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Attorneys for Petitioners

UNITED STATES DISTRICT COURT OF CALIFORNIA

EASTERN DISTRICT - SACRAMENTO

Joy Garner, individually and on behalf of The Control Group; Joy Elisse Garner, individually and as parent of J.S. and F.G.; Evan Glasco, individually and as parent of F.G.; Traci Music, individually and as parent of K.M. and J.S., Michael Harris, individually and as parent of S.H., Nicole Harris, individually and as parent of S.H.,

Petitioners,

v.

DONALD JOHN TRUMP, in his official capacity as PRESIDENT OF THE UNITED STATES OF AMERICA,

Respondent.

Case No.:

PETITIONERS' REQUEST FOR JUDICIAL NOTICE, APPENDIX NUMBER TWO

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TO THE COURT, RESPONDENT, AND RESPONDENT'S COUNSEL OF RECORD:

PLEASE TAKE NOTICE that Pursuant to Federal Rule of Evidence 201, Petitioners in the above-entitled action hereby request the Court take judicial notice of the following readily verified facts, authorities, and attached documents, in support of Petitioners' Petition for Declaratory and Injunctive Relief. This motion is submitted together with Petitioners' concurrently filed Notice of Motion and Motion, Memorandum of Points and Authorities, and Declaration of Counsel.

INTRODUCTION

Medical dictionaries and government documents confirm: vaccination is not immunization. The two terms are not synonymous.

New evidence shows entirely unvaccinated Americans as a population cohort are extraordinarily healthy (evidencing their robust immune systems), whilst vaccinated Americans as a population cohort are suffering the worst pandemic of chronic illness in American history (evidencing their weakened immune systems).

Every individual's immune system and every vaccine must be accounted on its own merits, free of one-size-fits-all assumptions. For example, a healthy unvaccinated individual can acquire natural immunity to chicken pox with zero injuries whilst an unhealthy vaccinated person can suffer multiple serious injuries to the varicella vaccine that weakens their immune system to millions of other pathogens intruding their human biome.

Vaccine science is not settled. It is emerging daily. Vaccines remain one of the most controversial scientific subjects in the modern world, primarily because vaccines are manufactured with legally classified neurotoxins, and vaccines have never followed the scientific method for testing with true placebos or a control group of entirely unvaccinated individuals. Instead, vaccine regulatory approvals are supported by fake placebos (so-called "placebos" that contain neurotoxins), fake controls (so-called "controls" of people who are also vaccinated), short-term testing windows (so-called "tests" with monitoring periods as short as 3-days), and long-term passive surveillance of vaccine injuries (so-called "surveillance" with an unknown to approximately 99% failure rate of reporting).

Thus, vaccine science has not even evolved enough to recognize the basic dictionary definition of words, let alone become advanced enough to reach the status of "settled science".

Every vaccine product insert (a document required by law) admits the lack of safety testing for that vaccine, and further admits the vaccine's list of known side effects. Likewise, government documents and top scientific journals have also admitted the observed, but un-calculated, role of vaccination in America's chronic illness pandemic. To support without questioning the un-calculated numbers of vaccine injuries, credentialed professionals repeat empty phrases about vaccines in an echo-chamber, "vaccines are safe and effective", "side effects are rare". Such phrases are empty and dogmatic because they are mathematically unsupported. Quite literally, zero data supports these phrases.

For example, the Institute of Medicine (IOM) admitted that "studies designed to examine the long-term effects of the cumulative number of vaccines or other aspects of the immunization schedule have not been conducted." Literally, zero studies, and yet the IOM dogmatically claims vaccines are "safe". Dogma is defined according to Merriam-Webster, "dogma: a point of view or tenet put forth as authoritative without adequate grounds".

As highlighted above, the passive surveillance system maintained by Health and Human Services (HHS) for monitoring vaccine injuries has an unknown to approximately 99% failure rate, which results in literally zero statistical confidence in its ability to report accurately on the number of vaccine injuries in the American populace.

The most accurate and lawful way to describe vaccination is that it is an experimental procedure that has been falsely labeled as "safe and effective". Vaccine side effects have been falsely labeled as "rare". Compare the Council for International Organizations of Medical Sciences Working Group III, which set forth the following definitions for drug adverse events:

> "Very common ≥ 1/10 (≥ 10%)
> "Common ≥ 1/100 and < 1/10 (≥ 1% and < 10%)
> "Uncommon ≥ 1/1000 and < 1/100 (≥ 0.1% and < 1%)
> "Rare ≥ 1/10,000 and < 1/1000 (≥ 0.01% and < 0.1%)
> "Very rare < 1/10,000 (< 0.01%)"

Vaccine adverse events are not "rare" by this scientific definition. Until vaccines are compared long-term against a large control group of entirely unvaccinated individuals, it is scientifically impossible to state that vaccines are "safe" or that vaccine side effects are "rare".

The international pharmaceutical industry conducts studies of "vaccine hesitancy" (the reasons certain people decline vaccines). These studies consistently show that the population of individuals who avoid vaccination (the "vaccine hesitant") are better educated than those who submit to vaccination. Indeed, the international pharmaceutical industry publishes that increasing numbers of physicians are also rejecting vaccination for themselves and their families.

The international pharmaceutical industry's vaccination marketing campaigns are factually misleading and yet effective in frightening most Americans into submission to untested vaccination schedules. Consequently, today the number of individuals who remain entirely unvaccinated in America is small, estimated at less than 1% of our entire population.

The scientific method that respects control groups is in jeopardy due to both the overzealous international pharmaceutical industry and the health officials beholden to it. Many of these health officials have expressed publicly their desire to vaccinate 100% of the population within their jurisdiction. And Covid-19 has increased this overzealousness across the country.

Even though "vaccine hesitancy" studies prove the overall nature of the unvaccinated population is pro-science, today this group of conscientious Americans are persecuted, isolated, ridiculed, and vilified by politicians, bureaucrats, and the mainstream media. This creates a legal predicament for unvaccinated Americans as they suffer threats to their fundamental rights, in particular their rights to informed consent and informed refusal.

The international pharmaceutical industry that produces vaccines has a long-history of scientific corruption and conflicts of interest. In short, it is a trillion dollar industry that uses aborted babies to manufacture certain vaccines, adds known neurotoxins such as aluminum and mercury to vaccines, specifically engineers newer vaccines to manipulate human DNA, and then summarily labels every single one of their finished products "safe", without any mathematical proof that would comply with the scientific method.

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PETITIONERS' REQUESTS FOR JUDICIAL NOTICE

1. Vaccination

A. Definition of Vaccinate

1. Definition

For the truth of the matter stated, Petitioners request judicial notice of the following medical dictionary definition of "vaccinate":

Vaccinate: to inoculate with vaccine for the purpose of producing immunity".

Citation: Dorland's Illustrated Medical Dictionary, Elsevier 2020, page 1985, col 2. See Exhibit 220.

2. Limits of the Definition

For the truth of the matter stated, Petitioners further request judicial notice that 'the definition of vaccinate does not state the individual actually achieves immunity, but rather the purpose is to produce immunity.' Separate exhibit not needed; please refer to Exhibit 220.

B. Definition of Unvaccinated

1. Definition

For the truth of the matter stated, Petitioners request judicial notice of the following definition of "unvaccinated":

"Unvaccinated: (of a person) not inoculated with a vaccine to provide immunity against a disease."

Citation: Oxford Online Dictionary Lexico (2020). https://www.lexico.com/en/definition/unvaccinated (accessed June 18, 2020). See Exhibit 221.

2. Application

For the truth of the matter stated, Petitioners request judicial notice that 'an unvaccinated person is one who has not received any vaccinations.'

Citation: Mellerson, J, et al. (2018). Vaccination Coverage for Selected Vaccines and Exemption Rates Among Children in Kindergarten — United States, 2017–18 School Year. *US Department of Health and Human Services/Centers for Disease Control and Prevention: Morbidity and Mortality Weekly Report.* October 12, 2018 / 67(40);1115–1122

https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6740a3-H.pdf (accessed June 18, 2020). See Exhibit 222:

"Recent data from the National Immunization Survey indicate the percentage of children reaching age 2 years without having received any vaccinations has increased gradually, from 0.9% for children born in 2011 to 1.3% for children born in 2015."

C. Undervaccinated does not mean Unvaccinated

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quotes from *Pediatrics*:

1. "Each year 2.1 million children 19 to 35 months of age are undervaccinated. Among these are children who have received no vaccinations."
2. "Unvaccinated children have characteristics that are distinctly different from those of undervaccinated children."

Citation: Smith, et al. (2004). *Children Who Have Received No Vaccines: Who Are They and Where Do They Live? Pediatrics* 114 (1) 187-195; DOI: https://doi.org/10.1542/peds.114.1.187 (accessed June 18, 2020). See Exhibit 223.

D. Vaccinated person

For the truth of the matter stated, Petitioners request judicial notice that 'a vaccinated person is a person who has received one or more vaccines during their lifetime.'

Separate exhibit not needed; please refer to Exhibits 221-223.

2. Evidence Based

For the truth of the matter stated, Petitioners request judicial notice of the following medical dictionary definition of "evidence based":

"Evidence based: characterized by methods of diagnosis and treatment based on demonstrable evidence, i.e. whose effectiveness has been demonstrated by well designed, peer reviewed studies."

Citation: Dorland's Illustrated Medical Dictionary, p. 648. See Exhibit 224.

3. Common Sense

For the truth of the matter stated, Petitioners request judicial notice of the following dictionary definition of "common sense":

"Common sense: the ability to use good judgment in making decisions and to live in a reasonable and safe way."

Citation: Cambridge Academic Content Dictionary (2020). *Cambridge University Press.* https://dictionary.cambridge.org/dictionary/english/common-sense (accessed on June 18, 2020). See Exhibit 225.

4. Safe

A. Definition of Safe

For the truth of the matter stated, Petitioners request judicial notice of the following dictionary definition of "safe":

"Safe: 1 **:** free from harm or risk **:** unhurt
"2a **:** secure from threat of danger, harm, or loss
"b **:** successful at getting to a base in baseball without being put out
"3 **:** affording safety or security from danger, risk, or difficulty
"4 obsolete, of mental or moral faculties **:** healthy,
"5a **:** not threatening danger **:** harmless
"b **:** unlikely to produce controversy or contradiction
"6a **:** not likely to take risks **:** cautious
"b **:** trustworthy, reliable".

Citation: Merriam Webster Dictionary (2020). https://www.merriam-webster.com/dictionary/safe (accessed on June 18, 2020). See Exhibit 226.

B. Definition of Unsafe

For the truth of the matter stated, Petitioners request judicial notice of the following dictionary definition of "unsafe":

"Unsafe, a: able or likely to cause harm, damage, or loss

"b **:** not giving protection from danger, harm, or loss

"c **:** not protected from danger, harm, or loss

"d **:** likely to take risks : not careful"

Citation: Merriam Webster Dictionary (2020). https://www.merriam-webster.com/dictionary/unsafe (accessed on June 18, 2020). See Exhibit 227.

C. Definition of Dangerous

For the truth of the matter stated, Petitioners request judicial notice of the following dictionary definition of "dangerous":

"1 : involving possible injury, pain, harm, or loss **:** characterized by danger

"2 : able or likely to inflict injury or harm"

Citation: Merriam Webster Dictionary (2020). https://www.merriam-webster.com/dictionary/dangerous (accessed on June 18, 2020). See Exhibit 228.

D. Dangerous is a Correct Synonym of Unsafe

For the truth of the matter stated, Petitioners request judicial notice that in the thesaurus the first listed synonym for "unsafe" is "dangerous":

"Synonyms for unsafe: dangerous, grave, grievous, hazardous, jeopardizing, menacing, parlous, perilous, risky, serious, threatening, unhealthy, venturesome".

Citation: Merriam Webster Dictionary (2020). https://www.merriam-webster.com/dictionary/unsafe (accessed on June 15, 2020). See Exhibit 227.

E. Vaccines Are Legally Categorized as Unavoidably Unsafe

For the truth of the matter stated, Petitioners request judicial notice that 'vaccines are currently classified by American tort law as "unavoidably unsafe" due to the injuries and deaths resulting from their unavoidable side effects.'

Citation: *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 254-55, 131 S. Ct. 1068, 1089 (2011):

> "The 1986 Report expressly adopts comment *k* of § 402A of the Restatement of Torts (Second) (1963-1964) (hereinafter Restatement), which provides that "unavoidably unsafe" products--*i.e.*, those that 'in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use'--are not defective. As '[a]n outstanding example' of an '[u]navoidably unsafe' product, comment *k* cites 'the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected'; '[s]ince the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve.' *Id*., at 353. Comment *k* thus provides that 'seller[s]' of '[u]navoidably unsafe' products are 'not to be held to strict liability' provided that such products 'are properly prepared and marketed, and proper warning is given.'"

No separate exhibit needed; see legal citations.

5. Scientific Method

A. Description of Scientific Method

For recognition of a commonly known fact throughout the country, Petitioners request judicial notice of the following description of the "scientific method":

"As schoolchildren we are taught the scientific method involves a question and suggested explanation (hypothesis) based on observation, followed by the careful design and execution of controlled experiments, and finally validation, refinement or rejection of this hypothesis."

Citation: Nature (2009). Defining the scientific method (e*ditorial). Nat Methods* 6, 237. https://doi.org/10.1038/nmeth0409-237 (accessed June 18, 2020). See Exhibit 229.

B. Description of Unscientific

For truth of the matter stated, Petitioners request judicial notice of the following dictionary definition of "unscientific":

"Unscientific: 1. Not in accordance with scientific principles or methodology. 2. Lacking knowledge of or interest in science."

Citation: Oxford Online Dictionary Lexico (2020). https://www.lexico.com/en/definition/unscientific (accessed June 18, 2020). See Exhibit 230.

6. Controlled Experiment

For recognition of a commonly known fact throughout the country, Petitioners request judicial notice of the following quote from Encyclopedia Brittanica:

> "Ideally, the control group and the experimental groups are identical in every way except that the experimental groups are subjected to treatments or interventions believed to have an effect on the outcome of interest while the control group is not. Inclusion of a control group greatly strengthens researchers' ability to draw conclusions from a study. Indeed, only in the presence of a control group can a researcher determine whether a treatment under investigation truly has a significant effect on an experimental group, and the possibility of making an erroneous conclusion is reduced."

Citation: Godby, M (2020). Control Group. *Encyclopedia Brittanica*. https://www.britannica.com/science/control-group, (accessed June 18, 2020). See Exhibit 231.

7. Placebo

A. Definition of Placebo

For the truth of the matter stated, Petitioners request judicial notice of the following definition of "placebo":

"Placebo: A substance or treatment that has no effect on human beings."

Primary Citation: Centers for Disease Control and Prevention ("CDC") (2016): Glossary. Vaccines and Immunizations. https://www.cdc.gov/vaccines/terms/glossary.html (accessed June 18, 2020). See Exhibit 232.

Secondary Citation: National Institutes of Health ("NIH") (2020). *Health Info: Placebo effect.* https://www.nccih.nih.gov/health/placebo-effect, (accessed June 18, 2020). See Exhibit 233:

> "The 'gold standard' for testing interventions in people is the 'randomized, placebo-controlled' clinical trial, in which volunteers are randomly assigned to a test group receiving the experimental intervention or a control group receiving a placebo (an inactive substance that looks like the drug or treatment being tested). Comparing results from the two groups suggests whether changes in the test group result from the treatment or occur by chance."

B. Definition of Placebo Effect

For the truth of the matter stated, Petitioners request judicial notice of the dictionary definition of "placebo effect":

"Placebo effect: improvement in the condition of a patient that occurs in response to treatment but cannot be considered due to the specific treatment used".

Citation: Merriam Webster dictionary (2020). https://www.merriam-webster.com/dictionary/placebo%20effect (accessed June 18, 2020). See Exhibit 234.

C. Limitations of Placebos and Distinction From Controls

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following facts:

1. 'A placebo and a control are not the same thing, nor do they serve the same functions in vaccine safety testing.'

2. 'There is no evidence widely recognized by public health officials that the 'placebo effect' can affect outcomes in the contracting or spreading of infectious agents.'

3. 'There is no evidence widely recognized by public health officials that a subject's beliefs have a known effect on infectious agents, whether or not a subject will create antibodies, or whether or not the transmission of infectious agents will occur.'

4. 'There is no evidence that a person's beliefs about vaccines can cause them to suddenly become paralyzed, suffer brain and nervous system damage, suffer immune system injuries, contract arthritis or cancer, or even die, whether the subject believes they were vaccinated or not.'

5. 'There is no evidence that a new-born infant develops beliefs about being injected, or not being injected, such that there is a purpose to injecting an infant with a so-called placebo.'

Separate exhibit not needed; please refer to Exhibits 231-234.

8. Use of So-Called Placebos In Vaccine Safety Testing Are Designed to Harm Humans Overall

For the truth of the matter stated, Petitioners request judicial notice that 'for each pediatric vaccine that HHS promotes for routine injection into children,

1. 'the clinical trials relied upon to assess its safety prior to licensing its use in children did *not* use a true control group of entirely unvaccinated individuals'.

2. 'any clinical trials relied upon to assess its safety post licensing did *not* use a true control group of entirely unvaccinated individuals'.

Citation: US Food and Drug Administration ("FDA") (2020). Vaccines Licensed For Use In the United States. https://www.fda.gov/vaccines-blood-biologics/, (accessed June 18, 2020). See Exhibit 235, and Exhibits 236-267.

CDC Childhood Vaccine Schedule from Age Day One to Six Months

1. For the truth of the matter stated, Petitioners request judicial notice of the following facts regarding safety testing found in the vaccine product inserts published by the FDA:

a. 'The test group received at least Infanrix (GSK), and the so-called control group members received one or more vaccines and therefore no true control group was tested'.

Citation: FDA. Package Insert: *Infanrix*. https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm124514.pdf (accessed June 19, 2020). See Exhibit 236:

Pre-licensing
"Selected adverse reactions reported from a double-blind, randomized Italian clinical efficacy trial involving 4,696 children administered INFANRIX or 4,678 children administered whole-cell DTP vaccine (DTwP) (manufactured by Connaught Laboratories, Inc.) as a 3-dose primary series are shown in Table 4."

Post-licensing
*"*Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccination."

First additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the pre-licensure safety review time periods in the attached were too brief for test subjects to fully report all solicited and unsolicited adverse reactions.'

Second additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in the attached: "INFANRIX has not been evaluated for carcinogenic or mutagenic potential or for impairment of fertility."

Third additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of all adverse events listed in the attached package insert pursuant to 21 C.F.R. 201.57 ("This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.")

b. 'The test group received at least Daptacel (Sanofi), and the so-called control group members received one or more vaccines and therefore no true control

group was tested'.

Citation: FDA. Package Insert: *Daptacel*. https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm103037.pdf (accessed June 19, 2020). See Exhibit 237.

Pre-licensing
"In a randomized, double-blinded pertussis vaccine efficacy trial, the Sweden I Efficacy Trial, conducted in Sweden during 1992-1995, the safety of DAPTACEL was compared with DT and a whole-cell pertussis DTP vaccine."

Post-licensing
"Because these events are reported voluntarily from a population of uncertain size, it may not be possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure."

First additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the pre-licensure safety review time periods in the attached were too brief for test subjects to fully report all solicited and unsolicited adverse reactions.'

Second additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in the attached: "DAPTACEL has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility."

Third additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of all adverse events listed in the attached package insert pursuant to 21 C.F.R. 201.57 ("This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.")

2. For the truth of the matter stated, Petitioners request judicial notice of the following facts found in the Hib vaccine product inserts published by the FDA:

a. 'The test group received at least ActHIB (Sanofi), and the so-called control group members received one or more vaccines and therefore no true control

group was tested'.

Citation: FDA. Package Insert: *ActHIB*. https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM109841.pdf (accessed June 19, 2020), provided together with: FDA. Summary for Basis of Approval: Haemophilus b Conjugate Vaccine. http://wayback.archive-it.org/7993/20170723144656/https:/www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM244597.pdf (accessed June 21, 2020). See Exhibit 238.

First additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the pre-licensure safety review time periods in the attached were too brief for test subjects to fully report all solicited and unsolicited adverse reactions.'

Second additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in the attached: "ActHIB vaccine has not been evaluated for its carcinogenic or mutagenic potential or impairment of male fertility."

Third additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of all adverse events listed in the attached package insert pursuant to 21 C.F.R. 201.57 ("This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.")

b. 'The test group received at least Hiberix (GSK), and the so-called control group members received one or more vaccines and therefore no true control group was tested'.

Citation: FDA. Package Insert: *Hiberix*. https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines

/ApprovedProducts/UCM179530.pdf, (accessed June 19, 2020).

See Exhibit 239:

Pre-licensing
"In a randomized, controlled clinical trial conducted in the U.S., children were vaccinated with HIBERIX (n = 2,963), a U.S.-licensed monovalent Haemophilus b Conjugate Vaccine (Control PRP-T) (Sanofi Pasteur SA) (n = 520), or a U.S.-licensed combined Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate Vaccine (DTaP-IPV/Hib) (Sanofi Pasteur Ltd.) (n = 520) at 2, 4, and 6 months of age. HIBERIX and Control PRP-T (Sanofi Pasteur SA) were administered concomitantly with PEDIARIX (DTaP-HBV-IPV) [Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Hepatitis B (Recombinant) and Inactivated Poliovirus Vaccine] and Pneumococcal 13-valent Conjugate Vaccine (PCV13) (Wyeth Pharmaceuticals Inc.) with Doses 1, 2, and 3 and ROTARIX [Rotavirus Vaccine, Live, Oral] with Doses 1 and 2. DTaP- IPV/Hib was administered concomitantly with PCV13 and ENGERIX-B [Hepatitis B Vaccine (Recombinant)] with Doses 1, 2, and 3 and ROTARIX with Doses 1 and 2. …In 7 additional clinical studies, 1,008 children received HIBERIX as a booster dose following primary vaccination with either HIBERIX (n = 530), Haemophilus b Conjugate Vaccine (Control PRP-T) (Sanofi Pasteur SA) (n = 235), Haemophilus b Conjugate Vaccine (Merck & Co., Inc.) (n = 26), or Haemophilus b Conjugate Vaccine (Wyeth Pharmaceuticals Inc.) (no longer licensed in the U.S., n = 217). None of the studies included a comparator group that received a booster dose with a U.S.-licensed Haemophilus b Conjugate Vaccine….Each dose (Doses 1, 2, and 3) of HIBERIX or Control PRP-T (Sanofi Pasteur SA) was concomitantly administered with PEDIARIX (DTaP-HBV-IPV) and PCV13. Doses 1 and 2 were concomitantly administered with ROTARIX."

Post-licensing
"Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to vaccination."

First additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the pre-licensure safety review time periods in the attached were too brief for test subjects to fully report all solicited and unsolicited adverse reactions.'

Second additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in the attached: "HIBERIX has not been evaluated for carcinogenic or mutagenic potential, or for impairment of fertility."

Third additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of all adverse events listed in the attached package insert pursuant to 21 C.F.R. 201.57 ("This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.")

c. 'The test group received at least PedvaxHIB (Merck), and the so-called control group members received one or more vaccines and therefore no true control group was tested'.

Citation: FDA. Package Insert: *PedvaxHIB*. https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM253652.pdf (accessed June 15, 2020). See Exhibit 240:

Pre-licensing

> "Each infant in this study received two doses of either placebo or lyophilized PedvaxHIB with the first dose administered at a mean of 8 weeks of age and the second administered approximately two months later; DTP and OPV were administered concomitantly….The safety and immunogenicity of Liquid PedvaxHIB were compared with those of lyophilized PedvaxHIB in a randomized clinical study involving 903 infants 2 to 6 months of age from the general U.S. population. DTP and OPV were administered concomitantly to most subjects."
> Additional context: The study with a control to which the package insert refers is to the old Lyophilized PedvaxHIB version. In Lyophilized PedvaxHIB's pre-licensure trials, the test group received Lyophilized PedvaxHIB, OPV and DTP, and the control group received a so-called placebo, concomitantly with OPV and DTP.

First additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the pre-licensure safety review time periods in the attached were too brief for test subjects to fully report all solicited and unsolicited adverse reactions.'

Second additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following

quote in the attached: "Liquid PedvaxHIB has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility."

Third additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of all adverse events listed in the attached package insert pursuant to 21 C.F.R. 201.57 ("This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.")

3. For the truth of the matter stated, Petitioners request judicial notice of the following facts found in the Hepatitis B vaccine product inserts published by the FDA:

a. 'The test group received at least Engerix-B (GSK), and there was neither a true control group of entirely unvaccinated individuals, nor even a so-called control group.'

Citation: FDA. Package Insert: *Engerix-B*. https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224503.pdf (accessed June 19, 2020). See Exhibit 241.

First additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the pre-licensure safety review time periods in the attached were too brief for test subjects to fully report all solicited and unsolicited adverse reactions.'

Second additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in the attached: "ENGERIX-B has not been evaluated for carcinogenic or mutagenic potential, or for impairment of male fertility in animals. Vaccination of female rats with TWINRIX, which contains the same HBsAg component and quantity as ENGERIX-B, had no effect on fertility. [See Use in Specific Populations (8.1).]"

Third additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of all adverse

events listed in the attached package insert pursuant to 21 C.F.R. 201.57 ("This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.")

b. 'The test group received at least Recombivax HB (Merck), and there was neither a true control group of entirely unvaccinated individuals, nor even a so-called control group.'

Citation: FDA. Package Insert: *Recombivax HB*. https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110114.pdf (accessed June 19, 2020). See Exhibit 242.

First additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the pre-licensure safety review time periods in the attached were too brief for test subjects to fully report all solicited and unsolicited adverse reactions.'

Second additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in the attached: "RECOMBIVAX HB has not been evaluated for its carcinogenic or mutagenic potential, or its potential to impair fertility [see Use in Specific Populations(8)]".

Third additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of all adverse events listed in the attached package insert pursuant to 21 C.F.R. 201.57 ("This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.")

4. For the truth of the matter stated, Petitioners request judicial notice of the following facts found in the Pneumococcal vaccine product insert published by the FDA:

a. 'The test group received at least Prevnar 13 (Pfizer), and the so-called control group members received one or more vaccines and therefore no true control

group was tested'.

Citation: FDA. Package Insert: *Prevnar 13*.

https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM574852.pdf (accessed June 19, 2020). See Exhibit 243:

> *Pre-licensing*
> "The safety of Prevnar 13 was evaluated in 13 clinical trials in which 4,729 infants (6 weeks through 11 months of age) and toddlers (12 months through 15 months of age) received at least one dose of Prevnar 13 and 2,760 infants and toddlers received at least one dose of Prevnar active control….Three studies in the US (Studies 1, 2 and 3)[1,2,3] evaluated the safety of Prevnar 13 when administered concomitantly with routine US pediatric vaccinations at 2, 4, 6, and 12-15 months of age."
>
> *Post-licensing*
> *"*Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to the vaccine."

First additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the pre-licensure safety review time periods in the attached were too brief for test subjects to fully report all solicited and unsolicited adverse reactions.'

Second additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in the attached: "Prevnar 13 has not been evaluated for the potential to cause carcinogenicity, genotoxicity, or impairment of male fertility."

Third additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of all adverse events listed in the attached package insert pursuant to 21 C.F.R. 201.57 ("This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.")

5. For the truth of the matter stated, Petitioners request judicial notice of the following facts found in the Polio vaccine product insert published by the FDA:

a. 'The test group received at least Ipol (Sanofi), and there was neither a true control group of entirely unvaccinated individuals, nor even a so-called control group.'

Citation: FDA. Package Insert: *Ipol*. https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM133479.pdf (accessed June 19, 2020). See Exhibit 244.

First additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'any pre-licensure safety review time periods in the attached were too brief for test subjects to fully report all solicited and unsolicited adverse reactions.'

Second additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in the attached: "Long-term studies in animals to evaluate carcinogenic potential or impairment of fertility have not been conducted."

Third additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of all adverse events listed in the attached package insert pursuant to 21 C.F.R. 201.57 ("This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.")

6. For the truth of the matter stated, Petitioners request judicial notice of the following facts found in the Combination Vaccine product inserts published by the FDA:

a. 'The test group received at least Pediarix (GSK), and the so-called control group members received one or more vaccines and therefore no true control group was tested'.

Citation: FDA. Package Insert: *Pediarix*. https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM241874.pdf, (accessed June 19, 2020). See Exhibit 245:

Pre-Licensing
"…separate U.S.- licensed vaccines (INFANRIX, Hib conjugate vaccine [Sanofi Pasteur SA], and oral poliovirus vaccine [OPV] [Wyeth Pharmaceuticals, Inc.; no longer licensed in the United States])… [or] separately administered INFANRIX, ENGERIX-B [Hepatitis B Vaccine (Recombinant)], and IPV (Sanofi Pasteur SA) in 335 infants. In both groups, infants received Hib conjugate vaccine (Wyeth Pharmaceuticals Inc.; no longer licensed in the United States) and 7-valent pneumococcal conjugate vaccine (Wyeth Pharmaceuticals Inc.) concomitantly at separate sites."

Post-Licensing
"In a safety surveillance study conducted at a health maintenance organization in the United States, infants who received 1 or more doses of PEDIARIX from approximately mid-2003 through mid-2005 were compared with age-, gender-, and area-matched historical controls who received 1 or more doses of separately administered U.S.-licensed DTaP vaccine from 2002 through approximately mid-2003. Only infants who received 7-valent pneumococcal conjugate vaccine (Wyeth Pharmaceuticals Inc.) concomitantly with PEDIARIX or DTaP vaccine were included in the cohorts. Other U.S.-licensed vaccines were administered according to routine practices at the study sites, but concomitant administration with PEDIARIX or DTaP was not a criterion for inclusion in the cohorts. A birth dose of hepatitis B vaccine had been administered routinely to infants in the historical DTaP control cohort, but not to infants who received PEDIARIX….Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure."

First additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the pre-licensure safety review time periods in the attached were too brief for test subjects to fully report all solicited and unsolicited adverse reactions.'

Second additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in the attached: "PEDIARIX has not been evaluated for carcinogenic or mutagenic potential or for impairment of fertility."

Third additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of all adverse events listed in the attached package insert pursuant to 21 C.F.R. 201.57 ("This definition does not include all adverse events observed during use of a drug, only those adverse events for which there

is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.")

b. 'The test group received at least Pentacel (Sanofi), and the so-called control group members received one or more vaccines and therefore no true control group was tested'.

Citation: FDA. Package Insert: *Pentacel*. https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM109810.pdf (accessed June 19, 2020). See Exhibit 246:

> *Pre-Licensing*
> "HCPDT + POLIOVAX + ActHIB at 2, 4, 6, and 15 months…DAPTACEL + IPOL + ActHIB at 2, 4, and 6 months; and DAPTACEL + ActHIB at 15-16 months…PCV7* at 2, 4, and 6 months in all participants; and at 15 months in a random subset of participants. Hepatitis B vaccine at 2 and 6 months (if a dose was previously administered) ‡ or at 2, 4, and 6 months (if no previous dose). Measles, mumps, rubella vaccine§ (MMR) and varicella§ vaccine at 12 or 15 months in random subsets of participants…Study participants previously had received three doses of Pentacel vaccine by 8 months of age."
>
> *Post-licensing*
> "Because these events are reported voluntarily from a population of uncertain size, it may not be possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure."

First additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the pre-licensure safety review time periods in the attached were too brief for test subjects to fully report all solicited and unsolicited adverse reactions.'

Second additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in the attached: "Pentacel has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility."

Third additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of all adverse events listed in the attached package insert pursuant to 21 C.F.R. 201.57 ("This definition does not

include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.")

C. CDC Childhood Vaccine Schedule from Age Six Months to Eighteen Months

1. For the truth of the matter stated, Petitioners request judicial notice of the following facts found in the Hepatitis A vaccine product inserts published by the FDA:

   a. 'The test group received at least Havrix (GSK), and the so-called control group members received one or more vaccines and therefore no true control group was tested'.

   Citation: FDA. Package Insert: *Havrix*. https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224555.pdf (accessed June 19, 2020). See Exhibit 247:

Pre-licensing
"The safety of HAVRIX has been evaluated in 61 clinical trials involving approximately 37,000 individuals receiving doses of 360 EL.U. (n = 21,928 in 3- or 4-dose schedule), 720 EL.U. (n = 12,274 in 2- or 3-dose schedule), or 1440 EL.U. (n = 2,782 in 2- or 3-dose schedule)…. In 4 studies, 3,152 children 11 to 25 months of age received at least one dose of HAVRIX 720 EL.U. administered alone or concomitantly with other routine childhood vaccinations *[see Clinical Studies (14.2, 14.5)]*. The studies included HAV 210 (N = 1,084), HAV 232 (N = 394), HAV 220 (N = 433), and HAV 231 (N = 1,241). In the largest of these studies (HAV 231) conducted in the US, 1,241 children 15 months of age were randomized to receive: Group 1) HAVRIX alone; Group 2) HAVRIX concomitantly with measles, mumps, and rubella (MMR) vaccine (manufactured by Merck and Co.) and varicella vaccine (manufactured by Merck and Co.); or Group 3) MMR and varicella vaccines. Subjects in Group 3 who received MMR and varicella vaccines received the first dose of HAVRIX 42 days later. A second dose of HAVRIX was administered to all subjects 6 to 9 months after the first dose of HAVRIX."

Post-licensing
"In addition to reports in clinical trials, worldwide voluntary reports of adverse events received for HAVRIX since market introduction of this vaccine are listed below. This list includes serious adverse events or events which have a suspected causal connection to components of HAVRIX or other vaccines or drugs. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to the vaccine."

First additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the pre-licensure safety review time periods in the attached were too brief for test subjects to fully report all solicited and unsolicited adverse reactions.'

Second additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in the attached: "HAVRIX has not been evaluated for its carcinogenic potential, mutagenic potential, or potential for impairment of fertility."

Third additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of all adverse events listed in the attached package insert pursuant to 21 C.F.R. 201.57 ("This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.")

b. 'The test group received at least Vaqta (Merck), and the so-called control group members received one or more vaccines, including a subgroup receiving aluminum, and thimerosal, and therefore no true control group was tested'. Citation: FDA. Package Insert: *Vaqta*. https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110049.pdf (accessed June 19, 2020), provided together with the referenced clinical trial journal article referring to aluminum and thimerosal: Werzberger, A, et al. (1992). A Controlled Trial of Formalin-Inactivated Hepatitis A Vaccine in Healthy Children. *New England Journal of Medicine*, Vol. 327, No. 7. https://www.nejm.org/doi/pdf/10.1056/NEJM199208133270702 (accessed June 21, 2020). See Exhibit 248:

Pre-licensing
"In a double-blind, placebo-controlled efficacy trial (i.e. The Monroe Efficacy Study), 1037 healthy children and adolescents 2 through 16 years of age were randomized to receive a primary dose of 25U of VAQTA and a booster dose of

> VAQTA 6, 12, or 18 months later, or placebo (alum diluent)….Placebo (Alumdiluent) = amorphous aluminum hydroxyphosphate sulfate."
>
> *Post-licensing*
> "Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to a vaccine exposure."

First additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the pre-licensure safety review time periods in the attached were too brief for test subjects to fully report all solicited and unsolicited adverse reactions.'

Second additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in the attached: "VAQTA has not been evaluated for its carcinogenic or mutagenic potential, or its potential to impair fertility."

Third additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of all adverse events listed in the attached package insert pursuant to 21 C.F.R. 201.57 ("This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.")

2. For the truth of the matter stated, Petitioners request judicial notice of the following facts found in the MMR vaccine product insert published by the FDA:

   a. 'The test group received at least M-M-R II (Merck), and there was neither a true control group of entirely unvaccinated individuals, nor even a so-called control group.'

   Citation: FDA. Package Insert: *M-M-R II*. https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM123789.pdf (accessed June 15 and 20, 2020). See Exhibit 249.

First additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'any pre-

licensure safety review time periods in the attached were too brief for test subjects to fully report all solicited and unsolicited adverse reactions.'

Second additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in the attached: "M-M-R II has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility."

Third additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of all adverse events listed in the attached package insert pursuant to 21 C.F.R. 201.57 ("This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.")

3. For the truth of the matter stated, Petitioners request judicial notice of the following facts found in the Varicella vaccine product insert published by the FDA:

   a. 'The test group received Varivax (Merck), and the so-called control group members received at least a non-inert lyophilized antibiotic injection prepared by a Merck pharmaceutical laboratory, and therefore no true control group was tested'.

   Citation: FDA. Package Insert: *Varivax*. https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142813.pdf (accessed June 19, 2020), provided together with reference #18 in the package insert: Weibel R (1984). N Engl J Med 310:1409-1415. DOI: 10.1056/NEJM198405313102201. https://www.nejm.org/doi/full/10.1056/NEJM198405313102201 (accessed June 19, 2020). See Exhibit 250:

Pre-licensing
"The varicella vaccine and placebo used in this trial were prepared by Merck Sharp & Dohme Research Laboratories, West Point, Pa…. The placebo (Lot 909/C-H663) was identical in appearance to the vaccine in both lyophilized and

reconstituted forms but contained no viral material. The placebo consisted of lyophilized stabilizer containing approximately 45 mg of neomycin per milliliter."

First additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'any pre-licensure safety review time periods in the attached were too brief for test subjects to fully report all solicited and unsolicited adverse reactions.'

Second additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of all adverse events listed in the attached package insert pursuant to 21 C.F.R. 201.57 ("This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.")

4. For the truth of the matter stated, Petitioners request judicial notice of the following facts found in the Combo Vaccine product insert published by the FDA:

   a. 'The test group received ProQuad (Merck), and the so-called control group members received one or more vaccines and therefore no true control group was tested'.

   Citation: FDA. Package Insert: *ProQuad*. https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM123793.pdf (accessed June 19, 2020). See Exhibit 251:

Pre-licensing
"The safety of frozen ProQuad (N=4497) was compared with the safety of M-M-RII and VARIVAX given concomitantly (N=2038) at separate injection sites….In a double-blind clinical trial, 799 healthy 4- to 6-year-old children who received M-M-R II and VARIVAX at least 1 month prior to study entry were randomized to receive ProQuad and placebo (N=399), M-M-R II and placebo concomitantly (N=205) at separate injection sites, or M-M-R II and VARIVAX (N=195) concomitantly at separate injection sites *[see Clinical Studies (14)]*."

Post-Licensing
"Because the events are in some cases described in the literature or reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure."

First additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the pre-licensure safety review time periods in the attached were too brief for test subjects to fully report all solicited and unsolicited adverse reactions.'

Second additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in the attached: "ProQuad has not been evaluated for its carcinogenic, mutagenic, or teratogenic potential, or its potential to impair fertility."

Third additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of all adverse events listed in the attached package insert pursuant to 21 C.F.R. 201.57 ("This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.")

5. For the truth of the matter stated, Petitioners request judicial notice of the following facts found in the Flu vaccine product inserts published by the FDA:

   a. 'The test group received Fluarix (IIV4) (GSK), and the so-called control group members received one or more vaccines and therefore no true control group was tested'.

      Citation: FDA. Package Insert: *Fluarix*. https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM619534.pdf (accessed on June 19, 2020). See Exhibit 252.

Pre-licensing
"Trial 1 (NCT01204671) was a randomized, double-blind (2 arms) and open-label (one arm), active- controlled, safety, and immunogenicity trial. In this trial, subjects received FLUARIX QUADRIVALENT (n = 3,036) or one of 2 formulations of comparator trivalent influenza vaccine (FLUARIX; TIV-1, n = 1,010; or TIV-2, n = 610), each containing an influenza type B virus that corresponded to one of the 2 type B viruses in FLUARIX QUADRIVALENT (a type B virus of the Victoria lineage or a type B virus of the Yamagata lineage)….Trial 7 (NCT01439360) was a randomized, observer-blind, non-

> influenza vaccine-controlled trial evaluating the efficacy of FLUARIX QUADRIVALENT. In this trial, subjects aged 6 through 35 months received FLUARIX QUADRIVALENT (n = 6,006) or a control vaccine (n = 6,012). The comparator was pneumococcal 13-valent conjugate vaccine [Diphtheria CRM197 Protein] (Wyeth Pharmaceuticals, Inc.) in children younger than 12 months, HAVRIX (Hepatitis A Vaccine) in children 12 months and older with a history of influenza vaccination, or HAVRIX (Dose 1) and a varicella vaccine (U.S. Licensed Manufactured by Merck & Co., Inc. or Non-U.S. Licensed Manufactured by GlaxoSmithKline Biologicals) (Dose 2) in those with no history of influenza vaccination….Trial 2 (NCT01196988) was a randomized, double-blind, active-controlled, safety, and immunogenicity trial. In this trial, subjects received FLUARIX QUADRIVALENT (n = 915) or one of 2 formulations of comparator trivalent influenza vaccine (FLUARIX; TIV-1, n = 912; or TIV-2, n = 911), each containing an influenza type B virus that corresponded to one of the 2 type B viruses in FLUARIX QUADRIVALENT (a type B virus of the Victoria lineage or a type B virus of the Yamagata lineage)."
>
> *Post-Licensing*
> "Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to the vaccine."

First additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the pre-licensure safety review time periods in the attached were too brief for test subjects to fully report all solicited and unsolicited adverse reactions.'

Second additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in the attached: "FLUARIX QUADRIVALENT has not been evaluated for carcinogenic or mutagenic potential or male infertility in animals."

Third additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of all adverse events listed in the attached package insert pursuant to 21 C.F.R. 201.57 ("This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.")

b. 'The test group received FluLaval (IIV4) (ID Bio), and the so-called control group members received one or more vaccines and therefore no true control group was tested'.

Citation: FDA. Package Insert: *FluLaval (IIV4)*. https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM619548.pdf (accessed June 19, 2020). See Exhibit 253.

Pre-licensing
"Trial 1(NCT01196975) was a randomized, double-blind, active-controlled, safety and immunogenicity trial. In this trial, subjects received FLULAVAL QUADRIVALENT (n = 1,272), or one of 2 formulations of a comparator trivalent influenza vaccine (FLULAVAL, TIV-1, n = 213 or TIV-2, n = 218), each containing an influenza type B virus that corresponded to one of the 2 B viruses in FLULAVAL QUADRIVALENT (a type B virus of the Victoria lineage or a type B virus of the Yamagata lineage)….Trial 4 (NCT02242643) was a randomized, observer-blind, active-controlled immunogenicity and safety trial. The trial included subjects aged 6 through 35 months who received FLULAVAL QUADRIVALENT (n = 1,207) or FLUZONE QUADRIVALENT, a U.S.-licensed inactivated influenza vaccine (n = 1,217) used as comparator, manufactured by Sanofi Pasteur Inc. Children with no history of influenza vaccination received 2 doses of FLULAVAL QUADRIVALENT or the comparator vaccine approximately 28 days apart. Children with a history of influenza vaccination received one dose of FLULAVAL QUADRIVALENT or the comparator vaccine….Trial 2 (NCT01198756) was a randomized, double-blind, active-controlled trial. In this trial, subjects received FLULAVAL QUADRIVALENT (n = 932) or one of 2 formulations of a comparator trivalent influenza vaccine [FLUARIX (Influenza Vaccine), TIV-1 (B Victoria), n = 929 or TIV-2 (B Yamagata), n = 932], each containing an influenza type B virus that corresponded to one of the 2 B viruses in FLULAVAL QUADRIVALENT (a type B virus of the Victoria lineage or a type B virus of the Yamagata lineage)….Trial 3 (NCT01218308) was a randomized, observer-blind, non-influenza vaccine-controlled trial evaluating the efficacy of FLULAVAL QUADRIVALENT. The trial included subjects aged 3 through 8 years who received FLULAVAL QUADRIVALENT (n = 2,584) or HAVRIX (Hepatitis A Vaccine) (n = 2,584) as a control vaccine. Children with no history of influenza vaccination received 2 doses of FLULAVAL QUADRIVALENT or HAVRIX approximately 28 days apart (this dosing regimen for HAVRIX is not a U.S.-licensed schedule). Children with a history of influenza vaccination received one dose of FLULAVAL QUADRIVALENT or HAVRIX."

Post-licensing
"Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to the vaccine."

First additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the pre-licensure safety review time periods in the attached were too brief for test subjects to fully report all solicited and unsolicited adverse reactions.'

Second additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in the attached: "FLULAVAL QUADRIVALENT has not been evaluated for carcinogenic, mutagenic potential, or male infertility in animals."

Third additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of all adverse events listed in the attached package insert pursuant to 21 C.F.R. 201.57 ("This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.")

c. 'The test group received Fluzone (IIV4) (Sanofi), and the so-called control group members received one or more vaccines and therefore no true control group was tested'.

Citation: FDA. Package Insert: *Fluzone (IIV4)*. https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM356094.pdf, (accessed June 19, 2020). See Exhibit 254.

Pre-licensing
Study 1 (NCT01240746, see http://clinicaltrials.gov) was a single-blind, randomized, active- controlled multi-center safety and immunogenicity study conducted in the US. In this study, children 6 months through 35 months of age received one or two 0.25 mL doses of either Fluzone Quadrivalent or one of two formulations of a comparator trivalent influenza vaccine (TIV-1 or TIV-2), and children 3 years through 8 years of age received one or two 0.5 mL doses of either Fluzone Quadrivalent, TIV-1, or TIV-2. Each of the trivalent formulations contained an influenza type B virus that corresponded to one of the two type B viruses in Fluzone Quadrivalent (a type B virus of the Victoria lineage or a type B virus of the Yamagata lineage). For participants who received two doses, the doses were administered approximately 4 weeks apart…. Study 2 (NCT02915302 see http://clinicaltrials.gov) was a randomized, observer-blinded, 2-arm, multi-

> center safety and immunogenicity study conducted in the US. In this study, 1950 children 6 months through 35 months of age were randomly assigned to receive Fluzone Quadrivalent administered in either a volume of 0.25 mL (Group 1) or 0.5 mL (Group 2). For participants recommended to receive two doses of influenza vaccine as per Advisory Committee on Immunization Practices guidance, the same dose was administered 4 weeks after the first. The safety analysis set included 1941 participants who received at least 1 dose of study vaccine. …In Study 3 (NCT00988143, see http://clinicaltrials.gov), a multi-centered randomized, open-label trial conducted in the US, adults 18 years of age and older received one dose of either Fluzone Quadrivalent or one of two formulations of comparator trivalent influenza vaccine (TIV-1 or TIV- 2). Each of the trivalent formulations contained an influenza type B virus that corresponded to one of the two type B viruses in Fluzone Quadrivalent (a type B virus of the Victoria lineage or a type B virus of the Yamagata lineage). …In Study 4 (NCT01218646, see http://clinicaltrials.gov), a multi-center, randomized, double-blind trial conducted in the US, adults 65 years of age and older received one dose of either Fluzone Quadrivalent, or one of two formulations of comparator trivalent influenza vaccine (TIV-1 or TIV-2). Each of the trivalent formulations contained an influenza type B virus that corresponded to one of the two type B viruses in Fluzone Quadrivalent (a type B virus of the Victoria lineage or a type B virus of the Yamagata lineage)."
>
> *Post-licensing*
> "Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure. Adverse events were included based on one or more of the following factors: severity, frequency of reporting, or strength of evidence for a causal relationship to Fluzone (trivalent) or Fluzone Quadrivalent."

First additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the pre-licensure safety review time periods in the attached were too brief for test subjects to fully report all solicited and unsolicited adverse reactions.'

Second additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in the attached: "Fluzone Quadrivalent has not been evaluated for carcinogenic or mutagenic potential, or for impairment of male fertility in animals."

Third additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of all adverse events listed in the attached package insert pursuant to 21 C.F.R. 201.57 ("This definition does not

include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.")

D. CDC Childhood Vaccine Schedule from Age Eighteen Months to Eighteen Years

1. For the truth of the matter stated, Petitioners request judicial notice of the following facts found in the Tdap vaccine product inserts published by the FDA:

   a. 'The test group received Boostrix (GSK), and the so-called control group members received one or more vaccines and therefore no true control group was tested'.

   Citation: FDA. Package Insert: *Boostrix*. https://www.fda.gov/downloads/BiologicsBloodVaccines/UCM152842.pdf (accessed June 19, 2020). See Exhibit 255.

Pre-Licensing
"In clinical studies, 4,949 adolescents (10 to 18 years of age) and 4,076 adults (19 years of age and older) were vaccinated with a single dose of BOOSTRIX. Of these adolescents, 1,341 were vaccinated with BOOSTRIX in a coadministration study with meningococcal conjugate vaccine [see Drug Interactions (7.1), Clinical Studies (14.5)]. Of these adults, 1,104 were 65 years of age and older *[see Clinical Studies (14.4)]*. A total of 860 adults 19 years of age and older received concomitant vaccination with BOOSTRIX and influenza vaccines in a coadministration study [see Drug Interactions (7.1), Clinical Studies (14.5)]. An additional 1,092 adolescents 10 to 18 years of age received a non-US formulation of BOOSTRIX (formulated to contain 0.5 mg aluminum per dose) in non-US clinical studies. In a randomized, observer-blinded, controlled study in the US, 3,080 adolescents 10 to 18 years of age received a single dose of BOOSTRIX and 1,034 received the comparator Td vaccine, manufactured by MassBioLogics….Approximately 98% of participants in this study had received the recommended series of 4 or 5 doses of either Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed (DTwP) or a combination of DTwP and DTaP in childhood…. In a study conducted in Germany, BOOSTRIX was administered to 319 children 10 to 12 years of age previously vaccinated with 5 doses of acellular pertussis antigen-containing vaccines; 193 of these subjects had previously received 5 doses of INFANRIX® (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed)….The US adult (19 to 64 years of age) study, a randomized, observer-blinded study, evaluated the safety of BOOSTRIX (N = 1,522) compared with ADACEL® (Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed) (N = 762), a Tdap vaccine manufactured by Sanofi Pasteur SA. Vaccines were administered as a single

> dose….The US elderly (65 years of age and older) study, a randomized, observer-blinded study, evaluated the safety of BOOSTRIX (N = 887) compared with DECAVAC® (Tetanus and Diphtheria Toxoids Adsorbed) (N = 445), a US-licensed Td vaccine, manufactured by Sanofi Pasteur SA. Vaccines were administered as a single dose."
>
> *Post-Licensing*
> "Because these events are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to the vaccine."

First additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the pre-licensure safety review time periods in the attached were too brief for test subjects to fully report all solicited and unsolicited adverse reactions.'

Second additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in the attached: "BOOSTRIX has not been evaluated for carcinogenic or mutagenic potential, or for impairment of fertility."

Third additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of all adverse events listed in the attached package insert pursuant to 21 C.F.R. 201.57 ("This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.")

b. 'The test group received Adacel (Sanofi), and the so-called control group members received one or more vaccines and therefore no true control group was tested'.

Citation: FDA. Package Insert: *Adacel*. https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142764.pdf (accessed June 19, 2020). See Exhibit 256.

Pre-Licensing

> "Clinical study Td506 was a randomized, observer-blind, active-controlled trial that enrolled adolescents 11 through 17 years of age (Adacel N = 1,184; DECAVAC (Tetanus and Diphtheria Toxoids Adsorbed; manufactured by Sanofi Pasteur Inc., Swiftwater, PA) N = 792) and adults 18 through 64 years of age (Adacel N = 1,752; DECAVAC N = 573). Study participants had not received tetanus or diphtheria-containing vaccines within the previous 5 years….In a randomized, observer-blind, active-controlled, multi-center study (Td537), adults 18 through 64 years of age who had received a first dose of Adacel 8-12 years previously were enrolled and randomized to receive either Adacel (N = 1002) or a US licensed Td vaccine, TENIVAC (Tetanus and Diphtheria Toxoids Adsorbed; manufactured by Sanofi Pasteur, Limited) (N = 328). Subjects were recruited from the primary licensure study Td506 and the Canadian general public and had not received Td or Tdap vaccine since their initial Adacel dose….Study Td518 was a descriptive, open-label, post-marketing, multi-center study evaluating the safety of Adacel readministration in adults 5 years following a previous dose of Adacel."
>
> *Post-licensing*
> "Because these events are reported voluntarily from a population of uncertain size, it may not be possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure."

First additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the pre-licensure safety review time periods in the attached were too brief for test subjects to fully report all solicited and unsolicited adverse reactions.'

Second additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in the attached: "Adacel has not been evaluated for carcinogenic or mutagenic potential, or impairment of male fertility."

Third additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of all adverse events listed in the attached package insert pursuant to 21 C.F.R. 201.57 ("This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.")

2. For the truth of the matter stated, Petitioners request judicial notice of the following facts found in the HPV vaccine product inserts published by the FDA:

a. 'The test group received Gardasil (Merck), and the so-called control group received at least AAHS or Gardasil carrier solution (Sodium Chloride, L-histidine, Polysorbate 80, Sodium Chloride, and Yeast Protein), and was otherwise not a true control group of entirely unvaccinated individuals'. First Citation: FDA. Package Insert: *Gardasil*. https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM111263.pdf (accessed June 19, 2020). See Exhibit 257. Second Citation: Reisinger KS, Block SL, Lazcano-Ponce E, et al. Safety and persistent immunogenicity of a quadrivalent human papillomavirus types 6, 11, 16, 18 L1 virus-like particle vaccine in preadolescents and adolescents: a randomized controlled trial. *Pediatr Infect Dis J*. 2007;26(3):201-209. doi:10.1097/01.inf.0000253970.29190.5a (accessed June 19, 2020). See Exhibit 258.

First additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the pre-licensure safety review time periods in the attached were too brief for test subjects to fully report all solicited and unsolicited adverse reactions.'

Second additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in the attached: "GARDASIL has not been evaluated for the potential to cause carcinogenicity or genotoxicity."

Third additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of all adverse events listed in the attached package insert pursuant to 21 C.F.R. 201.57 ("This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.")

b. 'The test group received Gardasil-9 (Merck), and the so-called control group received at least Gardasil or else was within the group of 306 subjects that had already received 3 doses of Gardasil and therefore was not a true control group of unvaccinated individuals.'

Citation: FDA. Package Insert: *Gardasil-9*. https://www.fda.gov/media/90064/download (accessed June 20, 2020). See Exhibit 259.

First additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the pre-licensure safety review time periods in the attached were too brief for test subjects to fully report all solicited and unsolicited adverse reactions.'

Second additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in the attached: "GARDASIL 9 has not been evaluated for the potential to cause carcinogenicity, genotoxicity or impairment of male fertility."

Third additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of all adverse events listed in the attached package insert pursuant to 21 C.F.R. 201.57 ("This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.")

3. For the truth of the matter stated, Petitioners request judicial notice of the following facts found in the Meningococcal vaccine product inserts published by the FDA:

a. 'The test group received at least Menactra (Sanofi), and the so-called control group members received one or more vaccines and therefore no true control group was tested'.

Citation: FDA. Package Insert: *Menactra*. https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM131170.pdf (accessed June 19, 2020). See Exhibit 260.

Pre-licensing
"The safety of Menactra was evaluated in four clinical studies that enrolled 3721 participants who received Menactra at 9 and 12 months of age. At 12 months of age these children also received one or more other recommended vaccines [Measles, Mumps, Rubella and Varicella Virus Vaccine Live (MMRV) or Measles, Mumps, and Rubella Virus Vaccine (MMR) and Varicella Virus Vaccine Live (V) each manufactured by Merck & Co., Inc., Pneumococcal 7-valent Conjugate Vaccine (Diphtheria CRM197 Protein) manufactured by Wyeth Pharmaceuticals Inc. (PCV7), Hepatitis A Vaccine manufactured by Merck & Co., Inc. (HepA). A control group of 997 children was enrolled at 12 months of age and received two or more childhood vaccines [MMRV (or MMR+V), PCV7, HepA] at 12 months of age [see *Concomitant Vaccine Administration (14.3)*]. Three percent of individuals received MMR and V, instead of MMRV, at 12 months of age. The primary safety study was a controlled trial that enrolled 1256 children who received Menactra at 9 and 12 months of age. At 12 months of age these children received MMRV (or MMR+V), PCV7 and HepA. A control group of 522 children received MMRV, PCV7 and HepA. Of the 1778 children, 78% of participants (Menactra, N=1056; control group, N=322) were enrolled at United States (US) sites and 22% at a Chilean site. (Menactra, N=200; control group, N=200). …The safety of Menactra was evaluated in eight clinical studies that enrolled 10,057 participants aged 2-55 years who received Menactra and 5,266 participants who received Menomune® – A/C/Y/W-135, Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined."

Post-licensing
"Because these events were reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to vaccination."

First additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the pre-licensure safety review time periods in the attached were too brief for test subjects to fully report all solicited and unsolicited adverse reactions.'

Second additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in the attached: "Menactra has not been evaluated for carcinogenic or mutagenic potential, or for impairment of male fertility."

Third additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of all adverse events listed in the attached package insert pursuant to 21 C.F.R. 201.57 ("This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.")

b. 'The test group received at least Menveo (GSK), and the so-called control group members received one or more vaccines and therefore no true control group was tested'.

Citation: FDA. Package Insert: *Menveo*. https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201349.pdf (accessed June 19, 2020). See Exhibit 261.

Pre-licensing

"The safety of MENVEO in infants vaccinated at 2, 4, 6, and 12 months of age was evaluated in 3 randomized multicenter clinical studies[1-3] conducted in the U.S., Australia, Canada, Taiwan, and several countries of Latin America in which 8,735 infants received at least 1 dose of MENVEO and routine infant vaccines (diphtheria toxoid; acellular pertussis; tetanus toxoid; inactivated polio types 1, 2, and 3; hepatitis B; *Haemophilus influenzae* type b (Hib) antigens; pentavalent rotavirus; and 7-valent pneumococcal conjugate). With Dose 4 of MENVEO, toddlers received concomitantly the following vaccines: 7-valent pneumococcal conjugate; measles, mumps, rubella, and varicella; and inactivated hepatitis A. A total of 2,864 infants in these studies received the routine infant/toddler vaccines only…. Safety data for administration of 2 doses of MENVEO in children aged 6 through 23 months are available from 3 randomized studies[1,4,5] conducted in the U.S., Latin America, and Canada, of which one U.S. study specifically addressed the safety of MENVEO administered concomitantly with measles, mumps, rubella, and varicella vaccine (MMRV). …The safety of MENVEO in children aged 2 through 10 years was evaluated in 4 clinical trials[6-9] conducted in North America (66%), Latin America (28%), and Europe (6%) in which 3,181 subjects received MENVEO and 2,116 subjects received comparator vaccines (either Meningococcal Polysaccharide Vaccine, Groups A, C, Y, and W- 135 Combined - MENOMUNE, Sanofi Pasteur [n = 861], or Meningococcal (Groups A, C, Y, and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine - MENACTRA, Sanofi Pasteur [n = 1,255]). …The safety of MENVEO in individua ls aged 11 through 55 years was evaluated in 5 randomized controlled clinical trials[10-14] in which 6,185 participants received MENVEO alone (5,286 participants), MENVEO concomitant with other vaccine(s) (899 participants), or a U.S.-licensed comparator vaccine (1,966 participants). In the concomitant

> trials[11,14] MENVEO was given with vaccines containing: tetanus toxoid, diphtheria toxoid, and pertussis (Tdap), or Tdap with human papillomavirus (HPV). The comparator vaccine was either MENOMUNE (209 participants) or MENACTRA (1,757 participants). …In 2 of the studies, subjects received concomitant vaccination with Tdap or with Tdap plus HPV."
>
> *Post-Licensing*
> "Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to the vaccine."

First additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the pre-licensure safety review time periods in the attached were too brief for test subjects to fully report all solicited and unsolicited adverse reactions.'

Second additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in the attached: "MENVEO has not been evaluated for carcinogenic or mutagenic potential, or for impairment of male fertility in animals."

Third additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of all adverse events listed in the attached package insert pursuant to 21 C.F.R. 201.57 ("This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.")

4. For the truth of the matter stated, Petitioners request judicial notice of the following facts found in the Combination Vaccine product inserts published by the FDA:

    a. 'The test group received at least Kinrix (GSK), and the so-called control group members received one or more vaccines and therefore no true control group was tested'.

    Citation: FDA. Package Insert: *Kinrix*.

https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM241453.pdf (accessed June 19, 2020). See Exhibit 262.

> *Pre-licensing*
> "A total of 4,013 children were vaccinated with a single dose of KINRIX in 4 clinical trials. Of these, 381 children received a non-U.S. formulation of KINRIX (containing [less than or equal to] 2.5 mg 2-phenoxyethanol per dose as preservative). The primary study (Study 048), conducted in the United States, was a randomized, controlled clinical trial in which children aged 4 to 6 years were vaccinated with KINRIX (n = 3,156) or control vaccines (INFANRIX and IPOL vaccine [IPV, Sanofi Pasteur SA]; n = 1,053) as a fifth DTaP vaccine dose following 4 doses of INFANRIX and as a fourth IPV dose following 3 doses of IPOL. Subjects also received the second dose of U.S.-licensed measles, mumps, and rubella (MMR) vaccine (Merck & Co., Inc.) administered concomitantly, at separate sites."
>
> *Post-licensing*
> "Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccination."

First additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the pre-licensure safety review time periods in the attached were too brief for test subjects to fully report all solicited and unsolicited adverse reactions.'

Second additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in the attached: "KINRIX has not been evaluated for carcinogenic or mutagenic potential or for impairment of fertility."

Third additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of all adverse events listed in the attached package insert pursuant to 21 C.F.R. 201.57 ("This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.")

b. 'The test group received at least Quadracel (Sanofi), and the so-called control group members received one or more vaccines and therefore no true control

group was tested'. Citation: FDA. Package Insert: *Quadracel*. https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM439903.pdf (accessed June 19, 2020). See Exhibit 263.

> *Pre-licensing*
> "In a randomized, controlled, multicenter study conducted in the US and Puerto Rico (Study M5I02; ClinicalTrials.gov Identifier: NCT01346293), 3,372 children, 4 to 6 years of age, who had received 4 doses of DAPTACEL and/or Pentacel vaccine(s) received Quadracel, or DAPTACEL + IPOL (Poliovirus Vaccine Inactivated) vaccines administered concomitantly but at separate sites. Subjects also received Measles, Mumps, and Rubella Virus Vaccine Live (MMR) (Merck & Co., Inc.) and Varicella Virus Vaccine Live (Varicella vaccine) (Merck & Co., Inc.) administered concomitantly at separate sites. Safety was evaluated in 2,733 subjects who received Quadracel and 621 subjects who received DAPTACEL + IPOL vaccines."
>
> *Post-licensing*
> "Because these events are reported voluntarily from a population of uncertain size, it is not possible to estimate their frequency reliably or establish a causal relationship to vaccine exposure."

First additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the pre-licensure safety review time periods in the attached were too brief for test subjects to fully report all solicited and unsolicited adverse reactions.'

Second additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in the attached: "Quadracel has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility."

Third additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of all adverse events listed in the attached package insert pursuant to 21 C.F.R. 201.57 ("This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.")

5. For the truth of the matter stated, Petitioners request judicial notice of the following facts found in the Flu vaccine product inserts published by the FDA:

a. 'The test group received Afluria (IIV3) (Seqirus), and the so-called control group members received one or more vaccines, or else a mercury-containing "placebo", and therefore no true control group was tested'.

First Citation: FDA. Package Insert: *Afluria (IIV3).* https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM263239.pdf (accessed June 19, 2020). See Exhibit 264.

Second Citation: FDA. Approval History, Letters, Reviews, and Related Documents - AFLURIA. Review by Cynthia Nolletti, MD (September 19, 2007). Pages 20, 32, 214. https://www.fda.gov/vaccines-blood-biologics/vaccines/afluria (accessed June 19, 2020). See Exhibit 265.

Pre-licensing
"Study 1 included 1,468 subjects for safety analysis, ages 6 months through 17 years, randomized to receive AFLURIA (735 subjects) or another U.S.-licensed trivalent inactivated influenza vaccine (manufactured by Sanofi Pasteur, Inc.) (733 subjects).... . Subjects in the safety population (N=2232) received either AFLURIA QUADRIVALENT (N=1673) or a U.S.-licensed comparator quadrivalent influenza vaccine (N=559). Study subjects were scheduled to receive either a single vaccination or two vaccinations 28 days apart based on their previous vaccination history. In this study, AFLURIA QUADRIVALENT and comparator vaccine were administered by needle and syringe (see Clinical Studies [14]). …Study 5 included 1,357 subjects for safety analysis, ages 18 through 64 years, randomized to receive AFLURIA (1,089 subjects) or placebo (268 subjects) (*see Clinical Studies [14]*). Study 6 included 15,020 subjects for safety analysis, ages 18 through 64 years, randomized to receive AFLURIA (10,015 subjects) or placebo (5,005 subjects) (*see Clinical Studies [14]*). Study 7 included 1,266 subjects for safety analysis, ages 65 years and older, randomized to receive AFLURIA (630 subjects) or another U.S.-licensed trivalent inactivated influenza vaccine (manufactured by Sanofi Pasteur Inc.) as an active comparator (636 subjects) (*see Clinical* Studies [14]). Study 8 included 275 subjects for safety analysis, ages 65 years and older, randomized to receive AFLURIA (206 subjects) or a UK-licensed trivalent inactivated influenza vaccine (manufactured by GSK) as an active comparator (69 subjects)."

Post-licensing
"Because postmarketing reporting of adverse reactions is voluntary and from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure."

First additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the pre-

licensure safety review time periods in the attached were too brief for test subjects to fully report all solicited and unsolicited adverse reactions.'

Second additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in the attached: "AFLURIA has not been evaluated for carcinogenic or mutagenic potential, or male infertility in animals."

Third additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of all adverse events listed in the attached package insert pursuant to 21 C.F.R. 201.57 ("This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.")

b. 'The test group received Afluria (IIV4) (Seqirus), and the so-called control group members received one or more vaccines and therefore no true control group was tested'.

Citation: FDA. Package Insert: *Afluria (IIV4).* https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM518295.pdf (accessed June 19, 2020). See Exhibit 266.

Pre-licensing

"Clinical safety data for AFLURIA QUADRIVALENT in adults have been collected in one clinical trial, Study 1, a randomized, double-blind, active-controlled trial conducted in the U.S. in 3449 subjects ages 18 years and older. Subjects in the safety population received one dose of either AFLURIA QUADRIVALENT (N=1721) or one of two formulations of comparator trivalent influenza vaccine (AFLURIA, TIV-1 N=864 or TIV-2 N=864) each containing an influenza type B virus that corresponded to one of the two B viruses in AFLURIA QUADRIVALENT (a type B virus of the Yamagata lineage or a type B virus of the Victoria lineage), respectively….Subjects in the safety population (N=2252) received either AFLURIA QUADRIVALENT (N=1692) or a U.S.-licensed comparator quadrivalent influenza vaccine (N=560). Study subjects were scheduled to receive either a single vaccination or two vaccinations 28 days apart based on their previous vaccination history. In this study, AFLURIA QUADRIVALENT and comparator vaccine were administered by needle and syringe (see Clinical Studies [14])….Subjects in the safety population (N=2232) received either AFLURIA QUADRIVALENT (N=1673) or a U.S.-

> licensed comparator quadrivalent influenza vaccine (N=559). Study subjects were scheduled to receive either a single vaccination or two vaccinations 28 days apart based on their previous vaccination history. In this study, AFLURIA QUADRIVALENT and comparator vaccine were administered by needle and syringe (see Clinical Studies [14]).”
>
> *Post-Licensing*
> “Because postmarketing reporting of adverse events is voluntary and from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure.”

First additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that ‘the pre-licensure safety review time periods in the attached were too brief for test subjects to fully report all solicited and unsolicited adverse reactions.’

Second additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in the attached: “AFLURIA QUADRIVALENT has not been evaluated for carcinogenic or mutagenic potential, or male infertility in animals.”

Third additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of all adverse events listed in the attached package insert pursuant to 21 C.F.R. 201.57 (“This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.”)

c. ‘The test group received Flucelvax (IIV4) (Seqirus), and the so-called control group members received one or more vaccines and therefore no true control group was tested’.

First Citation: FDA. Package Insert: *Flucelvax (IIV4).* https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM619588.pdf (accessed June 19, 2020). See Exhibit 267.

Second Citation: FDA. Approval History, Letters, Reviews, and Related Documents - AFLURIA. Review by Cynthia Nolletti, MD (September 19, 2007). Pages 20, 32, 214. https://www.fda.gov/vaccines-blood-biologics/vaccines/afluria (accessed June 19, 2020). See Exhibit 265.

> *Pre-licensing*
> "In this study, subjects received FLUCELVAX QUADRIVALENT or one of the two formulations of comparator trivalent influenza vaccine (TIV1c and TIV2c) (FLUCELVAX QUADRIVALENT (n=1335), TIV1c, n=676 or TIV2c, n= 669)….In this study, subjects received FLUCELVAX QUADRIVALENT or one of the two formulations of comparator trivalent influenza vaccine (FLUCELVAX QUADRIVALENT n=1159, TIV1c, n=593 or TIV2c, n= 580). Children 9 through 17 years of age received a single dose of FLUCELVAX QUADRIVALENT or comparator vaccine. Children 4 through 8 years of age received one or two doses (separated by 4 weeks) of FLUCELVAX QUADRIVALENT or comparator vaccine based on determination of the subject's prior influenza vaccination history."
>
> *Post-licensing*
> "Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to the vaccine."

First additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the pre-licensure safety review time periods in the attached were too brief for test subjects to fully report all solicited and unsolicited adverse reactions.'

Second additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in the attached: "FLUCELVAX QUADRIVALENT has not been evaluated for carcinogenic or mutagenic potential, or for impairment of male fertility in animals."

Third additional request for judicial notice: For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of all adverse events listed in the attached package insert pursuant to 21 C.F.R. 201.57 ("This definition does not include all adverse events observed during use of a drug, only those adverse events for which there

is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.")

9. Statistical Significance Can Be Utilized To Question Vaccine Safety

A. Definition of Statistical Significance

For the truth of the matter stated, Petitioners request judicial notice of the following medical dictionary definition of "statistical significance":

"Statistical significance: an interpretation of statistical data that indicates that an occurrence was probably the result of a causative factor and not simply a chance result. Statistical significance at the 1% level indicates a 1 in 100 chance that a result can be ascribed to chance."

Citation: Mosby's Medical Dictionary (10th edition, 2017). *Elsevier,* page 1682, col 2. See Exhibit 268.

B. Probability

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following description of "statistical significance" published by the National Institutes of Health:

> "In research, statistical significance is a measure of the probability of the null hypothesis being true compared to the acceptable level of uncertainty regarding the true answer. If we break apart a study design, we can better understand statistical significance…. Our researcher wants to be correct about their outcome 95% of the time, or the researcher is willing to be incorrect 5% of the time. Probabilities are stated as decimals with 1.0 being completely positive (100%) and 0 being completely negative (0%). Thus, the researcher who wants to be 95% sure about the outcome of their study is willing to be wrong 5% of the time about the study result. The alpha is the decimal expression of how much they are willing to be wrong. For the current example, the alpha is 0.05. We now have the level of uncertainty the researcher is willing to accept (alpha or significance level) of 0.05 or 5% chance they are not correct about the outcome of the study."

Citation: Tenny S, Abdelgawad I (updated 2019). Statistical Significance. *StatPearls.* https://www.ncbi.nlm.nih.gov/books/NBK459346/ (accessed on June 15, 2020). See Exhibit 269.

10. Vaccine Hesitancy is Criticized by Pharmaceutical Companies and Others as an Obstacle to Mass Vaccination

A. Description

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following description of "vaccine hesitancy" in Vaccine:

"The SAGE Working Group on Vaccine Hesitancy concluded that vaccine hesitancy refers to delay in acceptance or refusal of vaccination despite availability of vaccination services. Vaccine hesitancy is complex and context specific, varying across time, place and vaccines."

Citation: MacDonald NE (2015). SAGE Working Group on Vaccine Hesitancy. Vaccine hesitancy: Definition, scope and determinants. *Vaccine* 33(34):4161-4164. doi:10.1016/j.vaccine.2015.04.036. https://www.sciencedirect.com/science/article/pii/S0264410X15005009 (accessed June 20, 2020). See Exhibit 270.

B. Vaccine Hesitancy Includes But Is Not Limited to Vaccine Refusal

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'vaccine hesitancy includes but is not limited to vaccine refusal.'

Citation: Gowda C, Dempsey AF (2013). The rise (and fall?) of parental vaccine hesitancy. *Hum Vaccin Immunother* 9(8):1755-1762. doi:10.4161/hv.25085. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3906278/ (accessed on June 15, 2020). See Exhibit 271:

"Vaccine hesitancy can take several forms. At its most severe, parents refuse all recommended vaccines. However, this viewpoint is relatively rare, adopted by only 1–2% of parents nationally. [footnotes omitted] Instead, delay or refusal of one or more specific vaccines is much more common."

C. Vaccine Hesitancy Increasing Due To Research

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'vaccine hesitancy increases due to research rather than submission to authority'.

Citation: Wang E, Baras Y, Buttenheim AM (2015). "Everybody just wants to do what's best for their child": Understanding how pro-vaccine parents can support a culture of vaccine hesitancy.

Vaccine 33(48):6703-6709. doi:10.1016/j.vaccine.2015.10.090.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5554443/ (accessed June 20, 2020). See Exhibit 272:

> "… vaccine hesitancy and questions about the instituted immunization schedule have become more common as parents continue to raise doubts and concerns about vaccines…. When describing their decision-making process around vaccination, parents reported being very well-informed, with many conducting their own research to inform their vaccination decisions. Rather than defaulting to vaccination as recommended by their pediatrician, parents made a conscious decision to vaccinate based on the available evidence.
>
> "However, parents expressed frustration at the overwhelming quantity of information available as well as perceived conflicting information from multiple sources. This led to ambiguity and uncertainty when interpreting that information. Parents cited many information sources used during their research: the scientific literature, the CDC website, books, a vaccine class, television shows, etc. Although confident about their data gathering and synthesis skills, the diversity and discrepancy across sources made it challenging (and time-consuming) to make an unequivocal decision."

D. Highly Educated Doctors Rejecting Vaccines

1. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in Pediatrics:

> "In conclusion, 95% of pediatricians practicing in Switzerland immunize, or would immunize, their children according to recommended schedules and vaccines. They give at least as many vaccines to their own child as to their patients (and frequently many more), immunize as early as recommended, and also make a comprehensive use of the most recent combination vaccines. In contrast, a relatively large proportion of nonpediatricians do not follow, nor plan to follow, current immunization recommendations for their own children. Despite their scientific training and education, they express the same concerns as those that prevail in the public."

Citation: Posfay-Barbe KM, Heininger U, et al. (2005). How do physicians immunize their own children? Differences among pediatricians and non-pediatricians. *Pediatrics* 116(5): e623-33. https://pediatrics.aappublications.org/content/116/5/e623 (accessed June 21, 2020). See Exhibit 273.

2. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in Human Vaccines and Immunotherapeutics:

> "Despite almost a decade of efforts, the vaccination coverage rates registered at our hospital steadily remain unsatisfactory and very distant by the minimum objective of 75% defined by the Italian Ministry of Health. During the last influenza season (2013/14), vaccination coverage rates by occupation type resulted 30% among physicians, 11% among nurses and 9% among other clinical personnel."

Citation: Alicino C, Iudici R, et al. (2015). Influenza vaccination among healthcare workers in Italy: the experience of a large tertiary acute-care teaching hospital. *Hum Vaccin Immunother* 11(1): 95-100. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4514208/ (accessed June 21, 2020). See Exhibit 274.

3. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in Infection:

> "Influenza vaccination coverage among healthcare workers (HCW) is insufficient despite health authority recommendations in many countries. Numerous vaccination campaigns encouraging HCW to be vaccinated have met with resistance. We reviewed published influenza vaccination programs in healthcare settings to understand the reasons for their success and failure, as well as the attitudes and beliefs of HCW."

Citation: Hoffman F, Ferracin C, et al. (2006). Influenza vaccination of healthcare workers: a literature review of attitudes and beliefs. *Infection* 34(3) 14-47. https://pubmed.ncbi.nlm.nih.gov/16804657/ (accessed June 21, 2020). See Exhibit 275.

4. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in Infection:

"Since 1988, the Standing Committee on Vaccination (STIKO) at the Robert Koch-Institute, Berlin, has explicitly recommended that health-care workers (HCWs) should be vaccinated against seasonal influenza. However, acceptance of the influenza vaccination by medical personnel is low."

Citation: Wicker S, Rabenau HF, et al. (2009). Influenza vaccination compliance among health care workers in a German university hospital. *Infection* 37(3); 197-202. https://pubmed.ncbi.nlm.nih.gov/19139807/ (accessed June 21, 2020). See Exhibit 276.

E. Unvaccinated children tend to have more educated parents

1. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in Vaccine:

> "Of the 283 respondents, 123 (43%) reported a positive attitude towards all vaccinations, 129 (46%) reported to have a positive attitude to have their child vaccinated against some diseases and 31 (11%) had no intention to comply with any new vaccination. Determinants of a fully negative attitude were a high education of the parent (odds ratio [OR] 3.3, 95% confidence interval [95% CI]: 1.3–8.6), being a health care worker (OR 4.2, 95% CI: 1.4–12.6), absence of religion (OR 2.6, 95% CI: 1.0–6.7), perception of vaccine ineffectiveness (OR 6.9, 95% CI: 2.5–18.9) and the perception that vaccinations cause asthma or allergies (OR 82.4, 95% CI: 8.9–766.8)."

Citation: Hak E, Schonbeck Y, et al. (2005). Negative attitude of highly educated parents and health care workers towards future vaccinations in the Dutch childhood vaccination program. *Vaccine* 23(24): 3103-7. https://www.sciencedirect.com/science/article/pii/S0264410X05001143 (accessed June 21, 2020). See Exhibit 277.

2. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in American Journal of Public Health:

"Low maternal educational levels and low socioeconomic status were associated with high 4:3:1:3 series completion rates."

Citation: Kim SS, Frimpong JA, et al. (2007). Effects of maternal and provider characteristics on up-to-date immunization status of children aged 19 to 35 months. *Am J Public Health* 97(2): 259-66. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1781415/ (accessed June 21, 2020). See Exhibit 278.

3. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from the New Mexico Department of Health:

"Parents requesting vaccination exemption in New Mexico tend to [] have at least a 4-year college degree."

Citation: New Mexico Department of Health, Office of the Secretary. Department of health announces results of vaccination exemption survey. *Press Release*, November 18, 2013. See Exhibit 279.

4. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in PLOS Medicine:

"…further studies are needed to discover why, for example, parents with more education are less likely to agree to vaccination than parents with less education."

Citation: Ogilvie G, Anderson M, et al. (2010). A population-based evaluation of a publicly funded, school-based HPV vaccine program in British Columbia, Canada: parental factors associated with HPV vaccine receipt. *PLoS Med* 7(5): e1000270. https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1000270 (access June 21, 2020). See Exhibit 280.

5. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in the Journal of Adolescent Health:

"Mothers who had less than a high school degree… were more likely to be favorable about their daughter being vaccinated."

Citation: Rosenthal SL, Rupp R, et al. (2008). Uptake of HPV vaccine: demographics, sexual history and values, parenting style, and vaccine attitudes. *J Adolesc Health* 43(3): 239-45. https://www.jahonline.org/article/S1054-139X(08)00264-4/fulltext (accessed June 21, 2020). See Exhibit 281.

6. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in Pediatrics:

"Unvaccinated children tended to … have parents who expressed concerns regarding the safety of vaccines and indicated that medical doctors have little influence over vaccination decisions for their children."

Citation: Smith PJ, Chu SY, Barker LE (2004). Children who have received no vaccines: who are they and where do they live? *Pediatrics* 114: 187-95. https://pubmed.ncbi.nlm.nih.gov/15231927/ (accessed June 16, 2020). See Exhibit 223.

11. Anti-Vaxxer

For the truth of the matter stated, Petitioners request judicial notice of the following dictionary definition of "anti-vaxxer":

"Anti-vaxxer: a person who opposes vaccination or laws that mandate vaccination"

Citation: Merriam Webster Dictionary (2020). https://www.merriam-webster.com/dictionary/anti-vaxxer (accessed June 21, 2020). See Exhibit 282**.**

12. Informed Consent and Refusal

A. Definition of Informed Consent

1. For the truth of the matter stated, Petitioners request judicial notice of the following definition of "informed consent":

"Informed consent: Consent by a person to undergo a medical procedure, participate in a clinical trial, or be counseled by a professional such as a social worker or lawyer, after receiving all material information regarding risks, benefits, and alternatives."

Citation: *The American Heritage Medical Dictionary*. (2007). https://medical-dictionary.thefreedictionary.com/informed+consent (accessed June 21, 2020). See Exhibit 283.

2. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote re "informed consent" from the American Medical Association:

> "Informed consent to medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making.
> "The process of informed consent occurs when communication between a patient and physician results in the patient's authorization or agreement to undergo a specific medical intervention. In seeking a patient's informed consent (or the consent of the patient's surrogate if the patient lacks decision-making capacity or declines to participate in making decisions), physicians should:

> "(a) Assess the patient's ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision.
> "(b) Present relevant information accurately and sensitively, in keeping with the patient's preferences for receiving medical information. The physician should include information about:
> "1. The diagnosis (when known)
> "2. The nature and purpose of recommended interventions
> "3. The burdens, risks, and expected benefits of all options, including forgoing treatment".

Citation: American Medical Association (2020). AMA Principles of Medical Ethics: I, II, V, VIII. Informed Consent. https://www.ama-assn.org/delivering-care/ethics/informed-consent (accessed June 21, 2020). See Exhibit 284.

B. Informed Refusal

1. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from The American College of Obstetricians and Gynecologists (ACOG), Committee on Professional Liability:

"Informed refusal is a fundamental component of the informed consent process. Informed consent laws have evolved to the "materiality or patient viewpoint" standard. A physician must disclose to the patient the risks, benefits, and alternatives that a reasonable person in the patient's position would want to know to make an informed decision. Throughout this process, the patient's autonomy, level of health literacy, and cultural background should be respected. The subsequent election by the patient to forgo an intervention that has been recommended by the physician constitutes informed refusal."

Citation: ACOG Committee on Professional Liability (2004). ACOG Committee Opinion No. 306. Informed refusal. *Obstet Gynecol*. 104(6):1465-1466. doi:10.1097/00006250-200412000-00048. https://pubmed.ncbi.nlm.nih.gov/15572515/ (accessed June 21, 2020). See Exhibit 285.

2. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from ACOG, Committee on Ethics:

> "As with all forms of medical therapy, informed consent must precede vaccination administration. In the informed consent discussion, health care professionals must discuss information central to the decision-making process for vaccination, including the indications, risks, and benefits of the vaccine and available alternatives, as well as possible consequences from nonvaccination. Data to inform these discussions are available to both health care professionals and the general public through Vaccine Information Statements found on the CDC's web site (http://www.cdc.gov/vaccines/pubs/vis). Federal law requires that a Vaccine Information Statement be given to patients (or their parents or guardians) before each dose of certain vaccines…. In addition, health care professionals should respect patients' informed refusal of vaccinations. For some patients, receiving vaccines conflicts with personal or cultural beliefs. For others, the perceived uncertainty of scientific research on vaccine safety hinders their acceptance of clinical recommendations for vaccination…. In cases where vaccination is declined, although termination of the physician–patient relationship is a possible option, it is often counterproductive and disruptive. Instead, [clinicians] have the opportunity to put alternative strategies into place to protect the health of the patient and that of the general community. Such strategies include patient education to monitor and manage symptoms at home and behavioral approaches to reduce risk associated with infection and transmission. [footnotes omitted]"

Citation: The American College of Obstetricians and Gynecologists, Committee on Ethics, Ethical Issues With Vaccination for the Obstetrician–Gynecologist, Committee Opinion Number 564, May 2013, *(Reaffirmed 2016)* https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Ethics/Ethical-Issues-With-Vaccination-for-the-Obstetrician-Gynecologist (accessed June 21, 2020). See Exhibit 286.

13. No Recognized Studies of the Unvaccinated

Introduction

The Institute of Medicine (IOM) does not recognize that any studies have ever been conducted which compared the health outcomes of children receiving HHS's childhood vaccine schedule with children that had not been vaccinated.

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from the IOM:

"… studies designed to examine the long-term effects of the cumulative number of vaccines or other aspects of the immunization schedule have not been conducted."

Citation: The National Academy of Sciences (2013). The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies. Washington, DC: The National Academies Press. doi: 10.17226/13563. https://download.nap.edu/cart/download.cgi?record_id=13563&file=1-16 (accessed June 21, 2020). See Exhibit 287.

14. Vaccine Safety Datalink Comparison of Unvaccinated Individuals

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the IOM acknowledged that various health comparisons of unvaccinated children to vaccinated children are scientifically possible from a large database, including data within the Vaccine Safety Datalink.'

Citation: The National Academy of Sciences (2013). The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies. Washington, DC: The National Academies Press. doi: 10.17226/13563. https://download.nap.edu/cart/download.cgi?record_id=13563&file=1-16 (accessed June 21, 2020). See Exhibit 287:

"It is possible to make this comparison through analyses of patient information contained in large databases such as VSD…"

15. Evidence is lacking regarding the safety of the CDC schedule

A. Paucity of Information

For the truth of the matter stated, Petitioners request judicial notice of the following quote stating that 'in 2011 the IOM "found a paucity of information, scientific or otherwise, that addressed the risk of adverse events in association with the complete recommended immunization schedule…."'

Citation: The National Academy of Sciences (2013). The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies. Washington, DC: The National Academies Press. doi: 10.17226/13563. https://download.nap.edu/cart/download.cgi?record_id=13563&file=59-74 (accessed June 21, 2020). See Exhibit 288.

B. IOM 1994 Report

1. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'in 1994 IOM evaluated vaccines for Diphtheria, Tetanus, Measles, Mumps, Polio, Hepatitis B, and Hib, and IOM located sufficient evidence to support a causal connection between a vaccine and 12 serious injuries, including death, thrombocytopenia, and Guillain-Barré Syndrome.'

Citation: Institute of Medicine (1994). Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality. Washington, DC: The National Academies Press. https://doi.org/10.17226/2138 (accessed June 16, 2020). See Exhibit 289.

2. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from the IOM regarding Arthritis, Aseptic Meningitis, Demyelinating diseases of the central nervous system, Insulin-Dependent Diabetes Mellitus, Myelitis, Neuropathy, Residual Seizure Disorder, Sensorineural Deafness, Sudden Infant Death Syndrome, Sterility, Transverse Optic Neuritis: "The lack of adequate data regarding many of the adverse events under study was of major concern to the committee. Presentations at public meetings indicated that many parents and physicians share this concern."

Citation: Institute of Medicine (1994). *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. Washington, DC: The National Academies Press. https://doi.org/10.17226/2138 (accessed June 21, 2020). See Exhibit 290.

C. IOM 2011 Report

1. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'in 2011 IOM evaluated vaccines for Varicella, Hepatitis B, Tetanus, Measles, Mumps, and Rubella, and IOM located sufficient evidence to support a causal connection between a vaccine and 18 injuries, including pneumonia, meningitis, MIBE, and febrile seizures.'

Citation: Citation: Institute of Medicine (2012). *Adverse effects of vaccines: Evidence and causality.* Washington, DC: The National Academies Press. https://www.nap.edu/read/13164/chapter/2#3 (accessed June 16, 2020). See Exhibit 291.

2. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the IOM found the scientific literature insufficient to conclude whether or not those vaccines caused 135 other serious injuries commonly reported after their administration, including: Acute Disseminated Encephalomyelitis, Afebrile Seizures, Amyotrophic Lateral Sclerosis, Arthralgia, Autoimmune Hepatitis, Brachial Neuritis, Cerebellar Ataxia, Chronic Headache, Chronic Inflammatory Demyelinating Poly-neuropathy, Chronic Urticaria, Encephalitis, Encephalopathy, Erythema Nodosum, Fibromyalgia, Guillain-Barré Syndrome, Hearing Loss, Immune Thrombocytopenic Purpura, Infantile Spasms, Juvenile Idiopathic Arthritis, Multiple Sclerosis, Neuromyelitis Optica, Optic Neuritis, Polyarteritis Nodosa, Psoriatic Arthritis, Reactive Arthritis, Rheumatoid Arthritis, Seizures, Small Fiber Neuropathy, Stroke, Sudden Infant Death Syndrome, Systemic Lupus Erythematosus, Thrombocytopenia, Transverse Myelitis.'

Citation: Citation: Institute of Medicine (2012). *Adverse effects of vaccines: Evidence and causality.* Washington, DC: The National Academies Press. https://www.nap.edu/read/13164/chapter/2#3 (accessed June 16, 2020). See Exhibit 291.

16. VAERS Has An Unknown To Above 99% Failure Rate

A. About VAERS

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from the HHS:

> "(VAERS) is a national early warning system to detect possible safety problems in U.S.-licensed vaccines. VAERS is co-managed by the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA). VAERS accepts and analyzes reports of adverse events (possible side effects) after a person has received a vaccination…VAERS is a passive reporting system, meaning it relies on individuals to send in reports of their experiences to CDC and FDA."

Citation: United States Health and Human Services (2020). About VAERS Background and Public Health Importance. https://vaers.hhs.gov/about.html (accessed June 21, 2020). See Exhibit 292.

B. Underreporting

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from this Final Report submitted to HHS:

> "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."

Primary Citation: Lazarus, R., et al. (2007). Grant Final Report: Electronic Support for Public Health–Vaccine Adverse Event Reporting System (ESP:VAERS). *The Agency for Healthcare Research and Quality (AHRQ) U.S. Department of Health and Human Services.* https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf (accessed June 21, 2020). See Exhibit 293.

Secondary Citation: FDA (2006). Guidance Document: Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products — Content and Format. https://www.fda.gov/media/72139/download (accessed June 21, 2020). See Exhibit 294:

"The following adverse reactions have been identified during postapproval use of drug X. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure."

C. Systemic Failure to Compare To An Unvaccinated Group

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following CDC quote:

> "Inability to determine causation. VAERS reports are usually not helpful in assessing whether a vaccine actually caused the reported AEs because they lack either unique laboratory findings or other information necessary to draw such conclusions. Often multiple vaccines are administered at the same visit, making attribution of causation to a single vaccine or antigen difficult. Additionally, there is lack of an unvaccinated group for comparison in VAERS."

Citation: Miller E, et al. (2017). Chapter 21: Surveillance for Adverse Events Following Immunization Using the Vaccine Adverse Event Reporting System. *CDC: Manual for the Surveillance of Vaccine-Preventable Diseases*. https://www.cdc.gov/vaccines/pubs/surv-manual/chpt21-surv-adverse-events.html (accessed June 21, 2020). See Exhibit 295.

D. Long Term Surveillance

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in Perspectives in Clinical Research:

> "No matter how many patients are studied pre-marketing in a controlled environment, the true safety profile of a drug is characterized only by continuing safety surveillance through a spontaneous adverse event monitoring system and a post-marketing surveillance/non-interventional study… Surveillance of spontaneously reported adverse events continues as long as a product is marketed."

Citation: Suvarna V (2010). Phase IV of Drug Development. *Perspect Clin Res.* 1(2): 57–60. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3148611/ (accessed June 21, 2020). See Exhibit 296.

17. Approximately 99% or more of Americans have Received One or More Vaccines

A. Overall

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'approximately 1% or less of Americans are fully unvaccinated.'

Citation: Gowda C, Dempsey A (2013). The rise (and fall?) of parental vaccine hesitancy. *Hum Vaccin Immunother* 9(8): 1755–1762.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3906278/ (accessed June 21, 2020). See Exhibit 271:

"Vaccine hesitancy can take several forms. At its most severe, parents refuse all recommended vaccines. However, this viewpoint is relatively rare, adopted by only 1–2% of parents nationally. [footnotes omitted] Instead, delay or refusal of one or more specific vaccines is much more common."

B. Child Vaccination Rate

1. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following statement published by the CDC:

"The percentage of children who have received no vaccines has increased, reaching 1.3% for children born in 2015, compared with 0.3% among those 19–35 months when surveyed in 2001."

Citation: Hill HA, Elam-Evans LD, Yankey D, Singleton JA, Kang Y. Vaccination Coverage Among Children Aged 19–35 Months — United States, 2017. MMWR Morb Mortal Wkly Rep 2018;67:1123–1128. DOI: http://dx.doi.org/10.15585/mmwr.mm6740a4 (accessed June 21, 2020). See Exhibit 297.

2. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the attached graph from Our World In Data.

Citation: Global Change Data Lab (2015, updated 2019). Our World In Data: Vaccination coverage of children, by US state in 2016/17. https://ourworldindata.org/vaccination#progress-made-with-vaccination (accessed June 21, 2020). See Exhibit 298.

3. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from Kristine Sheedy, MPH, associate director of communication science for the CDC's National Center for Immunization and Respiratory Diseases: "At a national level, we have maintained record-high immunization rates and the number of children who are completely unvaccinated remains below 1%."

Citation: WebMD Health News (2011). Most Parents Confident About Vaccine Safety. Reviewed by Laura J. Martin, MD. https://www.webmd.com/children/vaccines/news/20110418/most-parents-confident-about-vaccine-safety#2 (accessed June 21, 2020). See Exhibit 299.

4. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following historical vaccination rates recognized by the CDC:

NIS Survey Year	Month/Year Born (range)	% (95% CI)	Source
1995	February 1992 - May 1994	0.3%	a
1996	February 1993 - May 1995	0.3%	a
1997	February 1994 - May 1996	0.5%	a
1998	February 1995 - May 1997	0.5%	a
1999	February 1996 - May 1998	0.3%	a
2000	February 1997 - May 1999	0.6%	a
2001	February 1998 - May 2000	0.3%	a
2002	January 1999 - June 2001	0.5%	b
2003	January 2000 - July 2002	0.4%	c
2004	January 2001 - July 2003	0.4%	c
2005	February 2002 - July 2004	0.4%	c
2006	January 2003 - June 2005	0.4%	c
2007	January 2004 - July 2006	0.6%	c
2008	January 2005 - June 2007	0.6%	d
2009	January 2006 - July 2008	0.6%	d
2010	January 2007 - July 2009	0.7%	d
2011	January 2008 - May 2010	0.8%	d
2012	January 2009 - May 2011	0.8%	d
2013	January 2010 - May 2012	0.7%	e
2014	January 2011 - May 2013	0.8%	e

2015	January 2012 - May 2014	0.8%	e
2016	January 2013 - May 2015	0.8%	e
2017	January 2014 - May 2016	1.1 %	e

Source	
a	Smith, et al. (2004). *Children Who Have Received No Vaccines: Who Are They and Where Do They Live? Pediatrics* 114 (1) 187-195; DOI: https://doi.org/10.1542/peds.114.1.187 (accessed June 16, 2020). See Exhibit 223.
b	U.S. Department of Health and Human Services (DHHS). National Center for Health Statistics. The 2002 National Immunization Survey, CD-ROM No. 8. Hyattsville, MD: Centers for Disease Control and Prevention, 2003. ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/Datasets/nis/nispuf02dat.zip (accessed June 21, 2020). For additional context the weighted percentage was calculated from the 2002 dataset. The "users guide" for 2002 lists how the dataset is to be cited. See CDC (2015). Datasets and Related Documentation for the National Immunization Survey - Child, 2009 and Prior. National Immunization Surveys. https://www.cdc.gov/nchs/nis/data_files_09_prior.htm (accessed June 21, 2020). Presented together as Exhibit 300.
c	CDC (2008). National, State, and Local Area Vaccination Coverage Among Children Aged 19--35 Months --- United States, 2007. MMWR 2008;57: 961-966. https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5735a1.htm (accessed June 21, 2020). See Exhibit 301 (specially Table 1).
d	CDC. National, State, and Local Area Vaccination Coverage Among Children Aged 19–35 Months — United States, 2012. MMWR 2013;62:733-740. https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6236a1.htm (accessed June 21, 2020). See Exhibit 302 (specially Table 1).
e	Hill HA, Elam-Evans LD, Yankey D, Singleton JA, Kang Y. Vaccination Coverage Among Children Aged 19–35 Months — United States, 2017. MMWR Morb Mortal Wkly Rep 2018;67:1123–1128. DOI: http://dx.doi.org/10.15585/mmwr.mm6740a4 (accessed June 21, 2020). See Exhibit 297.

C. Adult Vaccination Rate

1. **Unpublished**

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the CDC's National Health Interview Survey does not publish an estimate of the number of American adults who are fully unvaccinated.'

Citation: CDC (2018). Vaccination Coverage Among Adults in the United States, National Health Interview Survey, 2016. *Adult Vax View.* https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/NHIS-2016.html (accessed June 21, 2020). See Exhibit 303.

2. Less Than

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the percentage of adult Americans who are completely unvaccinated is less than the percentage of child Americans who are completely unvaccinated'.

Citation: No separate exhibit needed. See Exhibits 297-303.

18. Scientific Corruption and Conflicts of Interest

A. False Data

1. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in PLOS Medicine:

"Simulations show that for most study designs and settings, it is more likely for a research claim to be false than true. Moreover, for many current scientific fields, claimed research findings may often be simply accurate measures of the prevailing bias."

Citation: Ioannidis JP (2005). Why most published research findings are false. *PloS Med* 2(8): e124. https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0020124 (accessed June 21, 2020). See Exhibit 304.

2. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in PLOS One:

"This is the first meta-analysis of surveys asking scientists about their experiences of misconduct. It found that, on average, about 2% of scientists admitted to have fabricated, falsified

or modified data or results at least once –a serious form of misconduct my any standard [footnotes omitted] – and up to one third admitted a variety of other questionable research practices including 'dropping data points based on a gut feeling', and 'changing the design, methodology or results of a study in response to pressures from a funding source'."

Citation: Fanelli D (2009) How many scientists fabricate and falsify research? A systematic review and meta-analysis of survey data. *PloS One* 4(5): e5738. https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0005738 (accessed June 21, 2020). See Exhibit 305.

3. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in Nature: "Our findings reveal a range of questionable practices that are striking in their breadth and prevalence…. Our findings suggest that U.S. scientists engage in a range of behaviors extending far beyond fabrication, falsification or plagiarism that can damage the integrity of science."

Citation: Martinson BC, Anderson MS, de Vries R (2005). Scientists behaving badly. *Nature* 435: 737-38. https://pubmed.ncbi.nlm.nih.gov/15944677/ (accessed June 21, 2020). See Exhibit 306.

B. Conflicts of Interest

1. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in the British Medical journal:

> "The CDC's image as an independent watchdog over the public health has given it enormous prestige, and its recommendations are occasionally enforced by law. Despite the agency's disclaimer, the CDC does receive millions of dollars in industry gifts and funding, both directly and indirectly, and several recent CDC actions and recommendations have raised questions about the science it cites, the clinical guidelines it promotes, and the money it is taking."

Citation: Lenzer J (2015). Centers for Disease Control and Prevention: protecting the private good? *BMJ* 350: h2362. https://www.bmj.com/content/350/bmj.h2362 (accessed June 22, 2020). See Exhibit 307.

2. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in Accountability in Research:

"Our data demonstrate that senior-level investigators who responded to the survey received a wide variety of industry-sponsored support which is important for their careers, and that industry support of research and researchers is pervasive in the clinical and research departments of top U.S. research institutions."

Citation: Tereskerz PM, Hamric, AB, et al. (2009). Prevalence of industry support and its relationship to research integrity. *Account Res* 16(2); 78-105. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2758529/ (accessed June 21, 2020). See Exhibit 308.

3. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in Psychotherapy and Psychosomatics:

"For a pharmaceutical company, delaying or minimizing knowledge of a side effect of a medication has cash value. Similarly, not publishing negative studies may shift the balance of subsequent meta-analysis."

Citation: Fava GA (2009). Preserving intellectual freedom in clinical medicine. *Psychother Psychosom* 78: 1-5. https://pubmed.ncbi.nlm.nih.gov/18852496/ (accessed June 21, 2020). See Exhibit 309.

4. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote in PLOS Medicine:

"Journals have devolved into information laundering operations for the pharmaceutical industry".

Citation: Smith R (2005). Medical journals are an extension of the marketing arm of pharmaceutical companies. *PLoS Med* 2(5): e138. https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0020138 (accessed June 21, 2020). See Exhibit 310.

5. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from Journal of General Internal Medicine:

"COI [conflict of interest] is widespread among the authors of published manuscripts and these authors are more likely to present positive findings."

Citation: Friedman LS, Richter ED (2004). Relationship between conflicts of interest and research results. *J Gen Intern Med* 19(1): 51-56. https://pubmed.ncbi.nlm.nih.gov/14748860/ (accessed June 21, 2020). See Exhibit 311.

6. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'drug companies donated millions to California lawmakers before a mandatory vaccine debate in order to promote mandatory vaccination'.

Citation: Miller, J (2015). Drug companies donated millions to California lawmakers before vaccine debate. *The Sacramento Bee.* https://www.sacbee.com/news/politics-government/capitol-alert/article24913978.html (accessed June 21, 2020). See Exhibit 312.

7. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'HHS spends billions of dollars annually purchasing, distributing and promoting vaccines.'

Citation: HHS (2017). Fiscal Year 2017 Budget in Brief. https://www.hhs.gov/sites/default/files/fy2017-budget-in-brief.pdf?language=es (accessed June 21, 2020), excerpts. See Exhibit 313.

C. Contradiction and Controversy Are Actually Common With Highly Cited Science

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from JAMA:

"Contradiction and initially stronger effects are not unusual in highly cited research of clinical interventions and their outcomes. Controversies are most common with highly cited non-

randomized studies, but even the most highly cited randomized trials may be challenged and refuted over time, especially small ones."

Citation: Ioannidis JP (2005). Contradicted and initially stronger effects in highly cited clinical research. *JAMA* 294(2): 218-28. https://pubmed.ncbi.nlm.nih.gov/16014596/ (accessed June 21, 2020). See Exhibit 314.

19. Vilification of the Unvaccinated

A. Suppression of Dissent

Introduction

In the attached paper, the author found some proponents of vaccination believe that anyone who is critical of vaccines cannot be credible. They may be labeled anti-vaccine or anti-science, implying that there are no legitimate scientific concerns about vaccination.

The author found that doctors and scientists who question vaccines are considered threats to the public perception that all experts support vaccination.

The author found that many who question the dominant views about vaccines are subject to abuse, including threats, formal complaints, censorship, and loss of their livelihood.

The author found that many proponents of vaccination suppress dissent in ways that are unfair, such as spreading rumors that threaten professional reputations, harassment, and denial of funding and access to research material.

The author found that there is a double standard in biomedical and vaccine research, whereby when orthodox views are promoted serious ethical violations such as undeclared conflicts of interest, using false placebos, and withholding evidence, are often ignored.

The author found that suppression of dissent impedes open debate and deters vaccines supporters from considering all available evidence.

The author found that scientific advancement requires challenging orthodox ideas, and that suppression of dissent sends a warning to scientists and has a chilling effect on research.

Request for Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the attached paper published by Science and Engineering Ethics.

Citation: Martin, B. (2015). On the suppression of vaccination dissent. *Science and Engineering Ethics* 21 (1), 143-157. https://doi.org/10.1007/s11948-014-9530-3 (accessed June 21, 2020). See Exhibit 315, especially:

"According to the highest ideals of science, ideas should be judged on their merits, and addressed through mustering evidence and logic. Suppression of dissent is a violation of these ideals."

B. Censorship

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from Vaccine:

"Online communities with greater freedom of speech lead to a dominance of anti-vaccine voices. Moderation of content by editors can offer balance between free expression and factual accuracy. Health communicators and medical institutions need to step up their activity on the internet."

Citation: Venkatraman A, Garg N, Kumar N (2015). Greater freedom of speech on Web 2.0 correlates with dominance of views linking vaccines to autism. *Vaccine* 33(12): 1422-25. https://www.sciencedirect.com/science/article/pii/S0264410X15001358 (accessed June 21, 2020). See Exhibit 316.

20. Government and Industry Alliance To Exterminate The Control Group of Unvaccinated Persons

A. Common Goal Among Various Governments and Healthcare Institutions To Exterminate the Control Group of Unvaccinated Persons

1. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the CDC advocates multiple strategies utilizing the force of law to increase vaccination rates among Americans, including the following quote:

"Many strategies have been used to increase immunizations. Some, such as school entry laws, have effectively increased demand for vaccines, but the effectiveness

> of other strategies (e.g., advertising) is less well documented. Some proven strategies (e.g., reducing costs, linking immunization to Women Infants and Children (WIC) services, home visiting) are well suited to increasing rates among specific populations, such as persons with low access to immunization services."'

Citation: CDC (2018). Reminder Systems and Strategies for Increasing Childhood Vaccination Rates. *Healthcare Providers / Professionals.* https://www.cdc.gov/vaccines/hcp/admin/reminder-sys.html (accessed June 21, 2020). See Exhibit 317.

2. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from the Maine Department of Health and Human Services, Maine Center for Disease Control and Prevention:

"This is perhaps one of the most important reasons why it would be advantageous for Maine State educational institutions to meet all requirements of the Immunization Requirements for School Children state law and to help reach the goal of the Maine Immunization Program to bring the State vaccine coverage rate average for each of these vaccines to 100%."

Citation: Maine Department of Health and Human Services. 2018-2019 Maine School Immunization Assessment Report. *Maine Center for Disease Control and Prevention.* https://www.maine.gov/dhhs/mecdc/infectious-disease/immunization/publications/2018-2019-School-Age-Immunization-Assessment-Report.pdf (accessed June 21, 2020). See Exhibit 318.

3. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following press release quote from the manager of the Healthcare-Associated Infections and Emerging Infections programs in the Acute and Communicable Disease Prevention Section for the Oregon Health Authority Public Health Division:

"While 90 percent vaccination rate is our goal for the next two years, a 100 percent vaccination rate is what we'd really like to see."

Citation: Oregon Health Authority (May 9, 2018). Influenza vaccination rates among Oregon health care workers fall short. *Press Release.*

https://www.oregon.gov/oha/ERD/Pages/OregonHealthCareWorkersInfluenzaVaccinationRatesFallShort.aspx (accessed June 21, 2020). See Exhibit 319.

4. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quotes from the Houston Chronicle:

a. "The goal -- on both sides of the border -- was a 100 percent vaccination rate."

b. "One hundred percent of the time they are in need of shots," said Dr. Anu McDonald of Super Kids ("*Buenos Niños*") who receives funding from Texas Children's Hospital.

Citation: Hegstrom, E (December 22, 2002). Mexico bests U.S. in vaccinations. *Houston Chronicle*. https://www.chron.com/news/nation-world/article/Mexico-bests-U-S-in-vaccinations-2097615.php (accessed June 21, 2020). See Exhibit 320.

5. For recognition of mandatory vaccine laws and regulations in California, Petitioners request judicial notice of the following stated policy in California's mandatory vaccination law and regulation for schoolchildren, requesting total vaccination of children, as only the administration of an ACIP-recommended vaccine qualifies as "immunization" for school admission:

Cal. Health & Safety Code section 120325 et seq.
Section 120325
"In enacting this chapter, but excluding Section 120380, and in enacting Sections 120400, 120405, 120410, and 120415, it is the intent of the Legislature to provide:
"(a) A means for the eventual achievement of total immunization of appropriate age groups against the following childhood diseases:
"(1) Diphtheria.
"(2) Hepatitis B.
"(3) Haemophilus influenzae type b.
"(4) Measles.
"(5) Mumps.
"(6) Pertussis (whooping cough).
"(7) Poliomyelitis.
"(8) Rubella.
"(9) Tetanus.
"(10) Varicella (chickenpox).

"(11) Any other disease deemed appropriate by the department, taking into consideration the recommendations of the Advisory Committee on Immunization Practices of the United States Department of Health and Human Services, the American Academy of Pediatrics, and the American Academy of Family Physicians.

"(b) That the persons required to be immunized be allowed to obtain immunizations from whatever medical source they so desire, subject only to the condition that the immunization be performed in accordance with the regulations of the department and that a record of the immunization is made in accordance with the regulations.…

Section 120335

"(e) The department may specify the immunizing agents that may be utilized and the manner in which immunizations are administered."

See Exhibit 321.

Cal. Code of Regulations, Title 17, Division 1, Chapter 4, Subchapter 8, section 6000:

"(c)The following are abbreviations for immunizations:

(1)"DTaP" means diphtheria toxoid, tetanus toxoid, and acellular pertussis vaccine.

(2)"DTP" means diphtheria toxoid, tetanus toxoid, and pertussis vaccine.

(3)"Tdap" means tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine.

(4)"Td" means tetanus toxoid and reduced diphtheria toxoid vaccine.

(5)"Hep B" means hepatitis B vaccine.

(6)"Hib" means Haemophilus influenzae, type b vaccine.

(7)"IPV" means inactivated polio vaccine.

(8)"OPV" means oral polio vaccine.

(9)"MMR" means measles, mumps, and rubella vaccine.

(10)"MMRV" means measles, mumps, rubella, and varicella vaccine.

…

"(m) For purposes of this Article, "vaccine" means an immunization administered in the United States of America or other countries that is recommended by the federal Advisory Committee on Immunization Practices for the prevention of the respective diseases identified in section 120335 of the Health and Safety Code."

See Exhibit 322.

6. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from the NIH:

"This article describes evidence-based methods by which a pediatric clinic can become a vaccine champion by aiming at vaccination rates of 100 percent. This goal can be attained by a team effort that addresses the challenges of vaccination

> by using every visit as a chance to vaccinate, educate, address the fears and the concerns of the parents and provide articles and other written documentations on the benefits and side effects of vaccines"

Citation: Temoka E (2013). Becoming a vaccine champion: evidence-based interventions to address the challenges of vaccination. National Institutes of Health. *S D Med* Spec no:68-72. https://www.ncbi.nlm.nih.gov/pubmed/23444594 (accessed June 21, 2020). See Exhibit 323.

21. Five States Mandate Pharmaceutical Injections Into Schoolchildren Without Religious or Philosophical Exemption

A. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from the National Conference of State Legislatures:

> "All 50 states have legislation requiring specified vaccines for students. Although exemptions vary from state to state, all school immunization laws grant exemptions to children for medical reasons. There are 45 states and Washington D.C. that grant religious exemptions for people who have religious objections to immunizations. Currently, 15 states allow philosophical exemptions for those who object to immunizations because of personal, moral or other beliefs."

Citation: National Conference of State Legislatures (January 3, 2020). States With Religious and Philosophical Exemptions From School Immunization Requirements. https://www.ncsl.org/research/health/school-immunization-exemption-state-laws.aspx (accessed June 21, 2020). See Exhibit 324.

B. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from the American Academy of Pediatrics:

> "AAP leaders have called for elimination of non-medical* exemptions to vaccination to be the top priority for the year, ranking it first among the top 10 resolutions during the Annual Leadership Forum (ALF)…. The resolution asks the Academy's Board of Directors to advocate for the 'development of a toolkit that highlights successful chapter strategies for the purpose of helping chapters work with their state legislatures to eliminate/reduce non-medical* exemptions that have allowed immunization refusals.'"

Citation: American Academy of Pediatrics (March 16, 2019). Elimination of non-medical vaccine exemptions ranked top priority at Annual Leadership Forum. *AAP News.*

https://www.aappublications.org/news/2019/03/16/alfresolutions031619 (accessed June 21, 2020). See Exhibit 325.

22. Coerced Consent is not Consent

A. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'coerced consent to a medical procedure violates the medical ethics of informed consent and informed refusal, as for example where an individual who has been coerced to consent to injection of biotechnology, due to governmental threat of loss of access to basic necessities of life such as food and medical care, cannot be presumed to have provided lawful informed consent to the injection.'

Citation: Bi, S. and Klusty, T (2015). Forced Sterilizations of HIV-Positive Women: A Global Ethics and Policy Failure. *AMA J Ethics* 17(10):952-957. doi:10.1001/journalofethics. 2015.17.10.pfor2-1510. https://journalofethics.ama-assn.org/article/forced-sterilizations-hiv-positive-women-global-ethics-and-policy-failure/2015-10 (accessed June 21, 2020). See Exhibit 326.

B. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'in 2019 Rockland County in New York banned unvaccinated individuals from parks and schools.'

Citation: Washington Post (April 6, 2019). Judge rules New York county can't ban unvaccinated children from schools, parks. https://www.washingtonpost.com/national/judge-rules-new-york-county-cant-ban-unvaccinated-children-from-schools-parks/2019/04/06/589ae326-587e-11e9-8ef3-fbd41a2ce4d5_story.html (accessed June 21, 2020). See Exhibit 327:

"Ten days after a New York county banned unvaccinated children from public places in an effort to stem the rise of measles cases, a state judge put the injunction on hold…. 'Children are hereby permitted to return to their respective schools forthwith and otherwise to assemble in public places,' Judge Rolf Thorsen wrote in his Friday decision."

C. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from WTSP News in Tampa Bay, Florida:

> "One case was all it took. Florida College is not taking chances with the measles, after the health department confirmed one person on campus came down with the highly contagious virus. The school in Temple Terrace announced on its website students who can't prove they've been vaccinated are being isolated in their dorms, and two upcoming events are being canceled."

Citation: Greentstein, D (January 28, 2020). Florida College Isolating Unvaccinated Students Amid Measles Scare. *WTSP News Tampa Bay.* https://www.wtsp.com/article/news/local/florida-college-isolating-unvaccinated-students-amid-measles-scare/67-dd2d27ff-9072-4a68-80ef-b248a08ef669 (accessed June 21, 2020). See Exhibit 328.

D. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from Fox News:

> "Hundreds of grumbling parents facing a threat of jail lined up at a courthouse Saturday to either prove that their school-age kids already had their required vaccinations or see that the youngsters submitted to the needle. The get-tough policy in the Washington suburbs of Prince George's County was one of the strongest efforts made by any U.S. school system to ensure its youngsters receive their required immunizations. Two months into the school year, school officials realized that more than 2,000 students in the county still didn't have the vaccinations they were supposed to have before attending class. So Circuit Court Judge C. Philip Nichols ordered parents in a letter to appear at the courthouse Saturday and either get their children vaccinated on the spot or risk up to 10 days in jail."

Citation: Associated Press (November 17, 2007, updated January 13, 2015). Md. Judge to Parents: Vaccinate Kids or Go to Jail. *Fox News.* https://www.foxnews.com/story/md-judge-to-parents-vaccinate-kids-or-go-to-jail (accessed June 21, 2020). See Exhibit 329.

E. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from the American Journal of Public Health:

> "Pediatric providers (and other mandatory reporters) have an obligation to report suspected child abuse or neglect to CPS. CPS must determine whether a report requires an investigation and, if so, whether investigation findings meet the relevant legal standards. A finding of medical neglect can trigger court action that may result in the temporary or permanent loss of custody or parental decision-making authority….. because so few courts have addressed whether vaccine refusal constitutes medical neglect, invoking child welfare laws to improve compliance with vaccine recommendations deserves caution."

Citation: Parasidis E (2017). Parental Refusal of Childhood Vaccines and Medical Neglect Laws. *Am J Public Health* 107(1): 68–71. PMCID: PMC5308147 PMID: 27854538. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC5308147/ (accessed June 21, 2020). See Exhibit 330.

23. Social Isolation

A. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from the Washington Post:

> "Facebook has announced it is down-ranking anti-vaxxer groups and pages in users' news feeds and in searches, as well as cutting them out entirely from recommendations and predictions and getting rid of their advertisements. Its sister company Instagram has blocked hashtags such as #vaccinescauseautism or #vaccineskill.
>
> "YouTube, which is owned by Google, has stopped anti-vaccination channels from running ads, and says hoaxes will appear less often in its 'up next' module. When viewers do watch those videos, they'll also see 'information panels' with corrective context. Twitter has created a tool that pulls up a handy link to a government website offering facts about vaccination for anyone who searches for the subject, and it won't auto-suggest terms that tend to lure people toward the inaccurate."

Citation: Roberts, M (May 23, 2019). Tech platforms must move against the anti-vaxxers now. *Washington Post Editorial.* https://www.washingtonpost.com/opinions/2019/05/23/tech-platforms-must-move-against-anti-vaxxers-now/ (accessed June 21, 2020). See Exhibit 331.

B. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from the NY Times:

> "Pinterest, a digital platform popular with parents, took an unusual step to crack down on the proliferation of anti-vaccination propaganda: It purposefully hobbled its search box. Type "vaccine" into its search bar and nothing pops up. "Vaccination" or "anti-vax"? Also Nothing….Other platforms like Facebook and YouTube have also been infiltrated with misinformation about vaccines, and are taking steps to combat it. One of YouTube's policies is to demonetize anti-vaccine videos.
>
> "But only Pinterest, as first reported by The Wall Street Journal, has chosen to banish results associated with certain vaccine-related searches, regardless of whether the results might have been reputable.
>
> "'Right now, blocking results in search is a temporary solution to prevent people from encountering harmful misinformation,' said Jamie Favazza, a spokeswoman.

> The company said it was working with experts to develop a more tailored long-term approach."

Citation: NY Times (February 20, 2019, updated February 21, 2019). Pinterest Cracks Down On Anti-Vaccination. *NewYork Times.* https://www.nytimes.com/2019/02/23/health/pinterest-vaccination-searches.html (accessed June 18, 2020). See Exhibit 332.

24. It Is Ethical To Survey and Study Unvaccinated Individuals

A. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'it is a common practice to include unvaccinated individuals in ethically designed surveys and studies.'

Citation: Hill, H, et al. (2019). Vaccination Coverage by Age 24 Months Among Children Born in 2015 and 2016 — National Immunization Survey-Child, United States, 2016–2018. *US Department of Health and Human Services/Centers for Disease Control and Prevention: Morbidity and Mortality Weekly Report.* October 18, 2019 / 68(41);913–918. https://www.cdc.gov/mmwr/volumes/68/wr/mm6841e2.htm (accessed June 21, 2020). See Exhibit 333:

> "The NIS-Child is a random-digit–dialed telephone survey† of parents or guardians of children aged 19–35 months. Respondents are asked to provide contact information for all providers who administered vaccines to their children. With parental consent, a survey is mailed to each identified provider, requesting the child's vaccination history. Multiple responses for an individual child are synthesized into a comprehensive vaccination history which is used to estimate vaccination coverage."

B. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from the AMA Journal of Ethics:

> "The vaccination refusal that physicians see varies by community and specialty, but some surveys have found trends. One survey found that parents of unvaccinated children were more likely than parents of undervaccinated children (those who receive one or more vaccines) to be white, married, college-educated, and high-income earners and to have five or more children [17]. Another study found that the parents of unvaccinated children were more likely than the parents of vaccinated children to have the perceptions that their children were not as susceptible as other children to disease, that the diseases vaccines protected

> against did not have severe health consequences, and that vaccines were not efficacious in disease prevention [18]. For all parents refusing vaccination, the most common worry regarded vaccine safety."

Citation: Insel K (2012). Treating Children Whose Parents Refuse to Have Them Vaccinated. *Virtual Mentor* 14(1):17-22. doi: 10.1001/virtualmentor.2012.14.1.ccas3-1201. https://journalofethics.ama-assn.org/article/treating-children-whose-parents-refuse-have-them-vaccinated/2012-01 (accessed June 21, 2020). See Exhibit 334.

C. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from the British Medical Journal:

> "Arguments against the use of placebo groups in clinical trials have been based on opinion rather than evidence. [citation omitted] Ethical issues have been raised, but these are contentious. [citation omitted] Scientific requirements should not override ethical ones, but if placebo controls are not used, then active controlled trials (trials using other active drugs as controls) have to be able to determine the efficacy of an intervention and its likelihood of causing harm."

Citation: Tramer, M. et al (1998). When placebo controlled trials are essential and equivalence trials are inadequate. *BMJ* 317(7162): 875–880. PMCID: PMC1113953. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1113953/ (accessed June 21, 2020). See Exhibit 335.

25. Vaccines are Profitable

A. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from Statista:

> "The global vaccine market is showing some escalating growth and it is expected that it will reach total revenues of nearly 60 billion U.S. dollars by 2020. That would be almost double the size the market had back in 2014. Driver of the growth is the increase of various infectious diseases like influenza, swine flu, hepatitis, tuberculosis, diphtheria, Ebola, and meningococcal and pneumococcal diseases…. At this moment, Pfizer's Prevnar 13 is the world's leading vaccine product, generating around 5.7 billion U.S. dollars of revenue…. The United States are the world's largest national market for vaccines…"

Citation: Matej M (August 9, 2019). Global vaccine market revenues 2014-2020. *Statista*. https://www.statista.com/statistics/265102/revenues-in-the-global-vaccine-market/ (accessed June 21, 2020). See Exhibit 336.

B. For the truth of the matter stated, Petitioners request judicial notice that 'the CDC buys and sells vaccines every year.'

Citation: CDC (June 1, 2020). Vaccine Price List. *Vaccines for Children Program.* https://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/ (accessed June 21, 2020). See Exhibit 337:

> "The CDC Vaccine Price Lists posted on this website provide current vaccine contract prices and list the private sector vaccine prices for general information. Contract prices are those for CDC vaccine contracts that are established for the purchase of vaccines by immunization programs that receive CDC immunization cooperative agreement funds (i.e., state health departments, certain large city immunization projects, and certain current and former U.S. territories)."

26. Artificial Immunity

A. Definition

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the CDC's definition of "Immunity":

"Immunity: Protection from an infectious disease. If you are immune to a disease, you can be exposed to it without becoming infected."

Citation: CDC (2018). Immunization: The Basics. Definition of Terms. *Vaccines and Immunizations.* https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm (accessed June 21, 2020). See Exhibit 338.

B. Herd Immunity

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that herd immunity is 'a theory regarding the proportion of subjects with immunity in a given population'.

Citation: John T, et al (2000). Herd Immunity and Herd Effect: New Insights and Definitions. *J Epidemiol* 16(7):601-6. doi: 10.1023/a:1007626510002. https://pubmed.ncbi.nlm.nih.gov/11078115/ (accessed June 21, 2020). See Exhibit 339.

C. **Definition of Antigen**

For the truth of the matter stated, Petitioners request judicial notice of the following definition of "antigen" in Encyclopedia Britannica:

"Antigen, substance that is capable of stimulating an immune response…"

Citation: Encyclopaedia Britannica (2020). https://www.britannica.com/science/antigen (accessed on June 21, 2020). See Exhibit 340.

D. Definition of Adjuvant

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the CDC's definition of "adjuvant":

"An adjuvant is an ingredient used in some vaccines that helps create a stronger immune response in people receiving the vaccine."

Citation: CDC (2018). What is an adjuvant and why is it added to a vaccine? *Vaccine Safety.* https://www.cdc.gov/vaccinesafety/concerns/adjuvants.html (accessed June 21, 2020). See Exhibit 1.

27. Risk To Benefit Ratio

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote published by HHS:

"Risk is defined as the probability of physical, psychological, social, or economic harm occurring as a result of participation in a research study. Both the probability and magnitude of possible harm in human research may vary from minimal to considerable."

Citation: Korenman, S. Teaching responsible conduct in research. Appropriate Risk to Benefit Ratio (page 1 of 3). *HHS Office of Research Integrity.* https://ori.hhs.gov/education/products/ucla/chapter3/page01.htm (accessed June 16, 2020). See Exhibit 341.

28. Rare

A. Rare Disease

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote published by NIH:

> "In the United States, a rare disease is defined as a condition that affects fewer than 200,000 people in the US. This definition was created by Congress in the Orphan Drug Act of 1983. Rare diseases became known as orphan diseases because drug companies were not interested in adopting them to develop

treatments. The Orphan Drug Act created financial incentives to encourage companies to develop new drugs for rare diseases."

Citation: NIH (2017). FAQS about rare diseases. *Genetic and Rare Diseases Information Center.* https://rarediseases.info.nih.gov/diseases/pages/31/ (accessed June 21, 2020). See Exhibit 342.

B. Rare Adverse Event

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote published by the Council for International Organizations of Medical Sciences Working Group III:

"Very common ≥ 1/10 (≥ 10%)
"Common ≥ 1/100 and < 1/10 (≥ 1% and < 10%)
"Uncommon ≥ 1/1000 and < 1/100 (≥ 0.1% and < 1%)
"Rare ≥ 1/10,000 and < 1/1000 (≥ 0.01% and < 0.1%)
"Very rare < 1/10,000 (< 0.01%)"

Citation: Council for International Organizations of Medical Sciences (1995). "Guidelines for Preparing Core Clinical-Safety Information on Drugs". *Report of CIOMS Working Group III.* https://cioms.ch/wp-content/uploads/2018/03/WG3_Guidelines-for-Preparing-Core-Clinical-Safety-Information-on-Drugs.pdf (accessed June 21, 2020), excerpt. See Exhibit 343.

29. Infectious Disease

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote published by the Mayo Clinic:

"Infectious diseases are disorders caused by organisms — such as bacteria, viruses, fungi or parasites. Many organisms live in and on our bodies. They're normally harmless or even helpful. But under certain conditions, some organisms may cause disease."

Citation: Mayo clinic (2019). Infectious diseases. https://www.mayoclinic.org/diseases-conditions/infectious-diseases/symptoms-causes/syc-20351173 (accessed June 21, 2020). See Exhibit 344.

30. Recommended Vaccine Schedules

A. Current Schedules

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the current vaccine schedules recommended by the CDC.

First Citation: CDC (2020). Immunization Schedules. Child & Adolescent Immunization Schedule. https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html (accessed June 21, 2020). See Exhibit 345.

Second Citation: CDC (2020). Immunization Schedules. Adult Immunization Schedule. https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html (accessed June 21, 2020). See Exhibit 346.

B. Historical Schedules

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the historical vaccine schedules recommended by the CDC.

First Citation: CDC (2020). Prior immunization schedules. https://www.cdc.gov/vaccines/schedules/hcp/schedule-related-resources.html (accessed June 21, 2020). See Exhibit 347.

Second Citation: Merck & Co., Inc. (1950). The Merck Manual, Eighth Edition. Pages 1462-1463. See Exhibit 348.

Third Citation: Karzon DT (1969). Immunization practice in the United States and Great Britain: a comparative study. *Postgrad Med J*. 45(520):147-160. doi:10.1136/pgmj.45.520.147 https://pmj.bmj.com/content/postgradmedj/45/520/147.full.pdf (accessed June 21, 2020). See Exhibit 349.

Fourth Citation: Branco N (2018). The Vaccine Schedule 1950-2018. *Marin Healthcare District.* http://www.marinhealthcare.org/upload/public-meetings/2018-06-19-600-pm-mhd-community-health-seminar-vaccination/BRANCO_06192018_MGH%20Vaccine%20Presentation.pdf (accessed June 22, 2020). See Exhibit 350.

Fifth Citation: Asturias E (May 9, 2016). Vaccination Schedules Past, Present and Future. *University of Colorado, Children's Hospital Colorado, and Center for Global Health.*

https://www.immunizecolorado.org/uploads/Vaccination-Schedules-Past-Present-and-Future.pdf (accessed June 21, 2020), excerpts. See Exhibit 351.

31. Vaccine Ingredients

A. Ingredients

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the attached "Vaccine Excipient Summary" published by the CDC.

Citation: CDC (2020). Vaccine Excipient Summary. *The Pink Book: Course Textbook.* https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf (accessed June 21, 2020). See Exhibit 352.

For context (but not for judicial notice), see also: FDA (2018). Common Ingredients in U.S. Licensed Vaccines. https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/common-ingredients-us-licensed-vaccines (accessed June 21, 2020). See Exhibit 353.

B. Toxicological, Technological, and Undefined Classifications

1. Hazardous Substances

For the truth of the matter stated, Petitioners request judicial notice that 'all vaccines contain multiple ingredients classified by the ATSDR as hazardous substances.'

Citation: Agency for Toxic Substances & Disease Registry (ATSDR) (2011). Substances A-Z. *Toxic substances portal.* https://www.atsdr.cdc.gov/substances/indexAZ.asp (accessed June 21, 2020). See Exhibit 354.

2. Aluminum in Vaccines

a. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the following CDC recommended vaccines contain aluminum, such that the CDC schedule recommends up to 22 doses of aluminum-containing vaccines administered from birth to 18-years of age:

- Hepatitis B (HepB)
- Diphtheria, tetanus, and pertussis (whooping cough) (DTaP and Tdap)

- Haemophilus influenzae type b (PedvaxHIB)
- Pneumococcal (PCV)
- Hepatitis A (HepA)
- Human papillomavirus (HPV)
- Meningococcal B (MenB)'

Citation: FDA (2020). Vaccines Licensed for Use in the United States. *Vaccines, Blood & Biologics.* https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states (accessed June 21, 2020). See Exhibit 355.

b. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'HHS recognizes aluminum is a known neurotoxin.'

Citation: ATSDR (2008). Toxicological profile for aluminum. *Toxic Substances Portal.* Pages 3, 13-24, 145, 171-7, 208. https://www.atsdr.cdc.gov/ToxProfiles/tp22.pdf (accessed June 21, 2020), excerpts. See Exhibit 356.

c. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the FDA has warned about the risks of aluminum toxicity in infants and children.'

Citation: Federal Register. Fed Regist. 2003 Jun;68(100):34286. Docket No. 78N–0064. RIN 0910–AA01. https://www.fda.gov/media/74236/download (accessed June 21, 2020). See Exhibit 357.

d. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the amount of aluminum in a vaccine dose varies. The amount of aluminum in an aluminum-containing childhood vaccine ranges from approximately 125 to 850 micrograms per dose.'

First Citation: Baylor NW, Egan W, Richman P (2002). Aluminum salts in vaccines—U.S. perspective. *Vaccine* 20 Suppl 3:S18-22. https://pubmed.ncbi.nlm.nih.gov/12184360/ (accessed June 21, 2020). See Exhibit 358.

Second Citation: Federal Register. Revision of the requirements for constituent materials. Final rule. Fed Regist. 2011 Apr 13;76(71):20513-8.

https://www.federalregister.gov/documents/2011/04/13/2011-8885/revision-of-the-requirements-for-constituent-materials (accessed June 21, 2020). See Exhibit 359.

e. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'in 1968, the federal government set the limit for the amount of aluminum in vaccines to 850 micrograms per dose based on the amount of aluminum needed to make certain vaccines effective.'

Citation: Office of the Federal Register, National Archives and Records Service, General Services Administration. Rules and regulations. Fed Regist. 1968 Jan; 33(6):369. https://tile.loc.gov/storage-services/service/ll/fedreg/fr033/fr033006/fr033006.pdf (accessed June 17, 2020), excerpt. See Exhibit 360.

f. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'vaccines are injected intramuscularly, and the rate at which aluminum from vaccines migrates from human muscle to the bloodstream is not known. Studies in animals suggest that it can take from a couple of months to more than a year for aluminum from vaccines to enter into the bloodstream, due to multiple variables.'

First Citation: Flarend RE et al (1997). In vivo absorption of aluminium-containing vaccine adjuvants using 26Al. *Vaccine* 15(12-13):1314-8. https://pubmed.ncbi.nlm.nih.gov/9302736/ (accessed June 21, 2020). See Exhibit 361.

Second Citation: Verdier F et al (2005). Aluminium assay and evaluation of the local reaction at several time points after intramuscular administration of aluminium containing vaccines in the Cynomolgus monkey. *Vaccine* 23(11):1359-67. https://pubmed.ncbi.nlm.nih.gov/15661384/ (accessed June 21, 2020). See Exhibit 362.

Third Citation: Weisser K et al (2019). Aluminium in plasma and tissues after intramuscular injection of adjuvanted human vaccines in rats. *Arch Toxicol.* 93(10):2787-96. https://pubmed.ncbi.nlm.nih.gov/31522239/ (accessed June 21, 2020). See Exhibit 363.

g. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'because the cumulative aluminum exposure from vaccines in children less than 1 year old exceeds the ATSDR-derived daily limit by several hundreds, the limit would still be exceeded if aluminum from vaccines entered the bloodstream over the course of about a year.'

First Citation: CDC (2010). National Center for Health Statistics: Data table for boys length-for-age and weight-for-age charts. https://www.cdc.gov/growthcharts/who/boys_length_weight.htm (accessed June 21, 2020). See Exhibit 364.

Second Citation: CDC (2010). National Center for Health Statistics: Data table for girls length-for-age and weight-for-age charts. https://www.cdc.gov/growthcharts/who/girls_length_weight.htm (accessed June 21, 2020). See Exhibit 365.

h. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the medical textbook Vaccines and Autoimmunity identifies aluminum containing vaccines as contributing to the rise in autoimmune disorders in the United States and internationally.'

Citation: Shoenfeld, Y, et al. (2015). Vaccines and Autoimmunity. *Wiley Blackwell.* See Exhibit 366.

i. 'The extent of the negative effects of aluminum in vaccines is not known, as safety studies comparing a population vaccinated with aluminum-containing vaccines to a population not vaccinated with such vaccines have not been conducted.'

Citation: Separate exhibit not needed. See Exhibits 355-366.

3. Mercury in Flu Vaccines

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that:

a. 'Mercury (thimerosol) is a known neurotoxin and ingredient in multiple flu vaccines recommended by the CDC.'

First Citation: ATSDR (2008). Toxicological profile for mercury. *Toxic Substances Portal.* Pages 3, 19. https://www.atsdr.cdc.gov/toxprofiles/tp46.pdf (accessed June 21, 2020). See Exhibit 367.

Second: Citation: CDC (2020). Vaccine Excipient Summary. *The Pink Book: Course Textbook.* https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf (accessed June 21, 2020). See Exhibit 352.

b. 'Infants adhering to the CDC vaccine schedule in the 1990s received up to 187.5 micrograms of mercury in the first six months of life.'

Citation: Bigham, M., Copes, R (2005). Thiomersal in Vaccines. *Drug-Safety* 28, 89–101. https://doi.org/10.2165/00002018-200528020-00001 (accessed June 21, 2020). See Exhibit 368.

c. 'The reference dose for methylmercury considered 'safe' by the EPA is 0.1 microgram per kilogram of body weight per day for chronic exposure, equivalent to about 0.3 micrograms per day for a newborn and 0.6 micrograms per day for a six-month-old baby.'

First Citation: Rice DC (2007). The U.S. EPA reference dose for methylmercury: sources of uncertainty. *Environ Res* 2004;95:406-13. https://pubmed.ncbi.nlm.nih.gov/15220074/ (accessed June 21, 2020). See Exhibit 369.

Second Citation: EPA (2017). Methylmercury. *IRIS Assessments.* https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=73 (accessed June 21, 2020). See Exhibit 370.

d. 'In 1999, the U.S. Public Health Service called for the reduction or elimination of thimerosal from childhood vaccines.'

Citation: CDC (2015). Thimerosal in Vaccines. *Vaccine Safety.* https://www.cdc.gov/vaccinesafety/concerns/thimerosal/index.html (accessed June 21, 2020). See Exhibit 371.

e. 'Mercury's toxicity may be amplified by exposure to other toxic metals, such as lead and aluminum.'

Citation: Marques R, et al (2014). Perinatal multiple exposure to neurotoxic (lead, methylmercury, ethylmercury, and aluminum) substances and neurodevelopment at six and 24 months of age. *Environmental Pollution*, Volume 187, Pages 130-135. https://www.sciencedirect.com/science/article/pii/S0269749114000104 (accessed June 21, 2020). See Exhibit 372.

4. Vaccines Are Not Immune From The Bizarre

a. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following excerpts from the deposition testimony of vaccine expert witness Stanley Plotkin, MD on January 11, 2018:

"QUESTION: So this study involved 74 fetuses, correct?
"PLOTKIN: Seventy-six.
"QUESTION: And these fetuses were all three months or older when aborted, correct?
"PLOTKIN: Yes.
"QUESTION: And these were all normally developed fetuses, correct?
"PLOTKIN: Yes.
QUESTION: These included fetuses that were aborted for social and psychiatric reasons, correct?
"PLOTKIN: Correct.
"QUESTION: What organs did you harvest from these fetuses?
"PLOTKIN: Well, I didn't personally harvest any, but a whole range of tissues were harvested by co-workers.
"QUESTION: And these pieces were then cut up into little pieces, right?
"PLOTKIN: Yes.
"QUESTION: And they were cultured?
"PLOTKIN: Yes.
"QUESTION: Some of the pieces of the fetuses were pituitary gland that were chopped up into pieces.
"PLOTKIN: Mm-hmm.
"QUESTION: Included the lung, skin, kidney, spleen, heart and tongue of the fetuses?
"PLOTKIN: Yes.
"QUESTION: So I just want to make sure I understand. In your entire career --this was just one study. So I'm going to ask you again, in your entire career, how many fetuses have you worked with approximately?

> "PLOTKIN: Well, I don't remember the exact number, but quite a few when we were studying them originally before we decided to use them to make 5 vaccines.
> "QUESTION: Some of these (fetuses) were in psychiatric institutions, correct? I'm just asking you, some of the fetuses that you did use did come from abortions from people who were in psychiatric institutions, correct?
> "PLOTKIN: I don't know that. What I'm telling you is that I got them from a co-worker; and if it's stated in the paper, it's true. But, otherwise, I do not know
> "QUESTION: So if it's in the paper, you don't contest it, right?
> "PLOTKIN: I don't contest it, no.
> "QUESTION: Have you ever used orphans to study an experimental vaccine?
> "PLOTKIN: Yes.
> "QUESTION: Have you ever used the mentally handicapped to study an experimental vaccine?
> "PLOTKIN: I don't recall specifically having done that, but that in the 1960s, it was not unusual to do that. And I wouldn't deny that I may have done so.
> "QUESTION: there's an article entitled "Attenuation of RA 27/3 Rubella Virus in WI-38 Human Diploid Cells." Are you familiar with that article?
> "PLOTKIN: Yes.
> "QUESTION: In that article, one of the things it says is 13 --is one of the things it says is: 13 seronegative mentally retarded children were given RA 27/3 vaccine?
> "PLOTKIN: Okay. Well, then that's, in that case that's what I did."

Citation: Matheson vs. Schmitt: Deposition of Stanley A. Plotkin, M.D. Case #2015-831539-DM, January 11, 2018. County of Oakland Circuit Court, Family Division, Michigan. Excerpt. See Exhibit 373.

b. For recognition of a commonly known fact to the general public, Petitioners request judicial notice of the following quote in Reuters re Seth Berkley (epidemiologist working for the U.S. State Department): "Berkley admits his determination is 'almost like a religious belief', but insists it is also pragmatic."

Citation: Kelland K (2012). GAVI man's mission to "immunize every kid on earth". Reuters Health News. https://www.reuters.com/article/us-vaccines-gavi/gavi-mans-mission-to-immunize-every-kid-on-earth-idUSBRE8410MB20120502 (accessed June 21, 2020). See Exhibit 374.

For additional context (but not judicial notice), note that certain members of the public and vaccine authorities are known to make visits to a historic building called "Temple of Vaccinia", in honor of Edward Jenner and his legacy.

Citation: CDC (2018). Advisory Committee on Immunization Practices – Summary Report, June 20-21, 2018. https://www.cdc.gov/vaccines/acip/meetings/downloads/min-archive/min-2018-06-508.pdf (excerpt) (accessed June 21, 2020). See Exhibit 375.

c. Petitioners request judicial notice of the following quote published by BBC News that was censored from the public immediately after its original publication:

> "Dr. Mark Enright, leader in molecular epidemiology at Imperial College, London, agreed but said the study was a good starting point. 'Making a vaccine is a bit like witchcraft – you really need to put stuff in, stir the pot round and then see what happens. And you only really known what happens when you try it out in patients and humans.'"

First Citation: BBC News (October 31, 2006). Superbug vaccine 'shows promise'. http://news.bbc.co.uk/go/pr/fr/-/2/hi/health/6098210.stm (censored from the public; underlines added for emphasis of relevant text) (accessed October 31, 2006). See Exhibit 376.

Second Citation: BBC News (updated October 31, 2006). Superbug vaccine 'shows promise'. http://news.bbc.co.uk/1/hi/health/6098210.stm (revised story omitting Dr. Enright's quote) (accessed June 17, 2020). See Exhibit 377.

5. Fetal Tissue Is The 'Gold Standard' for Vaccine Research

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from Democrat Congressman Jerry Nadler:

"Scientists have told Congress again and again that fetal tissue is the gold standard for vaccine research."

Citation: Office of Congressman Jerry Nadler (March 19, 2020). Rep. Nadler Statement Condemning Trump Administration for Refusing to Lift Fetal Tissue Ban for COVID-19 Vaccine Research. *Press Release.* https://nadler.house.gov/news/documentsingle.aspx?DocumentID=394222 (accessed June 21, 2020). See Exhibit 378.

6. Genetic Impact

a. RNA

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from Science News:

> "So Inovio and other companies have developed ways to make vaccines much more quickly. For their SARS-CoV-2 vaccine, Inovio scientists convert the virus's RNA into DNA and select pieces of the virus that computer simulations have suggested will prod the immune system into making antibodies. Those selected bits of DNA are then inserted into bacteria, which produce large quantities of protein snippets to be used in the vaccine."

Citation: Saey T (February 21, 2020). To tackle the new coronavirus, scientists are accelerating the vaccine process. ScienceNews. https://www.sciencenews.org/article/new-coronavirus-vaccine-development-process-accelerating (accessed June 21, 2020). See Exhibit 379.

b. Synthetic Genes

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from the New York Times:

"By delivering synthetic genes into the muscles of the monkeys, the scientists are essentially re-engineering the animals to resist disease."

Citation: NY Times (March 15, 2015). Protection Without a Vaccine. https://www.nytimes.com/2015/03/10/health/protection-without-a-vaccine.html (accessed June 18, 2020). See Exhibit 380.

c. Vaccines Incorporating Nanotechnology

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote published in Frontiers in Immunology:

> "Vaccine antigens can be encapsulated within the nanocarriers or decorated on their surface (Figure 1)…. Nanocarrier based delivery systems provide a suitable route of administration of vaccine molecules and enhance cellular uptake…. NPs have also been exploited as adjuvants to augment immunogenicity of vaccine candidates….The genetic molecules such as DNA, plasmids and RNA can also act as immuno-stimulants. Due to these characteristics, in addition to less risk to cause disease particularly in immunocompromised individuals, these genetic materials are considered as promising candidates for the development of next generation vaccines.… Additionally, NPs can be tailored for non-invasive administration and prolonged delivery of the vaccine antigens to a specific

> location, thus providing the possibility for formulation of the single dose vaccine.''

Citation: Rashmirekha P, et al (2018). Nanoparticle Vaccines Against Infectious Diseases. *Front Immunol* 9: 2224. PMCID: PMC6180194 PMID: 30337923. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6180194/ (accessed June 21, 2020). See Exhibit 381.

32. Vaccine Safety Trials for Pediatric Vaccines

A. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote published by the CDC:

"Finally, because the childhood immunization schedule is essentially a long-term exposure, occurring over 18 to 24 months, long-term adverse events may be more biologically plausible than short-term events."

Citation: Glanz, J, et al (2016) White Paper on the Study of the Safety of the Childhood. Immunization Schedule. Vaccine Safety Datalink. *CDC.* https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf (accessed June 21, 2020), excerpt. See Exhibit 382.

B. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from the FDA: "Until a vaccine is given to the general population, all potential adverse events cannot be anticipated."

Citation: FDA (2018). Vaccine Product Approval Process. https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-product-approval-process (accessed June 21, 2020). See Exhibit 383.

C. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from vaccine expert Marion Gruber, PhD with the FDA:

> "One of the additional issues that complicates safety evaluation is that if you look at, and you struggle with the length of follow-up that should be adequate in a, let's say a pre-licensure or even post-marketing study if that's even possible. And

> again, as you mentioned pre-licensure clinical trials may not be powered enough. It's also the subject population that you administer the adjuvant to because we've seen data presented to us where an adjuvant, a particular adjuvant added to a vaccine antigen did really nothing when administered to a certain population and usually the elderly, you know, compared to administering the same formulation to younger age strata. So, these are things which need to be considered as well and further complicate safety and effectiveness evaluation of adjuvants combined with vaccine antigens."

Citation: World Health Organization (2019). Global Vaccine Safety Summit. Marion Gruber, PhD – Director, FDA Office of Vaccines Research and Review (OVRR) and the FDA Center for Biologics Evaluation and Research (CBER). https://www.who.int/news-room/events/detail/2019/12/02/default-calendar/global-vaccine-safety-summit (accessed June 21, 2020). See Exhibit 384.

33. Vitamin K Shot

A. Aluminum Containing

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'the Vitamin K shot recommended by the American Academy of Pediatrics for all babies on their first day of life contains aluminum.'

Citation: Hospira, Inc. (2019) Vitamin K1 - phytonadione injection, emulsion. Package Label. Hospira, Inc. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=e8808230-2c44-44c6-8cab-8f29b6b34051&type=display (accessed June 21, 2020) ("This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they required large amounts of calcium and phosphate solutions, which contain aluminum.") See Exhibit 385.

B. Benzyl Alcohol Containing

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quotes from the package insert for the Vitamin K shot recommended by the American Academy of Pediatrics for all babies on their first day of life:

> "Use benzyl alcohol-free formulations in neonates and infants, if available. Serious and fatal adverse reactions including "gasping syndrome" can occur in

> neonates and infants treated with benzyl alcohol-preserved drugs, including AquaMEPHYTON. The "gasping syndrome" is characterized by central nervous system depression, metabolic acidosis, and gasping respirations….The minimum amount of benzyl alcohol at which serious adverse reactions may occur is not known."

Citation: FDA. AquaMEPHYTON Drug Label. *FDA Access Data.* https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/012223s041lbl.pdf (accessed June 21, 2020). See Exhibit 386.

34. Big Picture Gaps In Vaccine Safety

A. For the truth of the matter stated, Petitioners request judicial notice that 'the vaccine package inserts applicable to the CDC Schedules of recommended vaccines (both for adults and children) evidence that each vaccine has never been clinically evaluated in humans for its long-term potential to cause cancer, impair fertility, and mutate genes.'

First FDA (2020). Vaccines Licensed for Use in the United States. *Vaccines, Blood & Biologics.* https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states (accessed June 21, 2020). See Exhibit 355.

Second Citation: CDC (2020). Immunization Schedules. https://www.cdc.gov/vaccines/schedules/index.html (accessed June 21, 2020). See Exhibit 387.

B. For the truth of the matter stated, Petitioners request judicial notice that 'the vaccine package inserts applicable to the CDC Schedules of recommended vaccines (both for adults and children) evidence that the pivotal clinical trial relied upon by the FDA for approval of each vaccine did not evaluate the safety of the vaccine (1) for at least one year after the vaccine is administered, and (b) against a control group that received (i) a truly inert placebo, or (ii) another vaccine approved based on a pivotal clinical trial that included a control group that received a truly inert placebo'.

Citation: Separate exhibit not needed. See Exhibits 355, 387.

C. For the truth of the matter stated, Petitioners request judicial notice that 'the vaccine package inserts applicable to the CDC Schedules of recommended vaccines (both for adults

and children) evidence that each vaccine has not been proven safer than the infection it is intended to prevent'.

Citation: Separate exhibit not needed. See Exhibits 355, 387.

35. Vaccines as Therapeutics

A. For the truth of the matter stated, Petitioners request judicial notice that 'the USP Therapeutic Categories Model Guidelines published by the FDA lists the following vaccines in the "Therapeutic Category": Vaccines to Prevent Anthrax, Diphtheria, Haemophilus Type B, Hepatitis A, Hepatitis B, Measles, Meningococcal, Mumps, Papilomavirus, Pertussis, Poliovirus, Rotavirus, Rubella, Tetanus, and Varicella.'

Citation: FDA (2018). USP Therapeutic Categories Model Guidelines. *Regulatory Information.* https://www.fda.gov/regulatory-information/fdaaa-implementation-chart/usp-therapeutic-categories-model-guidelines (accessed June 21, 2020). See Exhibit 388.

B. For the truth of the matter stated, Petitioners request judicial notice that the FDA refers to certain CDC recommended vaccines as "therapeutic biological products".

Citation: FDA (2018). Transfer of Therapeutic Biological Products to the Center for Drug Evaluation and Research. *Combination Products.* https://www.fda.gov/combination-products/jurisdictional-information/transfer-therapeutic-biological-products-center-drug-evaluation-and-research (accessed June 21, 2020). See Exhibit 389.

36. Human Test Subjects

A. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following publication by FDA regarding waiver of informed consent in human test subjects.

Citation: FDA (2017). IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects. https://www.fda.gov/media/106587/download (accessed June 21, 2020). See Exhibit 390.

B. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following publication by FDA regarding

FDA's understanding of 'therapeutic privilege' in the context of human subjects and informed consent.

Citation: FDA (2019). Protection of Human Subjects; Informed Consent. *Science and Research.* https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/protection-human-subjects-informed-consent (accessed June 21, 2020), excerpt. See Exhibit 391.

37. HHS Fails To Report To Congress Re Vaccine Safety

For the truth of the matter stated, Petitioners request judicial notice of the stipulated order entered July 9, 2018 in the United States District Court (Southern District of New York), evidencing that HHS has no evidence that the Secretary completed any of the 16 reports, bi-annually pursuant to U.S. Code § 300aa–27(c) ("Report Within 2 years after December 22, 1987, and periodically thereafter . . .")

Citation: United States District Court, Southern District of New York. Informed Consent Action Network v. United States Department of Health and Human Services. Case 1:18-cv-03215-JMF Document 18 Filed 07/09/18. See Exhibit 392.

38. Medical Error Is the Third Leading Cause of Death In the United States

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote published by Johns Hopkins University:

> "Analyzing medical death rate data over an eight-year period, Johns Hopkins patient safety experts have calculated that more than 250,000 deaths per year are due to medical error in the U.S. Their figure, published May 3 in *The BMJ*, surpasses the U.S. Centers for Disease Control and Prevention's (CDC's) third leading cause of death — respiratory disease, which kills close to 150,000 people per year.
>
> "The Johns Hopkins team says the CDC's way of collecting national health statistics fails to classify medical errors separately on the death certificate. The researchers are advocating for updated criteria for classifying deaths on death certificates."

Citation: Johns Hopkins University (May 3, 2016). Study Suggests Medical Errors Now Third Leading Cause of Death in the U.S. *Johns Hopkins Medicine Press Release.*

https://www.hopkinsmedicine.org/news/media/releases/study_suggests_medical_errors_now_third_leading_cause_of_death_in_the_us (accessed June 21, 2020). See Exhibit 393.

39. Historical Vaccination Coverage Levels

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following vaccine coverage levels published by the CDC:

A. 1962-2016

Citation: CDC (2018). Vaccine Coverage Levels – United States, 1962-2016. *Pink Book*, 13th Edition, Appendix E. https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/e/coverage-levels.pdf (accessed July 5, 2020). See Exhibit 394.

B. 1998-2002

Citation: CDC (2003). National, State, and Urban Area Vaccination Levels Among Children Aged 19--35 Months --- United States, 2002. *MMWR Weekly*. 2003;52(31);728-732. https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5231a2.htm (accessed July 5, 2020). See Exhibit 395.

C. 2003-2007

Citation CDC (2008). National, State, and Local Area Vaccination Coverage Among Children Aged 19--35 Months --- United States, 2007. MMWR 2008;57: 961-966. https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5735a1.htm (accessed July 5, 2020). See Exhibit 301.

D. 2008-2012

Citation CDC (2013). National, State, and Local Area Vaccination Coverage Among Children Aged 19–35 Months — United States, 2012. MMWR 2013;62:733-740. https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6236a1.htm (accessed July 5, 2020). See Exhibit 302.

E. 2013 – 2017

Citation: CDC (2018). Vaccination Coverage Among Children Aged 19–35 Months — United States, 2017. MMWR Morb Mortal Wkly Rep 2018;67:1123–1128. DOI: http://dx.doi.org/10.15585/mmwr.mm6740a4 (accessed July 5, 2020). See Exhibit 297.

F. Hib >= 3 doses 2008 – 2011

Citation: CDC (2012). National, State, and Local Area Vaccination Coverage Among Children Aged 19–35 Months — United States, 2011. MMWR Weekly. 2012;61(35);689-696. https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6135a1.htm (accessed July 5, 2020). See Exhibit 396.

G. 1959-1970

Citation: CDC (1971). Immunization Survey – 1970. Morbidity and Mortality, 20(13), 114-115. www.jstor.org/stable/44069987 (accessed July 9, 2020). See Exhibit 397.

40. Severity of Infection Is Relative

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'infection severity is specific to the patient in question, such that the severity of a "vaccine preventable disease" can vary from patient to patient.'

Citation: Blood and Marrow Transplant Clinical Trials Network, funded by NIH (2004). *Definitions of Infection Severity*. https://web.emmes.com/study/bmt2/public/Definition/Definitions_of_Inf_Severity.pdf (accessed July 5, 2020). See Exhibit 398.

41. Infant Mortality

Introduction

CDC data shows an approximately 13% reduction in overall American infant mortality during the Covid-19 lockdowns in the period March 22, 2020 through May 30, 2020 (a time period representing America in lockdown under Covid-19 where some families were foregoing routine vaccination appointments).

As of October 14, 2020, the CDC reported for such lockdown period (3/22-5/30) the deaths of 3,610 infants under the age of one year, which is an average of 52 deaths per day. See Exhibit 399.

Compare the most recent CDC data on infant mortality (from 2018) showing a significantly higher average of 59 deaths per day. See Exhibit 400 below. Note also that deaths for non-biological reasons (i.e., car accidents) only accounted for an average of 4 infant deaths per day in 2018. See Exhibit 401 below.

So there is an unexplained drop in infant mortality for biological reasons during Covid-19 lockdowns. Vaccinations are a reasonable suspect in such correlation due to the drop in infant vaccine coverage during this same time period. See Exhibit 402 below.

Vaccinations have long been an obvious suspect in the infant death rate, even when public health officials deny significance of the correlation via their "conclusions". An illustrative example comes from this recent paper authored by CDC officials: "For child death reports [to VAERS], 79.4% received >1 vaccine on the same day.... Conclusions**.** No concerning pattern was noted among death reports submitted to VAERS during 1997–2013." See Exhibit 403 below. This evidence shows these public health officials observed that in 79.4% of reported child deaths to VAERS, the child death occurred on the very same day the child received one or more vaccines, and yet the officials' conclusion was "No concerning pattern was noted."

Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice that 'during the ongoing Covid-19 pandemic lockdowns in the USA, the following two metrics have reduced in tandem, revealing a correlation between them: (1) infant death rate, and (2) infant vaccine coverage.'

Citations:

(1) CDC (2020). Provisional COVID-19 Death Counts by Sex, Age, and Week. *National Center for Health Statistics.* https://data.cdc.gov/NCHS/Provisional-COVID-19-Death-Counts-by-Sex-Age-and-W/vsak-wrfu/data (accessed October 18, 2020). See Exhibit 399.

(2) CDC (2020), National Center for Health Statistics. Underlying Cause of Death 1999-2018 on CDC WONDER Online Database, released in 2020. Data are from the Multiple Cause of Death Files, 1999-2018, as compiled from data provided by the 57 vital statistics jurisdictions

through the Vital Statistics Cooperative Program. Accessed at http://wonder.cdc.gov/ucd-icd10.html (accessed on July 9, 2020). See Exhibit 400.

(3) CDC (2020), National Center for Health Statistics. Underlying Cause of Death 1999-2018 on CDC WONDER Online Database, released in 2020. Data are from the Multiple Cause of Death Files, 1999-2018, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Accessed at http://wonder.cdc.gov/ucd-icd10.html (accessed on July 9, 2020). See Exhibit 401.

(4) Santoli JM, et al. (2020). Effects of the COVID-19 Pandemic on Routine Pediatric Vaccine Ordering and Administration — United States, 2020. MMWR Morb Mortal Wkly Rep 2020;69:591–593. DOI: http://dx.doi.org/10.15585/mmwr.mm6919e2external icon (accessed July 5, 2020). See Exhibit 402.

(5) Moro, P., et al. (2015). Deaths Reported to the Vaccine Adverse Event Reporting System, United States, 1997–2013. *Clinical Infectious Diseases*, Volume 61, Issue 6, 15 September 2015, Pages 980–987, https://doi.org/10.1093/cid/civ423 (accessed on July 9, 2020). See Exhibit 403.

42. Pathogen Transmission

A. Risk of Transmission for Tetanus

Introduction

Neither vaccinated nor unvaccinated individuals pose risk of disease transmission for tetanus, due to tetanus being a non-communicable disease.

Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of a quote from the Centers for Disease Control and Prevention website: “Tetanus… does not spread from person to person.”

Citation: Centers for Disease Control and Prevention, *About Tetanus*. https://www.cdc.gov/tetanus/about/index.html, (accessed July 17, 2020). See Exhibit 404.

B. Risk of Transmission for Diphtheria

Introduction

Both vaccinated and unvaccinated individuals pose risk of pathogen transmission for diphtheria, due to failure of the diphtheria toxoid vaccine to prevent carrier state.

Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of a quote from a study published in *American Journal of Diseases of Children:* "These outbreaks, the known importance of carriers in the spread of diphtheria, and the demonstrated failure of toxoid to prevent the carrier state lead us to conclude that the concept of herd immunity is not applicable in the prevention of diphtheria. A high level of community immunization will not stop the transmission of diphtheria…"

Citation: Miller *et al*. (1972). Diphtheria immunization. Effect upon carriers and the control of outbreaks. *American Journal of Diseases of Children* 123(3):197-199. https://doi.org/10.1001/archpedi.1972.02110090067004, (accessed July 17, 2020). See Exhibit 405.

C. Risk of Transmission for Pertussis

Introduction

Both vaccinated and unvaccinated individuals pose risk of pathogen transmission for pertussis, due to failure of the acellular pertussis vaccine to prevent transmission and due to vaccine-selection pressure on pathogen evolution.

Judicial Notice

1. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of a quote from the Food and Drug Administration 2013 News Release: "…although individuals immunized with an acellular pertussis vaccine may be protected from disease, they may still become infected with the bacteria without always getting sick and are able to spread infection to others, including young infants, who are susceptible to pertussis disease."

Citation: U.S. Food and Drug Administration, *FDA News Release, Nov. 27, 2013*. https://web.archive.org/web/20131130004447/https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm376937.htm, (accessed July 17, 2020). See Exhibit 406.

2. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of a quote from a study published in *Proceedings of the National Academy of Sciences USA*: "The observation that aP, which induces an immune response mismatched to that induced by natural infection, fails to prevent colonization or transmission provides a plausible explanation for the resurgence of pertussis…"

Citation: Warfel *et al*. (2014). Acellular pertussis vaccines protect against disease but fail to prevent infection and transmission in a nonhuman primate model. *Proceedings of the National Academy of Sciences USA* 111(2):787-792. https://doi.org/10.1073/pnas.1314688110, (accessed July 17, 2020). See Exhibit 407.

3. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of a quote from a study published in *Clinical Infectious Diseases*: "A recent increase in Bordetella pertussis without the pertactin protein, an acellular vaccine immunogen, has been reported in the United States… The significant association between vaccination and isolate pertactin production suggests that the likelihood of having reported disease caused by PRN(-) compared with PRN(+) strains is greater in vaccinated persons."

Citation: Martin *et al*. (2015). Pertactin-negative Bordetella pertussis strains: evidence for a possible selective advantage. *Clinical Infectious Diseases* 60(2):223-227. https://doi.org/10.1093/cid/ciu788, (accessed July 17, 2020). See Exhibit 408.

D. Risk of Transmission for Polio

Introduction

Both vaccinated and unvaccinated individuals pose risk of pathogen transmission for polio, due to failure of inactivated polio vaccine (IPV) to prevent virus shedding.

Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of a quote from a systematic review published in *PLoS Pathogens:* "…IPV provided no protection against shedding [in stool samples] compared with unvaccinated individuals… There were insufficient studies of nasopharyngeal shedding to draw a conclusion."

Citation: Hird & Grassly (2012). Systematic review of mucosal immunity induced by oral and inactivated poliovirus vaccines against virus shedding following oral poliovirus challenge. *PLoS Pathogens* 8(4):e1002599. https://doi.org/10.1371/journal.ppat.1002599, (accessed July 17, 2020). See Exhibit 409.

E. Risk of Transmission for Flu

Introduction

Both vaccinated and unvaccinated individuals pose risk of pathogen transmission for influenza, due to failure of flu shots to prevent transmission.

Judicial Notice

1. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of a quote from a study published in *Clinical Infectious Diseases:* "There was no evidence that vaccination prevented household transmission once influenza was introduced."

Citation: Ohmit *et al*. (2013). Influenza vaccine effectiveness in the community and the household. *Clinical Infectious Diseases* 56(10):1363-1369. https://doi.org/10.1093/cid/cit060, (accessed July 17, 2020). See Exhibit 410.

2. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of a quote from a systematic review published in *Cochrane Database of Systematic Reviews:* "Offering influenza vaccination to HCWs [healthcare workers] based in long term care homes may have little or no effect on the number of residents who develop laboratory-proven influenza compared with those living in care homes where no vaccination is offered."

Citation: Thomas *et al*. (2016). Influenza vaccination for healthcare workers who care for people aged 60 or older living in long-term care institutions. *Cochrane Database of Systematic Reviews* (6):CD005187. https://doi.org/10.1002/14651858.CD005187.pub5, (accessed July 17, 2020). See Exhibit 411.

F. Risk of Transmission for Hepatitis B

Introduction

Both vaccinated and unvaccinated individuals pose minimal risk of pathogen transmission for Hepatitis B in a public setting, such as school.

Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of a quote from the Centers for Disease Control and Prevention website: "Hepatitis B is spread when blood, semen, or other body fluid infected with the hepatitis B virus enters the body of someone who is not infected… Hepatitis B is not spread through food or water, sharing eating utensils, breastfeeding, hugging, kissing, hand holding, coughing, or sneezing."

Citation: Centers for Disease Control and Prevention, *How is hepatitis B spread?* https://www.cdc.gov/hepatitis/hbv/bfaq.htm#bFAQc01, (accessed July 17, 2020). See Exhibit 412.

G. Risk of Transmission for Measles and Mumps

Both vaccinated and unvaccinated individuals pose risk of pathogen transmission for measles or mumps under close contact.

1. Measles

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of a quote from a study published in *American Journal of Epidemiology*: "When siblings shared a bedroom with a measles case, a 78 percent risk (seven out of nine children) was observed among vaccinees... Vaccinated and unvaccinated students were equally able to infect their siblings."

Citation: Paunio *et al*. (1998). Explosive school-based measles outbreak: intense exposure may have resulted in high risk, even among revaccinees. *American Journal of Epidemiology* 148(11):1103-1110. https://doi.org/10.1093/oxfordjournals.aje.a009588, (accessed July 17, 2020). See Exhibit 413.

1. Mumps

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of a quote from a study published in *Human Vaccines & Immunotherapeutics*: "During 2009-2010, a large US mumps outbreak occurred affecting two-dose vaccinated 9th-12th grade Orthodox Jewish boys attending all-male yeshivas (private, traditional

Jewish schools). Our objective was to understand mumps transmission dynamics in this well-vaccinated population.... mumps transmission requires close contact, and these environmental factors may have overwhelmed vaccine-mediated protection increasing the likelihood of vaccine failure among yeshiva students."

Citation: Fiebelkorn *et al*. (2013). Environmental factors potentially associated with mumps transmission in yeshivas during a mumps outbreak among highly vaccinated students: Brooklyn, New York, 2009-2010. *Human Vaccines & Immunotherapeutics* 9(1):189-194. https://doi.org/10.4161/hv.22415, (accessed July 17, 2020). See Exhibit 414.

H. Risk of Transmission for Live Vaccines

Introduction

Vaccinated individuals pose risk of horizontal transmission of live vaccines (rubella, varicella, rotavirus).

Judicial Notice

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of a quote from a Letter to Editor published in *Human Vaccines & Immunotherapeutics:*

> "A study in US reported evidence of the transmission of rubella vaccine virus from vaccinees to two susceptible contacts. With live varicella vaccines, there are at least three reports. The brother of a 3-y-old vaccinated girl developed fever and a rash; horizontal transmission of vaccine virus was later confirmed. A pregnant mother contracted the vaccine virus after her 12-mo-old boy received varicella vaccine. Horizontal transmission was reported in 15 (17%) susceptible healthy siblings after varicella vaccination of 156 children with leukemia. The package insert of live varicella vaccine (Varivax, Merck) states that 'Post-marketing experience suggests that transmission of vaccine virus may occur rarely between healthy vaccinees who develop a varicella-like rash and healthy susceptible contacts. Transmission of vaccine virus from vaccinees who do not develop a varicella-like rash has also been reported.' There are two reports with rotavirus vaccines. A randomized, double-blind study on human rotavirus vaccine (Rotarix™, Glaxo) in 100 pairs of healthy twins found that the transmission rate among placebo recipients was 18.8%. In another case, rotavirus vaccine (RotaTeq, Merck) transmission was reported from a vaccinated infant to an older, unvaccinated sibling, resulting in symptomatic rotavirus gastroenteritis."

Citation: Kulkarni *et al*. (2013). Horizontal transmission of live vaccines. *Human Vaccines & Immunotherapeutics* (1):197. https://doi.org/10.4161/hv.22132, (accessed July 17, 2020). See Exhibit 415.

43. 20th Century Disease Mortality Reductions Caused By Improved Living Conditions Prior to Vaccines

Introduction

Early 20th century America experienced substantial improved living conditions (i.e., decreased crowding in cities, improved plumbing, advanced water filtration, solid waste disposal), which caused America to experience a rapid decline in disease mortality rates. After such mortality rates were already on the rapid decline, vaccines were slowly introduced into licensure and widespread usage later in the century.

In 1977, it was reported that of the approximately 74% total decline in mortality since 1900, medical interventions such as antibiotics and vaccines were responsible for only approximately 1% to 3.5% of such decline (notably these figures omit the mortality caused by vaccines and other medical interventions).

Vaccines burdened Americans in the 20th Century.

Judicial Notice

A. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of a quote from a study published in The Journal of Infectious Diseases*:*

"This decline in rates of certain disorders, correlated roughly with socioeconomic circumstances, is merely the most important happening in the history of the health of man, yet we have only the vaguest and most general notions about how it happened and by what mechanisms socioeconomic improvement and decreased rates of certain diseases run in parallel."

Citation*:* Kass E. (1971). Infectious Diseases and Social Change. *The Journal of Infectious Diseases* 123(1):110-114. https://www.jstor.org/stable/30108855?seq=1 (accessed July 19, 2020). See Exhibit 416.

B. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of a quote from a study published in The Milbank Memorial Fund Quarterly*:*

> "Even if it were assumed that this change was entirely due to the vaccines, then only about one percent of the decline following interventions for the diseases considered here could be attributed to medical measures. Rather more conservatively, if we attribute some of the subsequent fall in the death rates for pneumonia, influenza, whooping cough, and diphtheria to medical measures, then perhaps 3.5 percent of the fall in the overall death rate can be explained through medical intervention in the major infectious diseases considered here. Indeed, given that it is precisely for these diseases that medicine claims most success in lowering mortality, 3.5 percent probably represents a reasonable upper-limit estimate of the total contribution of medical measures to the decline in mortality in the United States since 1900."

Citation: McKinlay, J., et al. (1977). The Questionable Contribution of Medical Measures to the Decline of Mortality in the United States in the Twentieth Century. *The Milbank Memorial Fund Quarterly. Health and Society* 55(3):405-428. https://www.jstor.org/stable/3349539?seq=1 (accessed July 19, 2020). See Exhibit 417.

44. Quantifying Benefits of Mass Vaccination Programs in the United States

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following excerpts from a study published in Vaccines*:*

> "It was estimated that 20 million infections and 12,000 deaths and permanent disabilities may have occurred in 2014 in the absence of mass vaccination, with 10,800 deaths and disabilities among individuals who have conditions or behaviors that would put them at higher risk of such outcomes and 1200 deaths and disabilities among persons without those conditions or behaviors."

> "To measure the benefit of a mass vaccination program targeting an infectious disease, it is useful to assess what the risk of death or permanent injury would be from the disease in the absence of the mass vaccination program. There is an abundance of medical literature detailing the risks associated with infectious diseases; however, the information is scattered through dozens of sources that are often lengthy and consider only a narrow scope of the risks involved. For example, some sources describe the symptoms of a disease without specifying how many patients fully recover [1]; other sources describe the number of deaths from an infection without addressing permanent disability in survivors [2,3]. Moreover, some sources do not account for the pre-vaccine rates of decline in mortality for some

infectious diseases [3,4,5]. We tried to address these challenges in our estimates.... Furthermore, this study only estimated the number of deaths and permanent disabilities prevented by mass vaccination programs. It did not consider similar outcomes that may be caused by these programs."

"In the early 20th century, significant declines in mortality rates were recorded for numerous infectious diseases that were not targeted by mass vaccination programs, such as those for tuberculosis, syphilis, typhoid fever, and dysentery [48]. The human immune system is evidently remarkably efficient when coupled with treatments for severe cases of diseases, such as antibiotics and when not hampered by factors like poor nutrition, poor sanitation, or limited access to health care."

Citation: Magno, H, Golomb, B. (2020). Measuring the Benefits of Mass Vaccination Programs in the United States. *Vaccines* 2020, *8*(4), 561; https://doi.org/10.3390/vaccines8040561 (accessed October 19, 2020). See Exhibit 418.

CONCLUSION

Petitioners hereby request judicial notice of the foregoing facts.

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Date: 12-6-20

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