

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.

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## 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.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SAFE HARBOR FOR COMMUNICATIONS ABOUT**  
2 **VACCINES AUTHORIZED FOR EMERGENCY**  
3 **USE.**

4 (a) IN GENERAL.—The Federal Food, Drug, and  
5 Cosmetic Act is amended by inserting after section 502  
6 (21 U.S.C. 352) the following:

7 **“SEC. 502A. SAFE HARBOR FOR COMMUNICATIONS ABOUT**  
8 **VACCINES AUTHORIZED FOR EMERGENCY**  
9 **USE.**

10 “(a) IN GENERAL.—The communication of informa-  
11 tion (through written or oral means), described in sub-  
12 section (b), with respect to the use of a vaccine authorized  
13 for emergency use under section 564 provided or distrib-  
14 uted to a covered health care entity shall not be a basis  
15 for treating such vaccine as, or be treated as evidence that  
16 such vaccine is—

17 “(1) misbranded under subsection (a) or (f) of  
18 section 502; or

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

22 “(b) INFORMATION DESCRIBED.—Information de-  
23 scribed in this subsection is any information relating to  
24 a use of a vaccine authorized for emergency use under sec-  
25 tion 564 within the scope of that authorization that—

1           “(1) is neither false nor misleading, when meas-  
2           ured objectively against the information available at  
3           the time the statement is made;

4           “(2) is accompanied, as required, by an appro-  
5           priate disclaimer, including—

6                   “(A) a statement identifying any dif-  
7                   ferences between the information and any au-  
8                   thorized labeling of the vaccine;

9                   “(B) a statement identifying contradictory  
10                  evidence; and

11                  “(C) such other information as may be re-  
12                  quired by regulation; and

13           “(3) is based on competent and reliable sci-  
14           entific evidence, as described in subsection (e).

15           “(c) COVERAGE NOT EXCLUDED.—The distribution  
16 of information that otherwise meets the requirements of  
17 this section shall not fail to meet the requirements of sub-  
18 section (a) because the manufacturer or distributor of the  
19 vaccine about which information is being distributed has—

20                   “(1) knowledge that such vaccine is being used  
21                   by patients or health care practitioners in a manner  
22                   not described in any authorized labeling of the vac-  
23                   cine, as applicable; or

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

4           “(d) RULE OF CONSTRUCTION.—Nothing in this sec-  
5 tion shall be construed—

6           “(1) to limit communication to which this sec-  
7 tion does not specifically apply; or

8           “(2) to alter or expand the authority of the Sec-  
9 retary to enforce the provisions of this Act of section  
10 351 of the Public Health Service Act, except with  
11 respect to the communication of information to  
12 which this section specifically applies.

13           “(e) DEFINITIONS.—In this section:

14           “(1) COMPETENT AND RELIABLE SCIENTIFIC  
15 EVIDENCE.—

16           “(A) IN GENERAL.—In this section, the  
17 term ‘competent and reliable scientific evidence’  
18 means evidence established through scientific  
19 methods that are widely accepted by experts in  
20 the relevant field and followed pursuant to a  
21 clear and well-described protocol, as scientif-  
22 ically appropriate, regardless of whether such  
23 evidence is supported by 2 adequate and well-  
24 controlled clinical studies.

1           “(B) INCLUSIONS.—Such term may in-  
2           clude information—

3                   “(i) derived from clinical trials, obser-  
4                   vational studies, clinical studies or bench  
5                   tests that describe performance, database  
6                   reviews, registries, patient utilization pro-  
7                   jections, and modeling techniques, and the  
8                   data, inputs, and components of such in-  
9                   formation;

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

15                   “(iii) related to the authorization for  
16                   emergency use under section 564, as appli-  
17                   cable; and

18                   “(iv) relating to the safety, effective-  
19                   ness, or benefit of a use or treatment that  
20                   is authorized for emergency use under sec-  
21                   tion 564 for a vaccine, including informa-  
22                   tion regarding—

23                           “(I) health outcomes, patient or  
24                           caregiver experience, or other quality  
25                           metrics; and

1                   “(II) the comparative effective-  
2                   ness of a vaccine relative to other  
3                   products, other health care interven-  
4                   tions, program and quality improve-  
5                   ment interventions, or no intervention.

6                   “(2) COVERED HEALTH CARE ENTITY.—The  
7                   term ‘covered health care entity’ means a health  
8                   care provider, health care institution, payor, for-  
9                   mulary committee, or other similar entity carrying  
10                  out responsibilities for making drug coverage, reim-  
11                  bursement, or usage decisions on a population  
12                  basis.”.

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