

product, or biosimilar biological product application or biosimilar biological product, may infringe any patent held by, or exclusively licensed to, the NDA holder or biological product license holder of the drug product or biological product, as applicable.

“(19) STATUTORY EXCLUSIVITY.—The term ‘statutory exclusivity’ means those prohibitions on the submission or the approval of drug applications under clauses (ii) through (iv) of section 505(c)(3)(E), clauses (ii) through (iv) of section 505(j)(5)(F), section 527, section 505A, or section 505E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(3)(E), 360cc, 355a, 355f), or on the submission or licensing of biological product applications under section 351(k)(7) or paragraph (2) or (3) of section 351(m) of the Public Health Service Act (42 U.S.C. 262) or under section 527 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc).”

(2) EFFECTIVE DATE.—Section 27 of the Federal Trade Commission Act, as added by this section, shall apply to all agreements described in section 27(a)(1) of that Act entered into on or after the date of enactment of this Act.

(d) CERTIFICATION OF AGREEMENTS.—

(1) NOTICE OF ALL AGREEMENTS.—Section 1111(7) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (21 U.S.C. 355 note) is amended by inserting “, or owner of a patent for which a claim of infringement could reasonably be asserted against any person for making, using, offering to sell, selling, or importing into the United States a biological product that is the subject of a biosimilar biological product application” before the period at the end.

(2) CERTIFICATION OF AGREEMENTS.—Section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (21 U.S.C. 355 note) is amended by adding at the end the following:

“(d) CERTIFICATION.—The Chief Executive Officer or the company official responsible for negotiating any agreement under subsection (a) or (b) that is required to be filed under subsection (c), within 30 days after such filing, shall execute and file with the Assistant Attorney General and the Commission a certification as follows: ‘I declare that the following is true, correct, and complete to the best of my knowledge: The materials filed with the Federal Trade Commission and the Department of Justice under section 1112 of subtitle B of title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, with respect to the agreement referenced in this certification—

“(1) represent the complete, final, and exclusive agreement between the parties;

“(2) include any ancillary agreements that are contingent upon, provide a contingent condition for, or are otherwise related to, the referenced agreement; and

“(3) include written descriptions of any oral agreements, representations, commitments, or promises between the parties that are responsive to subsection (a) or (b) of such section 1112 and have not been reduced to writing.”

(e) NOTIFICATION OF AGREEMENTS.—Section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (21 U.S.C. 355 note), as amended by subsection (d)(2), is further amended by adding at the end the following:

“(e) RULE OF CONSTRUCTION.—

“(1) IN GENERAL.—An agreement that is required under subsection (a) or (b) shall include agreements resolving any outstanding disputes, including agreements resolving or settling a Patent Trial and Appeal Board proceeding.

“(2) DEFINITION.—For purposes of subparagraph (A), the term ‘Patent Trial and Appeal Board proceeding’ means a proceeding con-

ducted by the Patent Trial and Appeal Board of the United States Patent and Trademark Office, including an inter partes review instituted under chapter 31 of title 35, United States Code, a post-grant review instituted under chapter 32 of that title (including a proceeding instituted pursuant to the transitional program for covered business method patents, as described in section 18 of the Leahy-Smith America Invents Act (35 U.S.C. 321 note)), and a derivation proceeding instituted under section 135 of that title.”

(f) FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.—Section 505(j)(5)(D)(i)(V) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V)) is amended by inserting “section 27 of the Federal Trade Commission Act or” after “that the agreement has violated”.

(g) COMMISSION LITIGATION AUTHORITY.—Section 16(a)(2) of the Federal Trade Commission Act (15 U.S.C. 56(a)(2)) is amended—

(1) in subparagraph (D), by striking “or” after the semicolon;

(2) in subparagraph (E)—

(A) by moving the margin 2 ems to the left; and

(B) by inserting “or” after the semicolon; and

(3) inserting after subparagraph (E) the following:

“(F) under section 27.”

(h) REPORT ON ADDITIONAL EXCLUSION.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Federal Trade Commission shall submit to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives a recommendation, and the Commission’s basis for such recommendation, regarding a potential amendment to include in section 27(b) of the Federal Trade Commission Act (as added by subsection (c)) an additional exclusion for consideration granted by an NDA holder to a ANDA filer or by a biological product license holder to a biosimilar biological product application filer as part of the resolution or settlement, a release, waiver, or limitation of a claim for damages or other monetary relief.

(2) DEFINITIONS.—In this section, the terms “ANDA filer”, “biological product license holder”, “biosimilar biological product application filer”, and “NDA holder” have the meanings given such terms in section 27(f) of the Federal Trade Commission Act (as added by subsection (c)).

(i) STATUTE OF LIMITATIONS.—The Federal Trade Commission shall commence any enforcement proceeding described in section 27 of the Federal Trade Commission Act, as added by subsection (c), except for an action described in section 27(e)(2) of the Federal Trade Commission Act, not later than 6 years after the date on which the parties to the agreement file the certification under section 1112(d) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (21 U.S.C. 355 note).

(j) SEVERABILITY.—If any provision of this section, an amendment made by this section, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this section, the amendments made by this section, and the application of the provisions of such section or amendments to any person or circumstance shall not be affected.

SA 3132. Mr. HOEVEN (for himself, Mr. SCHMITT, and Mr. COTTON) submitted an amendment intended to be proposed by him to the bill S. 4638, to authorize appropriations for fiscal year 2025 for military activities of the Department of Defense, for military con-

struction, and for defense activities of the Department of Energy, to prescribe military personnel strengths for such fiscal year, and for other purposes; which was ordered to lie on the table; as follows:

At the end of subtitle B of title III, add the following:

SEC. 318. EXTENSION OF PROHIBITION ON DISCLOSURE BY DEPARTMENT OF DEFENSE CONTRACTORS OF INFORMATION RELATING TO GREENHOUSE GAS EMISSIONS.

Section 318(a)(2) of the National Defense Authorization Act for Fiscal Year 2024 (Public Law 118-31; 10 U.S.C. 4651 note prec.) is amended by striking “one-year” and inserting “two-year”.

SA 3133. Mr. CORNYN submitted an amendment intended to be proposed by him to the bill S. 4638, to authorize appropriations for fiscal year 2025 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, to prescribe military personnel strengths for such fiscal year, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title XV, add the following:

Subtitle E—SAFE Orbit Act

SEC. 1549. SHORT TITLE.

This subtitle may be cited as the “Situational Awareness of Flying Elements in Orbit Act” or the “SAFE Orbit Act”.

SEC. 1550. SPACE SITUATIONAL AWARENESS AND SPACE TRAFFIC COORDINATION.

(a) IN GENERAL.—The Secretary of Commerce shall facilitate safe operations in space and encourage the development of commercial space capabilities by acquiring and disseminating unclassified data, analytics, information, and services on space activities.

(b) IMMUNITY.—The United States, any agencies and instrumentalities thereof, and any individuals, firms, corporations, and other persons acting for the United States, including nongovernmental entities, shall be immune from any suit in any court for any cause of action arising from the provision or receipt of space situational awareness services or information, whether or not provided in accordance with this section, or any related action or omission.

(c) ACQUISITION OF DATA.—The Assistant Secretary of Commerce for Space Commerce (established under section 50702(b) of title 51, United States Code, as amended by section 1551) is authorized to acquire—

(1) data, analytics, information, and services, including with respect to—

(A) location tracking data;

(B) positional and orbit determination information; and

(C) conjunction data messages; and

(2) such other data, analytics, information, and services as the Secretary of Commerce determines necessary to avoid collisions of space objects.

(d) DATABASE ON SATELLITE LOCATION AND BEHAVIOR.—The Assistant Secretary of Commerce for Space Commerce shall provide access for the public, at no charge, a fully updated, unclassified database of information concerning space objects and behavior that includes—

(1) the data and information acquired under subsection (c), except to the extent that such data or information is classified or a trade secret (as defined in section 1839 of title 18, United States Code); and

(2) the provision of basic space situational awareness services and space traffic coordination based on the data referred to in paragraph (1), including basic analytics, tracking calculations, and conjunction data messages.

(e) **BASIC SPACE SITUATIONAL AWARENESS SERVICES.**—The Assistant Secretary of Commerce for Space Commerce—

(1) shall provide to satellite operators, at no charge, basic space situational awareness services, including the data, analytics, information, and services described in subsection (c);

(2) in carrying out paragraph (1), may not compete with private sector space situational awareness products, to the maximum extent practicable; and

(3) not less frequently than every 3 years, shall review the basic space situational awareness services described in paragraph (1) to ensure that such services provided by the Federal Government do not compete with space situational awareness services offered by the private sector.

(f) **REQUIREMENTS FOR DATA ACQUISITION AND DISSEMINATION.**—In acquiring data, analytics, information, and services under subsection (c) and disseminating data, analytics, information, and services under subsections (d) and (e), the Assistant Secretary of Commerce for Space Commerce shall—

(1) leverage commercial capabilities to the maximum extent practicable;

(2) prioritize the acquisition of data, analytics, information, and services from commercial industry located in or licensed in the United States to supplement data collected by United States Government agencies, including the Department of Defense and the National Aeronautics and Space Administration;

(3) appropriately protect proprietary data, information, and systems of firms located in the United States, including by using appropriate infrastructure and cybersecurity measures, including measures set forth in the most recent version of the Cybersecurity Framework, or successor document, maintained by the National Institute of Standards and Technology;

(4) facilitate the development of standardization and consistency in data reporting, in collaboration with satellite owners and operators, commercial space situational awareness data and service providers, the academic community, nonprofit organizations, and the Director of the National Institute of Standards and Technology; and

(5) encourage foreign governments to participate in unclassified data sharing arrangements for space situational awareness and space traffic coordination.

(g) **OTHER TRANSACTION AUTHORITY.**—In carrying out the activities required by this section, the Secretary of Commerce shall enter into such contracts, leases, cooperative agreements, or other transactions as may be necessary.

SEC. 1551. OFFICE OF SPACE COMMERCE.

(a) **DEFINITIONS.**—

(1) **IN GENERAL.**—Section 50701 of title 51, United States Code, is amended to read as follows:

“§ 50701. Definitions

“In this chapter:

“(1) **ASSISTANT SECRETARY.**—The term ‘Assistant Secretary’ means the Assistant Secretary of Commerce for Space Commerce.

“(2) **BUREAU.**—The term ‘Bureau’ means the Bureau of Space Commerce established under section 50702.

“(3) **ORBITAL DEBRIS.**—The term ‘orbital debris’—

“(A) means—

“(i) any human-made space object orbiting Earth that—

“(I) no longer serves an intended purpose;

“(II) has reached the end of its mission; or

“(III) is incapable of safe maneuver or operation; and

“(ii) a rocket body and other hardware left in orbit as a result of normal launch and operational activities; and

“(B) includes fragmentation debris produced by failure or collision of human-made space objects.

“(4) **SECRETARY.**—The term ‘Secretary’ means the Secretary of Commerce.

“(5) **SPACE OBJECT.**—The term ‘space object’ means any object launched into space or created in space robotically or by humans, including the component parts of such an object.

“(6) **SPACE SITUATIONAL AWARENESS.**—The term ‘space situational awareness’ means—

“(A) the identification, characterization, tracking, and the predicted movement and behavior of space objects and orbital debris; and

“(B) the understanding of the space operational environment.

“(7) **SPACE TRAFFIC COORDINATION.**—The term ‘space traffic coordination’ means the planning, assessment, and coordination of activities to enhance the safety, stability, and sustainability of operations in the space environment.”

(2) **CLERICAL AMENDMENT.**—The table of sections for chapter 507 of title 51, United States Code, is amended by striking the item relating to section 50701 and inserting the following:

“50701. Definitions.”

(b) **TRANSITION OF OFFICE TO BUREAU.**—Subsection (a) of section 50702 of title 51, United States Code, is amended by inserting before the period at the end the following: “, which, not later than 5 years after the date of the enactment of this Act, shall be elevated by the Secretary of Commerce from an office within the National Oceanic and Atmospheric Administration to a bureau reporting directly to the Office of the Secretary of Commerce”.

(c) **ADDITIONAL FUNCTIONS OF BUREAU.**—Subsection (c) of such section is amended—

(1) in paragraph (4), by striking “; and” and inserting a semicolon;

(2) in paragraph (5), by striking the period at the end and inserting “; and”; and

(3) by adding at the end the following:

“(6) to perform space situational awareness and space traffic management duties pursuant to the SAFE Orbit Act.”

(d) **ASSISTANT SECRETARY OF COMMERCE FOR SPACE COMMERCE.**—

(1) **IN GENERAL.**—Subsection (b) of such section is amended to read as follows:

“(b) **ASSISTANT SECRETARY.**—The Bureau shall be headed by the Assistant Secretary of Commerce for Space Commerce, who shall—

“(1) be appointed by the President, by and with the advice and consent of the Senate;

“(2) report directly to the Secretary of Commerce; and

“(3) have a rate of pay that is equal to the rate payable for level IV of the Executive Schedule under section 5315 of title 5.”

(2) **CONFORMING AMENDMENTS.**—

(A) Section 50702(d) of title 51, United States Code, is amended—

(i) in the subsection heading, by striking “DIRECTOR” and inserting “ASSISTANT SECRETARY”; and

(ii) in the matter preceding paragraph (1), by striking “Director” and inserting “Assistant Secretary”.

(B) Section 5315 of title 5, United States Code, is amended by striking “Assistant Secretaries of Commerce (11)” and inserting “Assistant Secretaries of Commerce (12)”.

(3) **REFERENCES.**—On and after the date of the enactment of this Act, any reference in any law or regulation to the Director of the

Office of Space Commerce shall be deemed to be a reference to the Assistant Secretary of Commerce for Space Commerce.

(e) **TRANSITION REPORT.**—

(1) **IN GENERAL.**—Not later than 1 year after the date of the enactment of this Act, the Secretary of Commerce shall submit to the appropriate committees of Congress a report that sets forth transition and continuity of operations plans for the functional and administrative transfer of the Office of Space Commerce from the National Oceanic and Atmospheric Administration to a bureau reporting to the Office of the Secretary of Commerce.

(2) **GOAL.**—The goal of transition and continuity of operations planning shall be to minimize the cost and administrative burden of establishing the Bureau of Space Commerce while maximizing the efficiency and effectiveness of the functions and responsibilities of the Bureau of Space Commerce, in accordance with this section and the amendments made by this section.

(3) **APPROPRIATE COMMITTEES OF CONGRESS DEFINED.**—In this subsection, the term “appropriate committees of Congress” means—

(A) the Committee on Commerce, Science, and Transportation and the Committee on Appropriations of the Senate; and

(B) the Committee on Science, Space, and Technology and the Committee on Appropriations of the House of Representatives.

SA 3134. Mr. CORNYN (for himself and Mr. LUJÁN) submitted an amendment intended to be proposed by him to the bill S. 4638, to authorize appropriations for fiscal year 2025 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, to prescribe military personnel strengths for such fiscal year, and for other purposes; which was ordered to lie on the table; as follows:

At the end title XV, add the following:

Subtitle E—Licensing Aerospace Units to New Commercial Heights Act of 2024

SEC. 1549. SHORT TITLE.

This subtitle may be cited as the “Licensing Aerospace Units to New Commercial Heights Act of 2024” or the “LAUNCH Act”.

SEC. 1550. STREAMLINING REGULATIONS RELATING TO COMMERCIAL SPACE LAUNCH AND REENTRY REQUIREMENTS.

(a) **EVALUATION OF IMPLEMENTATION OF PART 450.**—

(1) **IN GENERAL.**—Not later than 120 days after the date of the enactment of this Act, the Secretary of Transportation (referred to in this subtitle as the “Secretary”) shall evaluate the implementation of part 450 of title 14, Code of Federal Regulations (in this section referred to as “part 450”) and the impacts of part 450 on the commercial spaceflight industry.

(2) **ELEMENTS.**—The evaluation required by paragraph (1) shall include an assessment of—

(A) whether increased uncertainty in the commercial spaceflight industry has resulted from the implementation of part 450;

(B) whether part 450 has resulted in operational delays to emerging launch programs; and

(C) whether timelines for reviews have changed, including an assessment of the impact of the incremental review process on those timelines and the root cause for multiple reviews, if applicable.

(3) **REPORT REQUIRED.**—Not later than 90 days after completing the review required by paragraph (1), the Secretary shall submit to the Committee on Commerce, Science, and