant to section 521(a) of
7 the Homeland Security Act of 2002, and any appropria-
8 tion made available pursuant to paragraph (1) of
9 this paragraph.”.

10 (g) EMERGENCY SYSTEM FOR ADVANCE REGISTRA-
11 TION OF HEALTH PROFESSIONS VOLUNTEERS.—Section
12 319I(k) of the Public Health Service Act (42 U.S.C.
13 247d–7b(k)) is amended by striking “are authorized to be
14 appropriated \$2,000,000 for fiscal year 2002, and such
15 sums as may be necessary for each of the fiscal years 2003
16 through 2011” and inserting “is authorized to be appro-
17 priated \$5,900,000 for each of fiscal years 2012 through
18 2016”.

19 (h) BIOMEDICAL ADVANCED RESEARCH AND DEVEL-
20 OPMENT AUTHORITY.—

21 (1) TRANSACTION AUTHORITIES.—Section
22 319L(c)(5) of the Public Health Service Act (42
23 U.S.C. 247d–7e(c)(5)) is amended by adding at the
24 end the following:

1 “(G) GOVERNMENT PURPOSE.—In award-
2 ing contracts, grants, and cooperative agree-
3 ments under this section, the Secretary shall
4 provide a clear statement of defined Govern-
5 ment purpose related to activities included in
6 subsection (a)(6)(B) for a qualified counter-
7 measure or qualified pandemic or epidemic
8 product.”.

9 (2) BIODEFENSE MEDICAL COUNTERMEASURE
10 DEVELOPMENT FUND.—Paragraph (2) of section
11 319L(d) of the Public Health Service Act (42 U.S.C.
12 247d–7e(d)) is amended to read as follows:

13 “(2) FUNDING.—To carry out the purposes of
14 this section, there is authorized to be appropriated
15 to the Fund \$415,000,000 for each of fiscal years
16 2012 through 2016, the amounts to remain available
17 until expended.”.

18 (3) CONTINUED INAPPLICABILITY OF CERTAIN
19 PROVISIONS.—Section 319L(e)(1)(C) of the Public
20 Health Service Act (42 U.S.C. 247d–7e(e)(1)(C)) is
21 amended by striking “7 years” and inserting “10
22 years”.

23 (i) NATIONAL DISASTER MEDICAL SYSTEM.—Section
24 2812 of the Public Health Service Act (42 U.S.C. 300hh–
25 11) is amended—

1 (1) in subsection (a)(3), by adding at the end
2 the following:

3 “(D) ADMINISTRATION.—The Secretary
4 may determine and pay claims for reimburse-
5 ment for services under subparagraph (A) di-
6 rectly or by contract providing for payment in
7 advance or by way of reimbursement.”; and

8 (2) in subsection (g), by striking “such sums as
9 may be necessary for each of the fiscal years 2007
10 through 2011” and inserting “\$56,000,000 for each
11 of fiscal years 2012 through 2016”.

12 (j) VOLUNTEER MEDICAL RESERVE CORPS.—Section
13 2813(i) of the Public Health Service Act (42 U.S.C.
14 300hh–15(i)) is amended by striking “\$22,000,000 for fis-
15 cal year 2007, and such sums as may be necessary for
16 each of fiscal years 2008 through 2011” and inserting
17 “\$11,900,000 for each of fiscal years 2012 through
18 2016”.

19 (k) EXTENSION OF LIMITED ANTITRUST EXEMP-
20 TION.—Section 405(b) of the Pandemic and All-Hazard
21 Preparedness Act (42 U.S.C. 247d–6a note) is amended
22 by striking “6-year” and inserting “10-year”.

1 **SEC. 3. COORDINATION BY ASSISTANT SECRETARY FOR**
2 **PREPAREDNESS AND RESPONSE.**

3 (a) IN GENERAL.—Section 2811 of the Public Health
4 Service Act (42 U.S.C. 300hh–10) is amended—

5 (1) in subsection (b)(3)—

6 (A) by inserting “stockpiling, distribution,”
7 before “and procurement”; and

8 (B) by inserting “, security measures (as
9 defined in section 319F–2,” after “qualified
10 countermeasures (as defined in section 319F–
11 1)”;

12 (2) in subsection (b)(4), by adding at the end
13 the following:

14 “(D) IDENTIFICATION OF INEFFICIEN-
15 CIES.—Identify gaps, duplication, and other in-
16 efficiencies in public health preparedness activi-
17 ties and the actions necessary to overcome these
18 obstacles.

19 “(E) DEVELOPMENT OF COUNTER-
20 MEASURE IMPLEMENTATION PLAN.—Lead the
21 development of a coordinated Countermeasure
22 Implementation Plan under subsection (d).

23 “(F) COUNTERMEASURES BUDGET ANAL-
24 YSIS.—Oversee the development of a com-
25 prehensive, cross-cutting 5-year budget analysis

1 with respect to activities described in paragraph
2 (3)—

3 “(i) to inform prioritization of re-
4 sources; and

5 “(ii) to ensure that challenges are
6 adequately addressed.

7 “(G) GRANT PROGRAMS FOR MEDICAL AND
8 PUBLIC HEALTH PREPAREDNESS CAPABILI-
9 TIES.—Coordinate, in consultation with the
10 Secretary of Homeland Security, grant pro-
11 grams of the Department of Health and
12 Human Services relating to medical and public
13 health preparedness capabilities and the ability
14 of local communities to respond to public health
15 emergencies, including by—

16 “(i) coordinating the program require-
17 ments, timelines, and measurable goals of
18 such grant programs; and

19 “(ii) establishing a system for gath-
20 ering and disseminating best practices
21 among grant recipients.”;

22 (3) by amending subsection (c) to read as fol-
23 lows:

24 “(c) FUNCTIONS.—The Assistant Secretary for Pre-
25 paredness and Response shall—

1 “(1) have authority over and responsibility
2 for—

3 “(A) the National Disaster Medical System
4 (in accordance with section 301 of the Pan-
5 demic and All-Hazards Preparedness Act);

6 “(B) the Hospital Preparedness Coopera-
7 tive Agreement Program pursuant to section
8 319C-2;

9 “(C) the Biomedical Advanced Research
10 and Development Authority under section
11 319L;

12 “(D) the Medical Reserve Corps pursuant
13 to section 2813;

14 “(E) the Emergency System for Advance
15 Registration of Volunteer Health Professionals
16 pursuant to section 319I;

17 “(F) the Strategic National Stockpile; and

18 “(G) the Cities Readiness Initiative; and

19 “(2) assume other duties as determined appro-
20 priate by the Secretary.”; and

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

22 “(d) COUNTERMEASURE IMPLEMENTATION PLAN.—
23 Not later than 6 months after the date of enactment of
24 this subsection, and annually thereafter, the Assistant
25 Secretary for Preparedness and Response shall submit

1 through the Secretary to relevant congressional commit-
2 tees a Countermeasure Implementation Plan that—

3 “(1) describes the chemical, biological, radio-
4 logical, and nuclear threats facing the Nation and
5 the corresponding efforts to develop qualified coun-
6 termeasures (as defined in section 319F–1), security
7 countermeasures (as defined in section 319F–2), or
8 qualified pandemic or epidemic products (as defined
9 in section 319F–3) for each threat;

10 “(2) evaluates the progress of all activities with
11 respect to such countermeasures or products, includ-
12 ing research, advanced research, development, pro-
13 curement, stockpiling, deployment, and utilization;

14 “(3) identifies and prioritizes near-, mid-, and
15 long-term needs with respect to such counter-
16 measures or products to address chemical, biological,
17 radiological, and nuclear threats;

18 “(4) identifies, with respect to each category of
19 threat, a summary of all advanced development and
20 procurement awards, including the time elapsed
21 from the issuance of the initial solicitation or re-
22 quest for a proposal to the adjudication (such as the
23 award, denial of award, or solicitation termination),
24 and including—

1 “(A) projected timelines for development
2 and procurement of such countermeasures or
3 products;

4 “(B) clearly defined goals, benchmarks,
5 and milestones for each countermeasure or
6 product, including information on the number
7 of doses required, the intended use of the coun-
8 termeasure or product, and the required coun-
9 termeasure or product characteristics; and

10 “(C) projected needs with regard to the re-
11 plenishment of the Strategic National Stockpile;

12 “(5) evaluates progress made in meeting the
13 goals, benchmarks, and milestones identified under
14 paragraph (4);

15 “(6) reports on the amount of funds available
16 for procurement in the special reserve fund as de-
17 fined in section 319F-2(g)(5) and the impact this
18 funding will have on meeting the requirements under
19 section 319F-2; and

20 “(7) incorporates input from Federal, State,
21 local, and tribal stakeholders.”.

22 (b) CONSULTATION IN AUTHORIZING MEDICAL
23 PRODUCTS FOR USE IN EMERGENCIES.—Subsection (c)
24 of section 564 of the Federal Food, Drug, and Cosmetic
25 Act (21 U.S.C. 360bbb-3) is amended by striking “con-

1 sultation with the Director of the National Institutes of
2 Health” and inserting “consultation with the Assistant
3 Secretary for Preparedness and Response, the Director of
4 the National Institutes of Health,”.

5 **SEC. 4. ELIMINATING DUPLICATIVE PROJECT BIOSHIELD**
6 **REPORTS.**

7 Section 5 of the Project Bioshield Act of 2004 (42
8 U.S.C. 247d–6c) is repealed.

9 **SEC. 5. ACCELERATE COUNTERMEASURE DEVELOPMENT**
10 **BY STRENGTHENING FDA’S ROLE IN REVIEW-**
11 **ING PRODUCTS FOR NATIONAL SECURITY**
12 **PRIORITIES.**

13 (a) IN GENERAL.—Section 565 of the Federal Food,
14 Drug, and Cosmetic Act (21 U.S.C. 360bbb–4) is amend-
15 ed to read as follows:

16 **“SEC. 565. COUNTERMEASURE DEVELOPMENT AND RE-**
17 **VIEW.**

18 “(a) COUNTERMEASURES AND PRODUCTS.—The
19 countermeasures and products referred to in this sub-
20 section are—

21 “(1) qualified countermeasures (as defined in
22 section 319F–1 of the Public Health Service Act);

23 “(2) security countermeasures (as defined in
24 section 319F–2 of such Act); and

1 “(3) qualified pandemic or epidemic products
2 (as defined in section 319F–3 of such Act).

3 “(b) IN GENERAL.—

4 “(1) INVOLVEMENT OF FDA PERSONNEL IN
5 INTERAGENCY ACTIVITIES.—For the purpose of ac-
6 celerating the development, stockpiling, approval,
7 and licensure of countermeasures and products re-
8 ferred to in subsection (a), the Secretary shall ex-
9 pand the involvement of Food and Drug Administra-
10 tion personnel in interagency activities with the As-
11 sistant Secretary for Preparedness and Response
12 (including the Biomedical Advanced Research and
13 Development Authority), the Centers for Disease
14 Control and Prevention, the National Institutes of
15 Health, and the Department of Defense.

16 “(2) TECHNICAL ASSISTANCE.—The Secretary
17 shall establish within the Food and Drug Adminis-
18 tration a team of experts on manufacturing and reg-
19 ulatory activities (including compliance with current
20 Good Manufacturing Practice) to provide both off-
21 site and on-site technical assistance to the manufac-
22 turers of countermeasures and products referred to
23 in subsection (a).

24 “(c) AGENCY INTERACTION WITH SECURITY COUN-
25 TERMEASURE SPONSORS.—

1 “(1) COUNTERMEASURE DEVELOPMENT PRO-
2 GRAM.—

3 “(A) IN GENERAL.—For each security
4 countermeasure (as defined in section 319F-2
5 of the Public Health Service Act) that is pro-
6 cured under such section 319F-2, the Secretary
7 shall initiate, in consultation with the security
8 countermeasure sponsor (referred to in this sec-
9 tion as the ‘countermeasure sponsor’), a pro-
10 gram of frequent scientific feedback and inter-
11 actions regarding the process of developing such
12 countermeasure, including—

13 “(i) regular meetings between appro-
14 priate Food and Drug Administration per-
15 sonnel and the countermeasure sponsor
16 during the process of developing the coun-
17 termeasure, to be scheduled within 45 days
18 after attainment of each milestone identi-
19 fied pursuant to subparagraph (B)(iv)(I)
20 in the regulatory management plan for the
21 countermeasure;

22 “(ii) written feedback from the Food
23 and Drug Administration within 30 days
24 after submission of a request for feedback
25 pursuant to subparagraph (B)(iv)(II) in

1 the regulatory management plan for the
2 countermeasure;

3 “(iii) written feedback from the Food
4 and Drug Administration within 30 days
5 after submission by the countermeasure
6 sponsor of a study report that is consid-
7 ered to be complete pursuant to subpara-
8 graph (B)(iv)(III) in the regulatory man-
9 agement plan for the countermeasure;

10 “(iv) at the request of the Director of
11 the Biomedical Advanced Research and
12 Development Authority, participation in
13 meetings of such Authority on the develop-
14 ment of the countermeasure; and

15 “(v) other meetings, including on-site
16 meetings, as appropriate.

17 “(B) REGULATORY MANAGEMENT PLAN.—

18 In carrying out the program under subpara-
19 graph (A), the Secretary shall, in consultation
20 with the countermeasure sponsor, develop a
21 written regulatory management plan for each
22 security countermeasure (as defined in section
23 319F–2 of the Public Health Service Act) that
24 is procured under such section 319F–2. The
25 regulatory management plan shall be completed

1 within 60 days of issuance of a contract for the
2 countermeasure under such section 319F–2 or,
3 for a countermeasure that was procured under
4 such section 319F–2 before the date of the en-
5 actment of the Pandemic and All-Hazards Pre-
6 paredness Reauthorization Act of 2011, within
7 60 days after such date of enactment. The reg-
8 ulatory management plan for a security coun-
9 termeasure shall include—

10 “(i) an assessment of the current reg-
11 ulatory status, an assessment of known
12 scientific gaps, and a proposed pathway to
13 approval or licensure of the counter-
14 measure;

15 “(ii) feedback from the Food and
16 Drug Administration regarding the data
17 required to support delivery of the counter-
18 measure to the Strategic National Stock-
19 pile;

20 “(iii) feedback from the Food and
21 Drug Administration regarding data re-
22 quired to support submission of a proposed
23 agreement on the design and size of clin-
24 ical trials for review under section
25 505(b)(5)(B); and

1 “(iv) an agreement between the Food
2 and Drug Administration and the counter-
3 measure sponsor to identify—

4 “(I) developmental milestones
5 that will trigger meetings between the
6 Administration and the sponsor;

7 “(II) the process for requesting
8 and receiving written or oral feedback
9 from the Administration; and

10 “(III) the type of study reports
11 that will be considered by the Admin-
12 istration to be complete.

13 “(C) APPLICABILITY TO CERTAIN QUALI-
14 FIED PANDEMIC OR EPIDEMIC PRODUCTS.—The
15 Secretary may, with respect to qualified pan-
16 demic or epidemic products (as defined in sec-
17 tion 319F–3 of the Public Health Service Act)
18 for which a contract for advanced research and
19 development is entered into under section 319L
20 of such Act, choose to apply the provisions of
21 subparagraphs (A) and (B) to the same extent
22 and in the same manner as such provisions
23 apply with respect to security countermeasures.

24 “(d) FINAL GUIDANCE ON DEVELOPMENT OF ANI-
25 MAL MODELS.—

1 “(1) IN GENERAL.—Not later than 1 year after
2 the date of the enactment of the Pandemic and All-
3 Hazards Preparedness Reauthorization Act of 2011,
4 the Secretary shall provide final guidance to indus-
5 try regarding the development of animal models to
6 support approval or licensure of countermeasures
7 and products referred to in subsection (a) when
8 human efficacy studies are not ethical or feasible.

9 “(2) AUTHORITY TO EXTEND DEADLINE.—The
10 Secretary may extend the deadline for providing
11 final guidance under paragraph (1) by not more
12 than 6 months upon submission by the Secretary of
13 a report on the status of such guidance to the rel-
14 evant congressional committees.

15 “(e) ANNUAL REPORT.—Not later than January 1,
16 2012, and every January 1 thereafter, the Secretary shall
17 submit a report to the Committee on Energy and Com-
18 merce of the House of Representatives and the Committee
19 on Health, Education, Labor, and Pensions of the Senate
20 that, with respect to the preceding fiscal year, includes—

21 “(1) the number of full-time equivalent employ-
22 ees of the Food and Drug Administration who di-
23 rectly support the review of countermeasures and
24 products referred to in subsection (a);

1 “(2) estimates of funds obligated by the Food
2 and Drug Administration for review of such counter-
3 measures and products;

4 “(3) the number of regulatory teams at the
5 Food and Drug Administration specific to such
6 countermeasures and products and, for each such
7 team, the assigned products, classes of products, or
8 technologies;

9 “(4) the length of time between each request by
10 the sponsor of such a countermeasure or product for
11 information and the provision of such information by
12 the Food and Drug Administration;

13 “(5) the number, type, and frequency of official
14 interactions between the Food and Drug Adminis-
15 tration and—

16 “(A) sponsors of a countermeasure or
17 product referred to in subsection (a); or

18 “(B) another agency engaged in develop-
19 ment or management of portfolios for such
20 countermeasures or products, including the
21 Centers for Disease Control and Prevention, the
22 Biomedical Advanced Research and Develop-
23 ment Authority, the National Institutes of
24 Health, and the appropriate agencies of the De-
25 partment of Defense;

1 “(6) any other measure that, as determined by
2 the Secretary, is appropriate to determine the effi-
3 ciency of the regulatory teams described in para-
4 graph (3); and

5 “(7) the regulatory science priorities which the
6 Food and Drug Administration is addressing and
7 the progress made on these priorities.”.

8 (b) DISCUSSIONS BETWEEN FDA AND SPONSOR ON
9 DESIGN AND SIZE OF ANIMAL AND CLINICAL TRIALS IN-
10 TENDED TO FORM THE PRIMARY BASIS OF AN EFFEC-
11 TIVENESS CLAIM WHEN HUMAN EFFICACY STUDIES ARE
12 NOT ETHICAL OR FEASIBLE.—Subparagraph (B) of sec-
13 tion 505(b)(5) of the Federal Food, Drug, and Cosmetic
14 Act (21 U.S.C. 355(b)(5)) is amended to read as follows:

15 “(B)(i) The Secretary shall meet with a sponsor of
16 an investigation or an applicant for approval for a drug
17 under this subsection or section 351 of the Public Health
18 Service Act if the sponsor or applicant makes a reasonable
19 written request for a meeting for the purpose of reaching
20 agreement on the design and size of—

21 “(I) clinical trials intended to form the primary
22 basis of an effectiveness claim; or

23 “(II) animal and clinical trials intended to form
24 the primary basis of an effectiveness claim when
25 human efficacy studies are not ethical or feasible.

1 “(ii) The sponsor or applicant shall provide informa-
2 tion necessary for discussion and agreement on the design
3 and size of the clinical trials. Minutes of any such meeting
4 shall be prepared by the Secretary and made available to
5 the sponsor or applicant upon request.”.

