(d) Disclosure

If a sponsor fails to complete an agreed upon study required by this section by its original or otherwise negotiated deadline, the Secretary shall publish a statement on the Internet site of the Food and Drug Administration stating that the study was not completed and, if the reasons for such failure to complete the study were not satisfactory to the Secretary, a statement that such reasons were not satisfactory to the Secretary.

(e) Notification

With respect to studies of the type required under section 356(c)(2)(A) of this title or under section 314.510 or 601.41 of title 21, Code of Federal Regulations, as each of such sections was in effect on the day before the effective date of this subsection, the Secretary may require that a sponsor who, for reasons not satisfactory to the Secretary, fails to complete by its deadline a study under any of such sections of such type for a drug or biological product (including such a study conducted after such effective date) notify practitioners who prescribe such drug or biological product of the failure to complete such study and the questions of clinical benefit, and, where appropriate, questions of safety, that remain unanswered as a result of the failure to complete such study. Nothing in this subsection shall be construed as altering the requirements of the types of studies required under section 356(c)(2)(A) of this title or under section 314.510 or 601.41 of title 21, Code of Federal Regulations, as so in effect, or as prohibiting the Secretary from modifying such sections of title 21 of such Code to provide for studies in addition to those of such type.

(June 25, 1938, ch. 675, § 506B, as added Pub. L. 105–115, title I, § 130(a), Nov. 21, 1997, 111 Stat. 2331; amended Pub. L. 107–188, title V, § 506, June 12, 2002, 116 Stat. 693; Pub. L. 112–144, title IX, § 902(c), July 9, 2012, 126 Stat. 1088.)

REFERENCES IN TEXT

The effective date of this subsection, referred to in subsec. (e), is Oct. 1, 2002, see Effective Date of 2002 Amendment note set out below.

AMENDMENTS

2012—Subsec. (e). Pub. L. 112–144 substituted ''section 356(c)(2)(A) of this title'' for ''section 356(b)(2)(A) of this title'' in two places.

2002—Subsecs. (d), (e). Pub. L. 107–188 added subsecs. (d) and (e).

EFFECTIVE DATE OF 2002 AMENDMENT

Pub. L. 107–188, title V, § 508, June 12, 2002, 116 Stat. 694, provided that: ''The amendments made by this subtitle [subtitle A (§§ 501–509) of title V of Pub. L. 107–188, amending this section and sections 379g and 379h of this title] shall take effect October 1, 2002.''

EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

REPORT TO CONGRESSIONAL COMMITTEES

Pub. L. 105–115, title I, § 130(b), Nov. 21, 1997, 111 Stat. 2331, provided that not later than Oct. 1, 2001, the Secretary was to submit to Congress a report containing a summary of the reports submitted under section 356b of this title and an evaluation and legislative recommendations relating to postmarketing studies of drugs.

§ 356c. Discontinuance or interruption in the production of life-saving drugs

(a) In general

A manufacturer of a drug—

(1) that is—

(A) life-supporting;

(B) life-sustaining; or

(C) intended for use in the prevention or treatment of a debilitating disease or condition, including any such drug used in emergency medical care or during surgery; and

(2) that is not a radio pharmaceutical drug product or any other product as designated by the Secretary,

shall notify the Secretary, in accordance with subsection (b), of a permanent discontinuance in the manufacture of the drug or an interruption of the manufacture of the drug that is likely to lead to a meaningful disruption in the supply of that drug in the United States, and the reasons for such discontinuance or interruption.

(b) Timing

A notice required under subsection (a) shall be submitted to the Secretary—

(1) at least 6 months prior to the date of the discontinuance or interruption; or

(2) if compliance with paragraph (1) is not possible, as soon as practicable.

(c) Distribution

To the maximum extent practicable, the Secretary shall distribute, through such means as the Secretary deems appropriate, information on the discontinuance or interruption of the manufacture of the drugs described in subsection (a) to appropriate organizations, including physician, health provider, and patient organizations, as described in section 356e of this title.

(d) Confidentiality

Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5 or section 1905 of title 18.

(e) Coordination with Attorney General

Not later than 30 days after the receipt of a notification described in subsection (a), the Secretary shall—

(1) determine whether the notification pertains to a controlled substance subject to a production quota under section 826 of this title; and

(2) if necessary, as determined by the Secretary—

(A) notify the Attorney General that the Secretary has received such a notification;

(B) request that the Attorney General increase the aggregate and individual production quotas under section 826 of this title applicable to such controlled substance and any ingredient therein to a level the Secretary deems necessary to address a shortage of a controlled substance based on the best available market data; and

(C) if the Attorney General determines that the level requested is not necessary to address a shortage of a controlled substance, the Attorney General shall provide to the Secretary a written response detailing the basis for the Attorney General's determination.

The Secretary shall make the written response provided under subparagraph (C) available to the public on the Internet Web site of the Food and Drug Administration.

(f) Failure to meet requirements

If a person fails to submit information required under subsection (a) in accordance with subsection (b)—

(1) the Secretary shall issue a letter to such person informing such person of such failure;

(2) not later than 30 calendar days after the issuance of a letter under paragraph (1), the person who receives such letter shall submit to the Secretary a written response to such letter setting forth the basis for noncompliance and providing information required under subsection (a); and

(3) not later than 45 calendar days after the issuance of a letter under paragraph (1), the Secretary shall make such letter and any response to such letter under paragraph (2) available to the public on the Internet Web site of the Food and Drug Administration, with appropriate redactions made to protect information described in subsection (d), except that, if the Secretary determines that the letter under paragraph (1) was issued in error or, after review of such response, the person had a reasonable basis for not notifying as required under subsection (a), the requirements of this paragraph shall not apply.

(g) Expedited inspections and reviews

If, based on notifications described in subsection (a) or any other relevant information, the Secretary concludes that there is, or is likely to be, a drug shortage of a drug described in subsection (a), the Secretary may—

(1) expedite the review of a supplement to a new drug application submitted under section 355(b) of this title, an abbreviated new drug application submitted under section 355(j) of this title, or a supplement to such an application submitted under section 355(j) of this title, that could help mitigate or prevent such shortage; or

(2) expedite an inspection or reinspection of an establishment that could help mitigate or prevent such drug shortage.

(h) Definitions

For purposes of this section—

(1) the term ''drug''—

(A) means a drug (as defined in section 321(g) of this title) that is intended for human use and that is subject to section 353(b)(1) of this title; and

(B) does not include biological products (as defined in section 262 of title 42), unless otherwise provided by the Secretary in the regulations promulgated under subsection (i);

(2) the term ''drug shortage'' or ''shortage'', with respect to a drug, means a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug; and

(3) the term ''meaningful disruption''—

(A) means a change in production that is reasonably likely to lead to a reduction in the supply of a drug by a manufacturer that is more than negligible and affects the ability of the manufacturer to fill orders or meet expected demand for its product; and

(B) does not include interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time.

(i) Regulations

(1) In general

Not later than 18 months after July 9, 2012, the Secretary shall adopt a final regulation implementing this section.

(2) Contents

Such regulation shall define, for purposes of this section, the terms ''life-supporting'', ''life-sustaining'', and ''intended for use in the prevention or treatment of a debilitating disease or condition''.

(3) Inclusion of biological products

(A) In general

The Secretary may by regulation apply this section to biological products (as defined in section 262 of title 42), including plasma products derived from human plasma protein and their recombinant analogs, if the Secretary determines such inclusion would benefit the public health. Such regulation shall take into account any supply reporting programs and shall aim to reduce duplicative notification.

(B) Rule for vaccines

If the Secretary applies this section to vaccines pursuant to subparagraph (A), the Secretary shall—

(i) consider whether the notification requirement under subsection (a) may be satisfied by submitting a notification to the Centers for Disease Control and Prevention under the vaccine shortage notification program of such Centers; and

(ii) explain the determination made by the Secretary under clause (i) in the regulation.

(4) 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 regulation's effective date.

(5) Restrictions

Notwithstanding any other provision of Federal law, in implementing this section, the

Secretary shall only promulgate regulations as described in paragraph (4).

(June 25, 1938, ch. 675, § 506C, as added Pub. L. 105–115, title I, § 131(a), Nov. 21, 1997, 111 Stat. 2332; amended Pub. L. 112–144, title X, § 1001(a), July 9, 2012, 126 Stat. 1099; Pub. L. 114–255, div. A, title III, § 3101(a)(2)(E), Dec. 13, 2016, 130 Stat. 1153.)

AMENDMENTS

2016—Subsec. (c). Pub. L. 114–255, § 3101(a)(2)(E)(i), substituted ''discontinuance'' for ''discontinuation''.

Subsec. (g)(1). Pub. L. 114–255, § 3101(a)(2)(E)(ii), substituted ''section 355(j) of this title, that could help'' for ''section 355(j) of this title that could help''.

2012—Pub. L. 112–144 amended section generally. Prior to amendment, section related to discontinuance of life saving products.

EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

EFFECT OF NOTIFICATION

Pub. L. 112–144, title X, § 1001(b), July 9, 2012, 126 Stat. 1101, provided that: ''The submission of a notification to the Secretary of Health and Human Services (referred to in this title [see Tables for classification] as the 'Secretary') for purposes of complying with the requirement in section 506C(a) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 356c(a)] (as amended by subsection (a)) shall not be construed—

''(1) as an admission that any product that is the subject of such notification violates any provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); or

''(2) as evidence of an intention to promote or market the product for an indication or use for which the product has not been approved by the Secretary.''

EX. ORD. NO. 13588. REDUCING PRESCRIPTION DRUG SHORTAGES

Ex. Ord. No. 13588, Oct. 31, 2011, 76 F.R. 68295, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. *Policy*. Shortages of pharmaceutical drugs pose a serious and growing threat to public health. While a very small number of drugs in the United States experience a shortage in any given year, the number of prescription drug shortages in the United States nearly tripled between 2005 and 2010, and shortages are becoming more severe as well as more frequent. The affected medicines include cancer treatments, anesthesia drugs, and other drugs that are critical to the treatment and prevention of serious diseases and life-threatening conditions.

For example, over approximately the last 5 years, data indicates that the use of sterile injectable cancer treatments has increased by about 20 percent, without a corresponding increase in production capacity. While manufacturers are currently in the process of expanding capacity, it may be several years before production capacity has been significantly increased. Interruptions in the supplies of these drugs endanger patient safety and burden doctors, hospitals, pharmacists, and patients. They also increase health care costs, particularly because some participants in the market may use shortages as opportunities to hoard scarce drugs or charge exorbitant prices.

The Food and Drug Administration (FDA) in the Department of Health and Human Services has been working diligently to address this problem through its existing regulatory framework. While the root problems and many of their solutions are outside of the FDA's control, the agency has worked cooperatively with manufacturers to prevent or mitigate shortages by expediting review of certain regulatory submissions and adopting a flexible approach to drug manufacturing and importation regulations where appropriate. As a result, the FDA prevented 137 drug shortages in 2010 and 2011. Despite these successes, however, the problem of drug shortages has continued to grow.

Many different factors contribute to drug shortages, and solving this critical public health problem will require a multifaceted approach. An important factor in many of the recent shortages appears to be an increase in demand that exceeds current manufacturing capacity. While manufacturers are in the process of expanding capacity, one important step is ensuring that the FDA and the public receive adequate advance notice of shortages whenever possible. The FDA cannot begin to work with manufacturers or use the other tools at its disposal until it knows there is a potential problem. Similarly, early disclosure of a shortage can help hospitals, doctors, and patients make alternative arrangements before a shortage becomes a crisis. However, drug manufacturers have not consistently provided the FDA with adequate notice of potential shortages.

As part of my Administration's broader effort to work with manufacturers, health care providers, and other stakeholders to prevent drug shortages, this order directs the FDA to take steps that will help to prevent and reduce current and future disruptions in the supply of lifesaving medicines.

SEC. 2. *Broader Reporting of Manufacturing Discontinuances*. To the extent permitted by law, the FDA shall use all appropriate administrative tools, including its authority to interpret and administer the reporting requirements in 21 U.S.C. 356c, to require drug manufacturers to provide adequate advance notice of manufacturing discontinuances that could lead to shortages of drugs that are life-supporting or life-sustaining, or that prevent debilitating disease.

SEC. 3. *Expedited Regulatory Review*. To the extent practicable, and consistent with its statutory responsibility to ensure the safety and effectiveness of the drug supply, the FDA shall take steps to expand its current efforts to expedite its regulatory reviews, including reviews of new drug suppliers, manufacturing sites, and manufacturing changes, whenever it determines that expedited review would help to avoid or mitigate existing or potential drug shortages. In prioritizing and allocating its limited resources, the FDA should consider both the severity of the shortage and the importance of the affected drug to public health.

SEC. 4. *Review of Certain Behaviors by Market Participants*. The FDA shall communicate to the Department of Justice (DOJ) any findings that shortages have led market participants to stockpile the affected drugs or sell them at exorbitant prices. The DOJ shall then determine whether these activities are consistent with applicable law. Based on its determination, DOJ, in coordination with other State and Federal regulatory agencies as appropriate, should undertake whatever enforcement actions, if any, it deems appropriate.

SEC. 5. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) authority granted by law to an agency, or the head thereof; or

(ii) functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

BARACK OBAMA.

§ 356c–1. Annual reporting on drug shortages

(a) Annual reports to Congress

Not later than March 31 of each calendar year, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report, with respect to the preceding calendar year, on drug shortages that—

(1) specifies the number of manufacturers that submitted a notification to the Secretary under section 356c(a) of this title during such calendar year;

(2) describes the communication between the field investigators of the Food and Drug Administration and the staff of the Center for Drug Evaluation and Research's Office of Compliance and Drug Shortage Program, including the Food and Drug Administration's procedures for enabling and ensuring such communication;

(3)(A) lists the major actions taken by the Secretary to prevent or mitigate the drug shortages described in paragraph (7);

(B) in the list under subparagraph (A), includes—

(i) the number of applications and supplements for which the Secretary expedited review under section 356c(g)(1) of this title during such calendar year; and

(ii) the number of establishment inspections or reinspections that the Secretary expedited under section 356c(g)(2) of this title during such calendar year;

(4) describes the coordination between the Food and Drug Administration and the Drug Enforcement Administration on efforts to prevent or alleviate drug shortages;

(5) identifies the number of and describes the instances in which the Food and Drug Administration exercised regulatory flexibility and discretion to prevent or alleviate a drug shortage;

(6) lists the names of manufacturers that were issued letters under section 356c(f) of this title; and

(7) specifies the number of drug shortages occurring during such calendar year, as identified by the Secretary.

(b) Trend analysis

The Secretary is authorized to retain a third party to conduct a study, if the Secretary believes such a study would help clarify the causes, trends, or solutions related to drug shortages.

(c) Definition

In this section, the term ''drug shortage'' or ''shortage'' has the meaning given such term in section 356c of this title.

(June 25, 1938, ch. 675, § 506C–1, as added Pub. L. 112–144, title X, § 1002, July 9, 2012, 126 Stat. 1102; amended Pub. L. 114–255, div. A, title III, § 3101(a)(2)(F), Dec. 13, 2016, 130 Stat. 1153.)

AMENDMENTS

2016—Subsec. (a). Pub. L. 114–255, in introductory provisions, substituted ''Not later than March 31 of each calendar year,'' for ''Not later than the end of calendar year 2013, and not later than the end of each calendar year thereafter,'' and inserted '', with respect to the preceding calendar year,'' after ''a report''.

§ 356d. Coordination; task force and strategic plan

(a) Task force and strategic plan

(1) In general

(A) Task force

As soon as practicable after July 9, 2012, the Secretary shall establish a task force to develop and implement a strategic plan for enhancing the Secretary's response to preventing and mitigating drug shortages.

(B) Strategic plan

The strategic plan described in subparagraph (A) shall include—

(i) plans for enhanced interagency and intra-agency coordination, communication, and decisionmaking;

(ii) plans for ensuring that drug shortages are considered when the Secretary initiates a regulatory action that could precipitate a drug shortage or exacerbate an existing drug shortage;

(iii) plans for effective communication with outside stakeholders, including who the Secretary should alert about potential or actual drug shortages, how the communication should occur, and what types of information should be shared;

(iv) plans for considering the impact of drug shortages on research and clinical trials; and

(v) an examination of whether to establish a ''qualified manufacturing partner program'', as described in subparagraph (C).

(C) Description of program

In conducting the examination of a ''qualified manufacturing partner program'' under subparagraph (B)(v), the Secretary—

(i) shall take into account that—

(I) a ''qualified manufacturer'', for purposes of such program, would need to have the capability and capacity to supply products determined or anticipated to be in shortage; and

(II) in examining the capability and capacity to supply products in shortage, the ''qualified manufacturer'' could have a site that manufactures a drug listed under section 356e of this title or have the capacity to produce drugs in response to a shortage within a rapid timeframe; and

(ii) shall examine whether incentives are necessary to encourage the participation of ''qualified manufacturers'' in such a program.

(D) Consultation

In carrying out this paragraph, the task force shall ensure consultation with the appropriate offices within the Food and Drug Administration, including the Office of the Commissioner, the Center for Drug Evaluation and Research, the Office of Regulatory Affairs, and employees within the Depart-