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112TH CONGRESS
1ST SESSION

H. R. 2227

To amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of medical gases, taking into account the special characteristics of medical gases, the special techniques and processes required to produce medical gases, and the established history of safe and effective use of medical gases.

IN THE HOUSE OF REPRESENTATIVES

JUNE 16, 2011

Mr. LANCE (for himself and Mr. MURPHY of Connecticut) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of medical gases, taking into account the special characteristics of medical gases, the special techniques and processes required to produce medical gases, and the established history of safe and effective use of medical gases.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Medical Gas Safety Act''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

SEC. 2. FINDINGS.

The Congress finds the following:

(1) Medical gases have been used broadly by the medical community for many decades and are critical to ensuring the public health.

(2) Most medical gases predate the new drug approval provisions in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and, consequently, medical gases have been marketed for many years without new drug approval.

SEC. 3. REGULATION OF MEDICAL GASES.

(a) ADULTERATION.—

(1) IN GENERAL.—Section 501(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)) is amended by striking ''; or (3)'' and inserting ''; or (D) if it is a medical gas (as defined in section 575) and it is manufactured, prepared, processed, packed, or held in violation of subchapter G or regulations thereunder; or (3)''.

(2) APPLICABILITY.—The amendment made by paragraph (1) applies beginning on the date that is 2 years after the date of the enactment of this Act.

(b) REGULATION.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"Subchapter G—Medical Gases

"SEC. 575. DEFINITIONS.

''In this subchapter:

''(1) The term 'designated medical gas' means any of the following:

''(A) Oxygen, as defined in the United States Pharmacopeia (or any successor publication).

''(B) Nitrogen, as defined in the National Formulary (or any successor publication).

''(C) Nitrous oxide, as defined in the United States Pharmacopeia (or any successor publication).

''(D) Carbon dioxide, as defined in the United States Pharmacopeia (or any successor publication).

''(E) Helium, as defined in the United States Pharmacopeia (or any successor publication).

"(F) Medical air, as defined in the United States Pharmacopeia (or any successor publication).

"(G) Any other medical gas deemed appropriate by the Secretary.

"(2) The term 'medical gas' means a drug that is—

"(A) manufactured or stored in a liquefied, non-liquefied, or cryogenic state; and

"(B) is administered as a gas.

"(3) The term 'Medical Gas Advisory Committee' means the Medical Gas Advisory Committee established under section 577.

"(4) The term 'medical gas manufacturer' means an entity that owns or operates an establishment registered under section 510 that manufactures, prepares, processes, packages, repackages, or labels a medical gas or that fills high-pressure medical gas cylinders or cryogenic medical gas containers by any of the following methods: liquid to liquid, liquid to gas, or gas to gas.

"SEC. 576. REGULATION OF MEDICAL GASES.

"(a) CERTIFICATION OF DESIGNATED MEDICAL GASES.—

''(1) SUBMISSION.—Any person may file with the Secretary a certification that a medical gas is a designated medical gas.

''(2) APPROVAL OF CERTIFICATION.—The Secretary shall approve a certification submitted under paragraph (1) with respect to a medical gas if the certification demonstrates to the Secretary's satisfaction that the medical gas is a designated medical gas.

''(3) EFFECT OF APPROVAL OF CERTIFICATION.—

''(A) IN GENERAL.—A medical gas subject to a certification for which an approval is in effect under paragraph (2) is deemed to be approved pursuant to an application filed pursuant to section 505(b) or 512(b)(1), as applicable, for—

''(i) those indications for which the medical gas has been marketed to a material extent for a material time; or

''(ii) for administration in a supervised clinical setting under the direction of a medical or veterinary, as applicable, professional.

"(B) INAPPLICABILITY OF EXCLUSIVITY PROVISIONS.—Sections 505(c)(3)(E), 505(j)(5)(F), and 512(c)(2)(F) do not apply with respect to the approval of a designated medical gas under this subsection.

"(4) REGISTRATION AND LISTING UNDER SECTION 510.—To the greatest extent possible, the Secretary shall streamline the certification and approval process under this subsection with the registration and listing process under section 510.

"(b) APPROVAL OF NON-DESIGNATED MEDICAL GASES.—

"(1) PROCEDURES.—Not later than 2 years after the date of the enactment of this subchapter, the Secretary, in consultation with the Medical Gas Advisory Committee, shall establish by rule appropriate procedures for the approval of medical gases that are not designated medical gases pursuant to section 505 or 512, as applicable.

"(2) SUBMISSION OF NEW DRUG APPLICATIONS AND ABBREVIATED NEW DRUG APPLICATIONS.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the Secretary shall not require the submission of a new drug application or an abbreviated new drug application under

subsection (b) or (j) of section 505, or a new animal drug application or an abbreviated new animal drug application under subsection (b)(1) or (b)(2) of section 512, for any medical gas that is not a designated medical gas during the period ending on the later of—

"(i) 4 years after the date of the enactment of this subchapter; or

"(ii) 2 years after the date on which the Secretary establishes applicable procedures under paragraph (1).

"(B) EXCEPTIONS.—Nothing in this subchapter—

"(i) prohibits the voluntary submission of an application under subsection (b) or (j) of section 505 or subsection (b)(1) or (b)(2) of section 512 for a medical gas; or

"(ii) constitutes an exemption from the requirements under section 505(i) or section 512(j) (relating to investigational new drugs and investigational new animal drugs, respectively).

"(c) SEPARATE REGULATIONS FOR MEDICAL GASES.—

''(1) IN GENERAL.—Not later than 2 years after the date of the enactment of this subchapter, the Secretary, in consultation with the Medical Gas Advisory Committee, shall establish by separate and specific regulation—

''(A) appropriate current good manufacturing practice requirements for medical gases;

''(B) separate labeling requirements for medical gases;

''(C) separate wholesale distribution requirements for medical gases;

''(D) a streamlined electronic process for registration, and listing of medical gases, under section 510 by medical gas manufacturers that are small business concerns (as defined in section 3 of the Small Business Act); and

''(E) separate and proportionate product tracking and anticounterfeiting rules for medical gases.

''(2) EVALUATION IN RULEMAKING.—In any regulation of the Food and Drug Administration pertaining to drugs or drug manufacturers that is pending finalization as of the date of the enactment of this subchapter or is proposed after such date, the Secretary shall specifically evaluate the effect of

such regulation on, and the suitability of such regulation for, medical gases and medical gas manufacturers. Based on such evaluation, the Secretary shall include in the regulation an accommodation, unique application, or exemption for medical gases and medical gas manufacturers as appropriate given the special characteristics of medical gases.

''(3) COORDINATION WITH STATES.—

''(A) IN GENERAL.—The Secretary, in consultation with the Medical Gas Advisory Committee, shall establish a separate risk-based inspection regime specific to medical gas manufacturers that ensures coordination with State and local inspection activities and seek to enter into partnership agreements in order to improve the coordination and efficiency of Federal and State efforts to regulate medical gas manufacturers and medical gases. Such agreements shall—

''(i) ensure consistent inspector training between State and Federal authorities;

''(ii) eliminate, to the extent practicable, any overlapping fees or inspection fees or activities between State and Federal inspectors;

"(iii) promote current good manufacturing practice compliance;

"(iv) ensure consistent application of Federal regulations with respect to medical gas manufacturers; and

"(v) include any mechanisms determined by the Secretary, in consultation with the Medical Gas Advisory Committee, to improve the coordination and efficiency of Federal and State efforts to regulate medical gas manufacturers and medical gases.

"(B) DISSEMINATION OF INFORMATION.—The Secretary shall disseminate appropriate information to States regarding application of Federal regulations to medical gas manufacturers and medical gases in order to improve the consistency of enforcement of applicable regulations.

"SEC. 577. MEDICAL GAS ADVISORY COMMITTEE.

"(a) ESTABLISHMENT.—Not later than 6 months after the date of the enactment of this subchapter, the Secretary shall establish a permanent advisory committee to be known as the Medical Gas Advisory Committee.

''(b) MEMBERSHIP.—The Medical Gas Advisory Committee—

''(1) shall include representatives of medical gas manufacturers and medical gas safety standards development organizations; and

''(2) may include representatives of patient advocacy groups, professional associations, physicians, scientists, other medical professionals licensed to manufacture or use medical gases (such as pulmonologists, respiratory therapists, veterinarians, and anesthesiologists), and other stakeholders as determined appropriate by the Secretary.

''(c) DUTIES.—The Medical Gas Advisory Committee shall provide the Secretary with regular guidance and specific advice on medical gas regulatory initiatives, including with respect to regulations concerning the approval of medical gases under sections 505 and 512, the manufacture of medical gases, and related activities.

''(d) FACA.—Except as inconsistent with this section, the Medical Gas Advisory Committee shall be subject to the Federal Advisory Committee Act.''.

SEC. 4. FEES RELATING TO MEDICAL GAS REGULATION.

(a) FINDING.—The Congress finds that the fees authorized by the amendment made in subsection (b) will be dedicated towards the costs of the Food and Drug Ad-

ministration's regulation of non-designated medical gases, as set forth in the goals identified for purposes of part 6 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

(b) AUTHORITY TO ASSESS AND COLLECT FEES.—Subchapter C of chapter VII (21 U.S.C. 379f et seq.) is amended by adding at the end the following:

"PART 6—FEES RELATING TO MEDICAL GASES

"SEC. 744. AUTHORITY TO ASSESS AND COLLECT FEES.

"(a) FEES RELATING TO NON-DESIGNATED MEDICAL GASES.—For fiscal year 2013 and each subsequent fiscal year, the Secretary, in consultation with the Medical Gas Advisory Committee, shall assess and collect fees under this section from each category of persons that, with respect to drugs that are non-designated medical gases, would be subject to a fee under section 736(a), 740(a), or 741(a) but for the operation of subsection (c).

"(b) EXEMPTION FOR DESIGNATED MEDICAL GASES.—Subsection (a) does not authorize the assessment

or collection of any fee with respect to drugs that are designated medical gases.

''(c) INAPPLICABILITY OF OTHER DRUG FEES TO MEDICAL GASES.—Fees under sections 736(a), 740(a), and 741(a) shall not be assessed or collected insofar as such fees relate to drugs that are medical gases.

''(d) ESTABLISHMENT.—The Secretary shall by regulation establish the amount of fees under this section for a fiscal year—

''(1) so as to generate a total revenue amount not exceeding the Secretary's estimate of 100 percent of the costs of the Food and Drug Administration's regulation of non-designated medical gases during such year; and

''(2) taking into consideration the special characteristics of non-designated medical gases, including the unique manufacturing and distribution system required to produce non-designated medical gases.

''(e) CREDITING AND AVAILABILITY OF FEES.—

''(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such

sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the costs of the Food and Drug Administration's regulation of non-designated medical gases.

''(2) COLLECTIONS AND APPROPRIATION ACTS.—

''(A) IN GENERAL.—The fees authorized by this section—

''(i) shall be retained in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for such fiscal year; and

''(ii) shall only be collected and available to pay the costs of the Food and Drug Administration's regulation of non-designated medical gases.

''(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for

the costs of the Food and Drug Administration's regulation of non-designated medical gases—

"(i) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

"(ii)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in such subparagraph; and

"(II) such costs are not more than 5 percent below the level specified in such subparagraph.

"(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2013 through 2017, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount determined under subsection (d) for the fiscal year.

"(4) OFFSET.—If the sum of the cumulative amount of fees collected under this section for the fiscal years 2013 through 2015 and the amount of

fees estimated to be collected under this section for fiscal year 2016 exceeds the cumulative amount appropriated under paragraph (3) for the fiscal years 2013 through 2016, the excess shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2017.

''(f) DEFINITIONS.—In this section:

''(1) The terms 'designated medical gas' and 'medical gas' have the meanings given to such terms in section 575.

''(2) The term 'non-designated medical gas' means a medical gas that is not a designated medical gas.''.

(c) REAUTHORIZATION; REPORTING REQUIREMENTS.—Part 6 of subchapter C of chapter VII (21 U.S.C. 379f et seq.), as added by subsection (a), is further amended by adding at the end the following:

''SEC. 744A. REAUTHORIZATION; REPORTING REQUIREMENTS.

''(a) PERFORMANCE REPORT.—Beginning with fiscal year 2013, not later than 120 days after the end of each

fiscal year for which fees are collected under this part, the Secretary shall prepare and 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 concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 4(a) of the Medical Gas Safety Act during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

''(b) FISCAL REPORT.—Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year for which fees are collected under this part, the Secretary shall prepare and 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 on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for such fiscal year.

''(c) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

''(d) REAUTHORIZATION.—

''(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals, and plans for meeting the goals, for the Food and Drug Administration's regulation of non-designated medical gases for the first 5 fiscal years after fiscal year 2017, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

''(A) the Committee on Energy and Commerce of the House of Representatives;

''(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

''(C) scientific and academic experts;

''(D) health care professionals;

''(E) representatives of patient and consumer advocacy groups; and

''(F) the regulated industry.

''(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the regulated industry on the reauthorization of this part, the Secretary shall—

''(A) publish a notice in the Federal Register requesting public input on the reauthorization;

''(B) hold a public meeting at which the public may present its views on the reauthoriza-

tion, including specific suggestions for changes to the goals referred to in subsection (a);

"(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and

"(D) publish the comments on the Food and Drug Administration's Internet Web site.

"(3) PERIODIC CONSULTATION.—Not less frequently than once every month during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).

"(4) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

"(A) present the recommendations developed under paragraph (1) to the Congressional committees specified in such paragraph;

"(B) publish such recommendations in the Federal Register;

"(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

"(D) hold a meeting at which the public may present its views on such recommendations; and

"(E) after consideration of such public views and comments, revise such recommendations as necessary.

"(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2017, the Secretary shall transmit to the Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

"(6) MINUTES OF NEGOTIATION MEETINGS.—

"(A) PUBLIC AVAILABILITY.—Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the Secretary shall make publicly available, on the public Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food

and Drug Administration and the regulated industry.

''(B) CONTENT.—The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.''.

(d) SUNSET DATES.—

(1) AUTHORIZATION.—The amendment made by subsection (b) ceases to be effective October 1, 2017.

(2) REPORTING REQUIREMENTS.—The amendment made by subsection (c) ceases to be effective January 31, 2018.

SEC. 5. MISCELLANEOUS PROVISIONS.

(a) RULE OF CONSTRUCTION.—Nothing in this Act and the amendments made by this Act shall be construed to impair any approval of an application submitted under section 505 or 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for a medical gas (as defined in section 575 of the Federal Food, Drug, and Cosmetic Act, as added by section 3(b) of this Act) that occurred prior to the date of the enactment of this Act.

(b) SAVINGS CLAUSE.—Except as expressly set forth in this Act and the amendments made by this Act, a medical gas (as defined in section 575 of the Federal Food, Drug, and Cosmetic Act, as added by section 3(b) of this Act) shall be subject to all applicable requirements for drugs under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

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