reports, including recommendations therein, regarding the topics addressed in the reports under this section, including with respect to—

''(A) improving public access to information from pediatric studies conducted under such sections 355a and 355c of this title; and

''(B) improving the timeliness of pediatric studies and pediatric study planning under such sections 355a and 355c of this title.''

Statutory Notes and Related Subsidiaries

RULE OF CONSTRUCTION

Nothing in amendment by Pub. L. 115–52 to limit the authority of the Secretary of Health and Human Services to issue written requests under section 355a of this title or section 262(m) of Title 42, The Public Health and Welfare, or to negotiate or implement amendments to such requests proposed by applicants, see section 504(e) of Pub. L. 115–52, set out as a note under section 355c of this title.

DEFINITION OF ''SECRETARY''

The term ''Secretary'' as used in this section means the Secretary of Health and Human Services, see section 503 of Pub. L. 112–144, set out as a note under section 355a of this title.

§ 355d. Internal committee for review of pediatric plans, assessments, deferrals, deferral extensions, and waivers

The Secretary shall establish an internal committee within the Food and Drug Administration to carry out the activities as described in sections 355a(f) and 355c(f) of this title. Such internal committee shall include employees of the Food and Drug Administration, with expertise in pediatrics (including representation from the Office of Pediatric Therapeutics), biopharmacology, statistics, chemistry, legal issues, pediatric ethics, neonatology, and the appropriate expertise pertaining to the pediatric product under review, such as expertise in child and adolescent psychiatry or pediatric rare diseases, and other individuals designated by the Secretary.

(June 25, 1938, ch. 675, § 505C, as added Pub. L. 110–85, title IV, § 403, Sept. 27, 2007, 121 Stat. 875; amended Pub. L. 112–144, title V, § 509(c), July 9, 2012, 126 Stat. 1049; Pub. L. 115–52, title V, § 505(f), Aug. 18, 2017, 131 Stat. 1047.)

Editorial Notes

AMENDMENTS

2017—Pub. L. 115–52 inserted ''or pediatric rare diseases'' after ''psychiatry''.

2012—Pub. L. 112–144 inserted ''deferral extensions,'' after ''deferrals,'' in section catchline and ''neonatology,'' after ''pediatric ethics,'' in text.

§ 355e. Pharmaceutical security

(a) In general

The Secretary shall develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs.

(b) Standards development

(1) In general

The Secretary shall, in consultation with the agencies specified in paragraph (4), manufacturers, distributors, pharmacies, and other supply chain stakeholders, prioritize and develop standards for the identification, validation, authentication, and tracking and tracing of prescription drugs.

(2) Standardized numeral identifier

Not later than 30 months after September 27, 2007, the Secretary shall develop a standardized numerical identifier (which, to the extent practicable, shall be harmonized with international consensus standards for such an identifier) to be applied to a prescription drug at the point of manufacturing and repackaging (in which case the numerical identifier shall be linked to the numerical identifier applied at the point of manufacturing) at the package or pallet level, sufficient to facilitate the identification, validation, authentication, and tracking and tracing of the prescription drug.

(3) Promising technologies

The standards developed under this subsection shall address promising technologies, which may include—

(A) radio frequency identification technology;

(B) nanotechnology;

(C) encryption technologies; and

(D) other track-and-trace or authentication technologies.

(4) Interagency collaboration

In carrying out this subsection, the Secretary shall consult with Federal health and security agencies, including—

(A) the Department of Justice;

(B) the Department of Homeland Security;

(C) the Department of Commerce; and

(D) other appropriate Federal and State agencies.

(c) Inspection and enforcement

(1) In general

The Secretary shall expand and enhance the resources and facilities of agency components of the Food and Drug Administration involved with regulatory and criminal enforcement of this chapter to secure the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs including biological products and active pharmaceutical ingredients from domestic and foreign sources.

(2) Activities

The Secretary shall undertake enhanced and joint enforcement activities with other Federal and State agencies, and establish regional capacities for the validation of prescription drugs and the inspection of the prescription drug supply chain.

(d) Definition

In this section, the term ''prescription drug'' means a drug subject to section 353(b)(1) of this title.

(June 25, 1938, ch. 675, § 505D, as added Pub. L. 110–85, title IX, § 913, Sept. 27, 2007, 121 Stat. 952.)

§ 355f. Extension of exclusivity period for new qualified infectious disease products

(a) Extension

If the Secretary approves an application pursuant to section 355 of this title for a drug that

has been designated as a qualified infectious disease product under subsection (d), the 4- and 5-year periods described in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of section 355 of this title, the 3-year periods described in clauses (iii) and (iv) of subsection (c)(3)(E) and clauses (iii) and (iv) of subsection (j)(5)(F) of section 355 of this title, or the 7-year period described in section 360cc of this title, as applicable, shall be extended by 5 years.

(b) Relation to pediatric exclusivity

Any extension under subsection (a) of a period shall be in addition to any extension of the period under section 355a of this title with respect to the drug.

(c) Limitations

Subsection (a) does not apply to the approval of—

(1) a supplement to an application under section 355(b) of this title for any qualified infectious disease product for which an extension described in subsection (a) is in effect or has expired;

(2) a subsequent application filed with respect to a product approved under section 355 of this title for a change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength;

(3) a product that does not meet the definition of a qualified infectious disease product under subsection (g) based upon its approved uses; or

(4) an application pursuant to section 262(a) of title 42.

(d) Designation

(1) In general

The manufacturer or sponsor of a drug may request the Secretary to designate a drug as a qualified infectious disease product at any time before the submission of an application under section 355(b) of this title or section 262(a) of title 42 for such drug. The Secretary shall, not later than 60 days after the submission of such a request, determine whether the drug is a qualified infectious disease product.

(2) Limitation

Except as provided in paragraph (3), a designation under this subsection shall not be withdrawn for any reason, including modifications to the list of qualifying pathogens under subsection (f)(2)(C).

(3) Revocation of designation

The Secretary may revoke a designation of a drug as a qualified infectious disease product if the Secretary finds that the request for such designation contained an untrue statement of material fact.

(e) Regulations

(1) In general

Not later than 2 years after July 9, 2012, the Secretary shall adopt final regulations implementing this section, including developing the list of qualifying pathogens described in subsection (f).

(2) Procedure

In promulgating a regulation implementing this section, the Secretary shall—

(A) issue a notice of proposed rulemaking that includes the proposed regulation;

(B) provide a period of not less than 60 days for comments on the proposed regulation; and

(C) publish the final regulation not less than 30 days before the effective date of the regulation.

(3) Restrictions

Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this section only as described in paragraph (2), except that the Secretary may issue interim guidance for sponsors seeking designation under subsection (d) prior to the promulgation of such regulations.

(4) Designation prior to regulations

The Secretary shall designate drugs as qualified infectious disease products under subsection (d) prior to the promulgation of regulations under this subsection, if such drugs meet the definition of a qualified infectious disease product described in subsection (g).

(f) Qualifying pathogen

(1) Definition

In this section, the term ''qualifying pathogen'' means a pathogen identified and listed by the Secretary under paragraph (2) that has the potential to pose a serious threat to public health, such as—

(A) resistant gram positive pathogens, including methicillin-resistant Staphylococcus aureus, vancomycin-resistant Staphylococcus aureus, and vancomycin-resistant enterococcus;

(B) multi-drug resistant gram negative bacteria, including Acinetobacter, Klebsiella, Pseudomonas, and E. coli species;

(C) multi-drug resistant tuberculosis; and

(D) Clostridium difficile.

(2) List of qualifying pathogens

(A) In general

The Secretary shall establish and maintain a list of qualifying pathogens, and shall make public the methodology for developing such list.

(B) Considerations

In establishing and maintaining the list of pathogens described under this section, the Secretary shall—

(i) consider—

(I) the impact on the public health due to drug-resistant organisms in humans;

(II) the rate of growth of drug-resistant organisms in humans;

(III) the increase in resistance rates in humans; and

(IV) the morbidity and mortality in humans; and

(ii) consult with experts in infectious diseases and antibiotic resistance, including the Centers for Disease Control and Prevention, the Food and Drug Administration, medical professionals, and the clinical research community.

(C) Review

Every 5 years, or more often as needed, the Secretary shall review, provide modifica-

tions to, and publish the list of qualifying pathogens under subparagraph (A) and shall by regulation revise the list as necessary, in accordance with subsection (e).

(g) Qualified infectious disease product

The term ''qualified infectious disease product'' means a drug (including a biological product), including an antibacterial or antifungal drug, for human use that—

(1) acts on bacteria or fungi or on substances produced by such bacteria or fungi; and

(2) is intended to treat a serious or life-threatening infection, including such an infection caused by—

(A) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens; or

(B) qualifying pathogens listed by the Secretary under subsection (f).

(June 25, 1938, ch. 675, § 505E, as added Pub. L. 112–144, title VIII, § 801(a), July 9, 2012, 126 Stat. 1077; amended Pub. L. 117–328, div. FF, title III, § 3212(a), Dec. 29, 2022, 136 Stat. 5826.)

Editorial Notes

AMENDMENTS

2022—Subsec. (c)(4). Pub. L. 117–328, § 3212(a)(1), added par. (4).

Subsec. (d)(1). Pub. L. 117–328, § 3212(a)(2), inserted ''or section 262(a) of title 42'' after ''section 355(b) of this title''.

Subsec. (g). Pub. L. 117–328, § 3212(a)(3), amended subsec. (g) generally. Prior to amendment, text read as follows: ''The term 'qualified infectious disease product' means an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by—

''(1) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens; or

''(2) qualifying pathogens listed by the Secretary under subsection (f).''

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Pub. L. 112–144, title VIII, § 801(b), July 9, 2012, 126 Stat. 1079, provided that: ''Section 505E of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355f], as added by subsection (a), applies only with respect to a drug that is first approved under section 505(c) of such Act (21 U.S.C. 355(c)) on or after the date of the enactment of this Act [July 9, 2012].''

§ 355g. Utilizing real world evidence

(a) In general

The Secretary shall establish a program to evaluate the potential use of real world evidence—

(1) to help to support the approval of a new indication for a drug approved under section 355(c) of this title; and

(2) to help to support or satisfy postapproval study requirements.

(b) Real world evidence defined

In this section, the term ''real world evidence'' means data regarding the usage, or the potential benefits or risks, of a drug derived from sources other than traditional clinical trials.

(c) Program framework

(1) In general

Not later than 2 years after December 13, 2016, the Secretary shall establish a draft framework for implementation of the program under this section.

(2) Contents of framework

The framework shall include information describing—

(A) the sources of real world evidence, including ongoing safety surveillance, observational studies, registries, claims, and patient-centered outcomes research activities;

(B) the gaps in data collection activities;

(C) the standards and methodologies for collection and analysis of real world evidence; and

(D) the priority areas, remaining challenges, and potential pilot opportunities that the program established under this section will address.

(3) Consultation

(A) In general

In developing the program framework under this subsection, the Secretary shall consult with regulated industry, academia, medical professional organizations, representatives of patient advocacy organizations, consumer organizations, disease research foundations, and other interested parties.

(B) Process

The consultation under subparagraph (A) may be carried out through approaches such as—

(i) a public-private partnership with the entities described in such subparagraph in which the Secretary may participate;

(ii) a contract, grant, or other arrangement, as the Secretary determines appropriate, with such a partnership or an independent research organization; or

(iii) public workshops with the entities described in such subparagraph.

(d) Program implementation

The Secretary shall, not later than 3 years after December 13, 2016, and in accordance with the framework established under subsection (c), implement the program to evaluate the potential use of real world evidence.

(e) Guidance for industry

The Secretary shall—

(1) utilize the program established under subsection (a), its activities, and any subsequent pilots or written reports, to inform a guidance for industry on—

(A) the circumstances under which sponsors of drugs and the Secretary may rely on real world evidence for the purposes described in paragraphs (1) and (2) of subsection (a); and

(B) the appropriate standards and methodologies for collection and analysis of real world evidence submitted for such purposes;

(2) not later than 5 years after December 13, 2016, issue draft guidance for industry as described in paragraph (1); and