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117TH CONGRESS
1ST SESSION

H. R. 3705

To amend the Federal Food, Drug, and Cosmetic Act to include a safe harbor for communication of information with respect to a vaccine authorized for emergency use under such Act that is provided or distributed to a health care provider, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 4, 2021

Mr. GRIFFITH 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 include a safe harbor for communication of information with respect to a vaccine authorized for emergency use under such Act that is provided or distributed to a health care provider, 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. SAFE HARBOR FOR COMMUNICATIONS ABOUT VACCINES AUTHORIZED FOR EMERGENCY USE.

(a) IN GENERAL.—The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 502 (21 U.S.C. 352) the following:

"SEC. 502A. SAFE HARBOR FOR COMMUNICATIONS ABOUT VACCINES AUTHORIZED FOR EMERGENCY USE.

''(a) IN GENERAL.—The communication of information (through written or oral means), described in subsection (b), with respect to the use of a vaccine authorized for emergency use under section 564 provided or distributed to a covered health care entity shall not be a basis for treating such vaccine as, or be treated as evidence that such vaccine is—

''(1) misbranded under subsection (a) or (f) of section 502; or

''(2) in violation of section 505 or 564 of this Act or subsection (a) or (k) of section 351(a)(1) of the Public Health Service Act, as applicable.

''(b) INFORMATION DESCRIBED.—Information described in this subsection is any information relating to a use of a vaccine authorized for emergency use under section 564 within the scope of that authorization that—

''(1) is neither false nor misleading, when measured objectively against the information available at the time the statement is made;

''(2) is accompanied, as required, by an appropriate disclaimer, including—

''(A) a statement identifying any differences between the information and any authorized labeling of the vaccine;

''(B) a statement identifying contradictory evidence; and

''(C) such other information as may be required by regulation; and

''(3) is based on competent and reliable scientific evidence, as described in subsection (e).

''(c) COVERAGE NOT EXCLUDED.—The distribution of information that otherwise meets the requirements of this section shall not fail to meet the requirements of subsection (a) because the manufacturer or distributor of the vaccine about which information is being distributed has—

''(1) knowledge that such vaccine is being used by patients or health care practitioners in a manner not described in any authorized labeling of the vaccine, as applicable; or

''(2) objective or subjective intent that such vaccine be used in a manner inconsistent with any labeling, as applicable, of such vaccine.

''(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

''(1) to limit communication to which this section does not specifically apply; or

''(2) to alter or expand the authority of the Secretary to enforce the provisions of this Act of section 351 of the Public Health Service Act, except with respect to the communication of information to which this section specifically applies.

''(e) DEFINITIONS.—In this section:

''(1) COMPETENT AND RELIABLE SCIENTIFIC EVIDENCE.—

''(A) IN GENERAL.—In this section, the term 'competent and reliable scientific evidence' means evidence established through scientific methods that are widely accepted by experts in the relevant field and followed pursuant to a clear and well-described protocol, as scientifically appropriate, regardless of whether such evidence is supported by 2 adequate and well-controlled clinical studies.

"(B) INCLUSIONS.—Such term may include information—

"(i) derived from clinical trials, observational studies, clinical studies or bench tests that describe performance, database reviews, registries, patient utilization projections, and modeling techniques, and the data, inputs, and components of such information;

"(ii) about the effects of a vaccine in subgroups defined by demographic or other variables, including groups defined by race, sex, risk factors, or other variables, such as genomic features or disease severity;

"(iii) related to the authorization for emergency use under section 564, as applicable; and

"(iv) relating to the safety, effectiveness, or benefit of a use or treatment that is authorized for emergency use under section 564 for a vaccine, including information regarding—

"(I) health outcomes, patient or caregiver experience, or other quality metrics; and

''(II) the comparative effectiveness of a vaccine relative to other products, other health care interventions, program and quality improvement interventions, or no intervention.

''(2) COVERED HEALTH CARE ENTITY.—The term 'covered health care entity' means a health care provider, health care institution, payor, formulary committee, or other similar entity carrying out responsibilities for making drug coverage, reimbursement, or usage decisions on a population basis.''.

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