DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

March 27, 2020

SENT VIA EMAIL

Allison Lucas
Siri & Glimstad
200 Park Ave
17th Floor
New York, NY 10166
foia@sirillp.com

Dear Ms. Lucas:

This letter is our final response to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of February 14, 2020, assigned #20-00627-FOIA, for:

an email enterprise search utilizing the following criteria:

Date range for the search:	June 1, 2019 to February 14, 2020
Individual(s) whose email account should be searched:	Bonita Johnson (bcj1@cdc.gov) Frank DeStefano (fxd1@cdc.gov)
Limit search to emails with any of the following terms in the subject line and/or body of the email:	Freedom of Information FOIA Enterprise

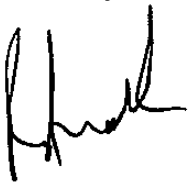
We located 20 pages of responsive records (19 pages released in full; one page released in part). After a careful review of these pages, some information was withheld from release pursuant to 5 U.S.C. §552 Exemption 6.

Exemption 6 protects information in personnel and medical files and similar files when disclosure would constitute a clearly unwarranted invasion of personal privacy. The information that has been withheld under Exemption 6 consists of personal information, such as the type of employee leave. We have determined that the individual to whom this information pertains has a substantial privacy interest in withholding it.

You may contact our FOIA Public Liaison at 770-488-6277 for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, Maryland 20740-6001, e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

If you are not satisfied with the response to this request, you may administratively appeal by writing to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, Suite 729H, Washington, D.C. 20201.You may also transmit your appeal via email to FOIARequest@psc.hhs.gov. Please mark both your appeal letter and envelope "FOIA Appeal." Your appeal must be postmarked or electronically transmitted by Thursday, June 25, 2020.

Sincerely,



Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
Phone: (770) 488-6399
Fax: (404) 235-1852

Enclosures

20-00627-FOIA

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP)
Sent: 19 Sep 2019 15:09:51 +0000
To: Destefano, Frank (CDC/DDID/NCEZID/DHQP)
Cc: Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP);Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Subject: FW: 19-00989-FOIA (results of Enterprise Search)
Attachments: 19-00989 Lucas.pdf
Importance: High

Good Morning Frank!

Yesterday, I received a request for a SME review of an FOIA Enterprise Search. The records are regarding " Email Communications Between DeStefano, Plotkin and Offit, January 2017 to Present. The search yield a total of 748 pages. I am currently reviewing them on your behalf. If I find anything that I feel you need to review personally, I will let you know. If you would like to review the document, you are welcome too as well. Please see the link below:

You can view/download the records here
https://centersfordiseasecontrol.sharefile.com/d-s84bf7a7abd341288

I am on (b)(6) leave all next week but I will likely finish this up by next Monday/Tuesday. I will keep you posted.

Best,
PerStephanie

From: Jackson, Eric (CDC/DDID/NCEZID/OD) <eoj0@cdc.gov>
Sent: Wednesday, September 18, 2019 2:06 PM
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Gresham, Angela (CDC/DDID/NCEZID/DHQP) (CTR) <nmc8@cdc.gov>
Cc: Jackson, Eric (CDC/DDID/NCEZID/OD) <eoj0@cdc.gov>; Brouillette, Colleen (CDC/DDID/NCEZID/OD) (CTR) <mfi3@cdc.gov>
Subject: FW: 19-00989-FOIA (results of Enterprise Search)

FYI below-link points to the combined results of a CDC FOIA Office Enterprise Search on this FOIA request. Please review and provide comments by COB **9/25/2019.**

Eric Jackson
NCEZID FOIA Coordinator
NCEZID Senior Records Liaison
Telework Tuesdays & Thursdays
E-mail: eoj0@cdc.gov
770-488-4761

From: Brouillette, Colleen (CDC/DDID/NCEZID/OD) (CTR) <mfi3@cdc.gov>
Sent: Wednesday, September 18, 2019 1:59 PM

To: NCEZID FOIA Enterprise Search (CDC) <ncezidfoiaes@cdc.gov>; Jackson, Eric (CDC/DDID/NCEZID/OD) <eoj0@cdc.gov>
Subject: FW: 19-00989-FOIA

Colleen Brouillette
Contractor, Chenega Professional Technical Services
Office of Policy, Analysis and Strategy
National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
Centers for Disease Control and Prevention (CDC)
1600 Clifton Rd. NE, (Bldg 16) MS C-12, Atlanta, GA 30329
Phone: 404-718-5208 | E-mail: cbrouillette@cdc.gov

Telework Wednesdays

From: Spencer, Laura (CDC/OCOO/OD) <vbx0@cdc.gov>
Sent: Wednesday, September 18, 2019 7:30 AM
To: Elswick, David C. (CDC/DDID/NCEZID/OD) <dce1@cdc.gov>
Cc: Brouillette, Colleen (CDC/DDID/NCEZID/OD) (CTR) <mfi3@cdc.gov>
Subject: RE: 19-00989-FOIA

Apologies. I forgot to attach the request itself.

From: Spencer, Laura (CDC/OCOO/OD)
Sent: Wednesday, September 18, 2019 7:29 AM
To: Elswick, David C. (CDC/DDID/NCEZID/OD) <dce1@cdc.gov>
Cc: Brouillette, Colleen (CDC/DDID/NCEZID/OD) (CTR) <mfi3@cdc.gov>
Subject: 19-00989-FOIA

David,

The FOIA Office conducted an enterprise search for this FOIA request. Given the subject matter, we are providing you with a chance to view the records prior to our final response to the requester.

You can view/download the records here https://centersfordiseasecontrol.sharefile.com/d-s84bf7a7abd341288

We plan to release to the requester next Wednesday. Please let me know if you have any questions or concerns. We are also providing OADC with a copy of the records.

Best,
Laura

SIRI & GLIMSTAD LLP

200 PARK AVENUE
SEVENTEENTH FLOOR
NEW YORK, NY 10166
P: (212) 532-1091
F: (646) 417-5967
WWW.SIRILLP.COM

FREEDOM OF INFORMATION ACT REQUEST

VIA FEDEX AND EMAIL July 22, 2019

Roger Andoh
Freedom of Information Officer
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., Building 57, Room MS D-54
Atlanta, Georgia 30333
Fax: (404) 235-1852
Email: FOIARequests@cdc.gov

Re: Email Communications Between DeStefano, Plotkin and Offit, January 2017 to Present (IR#0144)

Dear Mr. Andoh:

This firm represents Informed Consent Action Network ("ICAN"). On behalf of ICAN, we are requesting records pursuant to the Freedom of Information Act (5 U.S.C. § 552, as amended) from the files of the Centers for Disease Control and Prevention ("CDC").

By this letter, please provide the following records in the CDC's possession to the above referenced address in electronic form on a CD or DVD or via email to foia@sirillp.com:

> **Each and every email communication between January 1, 2017, and the present which includes Frank DeStefano or his email address on the "To", "From", "Cc" or "Bcc" line and also includes Stanley Plotkin or his email address on the "To", "From", "Cc" or "Bcc" line.**
>
> **Each and every email communication between January 1, 2017, and the present which includes Frank DeStefano or his email address on the "To", "From", "Cc" or "Bcc" line and also includes Paul Offit or his email address on the "To", "From", "Cc" or "Bcc" line.**

As a courtesy, note that email addresses for Stanley Plotkin include but are not limited to stanley.plotkin@sanofipasteur.com; and stanley.plotkin@vaxconsult.com, and emails for Paul Offit include but are not limited to offit@email.chop.edu.

We ask that you waive any and all fees or charges pursuant to 5 U.S.C. § 552 (a)(4)(A)(iii). ICAN is a not-for-profit 501(c)(3) organization whose mission is to raise public awareness about

vaccine safety and to provide the public with information to give informed consent. As part of their mission, ICAN actively investigates and disseminates information regarding vaccine safety issues, including through their website, and through press events and releases. They are seeking the information in this FOIA request to allow them to contribute to the public understanding of the government's vaccine safety programs, including the government's efforts to promote vaccine safety. The information we are requesting will not contribute to any commercial activities.

Please note that the FOIA provides that if only portions of a requested file are exempted from release, the remainder must still be released. We therefore request that we be provided with all non-exempt portions which are reasonably segregable. We further request that you describe any deleted or withheld material in detail and specify the statutory basis for the denial as well as your reasons for believing that the alleged statutory justification applies. Please also separately state your reasons for not invoking your discretionary powers to release the requested documents in the public interest. Such statements may help to avoid unnecessary appeal and litigation. ICAN of course reserves all rights to appeal the withholding or deletion of any information.

Access to the requested records should be granted within twenty (20) business days from the date of your receipt of this letter. Failure to respond in a timely manner shall be viewed as a denial of this request and ICAN may immediately file an administrative appeal.

If you would like to discuss our requests or any issues raised in this letter, please feel free to contact me at (212) 532-1091 or via email at foia@sirillp.com during normal business hours. Thank you for your time and attention to this matter.

Very truly yours,

Allison Lucas, Esq.
Licensed in MI

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP)
Sent: 15 Jul 2019 14:46:31 +0000
To: Destefano, Frank (CDC/DDID/NCEZID/DHQP)
Cc: Gresham, Angela (CDC/DDID/NCEZID/DHQP) (CTR);Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Subject: FW: Notice of Enterprise Search {19-00898-Lucas}
Attachments: 19-00898 Lucas.pdf
Importance: High

Good Morning,

This is an FYI. The FOIA office has received the attached FOIA Request and are conducting an enterprise search on emails related to the subject matter. If you have any questions please feel free to call me at 404-498-0683.

Best,
PerStephanie

From: NCEZID FOIA Requests (CDC) <NCEZIDFOIARequests@cdc.gov>
Sent: Monday, July 15, 2019 10:13 AM
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Gresham, Angela (CDC/DDID/NCEZID/DHQP) (CTR) <nmc8@cdc.gov>
Cc: Jackson, Eric (CDC/DDID/NCEZID/OD) <eoj0@cdc.gov>; Elswick, David C. (CDC/DDID/NCEZID/OD) <dce1@cdc.gov>
Subject: FW: Notice of Enterprise Search {19-00898-Lucas}

FYI—an enterprise search will be performed on the attached FOIA request. The CDC FOIA Office will let us know when/if they find any documents in order for us to review them.

Eric Jackson
NCEZID FOIA Coordinator
NCEZID Senior Records Liaison
Telework Tuesdays & Thursdays
E-mail: eoj0@cdc.gov
770-488-4761

From: Brouillette, Colleen (CDC/DDID/NCEZID/OD) (CTR) <mfi3@cdc.gov>
Sent: Monday, July 15, 2019 10:08 AM
To: NCEZID FOIA Requests (CDC) <NCEZIDFOIARequests@cdc.gov>; Jackson, Eric (CDC/DDID/NCEZID/OD) <eoj0@cdc.gov>
Subject: FW: Notice of Enterprise Search {19-00898-Lucas}

Forwarding the message below to you.

Colleen Brouillette
Contractor, Chenega Professional Technical Services

Office of Policy, Analysis and Strategy
National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
Centers for Disease Control and Prevention (CDC)
1600 Clifton Rd. NE, (Bldg 16) MS H16-5, Atlanta, GA 30329
Phone: 404-718-5208 | E-mail: cbrouillette@cdc.gov

Telework Mondays

From: Fon, Carolyn (CDC/OCOO/OD) <xxo5@cdc.gov>
Sent: Monday, July 15, 2019 9:46 AM
To: Elswick, David C. (CDC/DDID/NCEZID/OD) <dce1@cdc.gov>
Cc: Brouillette, Colleen (CDC/DDID/NCEZID/OD) (CTR) <mfi3@cdc.gov>; Andoh, Roger (CDC/OCOO/OD) <mhu9@cdc.gov>; Viana, Bruno A. (CDC/OCOO/OD) <cqy8@cdc.gov>; Fon, Carolyn (CDC/OCOO/OD) <xxo5@cdc.gov>; Diaz, Irma S. (CDC/OCOO/OD) <jyo9@cdc.gov>
Subject: Notice of Enterprise Search {19-00898-Lucas}

Good morning David,

Happy Monday! Please be advised that a FOIA Enterprise Search will be conducted for the aforementioned FOIA request.

If you have any questions, please feel free to contact me at any time via any means.

Thank you and please enjoy the rest of your day!

V/R

Carolyn Sanchang-Fon Okpewho
CDC/ATSDR Workstream Leader
Freedom of Information Act Office
Centers for Disease Control and Prevention
Agency for Toxic Substances and Disease Registry
770-488-6332 (Direct) | 770-488-6399 (Main)
404-235-1852 | Carolyn.Fon@cdc.hhs.gov
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SIRI & GLIMSTAD LLP

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FREEDOM OF INFORMATION ACT REQUEST

VIA FEDEX AND EMAIL June 24, 2019

Roger Andoh
Freedom of Information Officer
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., Building 57, Room MS D-54
Atlanta, Georgia 30333
Fax: (404) 235-1852
Email: FOIARequests@cdc.gov

Re: Emails Between DeStefano and Plotkin From January 2017 to Present (IR#0141)

Dear Mr. Andoh:

This firm represents Informed Consent Action Network ("ICAN"). On behalf of ICAN, we are requesting records pursuant to the Freedom of Information Act (5 U.S.C. § 552, as amended) from the files of the Centers for Disease Control and Prevention ("CDC").

By this letter, please provide the following records in CDC's possession to the above referenced address in electronic form on a CD or DVD or via email to alucas@sirillp.com:

1. Each and every email communication between January 1, 2017, and the present which includes Frank DeStefano or his email address on the "To", "From", "Cc" or "Bcc" line and also includes Stanley Plotkin or his email address on the "To", "From", "Cc" or "Bcc" line mentioning, regarding or relating to the publication entitled *Principal Controversies in Vaccine Safety in the United States*. A copy of this publication is appended hereto.

2. Each and every email communication between January 1, 2017, and the present which includes Frank DeStefano or his email address on the "To", "From", "Cc" or "Bcc" line and also includes Paul Offit or his email address on the "To", "From", "Cc" or "Bcc" line mentioning, regarding or relating to the publication entitled *Principal Controversies in Vaccine Safety in the United States*. A copy of this publication is appended hereto.

As a courtesy, note that email addresses for Stanley Plotkin include but are not limited to stanley.plotkin@sanofipasteur.com; and stanley.plotkin@vaxconsult.com, and for Paul Offit include but are not limited to offit@email.chop.edu.

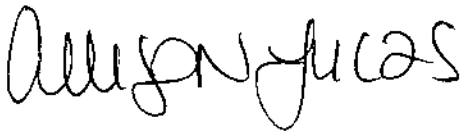
We ask that you waive any and all fees or charges pursuant to 5 U.S.C. § 552 (a)(4)(A)(iii). ICAN is a not-for-profit 501(c)(3) organization whose mission is to raise public awareness about vaccine safety and to provide the public with information to give informed consent. As part of their mission, ICAN actively investigates and disseminates information regarding vaccine safety issues, including through their website, and through press events and releases. They are seeking the information in this FOIA request to allow them to contribute to the public understanding of the government's vaccine safety programs, including the government's efforts to promote vaccine safety. The information we are requesting will not contribute to any commercial activities.

Please note that the FOIA provides that if only portions of a requested file are exempted from release, the remainder must still be released. We therefore request that we be provided with all non-exempt portions which are reasonably segregable. We further request that you describe any deleted or withheld material in detail and specify the statutory basis for the denial as well as your reasons for believing that the alleged statutory justification applies. Please also separately state your reasons for not invoking your discretionary powers to release the requested documents in the public interest. Such statements may help to avoid unnecessary appeal and litigation. ICAN of course reserves all rights to appeal the withholding or deletion of any information.

Access to the requested records should be granted within twenty (20) business days from the date of your receipt of this letter. Failure to respond in a timely manner shall be viewed as a denial of this request and ICAN may immediately file an administrative appeal.

If you would like to discuss our requests or any issues raised in this letter, please feel free to contact me at (212) 532-1091 or via email at alucas@sirillp.com during normal business hours. Thank you for your time and attention to this matter.

Very truly yours,



Allison Lucas, Esq.
Licensed in MI

Exhibit A

Clinical Infectious Diseases

INVITED ARTICLE

VACCINES: Stanley A. Plotkin, Section Editor.

Principal Controversies in Vaccine Safety in the United States

Frank DeStefano,[1] Heather Monk Bodenstab,[2] and Paul A. Offit[3]

[1]Immunization Safety Office, Centers for Disease Control and Prevention, Atlanta, Georgia; [2]Department of Pharmacy Services, and [3]Division of Infectious Diseases, The Children's Hospital of Philadelphia, Pennsylvania

Concerns about vaccine safety can lead to decreased acceptance of vaccines and resurgence of vaccine-preventable diseases. We summarize the key evidence on some of the main current vaccine safety controversies in the United States, including (1) measles, mumps, and rubella vaccine and autism; (2) thimerosal, a mercury-based vaccine preservative and the risk of neurodevelopmental disorders; (3) vaccine-induced Guillain-Barré syndrome (GBS); (4) vaccine-induced autoimmune diseases; (5) safety of human papillomavirus vaccine; (6) aluminum adjuvant-induced autoimmune diseases and other disorders; and (7) too many vaccines given early in life predisposing children to health and developmental problems. A possible small increased risk of GBS following influenza vaccination has been identified, but the magnitude of the increase is less than the risk of GBS following influenza infection. Otherwise, the biological and epidemiologic evidence does not support any of the reviewed vaccine safety concerns.

Keywords. aluminum; autism; autoimmunity; MMR vaccine; thimerosal.

Vaccines have been among the greatest successes of modern medicine and public health. The development of highly effective vaccines coupled with successful immunization programs have led to high vaccination coverage resulting in the prevention of immeasurable suffering and deaths from vaccine preventable diseases. In fact, vaccines have been so successful that many people today have never seen or have no direct knowledge of the diseases that vaccines prevent. This has created an environment in which concerns about possible adverse effects of vaccines is having a greater impact on vaccine acceptance, resulting in decreasing vaccination coverage and increases in vaccine preventable diseases. Below, we provide a brief synopsis of what we believe is the most pertinent scientific evidence on some of the main current controversies in vaccine safety, with a focus primarily on the United States (Table 1). This is not meant to be a comprehensive systematic review of vaccine safety, and we have not included discussion of known vaccine adverse reactions nor detailed consideration of the methods, strengths, and limitations of included studies.

MMR VACCINE AND AUTISM

Speculation that measles, mumps, and rubella (MMR) vaccine may cause autism has been and continues to be among the most damaging controversies in vaccine safety. Numerous studies provide conclusive evidence that MMR vaccine does not cause autism, but some parents continue to have questions about a possible association. The lack of MMR vaccine acceptance by some parents or larger segments of the public has led to renewed outbreaks of measles in the United States and resurgence of measles in Europe.

The suggestion that MMR vaccine might cause autism was first raised in a report in *The Lancet* in 1998 [1]. Although the article was ultimately retracted by the journal because of improprieties in subject recruitment and financial conflicts of interest [2], the doubts it raised have lingered. The article was a descriptive report of the clinical features of 12 children who had a history of pervasive developmental disorder (PDD; 9 had autism) and intestinal abnormalities. The only suggested link with MMR vaccination was that a parent or physician reported worsening of the child's behavioral problems shortly after receipt of MMR vaccine in 8 of the children. Despite its limitations, the article generated intense media and public attention resulting in decreased MMR vaccination coverage, particularly in the United Kingdom, with resultant re-emergence of measles disease and deaths.

Autism is a neurodevelopmental condition that has a strong genetic component and whose genesis begins in utero. Thus, it is not likely that a postnatal exposure at about one year of age, when MMR vaccine is typically administered, could cause autism; indeed, not long after the publication of the 1998 *Lancet* article, a number of epidemiologic studies were published that did not find an association between MMR vaccination and autism. The first was also published in *The Lancet* in 1999 and involved an analysis of whether the introduction

Received 29 November 2018; editorial decision 1 February 2019; accepted 7 February 2019; published online February 12, 2019.

Correspondence: F. DeStefano, Immunization Safety Office, Centers for Disease Control and Prevention, 1600 Clifton Rd. MS V18-4, Atlanta, GA 30329 (FDestefano@cdc.gov).

Clinical Infectious Diseases® 2019;XX(XX):0–0

DOI: 10.1093/cid/ciz135

Table 1. Summary of Evidence on Selected Vaccine Safety Controversies

Issue	Allegation	Evidence
MMR vaccine and autism	MMR vaccine causes autism	• Initial report suggesting an association was retracted • Autism is genetically determined with onset before recommended age of MMR vaccination (12 months) • Epidemiologic studies have not found an increased risk of autism associated with MMR vaccine
Thimerosal	Thimerosal, a mercury-based preservative in some vaccines, increases risk of autism and other neurodevelopmental disabilities	• Thimerosal contains ethylmercury, which does not accumulate in the body to harmful levels with consecutive vaccinations • After thimerosal was removed from childhood vaccines, autism prevalence continued to increase • Epidemiologic studies have not found an increased risk of autism or other neurodevelopmental disabilities associated with thimerosal-containing vaccines
GBS	Influenza vaccines can cause GBS	• Increased risk was found with the 1976 swine influenza vaccine • Findings have been mixed with subsequent seasonal influenza vaccines • Risk of GBS is greater following natural influenza infection than possible increased risk following vaccination
Autoimmunity	Vaccines can cause chronic diseases of autoimmune etiology	• No mechanisms have been demonstrated to explain how vaccines could cause autoimmune disease • Epidemiologic studies have not supported the hypothesis that vaccines cause autoimmune diseases
Safety of HPV vaccine	HPV vaccines may increase risk of autoimmune and other disorders	• Several large population-based studies have not found increased risks of autoimmune or neurologic diseases • Other studies have not found increased risks of POI, POTS, or CRPS
Aluminum	Aluminum in vaccines can cause autoimmune diseases and a variety of other disorders, including MMF	• Aluminum containing vaccines result in serum levels of aluminum that are well below the toxic range • No correlation found between infant blood or hair aluminum concentrations and vaccine history • Higher quantities of injected aluminum adjuvants correlated with lower incidence of autoimmune disease • Systemic symptoms of MMF related to finding aluminum salts at an injection site have never been established
Too many too soon	Too many vaccines given early in life might overwhelm the immune system and predispose to health and developmental problems	• Infants have the theoretical capacity to respond to at least 10 000 vaccines at 1 time • Childhood vaccines do not cause long-lasting, gross alterations of the immune system • Epidemiologic studies have not found an increased risk of disease or developmental disorders according to the number of vaccines or vaccine antigens received in early childhood

Abbreviations: CRPS, complex regional pain syndrome; GBS, Guillain-Barré syndrome; HPV, human papillomavirus; MMF, macrophagic myofasciitis; MMR, measles, mumps, and rubella; POI, primary ovarian insufficiency; POTS, postural orthostatic tachycardia syndrome.

of MMR vaccine in the United Kingdom in 1988 affected the incidence of autism [3]. The authors found no sudden change in the incidence of autism after introduction of MMR vaccine and no association between receipt of the vaccine and development of autism. Using national population and healthcare registries, a retrospective review of all children (> 500 000) born in Denmark between 1991 and 1998 found no association between ages at the time of MMR vaccination, the time since vaccination, or the date of vaccination and the development of autism [4]. A study utilizing a major UK general practitioner database compared patients diagnosed with autism or other PDDs over a 28-year period and similarly aged patients without those diagnoses; no association was found between MMR vaccine and risk of autism or other PDD [5]. A more recent study addressed the possibility that MMR vaccination is a risk factor only in certain high-risk children [6]. The study included about 100 000 younger siblings of children who had been diagnosed with autism spectrum disorder (ASD). The study found that receipt of MMR vaccine was not associated with increased risk of ASD even among children whose older siblings had ASD and therefore were presumed to be at higher risk for developing this disorder. Several other studies also have not found an increased risk of autism following MMR vaccination. These have been extensively reviewed by the National Academy of Medicine [7] and in a meta-analysis [8].

The evidence is strong that MMR vaccine does not cause autism.

THIMEROSAL AND NEURODEVELOPMENTAL DISORDERS

The mercury-containing preservative thimerosal has also been feared to possibly increase the risk of autism. Mercury is a naturally occurring element found in the earth's crust, air, soil, and water. Certain types of bacteria in the environment can change inorganic mercury to organic mercury (methylmercury). Methylmercury makes its way through the food chain in fish, animals, and humans. At high levels, it can be neurotoxic. Using standards for methylmercury, the Food and Drug Administration (FDA) conducted an assessment of mercury content in vaccines and found that infants up to 6 months of age could receive quantities of mercury from vaccines that exceeded Environmental Protection Agency recommended safety guidelines for methylmercury. Thimerosal, however, contains ethylmercury, not methylmercury. Ethylmercury is broken down and excreted much more rapidly than methylmercury and is therefore much less likely to accumulate in the body and cause harm. Nonetheless, as a precautionary measure, the United States transitioned to a childhood vaccine schedule free of thimerosal. Currently, in the United States only multidose vial influenza vaccines contain preservative quantities (ie, 25 mcg per dose) of thimerosal, and thimerosal-free influenza vaccine preparations are widely available.

A meta-analysis of several epidemiologic studies found no increased risk of autism associated with thimerosal-containing vaccines [8]. A large Danish study evaluated the incidence of autism in children born in Denmark between 1990 and 1996 who received either thimerosal-containing vaccines or thimerosal-free preparations of the same vaccine; the incidence of autism or autistic spectrum disorders did not differ significantly between the 2 groups [9]. A large US case-control study found that prenatal and early life exposure to thimerosal from vaccines or immunoglobulins was not related to increased risk of ASDs [10]. In the United States, all childhood vaccines containing thimerosal as a preservative (except multidose influenza vaccines) passed their expiration date by 2003 and were no longer available; nonetheless, autism prevalence continued to increase in the subsequent years [11]. Reviews of the evidence by the Institute of Medicine (IOM) concluded that evidence favored rejection of a causal association between thimerosal in vaccines and autism [7].

Related to concerns about autism, the possibility that thimerosal exposure could cause other developmental disabilities, such as speech problems or learning difficulties, has also been evaluated. Studies have not found an association between exposure to thimerosal in vaccines and neurodevelopmental problems. A large study in the United Kingdom evaluated the relationship between the quantity of thimerosal received from vaccines in the first 6 months of life with several measures of childhood cognitive and behavioral development between 6 and 91 months of age and found no evidence that early exposure to thimerosal had a negative effect on these outcomes [12]. In a US cohort study, standardized tests were administered to children between 7 and 10 years of age to assess the association between neuropsychological performance and exposure to thimerosal from vaccines or immune globulins during the prenatal period, the neonatal period (0–28 days), and the first 7 months of life; results did not support an association between early life exposure to mercury and deficits in neuropsychological functioning at the age of 7 to 10 years [13]. An Italian study compared the neuropsychological performance 10 years after vaccination in 2 groups of children exposed randomly to different amounts of thimerosal from vaccines. Although a few differences were noted, the authors concluded that these differences were likely due to chance given the large number of statistical comparisons performed [14].

The evidence is strong that thimerosal in vaccines does not increase the risk of autism or other neurodevelopmental disorders.

VACCINES AND GUILLAIN-BARRÉ SYNDROME

Guillain-Barré syndrome (GBS) as a possible consequence of vaccination was first identified during the swine influenza vaccine program administered in the United States in 1976 [15]. At the time, the estimated risk of GBS following receipt of the

swine flu vaccine was estimated to be about 1 per 100 000 recipients. Since then, the association between influenza vaccine and GBS has been closely monitored, and the findings have been variable; an increased risk has been detected in some seasons and not in others. A meta-analysis of studies published between 1981 and 2014 found that the receipt of any influenza vaccine carried a relative increased risk of GBS of 1.4 [16]. In the seasons when an increased risk has been found, the absolute increase has been 1 or 2 additional cases of GBS per million vaccinees. These studies, however, have accounted only for the short-term risk (usually within 42 days) following vaccination. Influenza infection is a stronger risk factor for GBS than is influenza vaccine; thus, during an entire influenza season, influenza vaccination has been shown to actually decrease the risk of GBS by protecting against influenza infection [17].

Additional studies of other vaccines have found that measles, mumps, rubella, human papillomavirus (HPV), meningococcal conjugate, polio, pneumococcal, varicella, *Haemophilus influenzae* type b (Hib), rabies, tetanus, diphtheria, hepatitis A, and hepatitis B vaccines do not increase the risk of GBS [18].

GBS has been inconsistently found to be associated with influenza vaccination, but the increase in risk is small and less than the increase in risk following natural influenza infection.

VACCINES AND AUTOIMMUNITY

Vaccines have also been feared to cause a variety of chronic autoimmune diseases. Autoimmunity involves an immune response directed against self-antigens and mechanisms are present at birth to prevent the development of such responses. The immune system anticipates that self-reactive T cells will be present and has mechanisms to control them. No mechanisms have been demonstrated to explain how vaccines could account for the development of autoimmune disease.

Published epidemiologic studies have evaluated the possible association of several vaccines with a variety of chronic diseases that at least potentially have an autoimmune etiology. Rigorous epidemiologic studies of infant vaccines and type 1 diabetes found that measles vaccine was not associated with an increased risk for diabetes; other investigations found no association between bacillus Calmette-Guerin (BCG), smallpox, tetanus, pertussis, rubella, or mumps vaccine and diabetes [19, 20]. The possibility that vaccines can cause or exacerbate multiple sclerosis has been evaluated in several epidemiologic studies. Two large case-control studies showed no association between hepatitis B vaccine and multiple sclerosis [21, 22]. Hepatitis B, tetanus, or influenza vaccines were found not to exacerbate symptoms of multiple sclerosis [23]. As detailed next, HPV vaccine has not been found to be associated with autoimmune diseases.

Many studies have found that vaccines do not increase the risk of chronic diseases of possible autoimmune origin.

HPV VACCINE SAFETY

HPV vaccine has received considerable media attention associated with reports of a variety of adverse events, many of which may have an autoimmune etiology. Extensive monitoring in the United States and internationally, however, supports the safety of HPV vaccine. The strongest studies that have evaluated risks of autoimmune diseases include a large population-based cohort study conducted in Denmark and Sweden that analyzed >696 000 doses of 4-valent HPV vaccine (HPV4) among females and found no consistent evidence supporting causal associations with several autoimmune and neurologic conditions [24]. A large case-control study in France found no increased risk of several autoimmune outcomes (idiopathic thrombocytopenic purpura, central demyelination, GBS, connective tissue disorders, type 1 diabetes mellitus, and autoimmune thyroiditis) following HPV vaccination [25]. Another analysis of national data from Sweden and Denmark covering 4 million women, including nearly 800 000 that had received HPV4, found no increased risk of multiple sclerosis or other demyelinating diseases following HPV4 vaccination [26]. Several other conditions have been purported to be related to HPV vaccine, but the associations have not been substantiated, including premature ovarian insufficiency [27], complex regional pain syndrome, and postural orthostatic tachycardia syndrome [28].

The evidence from several studies supports the safety of HPV vaccine.

ALUMINUM IN VACCINES

Aluminum is used in vaccines as an adjuvant to boost the immune response. Aluminum salts have safely been used to adjuvant vaccines since the 1930s and are currently used in vaccines such as hepatitis A, hepatitis B, diphtheria-tetanus-containing vaccines, Hib, and pneumococcal vaccines, but they are not used in the live, viral vaccines, such as measles, mumps, rubella, varicella, and rotavirus. Studies have shown that children who receive aluminum-containing vaccines have serum levels of aluminum that are well below the toxic range [29]. The strongest evidence of the safety of aluminum in childhood vaccines is provided by a recent study in which children aged 9–13 months were evaluated for blood and hair aluminum levels, vaccination history, and cognitive, language, and motor development scores. The authors found no correlation between infant blood or hair aluminum concentrations and vaccine history or between blood aluminum and overall developmental status [30].

A specific concern that has been raised about aluminum adjuvants is their possible relationship to macrophagic myofasciitis, a condition consisting of a variety of systemic complaints along with findings in muscle biopsies of minute lesions that contain aluminum salts [31]. Associated systemic symptoms related to finding aluminum salts in cells at an injection site of an

aluminum-containing vaccine, however, have never been established [32].

Shoenfeld and coworkers have proposed the existence of a condition that they term autoimmune autoinflammatory syndrome induced by adjuvants [33]. The syndrome, however, is poorly defined and includes many nonspecific and relatively common symptoms (eg, fatigue, insomnia, and fever) [34]. A study that evaluated the incidence of autoimmune disease in more than 18 000 patients who received subcutaneous allergen-specific immunotherapy containing large quantities of injected aluminum adjuvants found that patients receiving injected aluminum had a lower incidence of autoimmune disease compared with controls [35].

Current evidence supports the safety of aluminum adjuvants in vaccines.

TOO MANY VACCINES TOO SOON

Today's routine childhood immunization schedule in the United States includes 10 vaccines against 14 diseases; children in the first few years of life can receive as many as 26 vaccine injections and as many as 5 injections at 1 time. Some parents are concerned that too many vaccines given so early in life might overwhelm the immune system. Given the number of antibody-generating B cells in the circulation, the number of vaccine-specific antigens to which infants are exposed during the first few years of life, and the quantity of antibodies necessary to react to each antigen, it has been estimated that infants have the theoretical capacity to respond to at least 10 000 vaccines at 1 time [36]. A study of the immune response to general, nonvaccine specific stimuli in fully vaccinated and entirely unvaccinated children between 3 and 5 years of age found that childhood vaccines do not cause long-lasting, gross alterations of the immune system [37]. No epidemiologic study has found an increased risk of disease according to the number of vaccines or vaccine antigens received in childhood. A recent US study found no relationship between either the cumulative number of antigens or the number of antigens received in a single day and subsequent nonvaccine-targeted infections [38]. A study that compared long-term neuropsychological outcomes in more than 1000 children found no correlation between the number of vaccine-specific antigens received in infancy and adverse neuropsychological outcomes by age 7 to 10 years [39]. Finally, a large US case-control study that evaluated total cumulative vaccine-specific antigen exposure or maximum exposure on a single day found no association between antigen exposure from vaccines during the first 2 years of life and the risk of developing autism or different subtypes of autism [40].

The immune system of infants is perfectly capable of handling the number of antigens in vaccines, and studies have not found increased risks of adverse health outcomes related to the number of vaccines or vaccine antigens received early in life.

CONCLUSION

In this brief article, a focused summary is provided on the most pertinent evidence related to some of the more common vaccine safety controversies discussed with primary care providers in the United States. As this article is not intended to be a comprehensive systematic review of vaccine safety, we have not addressed all vaccine controversies, including those in other parts of the world, or included discussion of known vaccine adverse reactions that are not presently particularly controversial (eg, anaphylaxis following vaccination or intussusception following rotavirus vaccines). We hope that the concise format will be useful to busy healthcare providers and others with an interest in immunization safety. More detail on these and other vaccine safety concerns can be found at the websites of the Vaccine Education Center at the Children's Hospital of Philadelphia (vaccine.chop.edu/safety-references) and the Centers for Disease Control and Prevention (https://www.cdc.gov/vaccinesafety), among others.

Notes

Disclaimer. The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Potential conflicts of interest. All authors: No reported conflicts of interest. All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

References

1. Wakefield AJ, Murch SH, Anthony A, et al. Ileal-lymphoid-nodular hyperplasia, non specific colitis, and pervasive developmental disorder in children. Lancet **1998**; 351:637–41.
2. Dyer C. *Lancet* retracts Wakefield's MMR paper. BMJ **2010**; 340:c696.
3. Taylor B, Miller E, Farrington CP, et al. Autism and measles, mumps, and rubella vaccine: no epidemiological evidence for a causal association. Lancet **1999**; 353:2026–9.
4. Madsen KM, Hviid A, Vestergaard M, et al. A population-based study of measles, mumps, and rubella vaccination and autism. N Engl J Med **2002**; 347:1477–82.
5. Smeeth L, Cook C, Fombonne E, et al. MMR vaccination and pervasive developmental disorders: a case-control study. Lancet **2004**; 364:963–9.
6. Jain A, Marshall J, Buikema A, Bancroft T, Kelly JP, Newschaffer CJ. Autism occurrence by MMR vaccine status among US children with older siblings with and without autism. JAMA **2015**; 313:1534–40.
7. Immunization Safety Review Committee. Immunization safety review. Washington, DC: Vaccines and Autism Board of Health Promotion and Disease Prevention, Institute of Medicine (National Academy Press, **2004**.
8. Taylor LE, Swerdfeger AL, Eslick GD. Vaccines are not associated with autism: an evidence-based meta-analysis of case-control and cohort studies. Vaccine **2014**; 32:3623–9.
9. Hviid A, Stellfeld M, Wohlfahrt J, Melbye M. Association between thimerosal-containing vaccine and autism. JAMA **2003**; 290:1763–6.
10. Price CS, Thompson WW, Goodson B, et al. Prenatal and infant exposure to thimerosal from vaccines and immunoglobulins and risk of autism. Pediatrics **2010**; 126:656–64.
11. Schechter R, Grether JK. Continuing increases in autism reported to California's developmental services system: mercury in retrograde. Arch Gen Psychiatry **2008**; 65:19–24.
12. Heron J, Golding J; ALSPAC Study Team. Thimerosal exposure in infants and developmental disorders: a prospective cohort study in the United Kingdom does not support a causal association. Pediatrics **2004**; 114:577–83.
13. Thompson WW, Price C, Goodson B, et al; Vaccine Safety Datalink Team. Early thimerosal exposure and neuropsychological outcomes at 7 to 10 years. N Engl J Med **2007**; 357:1281–92.

14. Tozzi AE, Bisiacchi P, Tarantino V, et al. Neuropsychological performance 10 years after immunization in infancy with thimerosal-containing vaccines. Pediatrics **2009**; 123:475–82.
15. Schonberger LB, Bregman DJ, Sullivan Bolyai JZ, et al. Guillain Barre syndrome following vaccination in the National Influenza Immunization Program, United States, 1976–1977. Am J Epidemiol **1979**; 110:105–23.
16. Martín Arias LH, Sanz R, Sáinz M, Treceño C, Carvajal A. Guillain-Barré syndrome and influenza vaccines: a meta analysis. Vaccine **2015**; 33:3773–8.
17. Vellozzi C, Iqbal S, Stewart B, Tokars J, DeStefano F. Cumulative risk of Guillain-Barré syndrome among vaccinated and unvaccinated populations during the 2009 H1N1 influenza pandemic. Am J Public Health **2014**; 104:696–701.
18. Baxter R, Bakshi N, Fireman B, et al. Lack of association of Guillain Barré syndrome with vaccinations. Clin Infect Dis **2013**; 57:197–204.
19. DeStefano F, Mullooly JP, Okoro CA, et al; Vaccine Safety Datalink Team. Childhood vaccinations, vaccination timing, and risk of type 1 diabetes mellitus. Pediatrics **2001**; 108:E112.
20. Hviid A, Stellfeld M, Wohlfahrt J, Melbye M. Childhood vaccination and type 1 diabetes. N Engl J Med **2004**; 350:1398–404.
21. DeStefano F, Verstraeten T, Jackson LA, et al; Vaccine Safety Datalink Research Group, National Immunization Program, Centers for Disease Control and Prevention. Vaccinations and risk of central nervous system demyelinating diseases in adults. Arch Neurol **2003**; 60:504–9.
22. Ascherio A, Zhang SM, Hernán MA, et al. Hepatitis B vaccination and the risk of multiple sclerosis. N Engl J Med **2001**; 344:327–32.
23. Confavreux C, Suissa S, Saddier P, Bourdès V, Vukusic S; Vaccines in Multiple Sclerosis Study Group. Vaccinations and the risk of relapse in multiple sclerosis. Vaccines in Multiple Sclerosis Study Group. N Engl J Med **2001**; 344:319–26.
24. Arnheim-Dahlström L, Pasternak B, Svanström H, Sparén P, Hviid A. Autoimmune, neurological, and venous thromboembolic adverse events after immunisation of adolescent girls with quadrivalent human papillomavirus vaccine in Denmark and Sweden: cohort study. BMJ **2013**; 347:f5906.
25. Grimaldi-Bensouda L, Rossignol M, Koné-Paut I, et al; PGRx-AD Study Group. Risk of autoimmune diseases and human papillomavirus (HPV) vaccines: six years of case-referent surveillance. J Autoimmun **2017**; 79:84–90.
26. Scheller NM, Svanström H, Pasternak B, et al. Quadrivalent HPV vaccination and risk of multiple sclerosis and other demyelinating diseases of the central nervous system. JAMA **2015**; 313:54–61.
27. Naleway AL, Mittendorf KF, Irving SA, et al. Primary ovarian insufficiency and adolescent vaccination. Pediatrics **2018**; 142:e20180943.
28. European Medicines Agency Assessment Report. Human papillomavirus (HPV) vaccines. London, UK: EMA/762033/2015 Pharmacovigilance Risk Assessment Committee (PRAC), 11 November **2015**.
29. Mitkus RJ, King DB, Hess MA, Forshee RA, Walderhaug MO. Updated aluminum pharmacokinetics following infant exposures through diet and vaccination. Vaccine **2011**; 29:9538–43.
30. Karwowski MP, Stamoulis C, Wenren LM, et al. Blood and hair aluminum levels, vaccine history, and early infant development: a cross-sectional study. Acad Pediatr **2018**; 18:161–5.
31. Gherardi RK, Coquet M, Cherin P, et al. Macrophagic myofasciitis lesions assess long-term persistence of vaccine-derived aluminium hydroxide in muscle. Brain **2001**; 124:1821–31.
32. Principi N, Esposito S. Aluminum in vaccines: does it create a safety problem? Vaccine **2018**; 36:5825–31.
33. Shoenfeld Y, Agmon-Levin N. 'ASIA' - autoimmune/inflammatory syndrome induced by adjuvants. J Autoimmun **2011**; 36:4–8.
34. Ameratunga R, Gillis D, Gold M, Linneberg A, Elwood JM. Evidence refuting the existence of autoimmune/autoinflammatory syndrome induced by adjuvants (ASIA). J Allergy Clin Immunol Pract **2017**; 5:1551–1555.e1.
35. Linneberg A, Jacobsen RK, Jespersen L, Abildstrom SZ. Association of subcutaneous allergen specific immunotherapy with incidence of autoimmune disease, ischemic heart disease, and mortality. J Allergy Clin Immunol **2012**; 129:413–9.
36. Offit PA, Quarles J, Gerber MA, et al. Addressing parents' concerns: do multiple vaccines overwhelm or weaken the infant's immune system? Pediatrics **2002**; 109:124–9.
37. Sherrid AM, Ruck CE, Sutherland D, Cai B, Kollmann TR. Lack of broad functional differences in immunity in fully vaccinated vs. unvaccinated children. Pediatr Res **2017**; 81:601–8.
38. Glanz JM, Newcomer SR, Daley MF, et al. Association between estimated cumulative vaccine antigen exposure through the first 23 months of life and non-vaccine-targeted infections from 24 through 47 months of age. JAMA **2018**; 319:906–13.
39. Iqbal S, Barile JP, Thompson WW, DeStefano F. Number of antigens in early childhood vaccines and neuropsychological outcomes at age 7–10 years. Pharmacoepidemiol Drug Saf **2013**; 22:1263–70.
40. DeStefano F, Price CS, Weintraub ES. Increasing exposure to antibody stimulating proteins and polysaccharides in vaccines is not associated with risk of autism. J Pediatr **2013**; 163:561–7.

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP)

Sent: 25 Jul 2019 14:14:52 +0000

To: Destefano, Frank (CDC/DDID/NCEZID/DHQP);Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)

Cc: Gresham, Angela (CDC/DDID/NCEZID/DHQP) (CTR)

Subject: Fwd: 19-00989-FOIA

Attachments: 19-00989 Lucas.pdf

Good Morning,

This is a FYI. The FOIA Office is conducting an enterprise email search for the information requested in the attached FOIA.

Get Outlook for iOS

From: Jackson, Eric (CDC/DDID/NCEZID/OD) <eoj0@cdc.gov> on behalf of NCEZID FOIA Requests (CDC) <NCEZIDFOIARequests@cdc.gov>
Sent: Wednesday, July 24, 2019 3:34:56 PM
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Gresham, Angela (CDC/DDID/NCEZID/DHQP) (CTR) <nmc8@cdc.gov>
Cc: Jackson, Eric (CDC/DDID/NCEZID/OD) <eoj0@cdc.gov>
Subject: FW: 19-00989-FOIA

FYI—forthcoming enterprise search. As per agreed procedure, the CDC FOIA Office will let us know what they find and will want to know if we want to review it.

Eric Jackson

NCEZID FOIA Coordinator

NCEZID Senior Records Liaison

Telework Tuesdays & Thursdays

E-mail: eoj0@cdc.gov

770-488-4761

From: Brouillette, Colleen (CDC/DDID/NCEZID/OD) (CTR) <mfi3@cdc.gov>

Sent: Wednesday, July 24, 2019 2:37 PM

To: Jackson, Eric (CDC/DDID/NCEZID/OD) <eoj0@cdc.gov>; NCEZID FOIA Requests (CDC) <NCEZIDFOIARequests@cdc.gov>

Subject: FW: 19-00989-FOIA

FYI

Colleen Brouillette

Contractor, Chenega Professional Technical Services

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Telework Wednesdays

From: Spencer, Laura (CDC/OCOO/OD) <vbx0@cdc.gov>

Sent: Wednesday, July 24, 2019 1:41 PM

To: Elswick, David C. (CDC/DDID/NCEZID/OD) <dce1@cdc.gov>

Cc: Brouillette, Colleen (CDC/DDID/NCEZID/OD) (CTR) <mfi3@cdc.gov>

Subject: 19-00989-FOIA

David,

Good afternoon. This email is sent on behalf of FOIA Director Roger Andoh. We will be conducting an enterprise search for records responsive to the attached request. (Should the results be voluminous, we will work with the requester to obtain a more narrow focus.)

Please let me know if you would like to see the redacted records before we issue a response to the requester.

Sincerely,

Laura

Laura Spencer

Team Lead

Freedom of Information Act Office

Office of the Chief Operating Officer

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FREEDOM OF INFORMATION ACT REQUEST

VIA FEDEX AND EMAIL July 22, 2019

Roger Andoh
Freedom of Information Officer
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., Building 57, Room MS D-54
Atlanta, Georgia 30333
Fax: (404) 235-1852
Email: FOIARequests@cdc.gov

Re: Email Communications Between DeStefano, Plotkin and Offit, January 2017 to Present (IR#0144)

Dear Mr. Andoh:

This firm represents Informed Consent Action Network ("ICAN"). On behalf of ICAN, we are requesting records pursuant to the Freedom of Information Act (5 U.S.C. § 552, as amended) from the files of the Centers for Disease Control and Prevention ("CDC").

By this letter, please provide the following records in the CDC's possession to the above referenced address in electronic form on a CD or DVD or via email to foia@sirillp.com:

> **Each and every email communication between January 1, 2017, and the present which includes Frank DeStefano or his email address on the "To", "From", "Cc" or "Bcc" line and also includes Stanley Plotkin or his email address on the "To", "From", "Cc" or "Bcc" line.**
>
> **Each and every email communication between January 1, 2017, and the present which includes Frank DeStefano or his email address on the "To", "From", "Cc" or "Bcc" line and also includes Paul Offit or his email address on the "To", "From", "Cc" or "Bcc" line.**

As a courtesy, note that email addresses for Stanley Plotkin include but are not limited to stanley.plotkin@sanofipasteur.com; and stanley.plotkin@vaxconsult.com, and emails for Paul Offit include but are not limited to offit@email.chop.edu.

We ask that you waive any and all fees or charges pursuant to 5 U.S.C. § 552 (a)(4)(A)(iii). ICAN is a not-for-profit 501(c)(3) organization whose mission is to raise public awareness about

vaccine safety and to provide the public with information to give informed consent. As part of their mission, ICAN actively investigates and disseminates information regarding vaccine safety issues, including through their website, and through press events and releases. They are seeking the information in this FOIA request to allow them to contribute to the public understanding of the government's vaccine safety programs, including the government's efforts to promote vaccine safety. The information we are requesting will not contribute to any commercial activities.

Please note that the FOIA provides that if only portions of a requested file are exempted from release, the remainder must still be released. We therefore request that we be provided with all non-exempt portions which are reasonably segregable. We further request that you describe any deleted or withheld material in detail and specify the statutory basis for the denial as well as your reasons for believing that the alleged statutory justification applies. Please also separately state your reasons for not invoking your discretionary powers to release the requested documents in the public interest. Such statements may help to avoid unnecessary appeal and litigation. ICAN of course reserves all rights to appeal the withholding or deletion of any information.

Access to the requested records should be granted within twenty (20) business days from the date of your receipt of this letter. Failure to respond in a timely manner shall be viewed as a denial of this request and ICAN may immediately file an administrative appeal.

If you would like to discuss our requests or any issues raised in this letter, please feel free to contact me at (212) 532-1091 or via email at foia@sirillp.com during normal business hours. Thank you for your time and attention to this matter.

Very truly yours,

Allison Lucas, Esq.
Licensed in MI