

116TH CONGRESS
2D SESSION

H. R. 7971

To direct the Food and Drug Administration to solicit and consider the recommendations of the Vaccines and Related Biological Products Advisory Committee before taking certain actions with respect to COVID-19 vaccines, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 7, 2020

Mr. KRISHNAMOORTHY (for himself, Mr. CONNOLLY, Ms. TLAIB, Ms. PRESSLEY, Ms. PORTER, Mr. KHANNA, and Mr. DESAULNIER) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To direct the Food and Drug Administration to solicit and consider the recommendations of the Vaccines and Related Biological Products Advisory Committee before taking certain actions with respect to COVID-19 vaccines, 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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Expeditious Vaccine
5 Advice with Legitimate, Unbiased, Apolitical, and Tech-
6 nical Expertise Act” or the “EVALUATE Act”.

1 **SEC. 2. REQUIRED CONSIDERATION OF ADVISORY COM-**
2 **MITTEE RECOMMENDATIONS.**

3 (a) VACCINE LICENSURE OR AUTHORIZATION.—Be-
4 fore licensing or authorizing any vaccine for COVID–19
5 or SARS–CoV–2 infection (in this section referred to as
6 a “COVID–19 vaccine”), the Commissioner of Food and
7 Drugs shall—

8 (1) solicit recommendations from the Vaccines
9 and Related Biological Products Advisory Committee
10 on whether the available data are adequate to sup-
11 port the safety and effectiveness of the COVID–19
12 vaccine and whether additional studies to further
13 evaluate safety and effectiveness should be required
14 before or after licensing or authorization;

15 (2) receive such recommendations at an open
16 meeting;

17 (3) give public notice of such meeting at least
18 3 business days in advance of the meeting; and

19 (4) publicly document how such recommenda-
20 tions were considered when licensing or authorizing
21 the COVID–19 vaccine.

22 (b) MINOR OR TECHNICAL CHANGES.—Subsection
23 (a) does not apply—

24 (1) to minor or technical changes to a license
25 or authorization that is in effect; or

1 (2) in cases involving a change to a license or
2 authorization if the Commissioner of Food and
3 Drugs publishes a determination that the change is
4 not substantial and a meeting under subsection (a)
5 would not be appropriate.

6 (c) PROVISION OF INFORMATION.—

7 (1) IN GENERAL.—In connection with a meet-
8 ing of the Vaccines and Related Biological Products
9 Advisory Committee convened for purposes of sub-
10 section (a), the Commissioner of Food and Drugs
11 shall—

12 (A) provide to the Advisory Committee, at
13 least 3 business days prior to the meeting, any
14 data, summaries of data, briefing documents,
15 and other information to be presented at the
16 meeting by the Commissioner and the sponsor
17 of the COVID–19 vaccine, and make reasonable
18 efforts to provide any additional data, sum-
19 maries of data, or information requested by the
20 Advisory Committee before the meeting; and

21 (B) promptly make available on the Food
22 and Drug Administration’s website minutes,
23 audiovisual recordings, transcripts, data, sum-
24 maries of data, briefing documents, and other

1 information or documents made available to or
2 prepared for or by the Advisory Committee.

3 (2) EXCEPTION.—The Commissioner need not
4 make available minutes, audiovisual recordings,
5 transcripts, data, summaries of data, briefing docu-
6 ments, and other information or documents pursu-
7 ant to paragraph (1)(B) if the Commissioner—

8 (A) determines that the minutes, audio-
9 visual recordings, transcripts, data, summaries
10 of data, briefing documents, or other informa-
11 tion or documents should be withheld from dis-
12 closure in accordance with section 552b(c) of
13 title 5, United States Code; and

14 (B) promptly makes available on the public
15 website of the Food and Drug Administration a
16 written explanation of the reasons for not dis-
17 closing the minutes, audiovisual recordings,
18 transcripts, data, summaries of data, briefing
19 documents, or other information or documents.

○