(ii) with an outpatient clinical capacity equal to not less than twice the outpatient clinical capacity, with respect to acquired immune deficiency syndrome, possessed by the Clinical Center of the National Institutes of Health on June 1, 1988; and

(B) with such personnel, such administrative support, and such other support services as may be necessary.

(2) Facilities, personnel, administrative support, and other support services provided pursuant to paragraph (1) shall be in addition to the number or level of facilities, personnel, administrative support, and other support services that otherwise would be available at the Clinical Center at the National Institutes of Health for the provision of clinical care for individuals with diseases or disorders.

(c) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary.

(July 1, 1944, ch. 373, title XXIII, § 2311, as added Pub. L. 100–607, title II, § 201(4), Nov. 4, 1988, 102 Stat. 3066; amended Pub. L. 103–43, title XVIII, § 1811(2), June 10, 1993,107 Stat. 199.)

PRIOR PROVISIONS

A prior section 300cc–11, act July 1, 1944, § 2312, was successively renumbered by subsequent acts and transferred, see section 238i of this title.

AMENDMENTS

1993—Subsec. (a)(1). Pub. L. 103–43 inserted before semicolon at end ", including evaluations of methods of diagnosing immune deficiency and evaluations of methods of predicting, diagnosing, preventing, and treating opportunistic cancers and infectious diseases".

§ 300cc–12. Use of investigational new drugs with respect to acquired immune deficiency syndrome

(a) Encouragement of applications with respect to clinical trials

(1) If, in the determination of the Secretary, there is preliminary evidence that a new drug has effectiveness in humans with respect to the prevention or treatment of acquired immune deficiency syndrome, the Secretary shall, through statements published in the Federal Register—

(A) announce the fact of such determination; and

(B) with respect to the new drug involved, encourage an application for an exemption for investigational use of the new drug under regulations issued under section 355(i) of title 21.

(2)(A) The AIDS Research Advisory Committee established pursuant to section 300cc–3 of this title shall make recommendations to the Secretary with respect to new drugs appropriate for determinations described in paragraph (1).

(B) The Secretary shall, as soon as is practicable, determine the merits of recommendations received by the Secretary pursuant to subparagraph (A).

(b) Encouragement of applications with respect to treatment use in circumstances other than clinical trials

(1) In the case of a new drug with respect to which the Secretary has made a determination described in subsection (a) of this section and with respect to which an exemption is in effect for purposes of section 355(i) of title 21, the Secretary shall—

(A) as appropriate, encourage the sponsor of the investigation of the new drug to submit to the Secretary, in accordance with regulations issued under such section, an application to use the drug in the treatment of individuals—

(i) who are infected with the etiologic agent for acquired immune deficiency syndrome; and

(ii) who are not participating in the clinical trials conducted pursuant to such exemption; and

(B) if such an application is approved, encourage, as appropriate, licensed medical practitioners to obtain, in accordance with such regulations, the new drug from such sponsor for the purpose of treating such individuals.

(2) If the sponsor of the investigation of a new drug described in paragraph (1) does not submit to the Secretary an application described in such paragraph (relating to treatment use), the Secretary shall, through statements published in the Federal Register, encourage, as appropriate, licensed medical practitioners to submit to the Secretary such applications in accordance with regulations described in such paragraph.

(c) Technical assistance with respect to treatment use

In the case of a new drug with respect to which the Secretary has made a determination described in subsection (a) of this section, the Secretary may, directly or through grants or contracts, provide technical assistance with respect to the process of—

(1) submitting to the Secretary applications for exemptions described in paragraph (1)(B) of such subsection;

(2) submitting to the Secretary applications described in subsection (b) of this section; and

(3) with respect to sponsors of investigations of new drugs, facilitating the transfer of new drugs from such sponsors to licensed medical practitioners.

(d) "New drug" defined

For purposes of this section, the term "new drug" has the meaning given such term in section 321 of title 21.

(July 1, 1944, ch. 373, title XXIII, § 2312, as added Pub. L. 100–607, title II, § 201(4), Nov. 4, 1988, 102 Stat. 3066; amended Pub. L. 103–43, title XX, § 2008(d)(2), June 10, 1993, 107 Stat. 212.)

PRIOR PROVISIONS

A prior section 300cc–12, act July 1, 1944, § 2313, was successively renumbered by subsequent acts and transferred, see section 238j of this title.

AMENDMENTS

1993—Subsec. (a)(2)(A). Pub. L. 103–43 substituted "AIDS Research Advisory Committee" for "AIDS Clinical Research Review Committee".

§ 300cc–13. Terry Beirn Community-Based AIDS Research Initiative

(a) In general

After consultation with the Commissioner of Food and Drugs, the Director of the National In-