

VIA FEDEX & EMAIL

January 28, 2021

Special Rapporteur on the right to health, Ms. Tlaleng Mofokeng
c/o Office of the High Commissioner for Human Rights – Palais Wilson
United Nations Office at Geneva
CH 1211 Geneva 10
Switzerland
Fax: +41(0) 22.917.90.06
Email: urgent-action@ohchr.org; srhealth@ohchr.org

Online Submission Reference Number: 4awic22o

Re: *Death of Infants in Certain Developing Countries by Systematic Use of a Biologic*

Dear Ms. Mofokeng,

The former United Nations Commission on Human Rights established the mandate of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health with particular emphasis on, *inter alia*, modern medicine and primary care in developing countries of the world. With this background, the now United Nations Human Rights Council (UNHRC) has extended the Special Rapporteur’s mandate, which includes the duty “to make recommendations on appropriate measures to promote and protect the realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, with a view to supporting States’ efforts to enhance public health.” The Special Rapporteur’s mandate also includes issues pertaining to healthcare and bioethics (*see* E/CN.4/RES/2001/71).

We therefore bring to the Special Rapporteur’s attention a pressing case concerning deaths of thousands of infants in some of the least developed countries of the world. The diphtheria, tetanus, pertussis vaccine (“DTP”), first developed in the 1940s, began being widely used in the 1970s. However, between 1981 and 2008, every developed country in the world ceased using DTP due to its negative health effects. The clear scientific evidence reflects that the use of DTP significantly increases the risk of mortality in infants who receive this product. Nevertheless, we bring to your attention a case concerning the systematic and widespread use of DTP in no fewer than 40 developing nations by persons who know or should know that this product has caused, and continues to cause, the death of infants.

The seminal study regarding DTP and mortality found that children receiving this product during the first six months of life **died at 10 times the rate** when compared to children that did not receive this product. Despite this, and many similar studies, the United Nations International Children’s Emergency Fund (“UNICEF”), continues to purchase, promote, and distribute DTP to developing and under-developed countries, and pushes its use on every newborn child long after knowing that the clear dangers it poses caused developed nations to stop using DTP decades ago.

In this case, looking past titles and words and judging UNICEF by its knowledge and actions is critical. It appears that, despite reasoned pleas to the individual decision makers at UNICEF and their full knowledge of their ongoing actions, they have no intent to stop promoting a product that is causing the death of infants in some of the most disadvantaged countries in the world.

This communication, therefore, respectfully requests that the Special Rapporteur, pursuant to her mandate under Resolution 6/29, investigate the serious situation described herein. The mere acknowledgment of an investigation will provide the first formal signal that these deaths cannot go on with impunity.

I. DTP CAUSES INCREASE IN OVERALL MORTALITY AMONG CHILDREN

As UNICEF is aware, it is well established that a vaccine may affect the overall mortality beyond what would be expected from use of the vaccine alone. Meaning, introducing a vaccine into a region can cause a decrease or an increase in the overall mortality in that region from causes beyond the infection against which the vaccine is intended. This is known as a “non-specific effect” of the vaccine.

For example, studies have found that the measles, mumps, and rubella vaccine (“MMR”) has the “non-specific effect” of reducing mortality for reasons beyond just reducing death from measles, mumps, and rubella. These studies found that upon introducing MMR to a developing country, the overall mortality among children declined more than what could have occurred from the reduction in mortality only from these three infections. Meaning, the reduction in mortality after introducing MMR was greater than the total number of deaths from measles, mumps, and rubella before introducing MMR. This pattern has been seen with the introduction of other live attenuated (*e.g.*, weakened) vaccines, such as the oral polio vaccine (“OPV”) and the Bacillus Calmette–Guérin vaccine (“BCG”). Studies of these vaccines in developing countries have found an overall decrease in mortality upon using these products beyond what could have occurred from reducing mortality from the target infections alone.

In contrast, studies of DTP, an inactivated-adjuvanted product, have found an **increase** in overall mortality among children who were administered this product. The culmination of this body of science was a capstone study conducted by respected experts and vaccine proponents from the World Health Organization (the “WHO”) published in February 2017. This capstone study, titled ‘*The Introduction of Diphtheria-Tetanus-Pertussis and Oral Polio Vaccine Among Young Infants in an Urban African Community: A Natural Experiment*’ building on nearly a dozen other studies that found DTP increased overall mortality in infants, found that children vaccinated with

DTP were *10 times more likely to die* in the first six months of life than those children that were unvaccinated (the “**2017 Study**”).¹

UNICEF has and continues to be instrumental and the central worldwide actor in the purchase, promotion and distribution of DTP in many developing countries.² UNICEF has continued this conduct despite the clear evidence that it increases mortality and despite the fact that DTP has not been subjected to a single randomized placebo-controlled trial to prove its safety.³ UNICEF even continues to purchase, promote and distribute DTP to developing nations **decades after every single developed country in the world had ceased using DTP due to its adverse effects.**⁴ Developed countries instead use a different product believed to have fewer adverse reactions. The following are just a few examples of the nations that have ceased all use of the DTP vaccine, and the year in which they were phased out:

- Japan in 1981
- South Korea in 1989
- New Zealand in 1994
- Sweden in 1996
- Australia in 1996
- United States in 1997
- Canada in 1998
- China in 2008

A. The 2017 Study

Dr. Peter Aaby, the lead author of this study, is renowned for studying and promoting vaccines in Africa with over 300 published studies.⁵ Dr. Aaby, among other things, in 1978, established and continues to direct the Bandim Health Project, a Health and Demographic Surveillance System site in Guinea-Bissau.⁶ Among his accolades, in 2000, Dr. Aaby was awarded the Novo Nordisk Prize, the most important Danish award within health research,⁷ and in 2009, the Danish Ministry of Foreign Affairs selected Dr. Aaby as a leader in the fight against global poverty.⁸ Dr. Aaby conducted this capstone study along with Dr. Søren Wengel Mogensen, Dr. Andreas Andersen, Dr. Amabelia Rodrigues, and Dr. Christine S. Benn. The 2017 Study was published in an Elsevier peer-reviewed journal which collaborates with *The Lancet* and was funded by the Ministry of Foreign Affairs of Denmark and the European Union.

In the 2017 Study, Dr. Aaby and his colleagues studied the mortality rate among children between the ages three and five months in Guinea Bissau in the 1980s, by comparing children who

¹ P. Aaby et. al., *The Introduction of Diphtheria-Tetanus-Pertussis and Oral Polio Vaccine Among Young Infants in an Urban African Community: A Natural Experiment*, 17 EBIO MEDICINE 192–198 (2017) (available at <https://pubmed.ncbi.nlm.nih.gov/28188123/>) (the “**2017 Study**”). A copy of the 2017 Study is attached as **Exhibit A**.

² See UNICEF Supply Division Update Sept. 17, 2019 (available at <https://www.unicef.org/supply/media/3176/file/VIC-2019-Session-1-UNICEF-Update.pdf>) (the “**Supply Division Update 2019**”).

³ See the 2017 Study, Exhibit A *supra* note 1 at § 5 Conclusions.

⁴ See WHO Immunization Data (available at http://www.who.int/immunization/monitoring_surveillance/data/en/).

⁵ See Dr. Aaby’s published articles at <https://www.ncbi.nlm.nih.gov/pubmed/?term=PETER+AABY%5BAuthor+-+Full%5D>.

⁶ <https://www.bandim.org/>.

⁷ See Novo Nordisk Prize Recipients (available at <https://novonordiskfonden.dk/en/prizes/the-novo-nordisk-prize/>).

⁸ <https://www.bandim.org/press>.

were vaccinated with DTP and the children who had not received the DTP. They concluded in their study that children vaccinated with DTP were 10 times more likely to die in the first 6 months of life than the unvaccinated and stated:

All currently available evidence suggests that DTP vaccine *may kill more children* from other causes than it saves from diphtheria, tetanus or pertussis.”⁹

They also found that children vaccinated with DTP were dying from causes never associated with this vaccine, such as respiratory infections, diarrhea, and malaria.¹⁰ This indicated that while DTP reduced the incidence of diphtheria, tetanus, and pertussis, it increased susceptibility to other infections.¹¹

The most pivotal work addressing the correlation between DTP and mortality prior to the 2017 Study was a 2014 study published by the Strategic Advisory Group of Experts (“SAGE”), an advisory group to the WHO authored by Dr. Julian P T Higgins, Dr. Karla Soares-Weiser and Dr. Arthur L Reingold (the “SAGE Review”).¹² The SAGE Review identified 16 studies that compared death rates between children receiving DTP and children not receiving DTP.¹³ Shockingly, SAGE found that a “majority of studies indicated a negative effect of DTP,” meaning a majority of the studies SAGE reviewed found that DTP killed more children than it saved.¹⁴ For example, one study found that children receiving DTP were between 154% and 1,219% more likely to die than those who did not receive DTP.¹⁵ Nevertheless, SAGE chose to give little weight to these studies despite their being conducted by WHO’s respected vaccine experts, because SAGE stated: (i) these studies were not “randomized” (*i.e.*, children were not randomly assigned to either receive or not receive DTP, hence potentially introducing bias¹⁶), (ii) “OPV [Oral Polio Vaccine] was administered concomitantly with DTP in most included studies” and hence it “was not possible to separate any possible effects of DTP from OPV in the available studies,”¹⁷ and (iii)

⁹ The 2017 Study, Exhibit A *supra* note 1, at § 5, Conclusions.

¹⁰ *Ibid.*

¹¹ *Ibid.*

¹² J. Higgins *et al.*, *Systematic review of the non-specific effects of BCG, DTP and measles containing vaccines*, Report to WHO, Mar. 13, 2014 (available at https://www.who.int/immunization/sage/meetings/2014/april/1_NSE_Background_paper_final.pdf) (the “SAGE Review”).

¹³ *Ibid.*

¹⁴ *Ibid.*

¹⁵ *Ibid.*

¹⁶ For example, unvaccinated children often do not receive vaccines because they are very frail, malnourished or sick, and hence more likely to die irrespective of vaccination. Thus, the unvaccinated group is often sicker than the vaccinated group, making the vaccine appear safer. By randomly picking which children receive or do not receive the DTP vaccine, a researcher can avoid this type of bias.

¹⁷ See the SAGE Review *supra* note 12.

these studies were often conducted in communities with existing “herd immunity” that could have introduced further bias.¹⁸

The 2017 Study addressed the three shortcomings identified by the SAGE Review. The study addressed the “randomized” issue by comparing children vaccinated solely based on birthdates, thereby creating a random grouping.¹⁹ It addressed the “OPV with DTP” issue by comparing children receiving no vaccines with those only receiving DTP.²⁰ It also addressed the “herd immunity” issue by looking at death rates at the time of the introduction of DTP in that region.²¹ As explained in the introduction to the 2017 Study:

WHO’s Strategic Advisory Group of Experts on Immunization (SAGE) recently reviewed the potential NSEs [Non-Specific Effects] of ... diphtheria-tetanus-pertussis (DTP) ... and recommended further research (Higgins et al., 2014; Strategic Advisory Group of Experts on Immunization, 2014).

Though protective against the target diseases, DTP may increase susceptibility to unrelated infections (Aaby et al., 2003b, 2004a, 2012) (Appendix A). The SAGE review noticed that the majority of studies found a detrimental effect of DTP (Higgins et al., 2014). However, SAGE considered the evidence inconsistent because two studies reported beneficial effects (Higgins et al., 2014) and that most studies underestimated the benefit of DTP because studies were conducted in situations with herd immunity. Furthermore, all studies gave DTP and OPV together, making it impossible to separate effects of DTP and OPV (SAGE non-specific effects of vaccines Working Group, 2014).

On the other hand, the “unvaccinated” children in these studies have usually been frail children too sick or malnourish to get vaccinated, and the studies may therefore have underestimated the negative effect of DTP. We therefore examined what happened when DTP and OPV were first introduced, but not always given together, in 1981–1983 in the capital of Guinea-Bissau. In this situation the children were allocated by birthday to receive vaccines early or late and the “unvaccinated” were therefore not frail children.²²

The 2017 Study also explained why it is the best study and the best evidence that modern science will almost certainly ever have to determine whether DTP kills more children than it saves:

¹⁸ *Ibid.*

¹⁹ The 2017 Study, Exhibit A *supra* note 1.

²⁰ *Ibid.*

²¹ *Ibid.*

²² *Ibid* at § 1 Introduction.

The recently published SAGE review called for randomized trials of DTP (Higgins et al., 2014). However, at the same time the IVIR-AC committee [Immunization and Vaccines Related Implementation Research Advisory Committee] to which SAGE delegated the follow-up studies of the NSEs [Non-Specific Effects] of vaccines has indicated that it will not be possible to examine the effect of DTP in an unbiased way. If that decision by IVIR-AC remains unchallenged, the present study [the 2017 Study] may remain the closest we will ever come to a RCT [Randomized Controlled Trial] of the NSEs of DTP.²³

The 2017 Study, therefore, represents the closest and best data UNICEF will likely ever have regarding whether DTP kills more children than it saves; and as noted, it concluded that children receiving DTP in the first six months of life *died at ten times the rate* of those children who received no vaccines in the first six months of life.²⁴

B. The 2018 Study

Dr. Aaby and his colleagues published yet another study in 2018 titled ‘*Evidence of Increase in Mortality After the Introduction of Diphtheria–Tetanus–Pertussis Vaccine to Children Aged 6–35 Months in Guinea-Bissau: A Time for Reflection?*.’ (the “**2018 Study**”).²⁵ While the 2017 Study focused on children between the ages three and five months, the 2018 Study looked at children between six and thirty-five months of age and compared DTP-vaccinated children that were generally healthier and had better nutritional status with non-DTP-vaccinated children who generally were unhealthier and had worse nutritional status. The incredible result:

Although having better nutritional status and being protected against three infections, 6-35 months old DTP-vaccinated children tended to have higher mortality than DTP-unvaccinated children. All studies of the introduction of DTP have found increased overall mortality.²⁶

The 2018 Study also cautioned against the use of DTP stating the following:

Given the threat from diphtheria, tetanus, and pertussis and the less-effective acellular pertussis vaccine used in many countries, it is understandable that there has been reluctance in accepting that DTP could have negative effects for overall health in low-income

²³ *Ibid* at § 5 Conclusions.

²⁴ *Ibid* at § 4.1 Main Observations (emphasis supplied). The 2017 Study also found that infants receiving DTP *died at five times the rate* as compared to infants that received OPV.

²⁵ P. Aaby, et al., *Evidence of Increase in Mortality After the Introduction of Diphtheria–Tetanus–Pertussis Vaccine to Children Aged 6–35 Months in Guinea-Bissau: A Time for Reflection?*, 6 FRONT. PUBLIC HEALTH 79 (2019), available at (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5868131/pdf/fpubh-06-00079.pdf>). A copy of the 2018 Study is attached as **Exhibit B**.

²⁶ *Ibid*.

countries. However, the studies from low-income countries have been consistent in showing deleterious effect of DTP.

In the current global immunization system, the coverage for the third dose of DTP (DTP3) is used as the main performance indicator for national immunization programs. This will clearly lead to an emphasis on increasing the coverage for DTP3 more than the coverage for other vaccines. Given that all studies, including the present one, suggest that DTP is associated with increased female mortality, this is really an illogical position. We need to use program performance indicators which are positively associated with better child survival.²⁷

If the 2017 Study was not enough evidence to alert the persons responsible for providing developing countries, the 2018 Study cemented and reaffirmed the conclusions drawn in the previous study.

There have been other studies such as Dr. Peter C. Gøtzsche, Professor, DrMedSci, MSc's work titled '*Effect of DTP Vaccines on Mortality in Children in Low-Income Countries*' (the "**2019 White Paper**") that have analyzed the previous works and arrived at the same results as the 2017 Study.²⁸

II. UNICEF'S OFFICIALS WERE MADE AWARE REGARDING THE CLEAR SCIENTIFIC EVIDENCE THAT DTP INCREASES MORTALITY

At least since late 2017, UNICEF has been aware of Dr. Aaby's seminal works shedding light on the dangers posed by DTP. Independent non-profit organizations such as the Informed Consent Action Network ("ICAN") and the Vaccine Science Foundation ("VSF") have written to UNICEF officials bringing the 2017 Study to their notice and demanding that UNICEF either stop procurement of DTP or at least provide contrary evidence to support continual use of this deadly product.

A. ICAN's Communications with UNICEF

ICAN is a not-for-profit organization, based in the United States, that advocates for informed consent and disseminates information necessary for same with regard to all medical interventions. ICAN sent a letter to UNICEF on December 5, 2017 enclosing a copy of the 2017 Study.²⁹ ICAN demanded that UNICEF cease the distribution of this product or at least, pursuant to the Nuremberg Code,³⁰ advise the parents or the guardians of the children receiving DTP prior

²⁷ *Ibid.*

²⁸ P. Gøtzsche, *Expert Report on the Effect of DTP Vaccines on Mortality in Children in Low-Income Countries*, VACCINE SCIENCE FOUNDATION, Jun. 19, 2019 at 19 (available at <https://vaccinescience.org/wp-content/uploads/2019/07/Expert-Report-Effect-of-DTP-Vaccines-on-Mortality-in-Children-in-Low-Income-Countries.pdf>) (the "**2019 White Paper**").

²⁹ A copy of ICAN's letter of Dec. 5, 2017 is attached as **Exhibit C**.

³⁰ The Nuremberg Code (1947), 313 BMJ 1448 (1996) at ¶1 (also available at <http://www.cirp.org/library/ethics/nuremberg>) ("The voluntary consent of the human subject is absolutely essential. This means that the person ... should

to administering this product that, according to the best available scientific evidence, DTP will render their child more likely, not less likely, to die.³¹ ICAN's letter, further called on UNICEF to identify the infants who died by this product in order to provide their families with reparations.³²

On February 6, 2018, UNICEF responded to ICAN through a letter³³ merely pointing to the 2014 SAGE Review, which had found that "the available data neither excludes nor confirm[s] the possibility of beneficial or deleterious non-specific effects of DTP vaccines on all-cause mortality".³⁴ UNICEF's extensive response to ICAN, however, did not address or even discuss the 2017 Study, let alone explaining why the SAGE Review should be considered as the most reliable scientific study on the subject.³⁵

ICAN responded to UNICEF in a letter dated March 15, 2018,³⁶ in which it explained that the 2017 Study was expressly designed to address the particular shortcomings of the 2014 SAGE Review. ICAN, therefore, called for UNICEF to join every single developed country in the world in ceasing the use of DTP.³⁷ It pointed out that Japan, for example, ceased using this product in 1981, South Korea in 1989, New Zealand in 1994, the United States in 1997, and China in 2008.³⁸

ICAN also again implored UNICEF to cease distribution of this product or at least obtain informed consent from parents before administering this product. As ICAN made unmistakably clear: "Continued promotion and distribution of DTP vaccine without any evidence to refute the 2017 Study's unmistakable findings would violate various laws designed to protect children from harm."³⁹ Despite these strong arguments and the clear science against the continued distribution of DTP, UNICEF did not respond to ICAN's letter of March 15, 2018.

Due to UNICEF's silence, on July 26, 2018, ICAN sent UNICEF another letter,⁴⁰ which attached all prior letters and again attached a copy of the 2017 Study. This letter also pointed UNICEF to Dr. Aaby's 2018 Study and stated:

Despite the passage of over four months, UNICEF has failed to respond to our March 15, 2018 letter and it has now been over eight months since we brought to your attention the fact that UNICEF is

have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision.").

³¹ Exhibit C at 3.

³² *Ibid* at 2.

³³ A copy of UNICEF's letter of Feb. 6, 2018 is attached as **Exhibit D**.

³⁴ The SAGE Review, *supra* note 12.

³⁵ *See supra* § I.A.

³⁶ A copy of ICAN's letter of Mar. 15, 2018, is attached as **Exhibit E**.

³⁷ *Ibid*.

³⁸ *Ibid*.

³⁹ *Ibid*.

⁴⁰ A copy of ICAN's Jul. 26, 2018 letter is attached as **Exhibit F**.

purchasing, distributing and widely promoting a vaccine for which, as is plain from our letter exchange, the best available evidence clearly demonstrates it is killing far more children than it is saving.

As you are likely also already acutely aware, on the heels of our last letter, Dr. Aaby and his renown vaccine advocate colleagues published an article on March 19, 2018, in the journal *Frontiers in Public Health*, entitled *Evidence of Increase in Mortality After the Introduction of Diphtheria–Tetanus–Pertussis Vaccine to Children Aged 6–35 Months in Guinea-Bissau: A Time for Reflection?* (the “**2018 Study**”). ...

As you will recall, the 2017 Study found that babies younger than six months of age receiving DTP vaccine died at ten times the rate as babies in the same age range that did not receive any vaccines. The 2018 Study looked at children between six and thirty-five months of age and compared DTP-vaccinated children that were generally healthier and had better nutritional status with non-DTP-vaccinated children who generally were unhealthier and had worse nutritional status. The incredible result: “Although having better nutritional status and being protected against three infections, 6-35 months old DTP-vaccinated children tended to have higher mortality than DTP-unvaccinated children. All studies of the introduction of DTP have found increased overall mortality.”⁴¹

This letter then concluded, in relevant part, by imploring the decision makers at UNICEF to stop purchasing and distributing a product that they could no longer plausibly deny knowing was causing death of infants:

In our letter from March 2018, we ... asserted that continued promotion and distribution of DTP vaccine without any evidence to refute the 2017 Study’s unmistakable findings would violate various laws designed to protect children from harm.

It has now been over eight months since we provided you, on two occasions, a copy of the 2017 Study. Yet, despite your verbose response in February 2018, you have failed to provide even a single argument to contest the 2017 Study’s methodology or conclusions. In fact, you have failed to address this study altogether. And you have also failed to indicate that UNICEF will, at the least, as required by the Nuremberg Code, assure that parents are being advised of the increased risk of death from DTP vaccine prior to administering this vaccine to their child.

⁴¹ *Ibid.* (citations omitted).

Copies of this letter with all exhibits will be distributed directly to all members of UNICEF that we can identify that are involved in the purchase, distribution and promotion of DTP vaccine. For all UNICEF individuals receiving this letter, please take notice that your continued distribution of this for-profit product violates various laws, including various international human rights law. Furthermore, absent forthwith confirmation from UNICEF that it has either ceased distribution of DTP vaccine or has evidentiary support for why the 2017 Study and 2018 Study are incorrect, we intend to take appropriate remedial action, including referral to the International Criminal Court, against all individuals at UNICEF involved in continued purchase, distribution and promotion of a product that the best available evidence makes clear is killing far more children than it is saving.⁴²

ICAN's letter of July 26, 2018, was sent to the following individuals:

Henrietta H. Fore
Executive Director
UNICEF
3 United Nations Plaza
New York, New York 10017

Dr. Stefan Peterson
Associate Director, Health
UNICEF
3 United Nations Plaza
New York, New York 10017

Dr. Robin Nandy
Principal Advisor & Chief of Immunizations
UNICEF
3 United Nations Plaza
New York, New York 10017

Krista Hund
Partnership Specialist
UNICEF
3 United Nations Plaza
New York, New York 10017

Dmitri Davydov
Coordinator, Vaccine Management Systems
UNICEF
3 United Nations Plaza
New York, New York 10017

Heather Deehan
Chief, Vaccine Centre
UNICEF
3 United Nations Plaza
New York, New York 10017

Benjamin Hickler
Medical Anthropologist
Communication for Development
UNICEF
3 United Nations Plaza
New York, New York 10017

Aung Kyaw Lwin
Immunization Supply Chain Financing Consultant
UNICEF
18 Tremont St #820
Boston, MA 02108

Helena Ballester Bon
Communication for Immunization
UNICEF
3 United Nations Plaza
New York, New York 10017

⁴² *Ibid.*

Further, ICAN's first letter of December 5, 2017 was sent to Dr. Anthony Lake, then Executive Director of UNICEF who has since resigned from his post.

B. VSF's Communications with UNICEF

The Vaccine Science Foundation (VSF) is a non-profit organization, based in the United States, that supports research related to vaccines as well as compiles existing vaccine research and creates related white papers for use by the scientific community and general public.

UNICEF also received a letter from VSF⁴³ which attached the 2019 White Paper, published June 19, 2019, by world-renowned scientist Peter C. Gøtzsche, Professor, DrMedSci, MSc. The 2019 White Paper reviewed all existing evidence regarding DTP and its effect on mortality and reached the same conclusion as that in the 2017 Study. VSF's letter to UNICEF, therefore, provided, in relevant, part as follows:

The Vaccine Science Foundation proudly supports UNICEF's goal of reducing child mortality worldwide. For this reason, the Vaccine Science Foundation urges you to read the expert report *Effect of DTP Vaccines on Mortality in Children in Low-Income Countries*, to ensure that UNICEF can productively engage in its goal of reducing child mortality.

The Vaccine Science Foundation respectfully requests that UNICEF explain whether it accepts the conclusion of the attached expert report. If it does, explain the actions it intends to take. If it does not accept the conclusion of this report, please explain the basis for rejecting its conclusion.⁴⁴

UNICEF never responded to the letter from VSF. UNICEF has also never responded to the letters from ICAN dated March 15, 2018 and July 26, 2018.

III. UNICEF FAILS TO OFFER ANY EVIDENCE TO REBUT THE CLEAR SCIENTIFIC EVIDENCE THAT DTP INCREASES MORTALITY

UNICEF has never, in over 3 years, provided any evidence to rebut the findings of the 2017 Study, the 2018 Study, or the 2019 White Paper. It is believed that UNICEF nonetheless continues to purchase, promote, and distribute DTP to the following countries:

Afghanistan, Albania, Angola, Armenia, Azerbaijan, Bangladesh, Benin, Bhutan, Bolivia, Bosnia and Herzegovina, Bulgaria, Burkina Faso, Burundi, Cambodia, Cameroon, Central African Republic, Chad, Cote d'Ivoire, Cuba, Democratic Republic of Congo, Djibouti, Egypt, Equatorial Guinea, Eritrea, Eswatini, Ethiopia, Gabon, Georgia, Ghana, Guinea, Guinea-Bissau, Guyana, Haiti,

⁴³ A copy of the Vaccine Science Foundation's Letter is attached as **Exhibit G**.

⁴⁴ Exhibit G.

Honduras, India, Indonesia, Iraq, Jordan, Kenya, Kyrgyzstan, Laos, Lebanon, Lesotho, Liberia, Libya, Madagascar, Malawi, Mali, Mauritania, Moldova, Mongolia, Morocco, Mozambique, Myanmar, Namibia, Nepal, Nicaragua, Niger, Nigeria, North Korea, Pakistan, Palestine, Papua New Guinea, Philippines, Rwanda, Republic of Congo, Senegal, Seychelles, Sierra Leone, Singapore, Somalia, South Sudan, Sudan, Syria, Tajikistan, Tanzania, Togo, Turkey, Turkmenistan, Uganda, Ukraine, Uzbekistan, Vietnam, Yemen, Zambia, and Zimbabwe.⁴⁵

UNICEF's conduct may be, in part, explained by its conflicting interest in promoting a "healthy" pharmaceutical industry.

UNICEF has declared that a "healthy industry is vital to ensure uninterrupted and sustainable supply of vaccines" and has extensive financial arrangements and a "long-standing relationship with" pharmaceutical companies producing vaccines.⁴⁶ Indeed, in 2019 alone, UNICEF purchased over \$1.656 billions of vaccine products from these companies and spent an equally significant sum paying companies for their distribution, in total amounting to over a third of UNICEF's budget.⁴⁷ ICAN sincerely hoped that political and economic considerations, as well as UNICEF's understandable instinct of self-preservation and its desire to safeguard its reputation, would not cloud UNICEF's judgment when evaluating its clear moral, ethical and legal duty to protect children from death from DTP.

Sadly, despite repeated demands over three years, UNICEF has failed to provide a single explanation for why the 2017 Study, which confirmed earlier findings and whose findings were reaffirmed in the 2018 Study, is incorrect. Up until UNICEF's response letter on February 6, 2018, and even until ICAN's follow-up letter of March 15, 2018, UNICEF could potentially have claimed ignorance or mistake in distributing DTP. But after it had been provided the 2017 Study twice and could not provide any proof to contradict its findings, the decisionmakers within UNICEF were acting with full knowledge their inaction was, according to these studies, causing deaths of infants.

It is understandable that those making serious mistakes are reluctant to change course. UNICEF's desire for self-preservation is, however, no excuse for continuing to cause the death of children in developing and underdeveloped countries. These acts violate several fundamental

⁴⁵ This list was compiled from the following reports from the United Nations Children's Fund ("UNICEF"): https://www.dcvmn.org/IMG/pdf/27th_suvi_stockpiling_strategies_and_priorities.pdf; <https://www.fondation-merieux.org/wp-content/uploads/2017/03/vaccination-ecosystem-health-check-2015-heather-deehan.pdf>; [https://www.unicef.org/supply/media/556/file/Diphtheria,%20tetanus%20and%20pertussis%20\(DTP\)%20vaccines%20supply%20update.pdf](https://www.unicef.org/supply/media/556/file/Diphtheria,%20tetanus%20and%20pertussis%20(DTP)%20vaccines%20supply%20update.pdf); <https://www.gavi.org/progress-report>; <https://www.unicef.org/supply/resources/annual-reports>; https://www.unicef.org/mena/sites/unicef.org.mena/files/2018-04/immunization%20financing%20Web_0.pdf.

⁴⁶ See Supply Division Update 2019 *supra* note 2; see also, UNICEF Supply Division Website (available at <https://www.unicef.org/supply/pricing-data>).

⁴⁷ See UNICEF Supply Division Annual Report 2019 (available at <https://www.unicef.org/supply/sites/unicef.org/supply/files/2020-06/Supply-Annual-Report-2019.pdf>).

human rights under international law and thus, they must stop; those harmed must receive recompense.

IV. CONCLUSION

While medical interventions have saved countless lives, the graveyard of history is also replete with once lauded but later abandoned medical inventions and practices. When an issue with a medical procedure is identified, especially when it is causing death of innocent children, immediate action is demanded. Unfortunately, it appears that political and economic considerations at UNICEF have clouded its clear moral and ethical duty to protect children from death caused by its administration of DTP.

We also attach herein a link to the video testimony of parents who lost their infant daughter within hours after receiving DTP. (<https://www.youtube.com/watch?v=pm3A6Bq5JWU>.) The testimony of these parents is merely one example of the pain and suffering caused to parents around the world who have lost a child to this product.

We look forward to the response from the Special Rapporteur and pray for confirmation that she will proceed with an investigation pursuant to her mandate as charged by the UN HRC. We remain at the Special Rapporteurs disposal to provide any additional information as needed to assist the Special Rapporteur to conduct her analysis and investigation. It is our sincere hope that the mere existence of an investigation will finally move UNICEF to act to save the infants in developing countries who are dying each day due to its DTP program.

Thank you for the time taken to review this submission and for working toward protecting all children, especially the most disenfranchised, from premature death based on the actions of those in positions of power.

Respectfully submitted,



Aaron Siri, Esq.
Elizabeth Brehm, Esq.
Jessica Wallace, Esq.
Sonal Jain, Adv.*
SIRI & GLIMSTAD LLP
200 Park Avenue
17th Floor
New York, NY 10166
Telephone: (212) 532-1091
Facsimile: (646) 417-5967
Email: aaron@sirillp.com

Enclosure: Exhibits A – G

* Admitted to practice law in the Republic of India.