



**HealthFreedomLA.org**

**HHS has failed to comply with 42 U.S.C. §300aa-27**

*I believe there are more instances of the abridgement of freedom of the people by gradual and silent encroachments by those in power than by violent and sudden usurpations.*

- James Madison, 1788

*A man dies when he refuses to stand up for that which is right. A man dies when he refuses to stand up for justice. A man dies when he refuses to take a stand for that which is true.*

- Martin Luther King Jr., 1965

Health Freedom Louisiana  
3301 17th Street #7443  
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September 29, 2022

**Re: HHS has failed to comply with 42 U.S.C. §300aa--27**

One of the many egregious acts committed by federal public health agencies over the last two and a half years is the denial of natural immunity. Withholding that information violates the federal informed consent law for drugs under EUA, specifically [21 U.S.C. 360bbb-3, Section e\(1\)\(A\)\(ii\)\(III\)](#).<sup>1</sup> Natural immunity has been a viable alternative to covid vaccination from the outset. The subterfuge was necessary, though, for the intended goal of adding the shot to the childhood schedule and thereby gaining continuous immunity from product liability under [42 U.S.C. §300aa-11](#)<sup>2</sup> of the National Childhood Vaccine Injury Act (NCVIA). That is not the only goal, but a significant one, in my opinion.

The Secretary of Health and Human Services has failed to comply with the statutory requirements of NCVIA intended to ensure product safety and consumer protection, specifically [42 U.S.C. §300aa-27](#).<sup>3</sup> The failings are so significant that the immunity from liability granted under [42 U.S.C. §300aa-11](#) should be repealed and consumers protected from further vaccine mandates.

The passage of NCVIA in 1986 helped set the stage for the unbelievable nightmare of the last two years. Interestingly, some of the major players on the scene today were involved with its inception. Dr. Anthony Fauci was already installed at the National Institute of Allergy and Infectious Disease (NIAID) and then Senator Joe Biden undoubtedly voted for its passage as it was introduced and supported by fellow democrats Representative Henry Waxman and Senator Ted Kennedy. On several occasions in the last year, President Biden has erroneously stated that guns are the only product on the market with blanket immunity from product liability when, ironically, he was a sitting member of Congress when NCVIA was passed.

NCVIA also laid the groundwork in eliminating any incentive for supporting the natural, or unvaccinated, immune system. Drug manufacturers were given a cash cow with no incentive for product safety, a guaranteed consumer base with the introduction of school vaccination requirements, and a deceptive perception of vaccine safety with the elimination of one of the most essential market indicators of product safety - *litigation*.

Insidiously, vaccination became the “only” way to prevent disease.

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<sup>1</sup>

[uscode.house.gov/view.xhtml?hl=false&edition=prelim&req=granuleid%3AUSC-prelim-title21-section360bbb-3&num=0&saved=%7CZ3JhbnVsZWlkOIVTQy1wcmVsaW0tdGl0bGUyMS1zZWNOaW9uMzYwYmJiLTNh%7C%7C%7C0%7Cfalse%7Cprelim](https://uscode.house.gov/view.xhtml?hl=false&edition=prelim&req=granuleid%3AUSC-prelim-title21-section360bbb-3&num=0&saved=%7CZ3JhbnVsZWlkOIVTQy1wcmVsaW0tdGl0bGUyMS1zZWNOaW9uMzYwYmJiLTNh%7C%7C%7C0%7Cfalse%7Cprelim)

<sup>2</sup> [uscode.house.gov/view.xhtml?path=/prelim@title42/chapter6A/subchapter19&edition=prelim](https://uscode.house.gov/view.xhtml?path=/prelim@title42/chapter6A/subchapter19&edition=prelim)

<sup>3</sup> <https://uscode.house.gov/view.xhtml?path=/prelim@title42/chapter6A/subchapter19&edition=prelim>

Not surprisingly, Health and Human Services (HHS) has not complied with the few safeguards that were included in NCVIA, specifically [42 U.S.C. §300aa-27](#)<sup>4</sup> which requires:

(a) **General rule**

(2) ***make or assure improvements in***, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, ***adverse reaction reporting***, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

(c) **Report**

Within 2 years after December 22, 1987, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) during the preceding 2-year period.

***How has the Secretary of Health and Human Services made improvements in adverse event reporting according to 42 U.S.C. §300aa-27(a)(2)?***

In 2011, the CDC commissioned Harvard Pilgrim HMO to conduct [a study](#)<sup>5</sup> of the Vaccine Adverse Event Reporting System (VAERS) which concluded:

**“Likewise, fewer than 1% of vaccine adverse events are reported. Low reporting rates preclude or slow the identification of “problem” drugs and vaccines that endanger public health. New surveillance methods for drug and vaccine adverse effects are needed.”**

The study authors noted:

**“Unfortunately, there was never an opportunity to perform system performance assessments because the necessary CDC contacts were no longer available and the CDC consultants responsible for receiving data were no longer responsive to our multiple requests to proceed with testing and evaluation.”**

***No improvements have been made to VAERS since its inception, so it is safe to assume that the adverse event reporting rate is still less than 1%.***

***Did the Secretary of HHS submit reports to Congress every two years describing the actions taken pursuant to 42 U.S.C. §300aa-27(c), including improvements in adverse event reporting?***

In 2018, the Informed Consent Action Network (ICAN) sued HHS to produce the reports that should have been submitted biennially since 1989. On July 6, 2018, a judge issued a [stipulated order](#)<sup>6</sup> which acknowledges that ***there are no such reports.***

Since the inception of NCVIA in 1986, the childhood schedule has grown exponentially, going from 24 doses of seven different vaccines to 73 doses of sixteen different [vaccines today](#).<sup>7</sup> If covid vaccines are added to the childhood schedule, the number of doses by age 18 is open ended at this point.

<sup>4</sup> [uscode.house.gov/view.xhtml?path=/prelim@title42/chapter6A/subchapter19&edition=prelim](https://uscode.house.gov/view.xhtml?path=/prelim@title42/chapter6A/subchapter19&edition=prelim)

<sup>5</sup> [digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf](https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf)

<sup>6</sup> [icandecide.org/wp-content/uploads/2021/06/No-reports-exist-from-HHS-pursuant-to-42-U.S.C.-section-300aa-27c.pdf](https://icandecide.org/wp-content/uploads/2021/06/No-reports-exist-from-HHS-pursuant-to-42-U.S.C.-section-300aa-27c.pdf)

<sup>7</sup> [healthfreedomla.org/wp-content/uploads/2020/02/flyer\\_vaccine\\_schedule\\_UPDATED.pdf](https://healthfreedomla.org/wp-content/uploads/2020/02/flyer_vaccine_schedule_UPDATED.pdf)

HHS has had 36 years to comply with the requirements of NCVIA. On what do we base the assumption of “safety” if adverse event reporting is estimated to be less than 1% and there have been no biennial reports evaluating vaccine improvements submitted to Congress for the last 36 years as is required by federal law? Congress recognized in 1986 that improvements needed to be made in the vaccine program, which was on the verge of collapse because of the number and severity of claims against vaccine manufacturers.

It is time to place the responsibility for product safety squarely where it belongs: on vaccine manufacturers. These drugs are either safe or they are not. If they are safe, there needs to be no liability shield. If the drugs are not safe, they should be removed from the market or at the very least, prohibited from being mandated. The only true test of safety is product liability.

**Make pharma liable again.**

*Suggested amendment to 42 U.S.C. §300aa-1:*

(B) As a matter of informed consent, vaccine recipients must be made aware that they cannot bring a civil action for vaccine-related injury or death associated with the administration of a vaccine.

(C) A recipient retains a right to refuse vaccination with a vaccine covered under this program without fear of retribution or discrimination.

*Suggested amendment to 42 U.S.C. §300aa-11(a):*

(11) Individuals may bring a civil action for vaccine-related injury or death if the Secretary fails to fulfill obligations under 42 U.S.C. §300aa-27.

Sincerely,  
Jill Hines  
Co-Director  
Health Freedom Louisiana



# CDC RECOMMENDED VACCINE SCHEDULE<sup>1,2</sup>

## FROM BIRTH – 18 YEARS

### 1983

**24** Doses of  
**7** Different Vaccines

### 2020

**73** Doses of  
**16** Different Vaccines

**VS.**

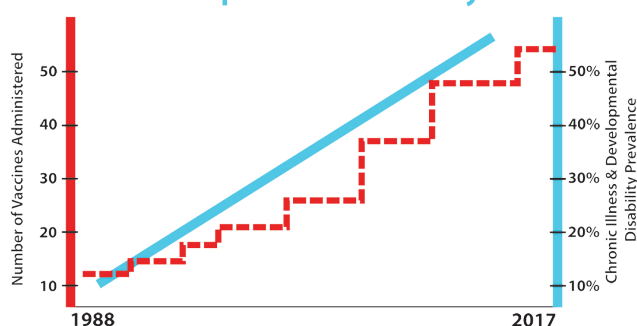
DTP (2 mos)  
OPV (2 mos)  
DTP (4 mos)  
OPV (4 mos)  
DTP (6 mos)  
MMR (15 mos)  
DTP (18 mos)  
OPV (18 mos)  
DTP (4 yrs)  
OPV (4 yrs)  
Td (14 yrs)

Tdap (pregnancy)  
Influenza (pregnancy)  
HepB (birth)  
HepB (2 mos)  
Rotavirus (2 mos)  
DTaP (2 mos)  
Hib (2 mos)  
PCV13 (2 mos)  
IPV (2 mos)  
Rotavirus (4 mos)  
DTaP (4 mos)  
Hib (4 mos)  
PCV13 (4 mos)  
IPV (4 mos)  
HepB (6 mos)  
Rotavirus (6 mos)  
DTaP (6 mos)  
Hib (6 mos)  
PCV13 (6 mos)  
IPV (6 mos)  
Influenza (6 mos)  
Influenza (7 mos)  
Hib (12 mos)  
PCV13 (12 mos)  
MMR (12 mos)  
VAR (12 mos)  
HepA (12 mos)  
DTaP (18 mos)  
Influenza (12-18 mos)

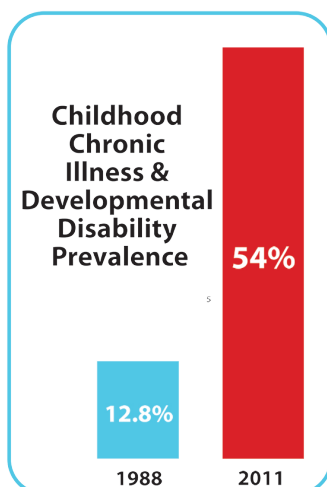
HepA (18 mos)  
Influenza (2 yrs)  
Influenza (3 yrs)  
DTaP (4 yrs)  
IPV (4 yrs)  
MMR (4 yrs)  
VAR (4 yrs)  
Influenza (4 yrs)  
Influenza (5 yrs)  
Influenza (6 yrs)  
Influenza (7 yrs)  
Influenza (8 yrs)  
Influenza (9 yrs)  
Influenza (10 yrs)  
Meningococcal (11 yrs)  
Tdap (11 yrs)  
HPV (11 yrs)  
HPV (11 yrs)  
Influenza (11 yrs)  
Influenza (12 yrs)  
Influenza (13 yrs)  
Influenza (14 yrs)  
Influenza (15 yrs)  
Meningococcal (16 yrs)  
Influenza (16 yrs)  
Influenza (17 yrs)  
Influenza (18 yrs)

**In 1986 Congress passed the Childhood Vaccine Injury Act that freed vaccine manufacturers from all liability, meaning vaccine manufacturers CANNOT BE SUED.**

**Number of Vaccines vs. Childhood Chronic Illness & Developmental Disability Prevalence<sup>3</sup>**



- **43% of children have a chronic illness<sup>4</sup>**
- **54% of children have a chronic illness and/or a developmental disability<sup>5</sup>**
- **1 in 6 children have a developmental disability<sup>6</sup>**



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***Grant Final Report***

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**Grant ID: R18 HS 017045**

**Electronic Support for Public Health–Vaccine Adverse  
Event Reporting System (ESP:VAERS)**

**Inclusive dates: 12/01/07 - 09/30/10**

**Principal Investigator:**

Lazarus, Ross, MBBS, MPH, MMed, GDCompSci

**Team members:**

Michael Klompas, MD, MPH

**Performing Organization:**

Harvard Pilgrim Health Care, Inc.

**Project Officer:**

Steve Bernstein

**Submitted to:**

**The Agency for Healthcare Research and Quality (AHRQ)**

**U.S. Department of Health and Human Services**

**540 Gaither Road**

**Rockville, MD 20850**

**[www.ahrq.gov](http://www.ahrq.gov)**

# Abstract

**Purpose:** To develop and disseminate HIT evidence and evidence-based tools to improve healthcare decision making through the use of integrated data and knowledge management.

**Scope:** To create a generalizable system to facilitate detection and clinician reporting of vaccine adverse events, in order to improve the safety of national vaccination programs.

**Methods:** Electronic medical records available from all ambulatory care encounters in a large multi-specialty practice were used. Every patient receiving a vaccine was automatically identified, and for the next 30 days, their health care diagnostic codes, laboratory tests, and medication prescriptions were evaluated for values suggestive of an adverse event.

**Results:** Restructuring at CDC and consequent delays in terms of decision making have made it challenging despite best efforts to move forward with discussions regarding the evaluation of ESP:VAERS performance in a randomized trial and comparison of ESP:VAERS performance to existing VAERS and Vaccine Safety Datalink data. However, Preliminary data were collected and analyzed and this initiative has been presented at a number of national symposia.

**Key Words:** electronic health records, vaccinations, adverse event reporting

The authors of this report are responsible for its content. Statements in the report should not be construed as endorsement by the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services of a particular drug, device, test, treatment, or other clinical service.

# Final Report

## Purpose

This research project was funded to improve the quality of vaccination programs by improving the quality of physician adverse vaccine event detection and reporting to the national Vaccine Adverse Event Reporting System (VAERS), via the following aims:

**Aim 1.** Identify required data elements, and develop systems to monitor ambulatory care electronic medical records for adverse events following vaccine administration.

**Aim 2.** Prepare, and securely submit clinician approved, electronic reports to the national Vaccine Adverse Event Reporting System (VAERS).

**Aim 3.** Comprehensively evaluate ESP:VAERS performance in a randomized trial, and in comparison to existing VAERS and Vaccine Safety Datalink data.

**Aim 4.** Distribute documentation and application software developed and refined in Aims 1 and 2 that are portable to other ambulatory care settings and to other EMR systems.

## Scope

Public and professional confidence in vaccination depends on reliable postmarketing surveillance systems to ensure that rare and unexpected adverse effects are rapidly identified. The goal of this project is to improve the quality of vaccination programs by improving the quality of physician adverse vaccine event detection and reporting to the national Vaccine Adverse Event Reporting System (VAERS). This project is serving as an extension of the Electronic Support for Public Health (ESP) project, an automated system using electronic health record (EHR) data to detect and securely report cases of certain diseases to a local public health authority. ESP provides a ready-made platform for automatically converting clinical, laboratory, prescription, and demographic data from almost any EHR system into database tables on a completely independent server, physically located and secured by the same logical and physical security as the EHR data itself. The ESP:VAERS project developed criteria and algorithms to identify important adverse events related to vaccinations in ambulatory care EHR data, and made attempts at formatting and securely sending electronic VAERS reports directly to the Centers for Disease Control and Prevention (CDC).

Patient data were available from Epic System's Certification Commission for Health Information Technology-certified EpicCare system at all ambulatory care encounters within Atrius Health, a large multispecialty group practice with over 35 facilities. Every patient receiving a vaccine was automatically identified, and for the next 30 days, their health care diagnostic codes, laboratory tests, and medication prescriptions are evaluated for values

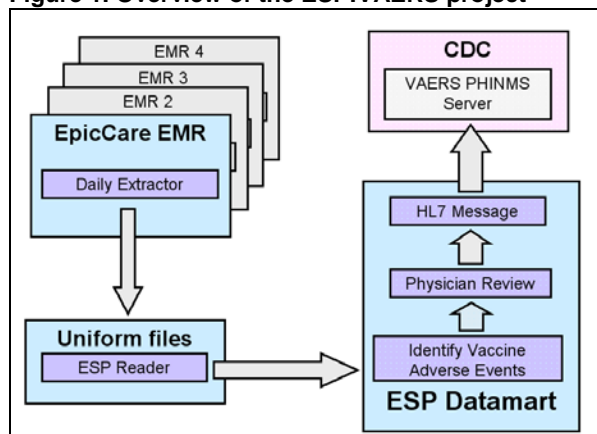
suggestive of an adverse vaccine event. When a possible adverse event was detected, it was recorded, and the appropriate clinician was to be notified electronically.

Clinicians in-basket messaging was designed to provide a preview a pre-populated report with information from the EHR about the patient, including vaccine type, lot number, and possible adverse effect, to inform their clinical judgment regarding whether they wish to send a report to VAERS. Clinicians would then have the option of adding free-text comments to pre-populated VAERS reports or to document their decision not to send a report. The CDC's Public Health Information Network Messaging System (PHIN-MS) software was installed within the facilities so that the approved reports could be securely transferred to VAERS as electronic messages in an interoperable health data exchange format using Health Level 7 (HL7).

## Methods

The goal of Aim 1: *Identify required data elements, and develop systems to monitor ambulatory care electronic medical records for adverse events following vaccine administration*, and Aim 2: *Prepare, and securely submit clinician approved, electronic reports to the national Vaccine Adverse Event Reporting System (VAERS)*, was to construct the below flow of data in order to support the first two Aims:

**Figure 1. Overview of the ESP:VAERS project**



Existing and functioning ESP components are shown on the left, and Aims 1 and 2 on the right. ESP:VAERS flags every vaccinated patient, and prospectively accumulate that patient's diagnostic codes, laboratory tests, allergy lists, vital signs, and medication prescriptions. A main component of Aim 1 was to *Develop AE criteria to assess these parameters for new or abnormal values that might be suggestive of an adverse effect*. A reporting protocol & corresponding algorithms were developed to detect potential adverse event cases using diagnostic codes, and methods were tested to identify prescriptions or abnormal laboratory values that might be suggestive of an adverse effect. These algorithms were designed to seek both expected and unexpected adverse effects.

This reporting protocol was approved by both internal & external partners. We initially prepared a draft document describing the elements, algorithms, interval of interest after vaccination, and actions for broad classes of post-vaccination events, including those to be reported immediately without delay (such as acute anaphylactic reaction following vaccination), those never to be reported (such as routine check-ups following vaccination) and those to be reported at the discretion and with additional information from the attending physician through a feedback mechanism. The draft was then widely circulated as an initial / working draft for comment by relevant staff in the CDC and among our clinical colleagues at Atrius. In addition to review by the internal CDC Brighton Collaboration liaison, this protocol has also received review & comment via the CDC's Clinical Immunization Safety Assessment (CISA) Network.

The goal of Aim 2 was the *Development of HL7 messages code for ESP:VAERS to ensure secure transmission to CDC via PHIN-MS*. The HL7 specification describing the elements for an electronic message to be submitted to Constella, the consultants engaged by CDC for this project was implemented. Synthetic and real test data was been generated and transmitted between Harvard and Constella. However, real data transmissions of non-physician approved reports to the CDC was unable to commence, as by the end of this project, the CDC had yet to respond to multiple requests to partner for this activity.

The goal of Aim 3 was to *Comprehensively evaluate ESP:VAERS performance in a randomized trial, and in comparison to existing VAERS and Vaccine Safety Datalink data*.

We had initially planned to evaluate the system by comparing adverse event findings to those in the Vaccine Safety Datalink project—a collaborative effort between CDC's Immunization Safety Office and eight large managed care organizations. Through a randomized trial, we would also test the hypothesis that the combination of secure, computer-assisted, clinician-approved, adverse event detection, and automated electronic reporting will substantially increase the number, completeness, validity, and timeliness of physician-approved case reports to VAERS compared to the existing spontaneous reporting system; however, due to restructuring at CDC and consequent delays in terms of decision making, it became impossible to move forward with discussions regarding the evaluation of ESP:VAERS performance in a randomized trial, and compare ESP:VAERS performance to existing VAERS and Vaccine Safety Datalink data. Therefore, the components under this particular Aim were not achieved.

Aim 4 *Distribution of documentation and application software developed and refined in Aims 1 and 2 that are portable to other ambulatory care settings and to other EMR systems* has been successfully completed. Functioning source code is available to share under an approved open source license. ESP:VAERS source code is available as part of the ESP source code distribution. It is licensed under the LGPL, an open source license compatible with commercial use. We have added the ESP:VAERS code, HL7 and other specifications and documentation to the existing ESP web documentation and distribution resource center <http://esphhealth.org>, specifically, the Subversion repository available at: <http://esphhealth.org/trac/ESP/wiki/ESPVAERS>.

## Results

Preliminary data were collected from June 2006 through October 2009 on 715,000 patients, and 1.4 million doses (of 45 different vaccines) were given to 376,452 individuals. Of these doses, 35,570 possible reactions (2.6 percent of vaccinations) were identified. This is an average of 890 possible events, an average of 1.3 events per clinician, per month. These data were presented at the 2009 AMIA conference.

In addition, ESP:VAERS investigators participated on a panel to explore the perspective of clinicians, electronic health record (EHR) vendors, the pharmaceutical industry, and the FDA towards systems that use proactive, automated adverse event reporting.

Adverse events from drugs and vaccines are common, but underreported. Although 25% of ambulatory patients experience an adverse drug event, less than 0.3% of all adverse drug events and 1-13% of serious events are reported to the Food and Drug Administration (FDA). Likewise, fewer than 1% of vaccine adverse events are reported. Low reporting rates preclude or slow the identification of “problem” drugs and vaccines that endanger public health. New surveillance methods for drug and vaccine adverse effects are needed. Barriers to reporting include a lack of clinician awareness, uncertainty about when and what to report, as well as the burdens of reporting: reporting is not part of clinicians’ usual workflow, takes time, and is duplicative. Proactive, spontaneous, automated adverse event reporting imbedded within EHRs and other information systems has the potential to speed the identification of problems with new drugs and more careful quantification of the risks of older drugs.

Unfortunately, there was never an opportunity to perform system performance assessments because the necessary CDC contacts were no longer available and the CDC consultants responsible for receiving data were no longer responsive to our multiple requests to proceed with testing and evaluation.

## Inclusion of AHRQ Priority Populations

The focus of our project was the Atrius Health (formerly HealthOne) provider & patient community. This community serves several AHRQ inclusion populations, specifically low-income and minority populations in primarily urban settings.

Atruis currently employs approximately 700 physicians to serve 500,000 patients at more than 18 office sites spread throughout the greater Metropolitan Boston area. The majority of Atruis physicians are primary care internal medicine physicians or pediatricians but the network also includes physicians from every major specialty.

The entire adult and pediatric population served by Atruis was included in our adverse event surveillance system (ESP:VAERS). Atruis serves a full spectrum of patients that reflects the broad diversity of Eastern Massachusetts. A recent analysis suggests that the population served by Atruis is 56% female, 16.6% African American, 4% Hispanic. The prevalence of type 2 diabetes in the adult population is 5.7%. About a quarter of the Atruis population is under age 18.

## List of Publications and Products

ESP:VAERS [source code available as part of the ESP source code distribution]. Licensed under the GNU Lesser General Public License (LGPL), an open source license compatible with commercial use. Freely available under an approved open source license at: <http://esphealth.org>.

Lazarus, R, Klompas M, Hou X, Campion FX, Dunn J, Platt R. Automated Electronic Detection & Reporting of Adverse Events Following Vaccination: ESP:VAERS. The CDC Vaccine Safety Datalink (VSD) Annual Meeting. Atlanta, GA; April, 2008.

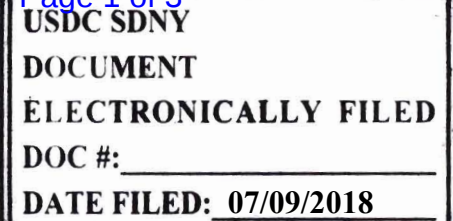
Lazarus R, Klompas M Automated vaccine adverse event detection and reporting from electronic medical records. CDC Public Health Informatics Network (PHIN) Conference August 27, 2008.

Klompas M, Lazarus R ESP:VAERS Presented at the American Medical Informatics Association Annual Symposium; 2009 November 17th.

Lazarus R, Klompas M, Kruskal B, Platt R Temporal patterns of fever following immunization in ambulatory care data identified by ESP:VAERS Presented at the American Medical Informatics Association Annual Symposium; 2009 November 14–18: San Francisco, CA.

Linder J, Klompas M, Cass B, et al. Spontaneous Electronic Adverse Event Reporting: Perspectives from Clinicians, EHR Vendors, Biopharma, and the FDA. Presented at the American Medical Informatics Association Annual Symposium; 2009 November 14–18: San Francisco, CA.





**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

INFORMED CONSENT ACTION NETWORK,

Plaintiff,

-against-

UNITED STATES DEPARTMENT OF HEALTH  
AND HUMAN SERVICES

Defendant.

**STIPULATION**

18-cv-03215 (JMF)

WHEREAS, 42 U.S.C. § 300aa-27, entitled "Mandate for safer childhood vaccines," provides as follows:

(a) General rule

In the administration of this part and other pertinent laws under the jurisdiction of the Secretary [of the Department of Health and Human Services], the Secretary shall—

(1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and

(2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

...

(c) Report

Within 2 years after December 22, 1987, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the

actions taken pursuant to subsection (a) of this section during the preceding 2-year period.

WHEREAS, on August 25, 2017, Informed Consent Action Network (“ICAN”) submitted a Freedom of Information Act request (the “FOIA Request”) to the Department of Health and Human Services (“HHS” or the “Department”), which was assigned control number 2017-01119-FOIA-OS, that sought the following records:

**Any and all reports transmitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate by the Secretary of HHS pursuant to 42 U.S.C. §300aa-27(c).**

WHEREAS, on April 12, 2018, ICAN filed a Complaint for Declaratory and Injunctive Relief in the United States District Court, Southern District of New York against HHS seeking records, if any, responsive to the FOIA Request;

WHEREAS, the HHS Immediate Office of the Secretary (“IOS”) maintains the official correspondence file of the Secretary of HHS, including reports to Congress by the Secretary of HHS, and therefore those files were most likely to contain records responsive to the FOIA Request;

WHEREAS, on June 27, 2018, HHS sent ICAN the following response to the FOIA Request:

The [Department]’s searches for records did not locate any records responsive to your request. The Department of Health and Human Services (HHS) Immediate Office of the Secretary (IOS) conducted a thorough search of its document tracking systems. The Department also conducted a comprehensive review of all relevant indexes of HHS Secretarial Correspondence records maintained at Federal Records Centers that remain in the custody of HHS. These searches did not locate records responsive to your request, or indications that records responsive to your request and in the custody of HHS are located at Federal Records Centers.

WHEREAS, ICAN believes the foregoing response from HHS now resolves all claims asserted in this action;

IT IS HEREBY STIPULATED AND AGREED, by and between the parties by and through their respective counsel:

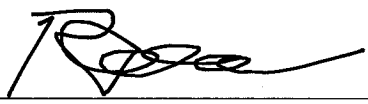
1. That the above-captioned action is voluntarily dismissed, with prejudice, pursuant to Federal Rule of Civil Procedure 41(a)(1)(A)(ii), each side to bear its own costs, attorney fees, and expenses; and

2. That this stipulation may be signed in counterparts, and that electronic (PDF) signatures may be deemed originals for all purposes.

Dated: July 6, 2018  
New York, New York

KENNEDY & MODONNA LLP  
*Attorney for Plaintiff*


By:

  
Robert F. Kennedy, Jr.  
48 Dewitt Mills Road  
Hurley, NY 12443  
(845) 481-2622


Dated: July 6, 2018  
New York, New York

GEOFFREY S. BERMAN  
United States Attorney  
*Attorney for Defendant*

By:

  
ANTHONY J. SUN  
Assistant United States Attorney  
86 Chambers Street, Third Floor  
New York, New York 10007  
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SO ORDERED:

  
HON. JESSE M. FURMAN, U.S.D.J.

Dated: New York, New York  
July 6, 2018

Any pending motions are moot. All conferences are vacated. The Clerk of Court is directed to close the case.