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August 11, 2022

VIA EMAIL AND U.S. MAIL

Senators U.S. Senate Committee on Health, Education, Labor and Pensions 428 Senate Dirksen Office Building, Washington, DC 20510

Representatives U.S. House Committee on Energy & Commerce, Subcommittee on Health 2125 Rayburn House Office Building Washington, DC 20515

Xavier Becerra Secretary, Health & Human Services 200 Independence Avenue S.W. Washington, D.C. 20201 c/o Sean McCluskie sean.mccluskie@hhs.gov

2022

Carole Johnson Administrator HRSA Headquarters U.S. Department of HHS 5600 Fishers Lane Rockville, MD 20857 Carole Johnson@hrsa.hhs.gov

CDR Reed Grimes ACCV Chair HRSA Headquarters U.S. Department of HHS 5600 Fishers Lane, 08N 1 46B Rockville, MD 20857 ACCV@HRSA.gov

Re: Meeting of the Advisory Commission on Childhood Vaccines (ACCV), June 2,

Dear Senators, Representatives, Secretary Becerra, Ms. Johnson, and CDR Grimes:

We write on behalf of our client, Informed Consent Action Network ("ICAN"), to bring to your attention serious concerns in connection with the June 2, 2022 meeting, and the overall operation of the Advisory Commission on Childhood Vaccines ("ACCV"). The ACCV has lost its way and is urgently in need of oversight and reform, including because it is failing to fulfill even its basic statutory obligations.

As explained in the charter of the ACCV, this committee was created by Congress. ¹ The charter states that "the ACCV **shall** meet four times per year." Despite this, the June 18, 2021 and March 2022 meetings were cancelled and not rescheduled. ACCV therefore only met three times in 2021 and, according to the website, only plans to meet three times this year (assuming the September 1 and December 1 meetings are not cancelled as well). ³

The charter also states that there "**shall** be" nine members appointed by the Secretary including two parents of vaccine injured children.⁴ But for much of the last three years there have been four or five vacancies that have not been filled and only one parent of a vaccine injured child, Karen Kain, has served on the ACCV instead of the two required by law.

The charter describes six duties that the ACCV "shall" undertake:

- (1) advise the Secretary on the implementation of the Program;
- (2) on its own initiative or as the result of the filing of a petition, recommend changes in the Vaccine Injury Table;
- (3) advise the Secretary in implementing the Secretary's responsibilities under Section 2127 of the PHS Act regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions;
- (4) survey federal, state, and local programs and activities relating to the gathering of information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of Section 2125(b), and advise the Secretary on means to obtain, compile, publish, and use credible data related to the frequency and severity of adverse reactions associated with childhood vaccines;
- (5) recommend to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out the Program; and
- (6) consult regarding the development or revision of vaccine information materials as required by Section 2126 of the PHS Act;

After watching the most recent ACCV meeting on June 2, 2022, it does not appear that any of these six duties have been fulfilled over the last three years (and perhaps longer). For example, vice chair Karen Kain proposed the creation of a Working Group to conduct a vaccinated vs.

¹ <u>https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/accv-charter.pdf</u>. ("the ACCV is required by 42 U.S.C. 300aa-19, Section 2119 of the Public Health Service (PHS) Act.")

² https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/accv-charter.pdf at p. 2.

³ See https://www.hrsa.gov/advisory-committees/vaccines/meetings.html.

see <u>https://www.mrsa.gov/advisory-committees/vaccines/meetings.html.</u>

⁴ https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/accv-charter.pdf at p. 2.

unvaccinated study using historical data, consistent with the responsibilities of the ACCV.⁵ A white paper published by the CDC concluded that it would be feasible to study the safety of the recommended childhood immunization schedule as a whole using the existing Vaccine Safety Datalink.⁶ The proposed Workgroup would have enabled the ACCV to fulfill all six of its duties as listed above. Instead, it was rejected by a vote of 3 to 2 with the industry representative providing the deciding vote against fulfilling the statutory obligations of the ACCV. Had the vacant seats been timely filled with new members as required by the ACCV charter, it is likely that the vote would have been in favor of the motion.

The ACCV has an essential role to play in making sure that our national vaccine supply is safe and effective. But it appears that neither HHS nor ACCV have taken seriously that critical obligation to the American public. We have learned from at least one member who shared openly at the recent meeting that the proceedings of the ACCV are characterized by bullying, harassment, and gaslighting of parents and of the larger vaccine injured community. The ACCV has repeatedly thwarted attempts to allow testimony by prominent epidemiologist Anthony Mawson who has conducted two landmark studies on vaccine adverse events.⁷

Running the ACCV pursuant to its charter is not optional or discretionary. A properly functioning ACCV is the potential difference between a safe and effective national vaccine program and widespread iatrogenic injury in American children. We strongly urge Secretary Becerra and the Senate and House committees addressed above to step in to restore the important mission and integrity of the ACCV by compelling this committee to fill all its open positions forthwith and all its duties as required by law.

Sincerely,

Aaron Siri, Esq.

Elizabeth A. Brehm, Esq.

Catherine Cline, Esq.

 $^{^{5} \, \}underline{\text{https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/meetings/2022/kain-presentation-june-} \underline{2022.pdf}$

⁶ https://www.cdc.gov/vaccinesafety/pdf/whitepapersafety web.pdf

⁷ https://www.oatext.com/pdf/JTS-3-186.pdf and https://www.oatext.com/pdf/JTS-3-187.pdf.