National Vaccine Information Center

www.NVIC.org

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*****Via Regulations.gov*****

Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA–2018–D–2613 for "Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer (DTC) Promotional Labeling and Advertisements.

The National Vaccine Information Center (NVIC), the oldest charitable organization in the United States dedicated to preventing vaccine injuries and deaths through public education and advocating for informed consent protections in medical policies and public health laws, welcomes the opportunity to provide written public comment on the above referenced docket.

The Food and Drug Administration seeks to guide manufacturers, distributors, and packers of prescription human drugs, biological products, prescription animal drugs, and in direct-to-consumer (DTC) promotional labeling for over-the-counter animal drugs. The guidance sets forth the FDA's recommendation that DTC advertising includes quantitative efficacy and risk information as follows:

- **Providing quantitative efficacy or risk information for the control group, when applicable;**
- **Presenting probability information in terms of absolute frequencies, percentages, and relative frequencies;**
- **Formatting quantitative efficacy or risk information; and**
- **Using visual aids to illustrate quantitative efficacy or risk information.**

NVIC Background and History

The National Vaccine Information Center is an educational, charitable organization (501c3) founded in 1982 by parents whose children were injured or died following DPT vaccine reactions. NVIC co-founders worked with Congress on the National Childhood Vaccine Injury Act of 1986 to secure vaccine safety informing, recording, reporting, and research provisions in that historic law. NVIC does not make vaccine use recommendations. NVIC's 40-plus year mission has been to prevent vaccine injuries

and deaths through public education and to secure informed consent protections in U.S. public health policies and laws.[1]

FDA Guidance Docket No. FDA–2018–D–2613 is Applicable to Vaccines

The FDA guidance sets forth recommendations to manufacturers, distributors, and packers of prescription human drug and biological products and prescription animal drugs and in direct-to-consumer (DTC) promotional labeling for over-the-counter animal drugs.

Accordingly, this guidance applies to all vaccines available and advertised DTC in the U.S.

DTC Promotional Material Should Include All Efficacy and Risk Information

The informed health care consumer in the U.S. deserves and expects the FDA to hold manufacturers, distributors, and packers of prescription, over the counter drugs and biological products to rigorous standards and guidelines. In DTC advertising for vaccines, effectiveness, risk, and safety information should be prominently displayed for the consumer to see. This information should be presented to potential consumers in such a manner that it is easily understood and includes the use of visual aids where appropriate. This should be true for all vaccines currently available for use and those licensed in the U.S.

For example, Comirnaty, the COVID-19 vaccine is authorized for use under emergency powers,[2] and is approved by the FDA[3]. Since COVID-19 vaccines have been made available to the public, ample evidence has emerged that taking these vaccines carry a risk for significant and life-threatening side effects.[4] [5] [6] [7] [8] [9]

These risks and side effects should be prominently displayed in an easy-to-read format on all DTC promotional material for Comirnaty as the FDA proposes for prescription human drugs, biological products, prescription animal drugs, and in direct-to-consumer (DTC) promotional labeling for over-the-counter animal drugs.

Furthermore, any DTC advertising should include quantitative efficacy or risk information for the control group, when applicable, present probability information in terms of absolute frequencies, percentages, and relative frequencies, format quantitative efficacy or risk information, and use visual aids to illustrate quantitative efficacy or risk information under FDA guidance to ensure that the public can make an informed decision to vaccination.

Any vaccine can cause adverse events.[10] The risk that an adverse event could occur should be evident on any DTC advertising and displayed according to the FDA's guidance and recommendations, including providing quantitative efficacy or risk information for the control group, when applicable, presenting probability information in terms of absolute frequencies, percentages, and relative frequencies, formatting quantitative efficacy or risk information, and using visual aids to illustrate quantitative efficacy or risk information.

The Childhood Vaccine Injury Act of 1986

The Childhood Vaccine Injury Act of 1986 (the Act) acknowledged that vaccination injuries and deaths were real, that the vaccine injured and their families should be financially compensated and established vaccine safety protections in the mass vaccination system.[11] This historic law requires vaccinators to provide to the legal representative of any child or other individual receiving a vaccine set forth in the Vaccine Injury Table with the CDC's Vaccine Information Statement (VIS) before vaccination. The VIS must contain a description of vaccine benefits and risks, and the availability of the National Vaccine Injury Compensation Program.[12]

However, the VIS is not required to be distributed for all vaccines currently licensed in the U.S. nor does it provide the level of information outlined in the FDA's DTC guidance, as noted above.[13]

The DTC promotional material will help the consumer to make an informed choice. It will provide timely information to the consumer above and beyond what is provided in the Vaccine Information Statement. The Vaccine Information statement is only provided to the legal representative of or to the vaccine recipient by the health care provider at the time of vaccination and not before. Therefore, while this information statement may provide helpful information, the patient's decision whether to take or not take a vaccine may be influenced by other factors present at the time. The patient may not have adequate time to make a fully informed decision after being presented with the risks and benefits of the vaccine.

By requiring DTC promotional labeling and advertising that reflect all quantitative efficacy or risk information, the consumer can make an informed decision about vaccination before being placed in a setting where vaccination is imminent.

Informed Consent

Since the Nuremberg Tribunal issued the Nuremberg Code after World War II, informed consent has been the central ethical principle of modern medicine. The First Principle of the Nuremberg Code states that patients must be allowed to voluntarily consent to medical intervention that inherently carry a risk of harm. Consent must not be given under duress, force, fraud, deceit, ulterior motive, or coercion.[14] Vaccination is a medical intervention that has the risk of injury and death. Accordingly, it is a human right as well as the ethical principle of modern medicine for patients to be provided the opportunity to give their informed consent to vaccination.[15]

Vaccine promotional material provided DTC must contain all quantitative efficacy or risk information in a clear and easy-to-understand format for patients to be able to exercise true informed consent to vaccination.

For all of the above reasons, the National Vaccine Information Center supports Docket No. FDA–2018–D–2613 for *"Presenting Quantitative Efficacy and Risk Information in*

Direct-to-Consumer (DTC) Promotional Labeling and Advertisements" and requests its application to all vaccines, as they are classified by the FDA as biological products.[16]

Sincerely,

Carolyn Hendler

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[1] National Vaccine Information Center. NVIC's Mission, Work & Vision for the Future.
[2] Bruer, W. FDA gives "Fast Track" status to two Covid-19 vaccine candidates. *CNN*. Jul. 13, 2020
[3] Comirnaty. U.S. Food & Drug Administration. Apr. 21, 2023.
[4] Lovelace B. Trump Covid vaccine czar says side effects 'significantly noticeable' in 10% to 15% of recipients. *CNBC.* Dec. 1, 2020.
[5] European Medical Agency. Safety of COVID-19 vaccines.
[6] Liberty Counsel. COVID Shot Damage Report Reveals Alarming Human and Economic Cost. Mar. 31. 2023.
[7] Renemane L. et al. First Episode Psychosis Following COVID-19 Vaccination: A Case Report. *Psychiatric Danubina* 2022; 34(Suppl 8): 56-59.
[8] Oster ME, Shary DK, Su JR et al. Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the U.S. From December 2020 to August 2021. *JAMA* 2022; 327(4): 331-340.
[9] Fraiman J, Erviti J, Jones M et al. Serious adverse events of special interest following mRNA COVID-19 vaccination in randomized trials in adults. *Vaccine* 2022; 40(40): 5798-5805.
[10] Possible Side effects from Vaccines. *Centers for Disease Control and Prevention.* Apr. 2, 2020.
[11] Overview of the National Childhood Vaccine Injury Act of 1986. *National Vaccine Information Center.*
[12] §300aa–25. Recording and reporting of information. TITLE 42—THE PUBLIC HEALTH AND WELFARE
[13] Vaccine Information Statements (VISs). *Centers for Disease Control and Prevention.* Dec. 17, 2021.
[14] National Institutes of Health. The Nuremberg Code. *U.S. Department of Health and Human Services* 1949.
[15] The National Vaccine Information Center. What Do I Need To Know About Informed Consent? Apr. 13, 2023.
[16] U.S. Food & Drug Administration. Licensed Biological Products with Supporting Documents. Accessed: Aug. 16, 2023