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117TH CONGRESS
2D SESSION

H. R. 7653

To amend the Federal Food, Drug, and Cosmetic Act to modernize the methods of authenticating controlled substances in the pharmaceutical distribution supply chain, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 3, 2022

Mr. MULLIN (for himself and Mr. O'HALLERAN) 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 modernize the methods of authenticating controlled substances in the pharmaceutical distribution supply chain, and for other purposes.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Modern Authentication of Pharmaceuticals Act of 2022''.

SEC. 2. MODERNIZING THE AUTHENTICATION OF CONTROLLED SUBSTANCES IN THE PHARMACEUTICAL DISTRIBUTION SUPPLY CHAIN.

(a) IN GENERAL.—Section 582(a)(9) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360eee–1(a)(9)) is amended—

(1) in subparagraph (A)(ii), by striking ''and'' at the end;

(2) by redesignating subparagraph (B) as subparagraph (C); and

(3) by inserting after subparagraph (A) the following:

''(B) a physical chemical identifier shall be included in or on each dose of a product that is—

''(i) a controlled substance (as defined in section 102 of the Controlled Substances Act);

''(ii) in solid oral dosage form; and

''(iii) manufactured on or after January 1, 2026; and''.

(b) CONFORMING CHANGES.—

(1) Section 581(14) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360eee(14)) is amended to read as follows:

''(14) PRODUCT IDENTIFIER.—The term 'product identifier' means—

''(A) a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product; or

''(B) a physical chemical identifier, possessing a unique physical or chemical substance or combination of substances, that—

''(i) is in or on a product;

''(ii) is machine-readable; and

''(iii) is intended to authenticate the product or a dosage form thereof.''.

(2) Section 581(28) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360eee(28)) is amended to read as follows:

''(28) VERIFICATION OR VERIFY.—The term 'verification' or 'verify' means—

''(A) determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the standardized numerical identifier or lot number

and expiration date assigned to the product by the manufacturer or the repackager, as applicable in accordance with section 582; or

"(B) determining whether a product or a dosage form thereof is authentic using a physical chemical identifier described in paragraph (14)(B).".

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