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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 ONE

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INTRODUCTION

Health Crisis in America

The People of the United States of America, and particularly our Nation's children, are suffering from an unprecedented pandemic of chronic diseases. More American children are sick today than in any previous generation. They are suffering from a wide range of conditions: from asthma and autoimmune diseases to neurodevelopmental and mental health disorders that are increasingly known to be associated with an underlying dysregulated immune activation. The fallout from this health emergency is an economic, healthcare and national security crisis for our Nation.

High Infant Mortality

Notwithstanding that the United States spends more on healthcare than any country in the world, American children have poorer outcomes and are less likely to survive their first year of life than children born in many other high-income nations.

On their first day of birth, American infants have the highest mortality rate of any industrialized nation in the world. Even when premature births are excluded, more apparently healthy American babies die in infancy of sudden and unexplained causes than infants in other wealthy countries.

Pandemic of Chronic Diseases

In recent decades, American children have experienced a decline in once common childhood infections, such as measles, whooping cough and chickenpox. At the same time, a growing number of children have begun suffering from a wide range of non-communicable, serious and often incurable illnesses, including neurodevelopmental disorders such as autism and learning disabilities, mental illnesses such as anxiety and obsessive compulsive disorder, and an array of immune-mediated diseases such as asthma and autoimmune diseases. These once rare pediatric anomalies now afflict American children in pandemic proportions.

A 2011 Health Affairs assessment estimated that 43 percent (32 million) of American children currently suffer from at least one of twenty chronic health conditions, which increases to more than half (54.1 percent) when overweight, obesity or being at risk for developmental delays

are included. Nearly one-fifth (14.2 million) of children have conditions resulting in a special health care need.

The Centers for Disease Control and Prevention (CDC) estimates that more than a quarter (27 percent) of American children have a chronic condition and one in fifteen are burdened with multiple chronic conditions.

It was reported in *The Journal of the American Medical Association* (JAMA) that chronic illnesses in children doubled from 12.8 to 26.6 percent between 1994 and 2006, with low-income, racial and ethnic minority children being disproportionately affected in an epidemic that has continued to grow.

Compared to children two generations ago (in the 1960s), as reported in *Health Affairs*, American children are now more than four times more likely to be burdened with a health condition so severe that it affects their usual daily activities.

A 2018 *Pediatrics* study reported that one-fifth of American children and adolescents regularly use prescription medication and 12% of boys aged six to 12 years are prescribed more than one drug.

Much of this disease burden has come from neurodevelopmental disorders, mental illness, and immune-mediated conditions.

Neurodevelopmental disorders

The profound neurodevelopmental disorder called Autism Spectrum Disorder, virtually non-existent less than a century ago, has increased to one in 54 in children aged 8 years in 2016.

ASD is projected to continue on its ascending trajectory into the future as its causes are unidentified and unaddressed.

In addition, the CDC reports that today more than seven million American children have been diagnosed with attention-deficit/hyperactivity disorder (ADHD), including 388,000 children aged just two to five years old.

The number of ADHD diagnoses swelled by 42 percent between 2003 and 2011 and continues to increase an average of five percent per year.

"The estimate for learning disabilities in 2011–2012 was 8.0 percent for children of ages 3–17 (NSCH, 2012a)."

"The root causes of the present global pandemic of neurodevelopmental disorders are only partly understood," according to a review in *Lancet Neurology,* which points to a significant role for environmental toxins in its causation. "Although genetic factors have a role, they cannot explain recent increases in reported prevalence, and none of the genes discovered so far seem to be responsible for more than a small proportion of cases."

Mental Illness

According to the Child Mind Institute, 17.1 million American children have had or have a diagnosable mental illness.

The CDC reports that one in five children "experience a mental disorder in a given year," and that the Nation spends an estimated $247 billion each year treating and managing childhood mental disorders.

The CDC reports that 7.1 percent (4.4 million) of American children aged three to 17 are diagnosed with anxiety disorders that have been increasing in recent years. Another 1.9 million children have been diagnosed with depression.

According to the National Institute of Mental Health, "an estimated 49.5% of adolescents [aged 13-18] had any mental disorder. Of adolescents with any mental disorder, an estimated 22.2% had severe impairment."

Self-harm-related emergency department visits by youth have skyrocketed, with 18.8% annual increase among females aged 10 to 14 years starting in 2009, from 109.8 (95% CI, 69.9-149.7) in 2009 to 317.7 (95% CI, 230.3-405.1) per 100 000 population in 2015.

In 2016, suicide became the second leading cause of death for those aged 10 - 34 years, with the greatest increases among those 10 to 24 years old.

Immune-Mediated Disorders

Immune-mediated disorders — those involving immune activation – have soared among American children in recent decades; allergies, asthma and autoimmune diseases are all inexplicably on a sharp upward trajectory.

Asthma is the most common chronic disease of childhood and, in the latter part of the 20th century, has reached epidemic proportions and continues to increase. According to the CDC, asthma affects 25 million people, including six million children under 18 and is a "significant health and economic burden to patients, their families, and society."

According to the Asthma and Allergy Foundation of America, more than 50 million Americans are affected by allergies.

This includes millions of American children with reported allergic rhinitis (5.2 million), respiratory allergies (7.1 million), food allergies (4.8 million) and skin allergies (9.2 million), in 2018.

A growing number of young Americans die from a life-threatening form of allergy called anaphylaxis, as its occurrence is increasing across all ages in the United States, with highest risk of mortality in teenagers and young adults.

Autoimmune diseases, of which there are at least 80 distinct conditions, occur as a result of the immune system attacking the body's own tissues and organs. Some of the more common autoimmune conditions include type 1 diabetes, rheumatoid arthritis, systemic lupus erythematosus and inflammatory bowel disease. Taken together, these conditions, once so rare they were virtually unheard of, have increased from year to year for mostly unknown reasons and are now, "as a group afflict 5%–9% of the U.S. population," according to a report in International Journal of Molecular Sciences.

Pediatric Cancer

According to American Cancer Society, childhood cancer rates have been rising for the past few decades.

It has been reported in the Journal of the National Cancer Institute that children born in the 1990s have double the risk of colon cancer and quadruple the risk of rectal cancer compared to people born in the 1950s.

The reasons for the increase in one of America's leading causes of childhood death, pediatric cancer, are unknown.

National Crisis

The pandemic of childhood illness is straining the Nation, imposing an enormous and growing burden on individuals, families and society. Chronically ill children become chronically ill adults.

According to the CDC, chronic disease and mental illness account for most American deaths, consume 90% of the Nation's $3.5 trillion in annual health care expenditures and are projected to account for more than $42 trillion in spending by 2030.

The burden of illness is straining America's school system as well, which is struggling to accommodate the demands of the growing population of students with special needs.

The health crisis of America's youth is a national security crisis as well; nearly a third (32 percent) of all young people have health problems – other than their weight – that prevent them from military service.

The underlying causes of the soaring pandemic of childhood and adult chronic illness in America must be identified, addressed and corrected in order to avert a national crisis.

The Role of Vaccination

Numerous peer-reviewed studies in the medical literature about increasing chronic illnesses point to unidentified environmental agents as likely causes for the rise. Many toxins and environmental and sociological changes have been implicated in children's chronic diseases but one factor that is most likely to engage immune activation, and hence trigger immune-mediated conditions, has not been thoroughly assessed. That factor is exposure to vaccination.

Vaccination has been linked to a range of side effects, from febrile seizures to serious central nervous system autoimmune disorders, such acute disseminated encephalomyelitis and Guillaine-Barré syndrome. Numerous studies note a temporal association between vaccination and onset of a wide-range of chronic conditions and sudden infant death.

Children in America receive more vaccines today than any previous generation in history. American children currently receive up to 79 vaccine doses against 16 diseases by age 18, compared to the 1983 schedule with just 22 recommended doses against eight diseases.

The safety of the ever-expanding CDC-recommended vaccination schedule for children has never been assessed against a control group—that is, no large-scale study has compared the health outcomes of children who receive currently recommended childhood vaccinations to those who

receive none. This research gap leaves important questions unanswered about the role the current vaccination schedule plays in the development of immune-mediated dysregulation that underlies much of chronic childhood illness today.

REQUESTS FOR JUDICIAL NOTICE

1. Common Definitions

A. Adjuvant

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'adjuvant' from the Centers for Disease Control and Prevention: "An adjuvant is an ingredient used in some vaccines that helps create a stronger immune response in people receiving the vaccine."

Citation: Centers for Disease Control and Prevention, *Adjuvants help vaccines work better*. https://www.cdc.gov/vaccinesafety/concerns/adjuvants.html, (accessed July 1, 2020). See Exhibit 1.

B. Alum

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'alum' from *Introduction to Biomedical Engineering*: "Alum is potassium aluminum sulfate that is used as the starting solution to precipitate antigens with either aluminum phosphate or aluminum hydroxide," and the following description of alum from *Clinical Immunology*: "Alum is utilized as an adjuvant in many of the currently available vaccines composed of inactivated toxins or recombinant proteins."

Citation: *Introduction to Biomedical Engineering, Third Edition*. (2012) and *Clinical Immunology, Third Edition.* (2008). https://www.sciencedirect.com/topics/medicine-and-dentistry/alum, (accessed July 1, 2020). See Exhibit 2.

C. Antibody

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'antibody' from *Segen's Medical Dictionary*: "an immunoglobulin produced by plasma cells, which has a specific amino acid

sequence and specifically binds to the antigen(s) (e.g., foreign proteins, microbes or toxins) that induced its synthesis; antibodies may also bind to closely related antigens."

Citation: *Segen's Medical Dictionary*. (2011). https://medical-dictionary.thefreedictionary.com/antibody, (accessed July 1, 2020). See Exhibit 3.

D. Arthralgia

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'arthralgia' from MedicineNet: 'arthralgia is "pain in a joint." '

Citation: MedicineNet, *Medical Definition of Arthralgia; Medical Author: William C. Shiel Jr., MD, FACP, FACR.* https://www.medicinenet.com/script/main/art.asp?articlekey=2343, (accessed July 1, 2020). See Exhibit 4.

E. Autoantibody

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'autoantibody' from *Miller-Keane Encyclopedia and Dictionary of Medicine, Nursing, and Allied Health*: "an antibody formed in response to, and reacting against, an antigenic constituent of the individual's own tissues."

Citation: *Miller-Keane Encyclopedia and Dictionary of Medicine, Nursing, and Allied Health, Seventh Edition*. (2003). https://medical-dictionary.thefreedictionary.com/Autoantibody, (accessed July 1, 2020). See Exhibit 5.

F. Chronic inflammation

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following description of 'chronic inflammation' from Healthline:

> "Inflammation refers to your body's process of fighting against things that harm it, such as infections, injuries, and toxins, in an attempt to heal itself… Chronic inflammation happens when this response lingers, leaving your body in a constant state of alert. Over time, chronic inflammation may have a negative impact on your tissues and organs. Some research suggests that chronic inflammation could also play a role in a range of conditions, from cancer to asthma."

Citation: Healthline, *Understanding and Managing Chronic Inflammation*; *Written by Adrienne Santos-Longhurst; Medically reviewed by Seunggu Han, MD, Updated on July 27, 2018.* https://www.healthline.com/health/chronic-inflammation, (accessed July 1, 2020). See Exhibit 6.

G. Comorbid

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'comorbid' from *Miller-Keane Encyclopedia and Dictionary of Medicine, Nursing, and Allied Health:* "pertaining to a disease or other pathological process that occurs simultaneously with another."

Citation: *Encyclopedia and Dictionary of Medicine, Nursing, and Allied Health, Seventh Edition*. (2003). https://medical-dictionary.thefreedictionary.com/comorbid, (accessed July 1, 2020). See Exhibit 7.

H. Cytotoxic

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'cytotoxic' from MedicineNet: 'cytotoxic is "toxic to cells, cell-toxic, cell-killing. Any agent or process that kills cells." '

Citation: MedicineNet, *Medical Definition of Cytotoxic; Medical Author: William C. Shiel Jr., MD, FACP, FACR.* https://www.medicinenet.com/script/main/art.asp?articlekey=19883, (accessed July 1, 2020). See Exhibit 8.

I. Demyelination

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following description of 'demyelination' from MedicineNet: "a degenerative process that erodes away the myelin sheath that normally protects nerve fibers. Demyelination exposes these fibers and appears to cause problems in nerve impulse conduction that may affect many physical systems. Demyelination is seen in a number of diseases, particularly multiple sclerosis."

Citation: MedicineNet, *Medical Definition of Demyelination*, *Medical Author: William C. Shiel Jr., MD, FACP, FACR.* https://www.medicinenet.com/script/main/art.asp?articlekey=11143, (accessed July 1, 2020). See Exhibit 9.

J. Epidemic

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'epidemic' from *Farlex Partner Medical Dictionary*: 'an epidemic is "the occurrence in a community or region of cases of an illness, specific health-related behavior, or other health-related events clearly in excess of normal expectancy." '

Citation: *Farlex Partner Medical Dictionary*. (2012). https://medical-dictionary.thefreedictionary.com/epidemic, (accessed July 1, 2020). See Exhibit 10.

K. Epitope

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'epitope' from *The American Heritage® Medical Dictionary:* "a localized region on the surface of an antigen capable of eliciting an immune response and of combining with a specific antibody to counter that response."

Citation: *The American Heritage® Medical Dictionary*. (2007). https://medical-dictionary.thefreedictionary.com/epitope, (accessed July 1, 2020). See Exhibit 11.

L. Etiology

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'etiology' from *Farlex Partner Medical Dictionary*: 'etiology is "1. The science and study of the causes of disease and their mode of operation. 2. The science of causes, causality; in common usage, the cause itself." '

Citation: *Farlex Partner Medical Dictionary*. (2012). https://medical-dictionary.thefreedictionary.com/etiology, (accessed July 1, 2020). See Exhibit 12.

M. Histopathology

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'histopathology' from *Farlex Partner Medical Dictionary*: 'histopathology is "the science or study dealing with the cytologic and histologic structure of abnormal or diseased tissue." '

Citation: *Farlex Partner Medical Dictionary*. (2012). https://medical-dictionary.thefreedictionary.com/histopathology, (accessed July 1, 2020). See Exhibit 13.

N. Immune-mediated inflammatory disorders (IMIDs)

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following description of 'immune-mediated inflammatory disorders (IMIDs)' from a Review article in *The American Journal of Managed Care*: "Immune-mediated inflammatory disorders (I.M.I.D.s) are a group of diseases that involve an immune response that is inappropriate or excessive, and is caused, signified, or accompanied by dysregulation of the body's normal cytokine milieu. I.M.I.D.s cause acute or chronic inflammatory injury, sometimes severe, in any organ system."

Citation: Williams & Meyers (2002). Immune-mediated Inflammatory Disorders (I.M.I.D.s): The Economic and Clinical Costs. *The American Journal of Managed Care* 8(21 Suppl):S664-S681. https://pubmed.ncbi.nlm.nih.gov/12516953, (accessed June 9, 2020). See Exhibit 14.

O. Immune system

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'immune system' from *Farlex Partner Medical Dictionary*: 'immune system is "an intricate complex of interrelated cellular, molecular, and genetic components that provides a defense, the immune response, against foreign organisms or substances and aberrant native cells." '

Citation: *Farlex Partner Medical Dictionary*. (2012). https://medical-dictionary.thefreedictionary.com/immune+system, (accessed July 1, 2020). See Exhibit 15.

P. Inflammation

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'inflammation' from *Miller-Keane Encyclopedia and Dictionary of Medicine, Nursing, and Allied Health*: "a localized protective response elicited by injury or destruction of tissues, which serves to destroy, dilute, or wall off both the injurious agent and the injured tissue."

Citation: *Miller-Keane Encyclopedia and Dictionary of Medicine, Nursing, and Allied Health, Seventh Edition*. (2003). https://medical-dictionary.thefreedictionary.com/inflammation, (accessed July 1, 2020). See Exhibit 16.

Q. Macrophage

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following description of 'macrophage' from MedicineNet: "a type of white blood cell that ingests foreign material. Macrophages are key players in the immune response to foreign invaders of the body, such as infectious microorganisms. They are normally found in the liver, spleen, and connective tissues of the body."

Citation: MedicineNet, *Medical Definition of Macrophage; Medical Author: William C. Shiel Jr., MD, FACP, FACR.* https://www.medicinenet.com/script/main/art.asp?articlekey=4238, (accessed July 1, 2020). See Exhibit 17.

R. Medical emergency

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'medical emergency' from *Segen's Medical Dictionary*:

> "a medical or behavioral condition, the onset of which is sudden and manifests itself by symptoms of sufficient severity, including severe pain, such that a prudent lay person could reasonably expect the absence of immediate medical attention to result in: (1) placing the health of the afflicted person with such a condition in serious jeopardy; (2) serious impairment to the person's bodily functions; (3) serious dysfunction of any bodily organ or part; or (4) serious disfigurement."

Citation: *Segen's Medical Dictionary*. (2012). https://medical-dictionary.thefreedictionary.com/medical+emergency, (accessed July 1, 2020). See Exhibit 18.

S. Myalgia

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'myalgia' from MedicineNet: "pain in the muscles or within muscle tissue."

Citation: MedicineNet, *Medical Definition of Myalgia; Medical Author: William C. Shiel Jr., MD, FACP, FACR.* https://www.medicinenet.com/script/main/art.asp?articlekey=12008, (accessed July 1, 2020). See Exhibit 19.

T. Myelin

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following description of 'myelin' from MedlinePlus:

> "Myelin is an insulating layer, or sheath that forms around nerves, including those in the brain and spinal cord. It is made up of protein and fatty substances. This myelin sheath allows electrical impulses to transmit quickly and efficiently along the nerve cells. If myelin is damaged, these impulses slow down. This can cause diseases such as multiple sclerosis." '

Citation: MedlinePlus, U.S. National Library of Medicine, *Myelin*. https://medlineplus.gov/ency/article/002261.htm, (accessed July 1, 2020). See Exhibit 20.

U. Pandemic

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following description of 'pandemic' from *Farlex Partner Medical Dictionary*:"disease affecting or attacking the population of an extensive region, country, continent, global; extensively epidemic."

Citation: *Farlex Partner Medical Dictionary*. (2012). https://medical-dictionary.thefreedictionary.com/pandemic, (accessed July 1, 2020). See Exhibit 21.

V. Pathogenesis

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'pathogenesis' from *Farlex Partner Medical Dictionary*:"the pathologic, physiologic, or biochemical mechanism resulting in the development of a disease or morbid process."

Citation: *Farlex Partner Medical Dictionary*. (2012). https://medical-dictionary.thefreedictionary.com/pathogenesis, (accessed July 1, 2020). See Exhibit 22.

W. Permanent injury

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'permanent injury' from Legal Information Institute, Cornell Law School: "physical or mental damage that will indefinitely restrict the employment or other normal activities of an individual."

Citation: Legal Information Institute, Cornell Law School. *Permanent Injury*. https://www.law.cornell.edu/wex/permanent_injury, (accessed June 29, 2020). See Exhibit 23.

X. Public health

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following description of 'public health' from the CDC Foundation: "Public health is the science of protecting and improving the health of people and their communities. This work is achieved by promoting healthy lifestyles, researching disease and injury prevention, and detecting, preventing and responding to infectious diseases."

Citation: CDC Foundation, *What Is Public Health?* https://www.cdcfoundation.org/what-public-health, (accessed July 1, 2020). See Exhibit 24.

Y. Progressive disease

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'progressive disease' from *Segen's Medical Dictionary*: "any chronic or dread disease (e.g., cancer), which progresses with time in scope and/or severity."

Citation: *Segen's Medical Dictionary*. (2012). https://medical-dictionary.thefreedictionary.com/progressive+disease, (accessed July 1, 2020). See Exhibit 25.

Z. Regression

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'regression' from *The American Heritage® Medical Dictionary* used in *Medicine*:"subsidence of the symptoms or process of a disease."

Citation: *The American Heritage® Medical Dictionary*. (2007). https://medical-dictionary.thefreedictionary.com/regression, (accessed July 1, 2020). See Exhibit 26.

2. U.S. Infant Mortality Rate (IMR)

A. Definition and infant mortality rate statistics for 2017

(1) For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'infant mortality rate' from the Centers for Disease Control and Prevention website: 'infant mortality rate (IMR) is "the ratio of infant deaths to live births in a given year." '

Citation: Murphy *et al*. (2018). Mortality in the United States, 2017. NCHS Data Brief No. 328. https://www.cdc.gov/nchs/data/databriefs/db328-h.pdf, (accessed June 9, 2020). See Exhibit 27.

(2) For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following statistics published by the Centers for Disease Control and Prevention for the most recent year (2017) for which data are available: "A total of 22,335 deaths occurred in children under age 1 year in the United States in 2017, with an infant mortality rate of 579.3 infant deaths per 100,000 live births."

Citation: Murphy *et al*. (2018). Mortality in the United States, 2017. NCHS Data Brief No. 328. https://www.cdc.gov/nchs/data/databriefs/db328-h.pdf, (accessed June 9, 2020). See Exhibit 27.

B. U.S. infant mortality rate comparison to other OECD countries

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 Centers for Disease Control and Prevention website:

> "In 2010, the U.S. infant mortality rate was 6.1 infant deaths per 1,000 live births, and the United States ranked 26th in infant mortality among Organization for Economic Cooperation and Development [OECD] countries. After excluding births at less than 24 weeks of gestation to ensure international comparability, the U.S. infant mortality rate was 4.2, still higher than for most European countries and about twice the rates for Finland, Sweden, and Denmark."

Citation: MacDorman *et al*. (2014). International comparisons of infant mortality and related factors: United States and Europe, 2010. *National Vital Statistics Reports* 63(5):1-6.

https://www.cdc.gov/nchs/data/nvsr/nvsr63/nvsr63_05.pdf, (accessed June 9, 2020). See Exhibit 28.

C. Vaccination in etiology of all-cause mortality

1. 5-Fold Higher Mortality

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from an article published in *EBioMedicine:*

> *"*DTP was associated with 5-fold higher mortality than being unvaccinated. No prospective study has shown beneficial survival effects of DTP. Unfortunately, DTP is the most widely used vaccine, and the proportion who receives DTP3 is used globally as an indicator of the performance of national vaccination programs. It should be of concern that the effect of routine vaccinations on all-cause mortality was not tested in randomized trials. All currently available evidence suggests that DTP vaccine may kill more children from other causes than it saves from diphtheria, tetanus or pertussis. Though a vaccine protects children against the target disease it may simultaneously increase susceptibility to unrelated infections."

Citation: Mogensen, S.W., et al. (2017), *The Introduction of Diphtheria-Tetanus-Pertussis and Oral Polio Vaccine Among Young Infants in an Urban African Community: A Natur...*, EBioMedicine, http://dx.doi.org/10.1016/j.ebiom.2017.01.041 (accessed June 23, 2020). See Exhibit 29.

2. Increased Susceptibility

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from an article published in *Natural Reviews Immunology*:

> "Non-live vaccines (such as DTP vaccine, the pentavalent vaccine for DTP, hepatitis B virus (HBV) and Haemophilus influenzae type b, inactivated polio vaccine, single HBV vaccine, the RTS,S/AS01 malaria vaccine, and the H1N1 influenza vaccine) seem to increase susceptibility to vaccine-unrelated infections, particularly in females. Hence, non-live vaccines may have beneficial effects in preventing the target infection but negative effects by enhancing susceptibility to non-target infections. In epidemiological studies, the negative effects seem to be more pronounced than the beneficial effects, with the net effect being increased overall mortality for females."

Citation: Aaby *et al*. (2020). *The non-specific and sex-differential effects of vaccines. Nature Reviews Immunology*. https://doi.org/10.1038/s41577-020-0338-x, (accessed June 9, 2020). See Exhibit 30.

3. Sudden Infant Death Syndrome (SIDS) and Sudden Unexpected Infant Death (SUID)

A. Definitions

1. SIDS

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'sudden infant death syndrome' from *Gale Encyclopedia of Medicine*: "Sudden infant death syndrome (SIDS) is the unexplained death without warning of an apparently healthy infant, usually during sleep."

Citation: *Gale Encyclopedia of Medicine*. (2008). https/medical-dictionary.thefreedictionary.com/sudden+infant+death+syndrome, (accessed July 1, 2020). See Exhibit 31.

2. SUID

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following description of 'sudden unexpected infant death' from the Centers for Disease Control and Prevention: "Sudden unexpected infant deaths include sudden infant death syndrome (SIDS), accidental suffocation in a sleeping environment, and other deaths from unknown causes."

Citation: Centers for Disease Control and Prevention, *About SUID and SIDS.* https://www.cdc.gov/sids/about/index.htm, (accessed July 1, 2020). See Exhibit 32.

B. SIDS is leading cause of U.S. infant mortality

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from a chapter in *SIDS Sudden Infant and Early Childhood Death: The Past, the Present and the Future:* "Despite national safe sleep campaigns, SIDS remains the leading cause of post-neonatal infant mortality in the United States, with an overall rate of 0.40 SIDS deaths per 1,000 live births."

Citation: Haynes RL. Chapter 32. Biomarkers of Sudden Infant Death Syndrome (SIDS) Risk and SIDS Death. In: Duncan JR, Byard RW, eds. *SIDS Sudden Infant and Early Childhood Death: The Past, the Present and the Future*. Adelaide (AU): University of Adelaide Press; 2018. https://www.ncbi.nlm.nih.gov/books/NBK513404, (accessed July 1, 2020). See Exhibit 33.

C. SUID proportion of full-term infant deaths in the U.S.

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from a study published in *Public Library of Science* (*PLoS*) *Medicine:* "Sudden unexpected death in infancy (SUID) accounted for 43% of FTIM [full-term infant mortality]."

Citation: Bairoliya & Fink. (2018). Causes of death and infant mortality rates among full-term births in the United States between 2010 and 2012: An observational study. *PLoS Med* 15(3): e1002531. https://doi.org/10.1371/journal.pmed.1002531, (accessed June 23, 2020). See Exhibit 34.

D. Vaccination in etiology of SIDS

(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 Centers of Disease Control and Prevention: "Babies receive multiple vaccines when they are between 2 to 4 months old. This age range is also the peak age for sudden infant death syndrome (SIDS)."

Citation: Centers for Disease Control and Prevention, *Vaccines and Sudden Infant Death Syndrome* (*SIDS*). https://www.cdc.gov/vaccinesafety/concerns/sids.html, (accessed June 23, 2020). See Exhibit 35.

(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 a study published in *Indian Journal of Medical Ethics:* "the number of observed deaths soon after vaccination among children older than one year was significantly higher than that expected by chance."

Citation: Puliyel & Sathyamala (2018). Infanrix hexa and sudden death: a review of the periodic safety update reports submitted to the European Medicines Agency. *Indian Journal of*

Medical Ethics 3(1):43-47. https://doi.org/10.20529/IJME.2017.079, (accessed June 9, 2020). See Exhibit 36.

(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 a 2008 post-mortem study of an infant SIDS death published in *Forensic Science International*: "acute respiratory failure likely due to post hexavalent immunization-related shock was the cause of death."

Citation: D'Errico *et al*. (2008). Beta-tryptase and quantitative mast-cell increase in a sudden infant death following hexavalent immunization. *Forensic Science International* 179(2-3):e25-e29. https://doi.org/10.1016/j.forsciint.2008.04.018, (accessed June 9, 2020). See Exhibit 37.

(4) For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from a study published in *Current Medicinal Chemistry*: "vaccine components could have a direct role in sparking off a lethal outcome in vulnerable babies."

Citation: Matturri *et al*. (2014). Sudden infant death following hexavalent vaccination: a neuropathologic study. *Current Medicinal Chemistry* 21(7):941-946. https://doi.org/10.2174/09298673113206660289, (accessed June 9, 2020). See Exhibit 38.

(5) Forensic Pathology

Introduction

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from A study published in The American Journal of Forensic Medicine and Pathology reported that 21.9 percent of 32 cases of SIDS death occurred within seven days of vaccination and three cases of infants who died within three days of vaccination selected for immunopathological examination were reported to have immunological pathology suggestive of a plausible role for vaccination in the deaths and stated that: "The important question of whether the disorders are truly related to vaccination remains."

Request for 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 The American Journal of

Forensic Medicine and Pathology: "Forensic pathologists must devote more attention to vaccination in sudden infant death cases."

Citation: Osawa *et al*. (2019). Sudden Infant Death After Vaccination. *The American Journal of Forensic Medicine and Pathology* 40(3):232-237. https://doi.org/10.1097/PAF.0000000000000494, (accessed May 19, 2020). See Exhibit 39.

4. Chronic Disease

A. Definition

There is a degree of variation in the definition of 'chronic disease' by authoritative sources. For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definitions of 'chronic disease' from (i) MedicineNet: 'chronic disease is "a disease that persists for a long time. A chronic disease is one lasting 3 months or more, by the definition of the U.S. National Center for Health Statistics," or from (ii) the Centers for Disease Control and Prevention website: 'chronic diseases are "conditions that last 1 year or more and require ongoing medical attention or limit activities of daily living or both." '

Citations:

(1) MedicineNet, *Medical Definition of Chronic disease; Medical Author: William C. Shiel Jr., MD, FACP, FACR.* https://www.medicinenet.com/script/main/art.asp?articlekey=33490, (accessed July 1, 2020). See Exhibit 40.

(2) National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, *About Chronic Diseases*. https://www.cdc.gov/chronicdisease/about/index.htm, (accessed July 1, 2020). See Exhibit 41.

B. Prevalence of pediatric chronic diseases

(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 *Academic Pediatrics*:

> "An estimated 43% of US children (32 million) currently have at least 1 of 20 chronic health conditions assessed, increasing to 54.1% when overweight, obesity, or being at risk for developmental delays are included; 19.2% (14.2 million) have conditions resulting in a special health care need, a 1.6 point

increase since 2003."

Citation: Bethell *et al*. (2011). A national and state profile of leading health problems and health care quality for US children: key insurance disparities and across-state variations. *Academic Pediatrics* 11(3 Suppl):S22-S33. https://doi.org/10.1016/j.acap.2010.08.011, (accessed June 10, 2020). See Exhibit 42.

(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 Centers for Disease Control and Prevention: "Approximately 27% of children in the United States have a chronic condition and 1 in 15 have MCCs [multiple chronic conditions]."

Citation: Centers for Disease Control and Prevention, *Multiple Chronic Conditions Among Outpatient Pediatric Patients, Southeastern Michigan, 2008–2013*. BRIEF, Vol. 12, 2015. https://www.cdc.gov/pcd/issues/2015/14_0397.htm, (accessed June 10, 2020). See Exhibit 43.

C. Growing prevalence of chronic illness among U.S. children

(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 a study published in *Journal of the American Medical Association (JAMA): ' "*Prevalence of chronic conditions among children and youth increased from 1988 to 2006," with end-study prevalence of any chronic health condition being 12.8% in 1994, 25.1% in 2000, and 26.6% in 2006, and with higher rates among male, Hispanic, and Black youth.'

Citation: Van Cleave *et al*. (2010). Dynamics of Obesity and Chronic Health Conditions among Children and Youth. *JAMA* 303(7):623–630. https://doi.org/10.1001/jama.2010.104, (accessed June 10, 2020). See Exhibit 44.

(2) For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quotes from a study published in *Health Affairs*: 1) "Despite decreases in infectious diseases and trends of initial survival improvement in generally rare and complex conditions followed by mainly stable rates of these conditions, total rates of chronic health conditions and disability among children and youth continued to rise steadily over the past half-century." 2) "In 1960, 1.8 percent of children were reported to have a health

condition severe enough to interfere with usual daily activities." 3) "In 2010, more than 8 percent of children had a health condition that interfered with daily activities—an increase of more than 400 percent in fifty years."

Citation: Perrin *et al*. (2014). The rise in chronic conditions among infants, children, and youth can be met with continued health system innovations. *Health Affairs* 33(12):2099-2105. https://doi.org/10.1377/hlthaff.2014.0832, (accessed June 10, 2020). See Exhibit 45.

(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 Centers for Disease Control and Prevention website: "Research indicates that the prevalence of chronic conditions is on the rise among pediatric patients."

Citation: Centers for Disease Control and Prevention, *Multiple Chronic Conditions Among Outpatient Pediatric Patients, Southeastern Michigan, 2008–2013*. BRIEF, Vol. 12, 2015. https://www.cdc.gov/pcd/issues/2015/14_0397.htm, (accessed June 10, 2020). See Exhibit 43.

D. Prescription drug use by American children and adolescents

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from a study published in *Pediatrics*: "One-fifth of children and adolescents regularly use prescription medications with nearly 1 in 12 concurrent users of prescription medications at risk for a major drug–drug interaction."

Citation: Dima *et al*. (2018). Prescription Medication Use Among Children and Adolescents in the United States. *Pediatrics* 142(3):e20181042. https://doi.org/10.1542/peds.2018-1042, (accessed June 10, 2020). See Exhibit 46.

E. Frequency of chronic disease in U.S. adults

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 Centers of Disease Control and Prevention website: "Six in 10 adults in the US have a chronic disease. Four in 10 have two or more."

Citation: National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, *Chronic Diseases in America*.

https://www.cdc.gov/chronicdisease/resources/infographic/chronic-diseases.htm, (accessed July 1, 2020). See Exhibit 47.

F. Growing prevalence of chronic disease in U.S. adults

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 Aspen Health Strategy Group report: "The prevalence of chronic disease and the number of patients with multiple chronic conditions have increased markedly over the past two decades. Compared to 8% in 1995, 18% of adults were treated for five or more chronic diseases in 2015."

Citation: Aspen Health Strategy Group, The Aspen Institute, Washington DC (2019). *Reducing the Burden of Chronic Disease*. https://assets.aspeninstitute.org/content/uploads/2019/02/AHSG-Chronic-Disease-Report-2019.pdf, (accessed May 2, 2020). See Exhibit 48.

G. Economic burden of chronic illness

(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 Centers of Disease Control and Prevention website: "90% of the nation's $3.5 trillion in annual health care expenditures, are for people with chronic and mental health conditions."

Citation: National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, *Health and Economic Costs of Chronic Diseases.* https://www.cdc.gov/chronicdisease/about/costs/index.htm#ref1, (accessed July 1, 2020). See Exhibit 49.

(2) For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quotes from a report in the *Annual Review of Public Health*: 1) "Chronic diseases impose an enormous and growing burden on individuals, families, and society, as well as on health care systems in the United States and globally." 2) "[chronic diseases] account for most deaths and are major contributors to disability and health care costs." 3) "Overall U.S. costs of chronic disease are projected to accumulate by

2030 to more than $42 trillion, with medical outlays and productivity losses costing $8,600 per person."

Citation: Allegrante *et al*. (2019). Interventions to Support Behavioral Self-Management of Chronic Diseases. *Annual Review of Public Health* 40:127-146. https://doi.org/10.1146/annurev-publhealth-040218-044008, (accessed May 2, 2020). See Exhibit 50.

(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 Partnership to Fight Chronic Disease Health fact sheet, "care coverage costs for people with a chronic condition average $6,032 annually – five times higher than for those without such a condition."

Citation: The Partnership to Fight Chronic Disease, *Fact Sheet: The Growing Crisis of Chronic Disease in the United States*. https://www.fightchronicdisease.org/sites/default/files/docs/GrowingCrisisofChronicDiseaseintheUSfactsheet_81009.pdf, (accessed May 2, 2020). See Exhibit 51.

5. Developmental disabilities

A. Definition

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'developmental disabilities' from the Centers for Disease Control and Prevention website: "Developmental disabilities are a group of conditions due to an impairment in physical, learning, language, or behavior areas."

Citation: Centers for Disease Control and Prevention, *Developmental Disabilities*. https://www.cdc.gov/ncbddd/developmentaldisabilities/index.html, (accessed July 1, 2020). See Exhibit 52.

B. Incidence of pediatric developmental disabilities

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following fact from the Centers for Disease Control and Prevention website: "Recent estimates in the United States show that about one in six, or about 17%, of children aged 3 through 17 years have one or more developmental disabilities…"

Citation: Centers for Disease Control and Prevention, *Developmental Disabilities*. https://www.cdc.gov/ncbddd/developmentaldisabilities/facts.html (accessed July 1, 2020). See Exhibit 53.

6. Neurodevelopmental disorders (NDD)

A. Definition

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'neurodevelopmental disorders' from *The American Heritage® Medical Dictionary:* "any of various conditions, including attention deficit hyperactivity disorder, autism, intellectual disability, and learning disabilities, that begin in childhood and involve impairments in neurological functioning that affect behavior, cognition, or motor skills."

Citation: *The American Heritage® Medical Dictionary*. (2007) https://medical-dictionary.thefreedictionary.com/Neurodevelopmental+disorders, (accessed July 1, 2020). See Exhibit 54.

B. Prevalence of NDD

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from a review published in *The Lancet Neurology*: "Neurodevelopmental disabilities, including autism, attention-deficit hyperactivity disorder, dyslexia, and other cognitive impairments, affect millions of children worldwide, and some diagnoses seem to be increasing in frequency."

Citation: Grandjean & Landrigan (2014). Neurobehavioural effects of developmental toxicity. *Lancet Neurology* 13(3):330–338. https://doi.org/10.1016/S1474-4422(13)70278-3, (accessed April 27, 2020). See Exhibit 55.

C. Etiology of NDD

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

> "The root causes of the present global pandemic of neurodevelopmental disorders are only partly understood. Although genetic factors have a role, they cannot explain recent increases in reported prevalence, and none of the genes discovered so far seem to be responsible for more than a small proportion of cases. Overall, genetic factors seem to account for no more than perhaps 30–40% of all cases of neurodevelopmental disorders. Thus, non-genetic, environmental exposures are involved in causation, in some cases probably by interacting with genetically inherited predispositions."

Citation: Grandjean & Landrigan (2014). Neurobehavioural effects of developmental toxicity. *Lancet Neurology* 13(3):330–338. https://doi.org/10.1016/S1474-4422(13)70278-3, (accessed April 27, 2020). See Exhibit 55.

7. Autism spectrum disorder (ASD)

A. Definitions

1. Autism

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'autism' from *Gale Encyclopedia of Medicine:* "Autism is a complex developmental disorder distinguished by difficulties with social interaction, verbal and nonverbal communication, and behavioral problems, including repetitive behaviors and narrow focus of interest."

Citation: *Gale Encyclopedia of Medicine*. (2008). https://medical-dictionary.thefreedictionary.com/autism, (accessed July 1, 2020). See Exhibit 56.

2. Autism spectrum disorder (ASD)

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'autism spectrum disorder' from *The American Heritage® Medical Dictionary*: "a neurodevelopmental disorder starting in early childhood, characterized by impairments in social interaction and communication and by restricted or repetitive patterns of behavior, with symptoms varying from mild to severe."

Citation: *The American Heritage® Medical Dictionary*. (2007). https://medical-dictionary.thefreedictionary.com/autism+spectrum+disorders, (accessed April 27, 2020). See Exhibit 57.

B. Prevalence of ASD

(1) For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following finding from a study published in *Pediatrics* that '1 in 40 children between ages 3 to 17 had ASD.'

Citation: Kogan *et al*. (2018). The Prevalence of Parent-Reported Autism Spectrum Disorder Among US Children. *Pediatrics* 142(6):e20174161. https://doi.org/10.1542/peds.2017-4161, (accessed April 27, 2020). See Exhibit 58.

(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 the 2020 report from the Centers for Disease Control and Prevention, "For 2016, across all 11 sites, ASD prevalence was 18.5 per 1,000 (one in 54) children aged 8 years, and ASD was 4.3 times as prevalent among boys as among girls."

Citation: Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, March 27, 2020. *Prevalence of Autism Spectrum Disorder Among Children Aged 8 Years — Autism and Developmental Disabilities Monitoring Network, 11 Sites, United States, 2016.* https://www.cdc.gov/mmwr/volumes/69/ss/ss6904a1.htm?s_cid=ss6904a1_w, (accessed July 1, 2020). See Exhibit 59.

C. Rising prevalence of ASD

(1) For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following finding from a study published in *Journal of Autism and Developmental Disorders* that 'diagnoses of autism spectrum disorder in western California experienced a more than 100 1000-fold between birth year 1931, when prevalence was only ~ 0.001%, and birth year 2012, when prevalence had increased to 1.18% among 5 year-olds born in that year.'

Citation: Nevison *et al*. (2018). California Autism Prevalence Trends from 1931 to 2014 and Comparison to National ASD Data from IDEA and ADDM. *Journal of Autism and Developmental Disorders* 48:4103–4117. https://doi.org/10.1007/s10803-018-3670-2, (accessed April 27, 2020). See Exhibit 60.

(2) For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following findings in the *Summary of Autism Spectrum Disorder* (*ASD*) *Prevalence Studies* from the Centers of Disease Control and Prevention website, which indicates that the prevalence of ASD has soared from 0.07-.31 per 1,000 American children in the 1960s to 14.6 in 1,000 American children in 2012.

Citation: Centers for Disease Control and Prevention, *Summary of Autism Spectrum Disorder* (*ASD*) *Prevalence Studies*. https://www.cdc.gov/ncbddd/autism/documents/ASDPrevalenceDataTable2016-508.pdf, (accessed April 27, 2020). See Exhibit 61.

D. Comorbid conditions in ASD

(1) For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following finding from a review published in *Psychiatry Research* that 'comorbid psychiatric disorders among people with ASD include "anxiety disorders, depressive disorders, bipolar and mood disorders, schizophrenia spectrum, suicidal behavior disorders, attention-deficit/hyperactivity disorder, disruptive, impulse-control and conduct disorders amongst diverse age groups, with a majority in younger participants." '

Citation: Hossain *et al*. (2020). Prevalence of comorbid psychiatric disorders among people with autism spectrum disorder: An umbrella review of systematic reviews and meta-analyses. *Psychiatry Research* 287:112922. https://doi.org/10.1016/j.psychres.2020.112922, (accessed April 27, 2020). See Exhibit 62.

(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 Autism Speaks website: "A range of physical and mental-health conditions frequently accompany autism. They include, but are not limited to, the following: Gastrointestinal (GI) problems, Epilepsy, Feeding issues, Disrupted sleep, Attention-deficit/hyperactivity disorder (ADHD), Anxiety, Depression, Obsessive compulsive disorder (OCD), Schizophrenia, Bipolar Disorder."

Citation: Autism Speaks, *Medical Conditions Associated with Autism*. https://www.autismspeaks.org/medical-conditions-associated-autism, (accessed July 1, 2020). See Exhibit 63.

E. Etiology of ASD

(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 Centers for Disease Control and Prevention website: "There may be many different factors that make a child more likely to have an ASD, including environmental, biologic and genetic factors."

Citation: Centers for Disease Control and Prevention, *What is Autism Spectrum Disorder?* https://www.cdc.gov/ncbddd/autism/facts.html, (accessed July 1, 2020). See Exhibit 64.

(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 a review published in Neuropsychopharmacology:

> "research emerging within the past two decades suggests that immune dysfunction is a viable risk factor contributing to the neurodevelopmental deficits observed in autism spectrum disorders (ASD)… Further definition of the role of immune dysregulation in ASD thus necessitates a deeper understanding of the interaction between both maternal and child immune systems."

Citation: Meltzer & Van de Water (2017). The Role of the Immune System in Autism Spectrum Disorder. Neuropsychopharmacology 42(1):284-298. https://doi.org/10.1038/npp.2016.158, (accessed May 7, 2020). See Exhibit 65.

(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 a review published in *Environmental Health Perspectives*: "There is a pressing need to move forward quickly and efficiently to understand environmental influences on autism in order to answer current regulatory questions and inform treatment and prevention efforts."

Citation: Pelch *et al*. (2019). Environmental Chemicals and Autism: A Scoping Review of the Human and Animal Research. *Environmental Health Perspectives* 127(4):46001. https://doi.org/10.1289/EHP4386, (accessed May 1, 2020). See Exhibit 66.

F. Prenatal immune activation in etiology of ASD

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from a review published in *Trends in Molecular Medicine*: "The offspring of infected, or immune-activated dams also display cardinal behavioral features of autism, as well as neuropathology consistent with that seen in human autism."

Citation: Patterson (2011). Maternal infection and immune involvement in autism. *Trends in Molecular Medicine* 17(7):389-394. https://doi.org/10.1016/j.molmed.2011.03.001, (accessed May 1, 2020). See Exhibit 67.

G. Economic burden of ASD

(1) For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following findings from a study published in *Pediatrics that* 'children with parent-reported ASD had higher levels of health care office visits and prescription drug use compared with children without ASD; 76% of children with ASD used special educational services compared to just 7% of children in the control group; and ASD was associated with $3020 higher health care costs and $14,061 higher aggregate non–health care costs, including $8610 higher school costs.'

Citation: Lavelle *et al*. (2014). Economic burden of childhood autism spectrum disorders. *Pediatrics* 133(3):e520–e529. https://doi.org/10.1542/peds.2013-0763, (accessed May 1, 2020). See Exhibit 68.

(2) For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following figures from the Autism Speaks website reflecting research by London School of Economics and the University of Pennsylvania that 'the cost to society of autism had tripled between 2006 and 2012 to $126 Billion per year and the costs of providing care for each person with autism affected by intellectual disability through his or her lifespan are $2.3 million compared to $1.4 for those with no intellectual disability.'

Citation: Autism Speaks, *New Research Finds Annual Cost of Autism Has More Than Tripled to $126 Billion in the U.S. and Reached £34 Billion in the U.K.*

https://www.autismspeaks.org/press-release/new-research-finds-annual-cost-autism-has-more-tripled-126-billion-us-and-reached, (accessed July 1, 2020). See Exhibit 69

8. Attention-deficit hyperactivity disorder (ADHD)

A. Definition

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'attention-deficit hyperactivity disorder' from *Gale Encyclopedia of Medicine*: 'attention-deficit hyperactivity disorder is "a condition in which a person (usually a child) has an unusually high activity level and a short attention span. People with the disorder may act impulsively and may have learning and behavioral problems." '

Citation: *Gale Encyclopedia of Medicine*. (2008). https://medical-dictionary.thefreedictionary.com/Attention-deficit+hyperactivity+disorder, (accessed July 1, 2020). See Exhibit 70.

B. Prevalence of ADHD in U.S. children

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 Centers for Disease Control and Prevention website: "The estimated number of children ever diagnosed with ADHD, according to a national 2016 parent survey, is 6.1 million (9.4%). This number includes: 388,000 children aged 2–5 years, 4 million children aged 6–11 years, 3 million children aged 12–17 years."

Citation: Centers for Disease Control and Prevention, *Data and Statistics about ADHD.* https://www.cdc.gov/ncbddd/adhd/data.html, (accessed July 1, 2020). See Exhibit 71.

C. Prevalence of ADHD in U.S. adults

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 Institute of Mental Health (NIMH) website: "The overall prevalence of current adult ADHD is 4.4%. Prevalence was higher for males (5.4%) versus females (3.2%). The non-Hispanic white group (5.4%) had a higher prevalence than all other race/ethnicity groups. The estimated lifetime prevalence of ADHD in U.S. adults aged 18 to 44 years was 8.1%."

Citation: National Institute of Mental Health, Attention-Deficit/Hyperactivity Disorder (ADHD), https://www.nimh.nih.gov/health/statistics/attention-deficit-hyperactivity-disorder-adhd.shtml, (accessed July 1, 2020). See Exhibit 72.

D. Growing Prevalence of ADHD

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 Centers for Disease Control and Prevention website:

> "The percentage of US children 4-17 years of age with an ADHD diagnosis by a health care provider, as reported by parents, continues to increase. A history of ADHD diagnosis by a health care provider increased by 42% between 2003 and 2011: 7.8% had ever had a diagnosis in 2003, 9.5% had ever had a diagnosis in 2007, 11.0% had ever had a diagnosis in 2011. Average annual increase was approximately 5% per year."

Citation: Centers for Disease Control and Prevention, *Trends in the Parent-Report of Health Care Provider-Diagnosis and Medication Treatment for ADHD: United States, 2003—2011*. https://www.cdc.gov/ncbddd/adhd/features/key-findings-adhd72013.html, (accessed February 29, 2020). See Exhibit 73.

E. Prevalence of medicated ADHD

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following description of 'attention-deficit hyperactivity disorder' from a study published in *Journal of the American Academy of Child & Adolescent Psychiatry*: "[in 2011], 69% of children with current ADHD were taking medication for ADHD (6.1%, 3.5 million children)." "Prevalence of medicated ADHD increased by 28% from 2007—2011."

Citation: Visser *et al*. (2014). Trends in the parent-report of health care provider-diagnosed and medicated attention-deficit/hyperactivity disorder: United States, 2003-2011. *Journal of the American Academy of Child & Adolescent Psychiatry* 53(1):34–46.e2. https://doi.org/10.1016/j.jaac.2013.09.001, (accessed May 1, 2020). See Exhibit 74.

F. Comorbid conditions in ADHD

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 Centers for Disease Control and Prevention website:

> "According to a national 2016 parent survey, 6 in 10 children with ADHD had at least one other mental, emotional, or behavioral disorder. About 5 in 10 children with ADHD had a behavior or conduct problem. About 3 in 10 children with ADHD had anxiety. Other conditions affecting children with ADHD: depression, autism spectrum disorder, and Tourette Syndrome."

Citation: Centers for Disease Control and Prevention, *Data and Statistics about ADHD*. https://www.cdc.gov/ncbddd/adhd/data.html, (accessed July 1, 2020). See Exhibit 71.

G. Etiology of ADHD

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from WebMD: "No one knows exactly what causes ADHD, but certain things are known to play a role…. Researchers believe that some toxins may interfere with brain development. That, they say, could lead to hyperactivity, impulsive behavior, and trouble paying attention."

Citation: WebMD, *Attention Deficit Hyperactivity Disorder: Causes of ADHD*. https://www.webmd.com/add-adhd/childhood-adhd/adhd-causes, (accessed April 28, 2020). See Exhibit 76.

H. Societal impact of ADHD

(1) For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quotes from a study published in *Journal of Abnormal Child Psychology*: 1. "For children with ADHD, an elevated risk for non-normative delinquency is just one of a slew of probable negative life outcomes, including school drop-out, interpersonal difficulties, substance use, and unemployment." 2."Individuals with childhood ADHD+CD [Conduct Disorder] displayed significantly worse delinquency outcomes than the other three groups, across almost all indices of offending. When compared to comparison participants, boys with ADHD-only and ADHD+ODD [Oppositional Defiant Disorder] in childhood displayed

earlier ages of delinquency initiation, a greater variety of offending, and higher prevalence of severe delinquency."

Citation: Sibley *et al*. (2010). The delinquency outcomes of boys with ADHD with and without comorbidity. *Journal of Abnormal Child Psychology* 39(1):21-32. https://doi.org/10.1007/s10802-010-9443-9, (accessed May 1, 2020). See Exhibit 77.

(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 an original article published in *Archives of Disease in Childhood*:

> "Attention deficit/hyperactivity disorder (ADHD) may affect all aspects of a child's life. Indeed, it impacts not only on the child, but also on parents and siblings, causing disturbances to family and marital functioning. The adverse effects of ADHD upon children and their families changes from the preschool years to primary school and adolescence, with varying aspects of the disorder being more prominent at different stages. ADHD may persist into adulthood causing disruptions to both professional and personal life."

Citation: Harpin (2005). The effect of ADHD on the life of an individual, their family, and community from preschool to adult life. *Archives of Disease in Childhood* 90(Suppl 1):i2-i7. https://doi.org/10.1136/adc.2004.059006, (accessed May 1, 2020). See Exhibit 78.

(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 a study published in *Child and Adolescent Psychiatry and Mental Health*: "Children with ADHD and comorbid depression, anxiety, or phobias had significantly greater odds of experiencing > 2 weeks of missed school days, ≥ 6 visits to a healthcare provider (HCP), and ≥ 2 visits to the ER, compared with ADHD children without those comorbidities."

Citation: Classi *et al*. (2012). Social and emotional difficulties in children with ADHD and the impact on school attendance and healthcare utilization. *Child and Adolescent Psychiatry and Mental Health* 6(1):33. https://doi.org/10.1186/1753-2000-6-33, (accessed May 1, 2020). See Exhibit 79.

(4) For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from a study published in *Journal of the American Academy of Child & Adolescent Psychiatry*:

> "Attention-deficit/hyperactivity disorder (ADHD) is a neurobehavioral disorder with childhood onset. Children with ADHD experience clinically significant functional impairment across settings (for example at home, in school, and with friends), resulting in higher rates of unintentional injury, emergency room visits, peer problems, and academic failure. Approximately one-third of children diagnosed with ADHD retain the diagnosis into adulthood, supporting the recognition of ADHD as a chronic health condition."

Citation: Visser *et al*. (2014). Trends in the parent-report of health care provider-diagnosed and medicated attention-deficit/hyperactivity disorder: United States, 2003-2011. *Journal of the American Academy of Child & Adolescent Psychiatry* 53(1):34–46.e2. https://doi.org/10.1016/j.jaac.2013.09.001, (accessed May 1, 2020). See Exhibit 74.

I. Lasting impairment in adults with history of ADHD in childhood

(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 a study published in *Journal of Clinical Child & Adolescent Psychology*:

> "Adults with childhood attention-deficit hyperactivity disorder (ADHD) experience impairment in core functional domains (e.g., educational attainment, occupational status, social relationships, substance abuse, and criminal behavior)" and in this study to characterize impairment it was found that, "Nearly all young adult ADHD profiles were impaired in peer, educational, and financial domains, and there was not a non-impaired ADHD profile."

Citation: Merrill *et al*. (2020). Functional Outcomes of Young Adults with Childhood ADHD: A Latent Profile Analysis. *Journal of Clinical Child & Adolescent Psychology*, 49(2):215-228. https://doi.org/10.1080/15374416.2018.1547968, (accessed June 24, 2020). See Exhibit 80.

(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 a study published in *Journal of Consulting and Clinical Psychology*:

> "At age 30, adults with a history of ADHD exhibited substantially worse outcomes than controls on most financial indicators, even when they and their

> parents no longer endorsed any DSM symptoms of ADHD. Between ages 25 and 30, probands had exhibited considerably slower growth than controls in positive financial indicators (e.g., monthly income) and substantially less reduction than controls in indicators of financial dependence (e.g., living with parents), indicating worsening or sustained deficits on nearly all measures. When earnings trajectories from age 25 to age 30 were extrapolated using matched census data, male probands were projected to earn $1.27 million less than controls over their working lifetime, reaching retirement with up to 75% lower net worth."

Citation: Pelham *et al*. (2020). The long-term financial outcome of children diagnosed with ADHD. *Journal of Consulting and Clinical Psychology* 88(2):160-171. https://doi.org/10.1037/ccp0000461, (accessed May 1, 2020). See Exhibit 81.

J. Economic burden of ADHD

(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 a review published in *Current Medical Research & Opinion*:

> "The total excess cost of ADHD in the US in 2000 was $31.6 billion. Of this total, $1.6 billion was for the ADHD treatment of patients, $12.1 billion was for all other healthcare costs of persons with ADHD, $14.2 billion was for all other healthcare costs of family members of persons with ADHD, and $3.7 billion was for the work loss cost of adults with ADHD and adult family members of persons with ADHD. *Conclusion:* The annual cost of ADHD in the US is substantial. Both treated and untreated persons with ADHD, as well as their family members, impose considerable economic burdens on the healthcare system as a result of this condition."

Citation: Birnbaum *et al*. (2005). Costs of attention deficit-hyperactivity disorder (ADHD) in the US: excess costs of persons with ADHD and their family members in 2000. *Current Medical Research & Opinion* 21(2):195-206. https://doi.org/10.1185/030079904X20303, (accessed June24, 2020). See Exhibit 82.

(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 a review published in *Journal of the American Academy of Child & Adolescent Psychiatry:*

> "Overall national annual incremental costs of ADHD ranged from $143 to $266 billion (B). Most of these costs were incurred by adults ($105 B-$194 B) compared with children/adolescents ($38 B-$72 B). For adults, the largest cost category was productivity and income losses ($87 B-$138 B). For children, the largest cost categories were health care ($21 B-$44 B) and education ($15 B-$25

> B). Spillover costs borne by the family members of individuals with ADHD were also substantial ($33 B-$43 B). Conclusion: Despite a wide range in the magnitude of the cost estimates, this study indicates that ADHD has a substantial economic impact in the United States."

Citation*:* Doshi *et al.* (2012). Economic Impact of Childhood and Adult Attention-Deficit/Hyperactivity Disorder in the United States. *Journal of the American Academy of Child & Adolescent Psychiatry* 51(10):990-1002.e2. https://doi.org/10.1016/j.jaac.2012.07.008, (accessed June24, 2020). See Exhibit 83.

(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 a review published in *Cost Effectiveness and Resource Allocation*:

> "Results of the medical cost studies consistently indicated that children with ADHD had higher annual medical costs than either matched controls (difference ranged from $503 to $1,343) or non-matched controls (difference ranged from $207 to $1,560) without ADHD. Two studies of adult samples found similar results, with significantly higher annual medical costs among adults with ADHD (ranging from $4,929 to $5,651) than among matched controls (ranging from $1,473 to $2,771)."

Citation: Matza *et al*. (2005). A review of the economic burden of ADHD. *Cost Effectiveness and Resource Allocation* 3:5. https://doi.org/10.1186/1478-7547-3-5, (accessed May 1, 2020). See Exhibit 84.

(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 a study published in *Journal of Attention Disorders*: 1. "In 2013, 1.4 million children aged 2 to 17 years were enrolled in NYS Medicaid." 2. "The ADHD cohort comprised 5.4% of all Medicaid-enrolled children." 3. "The total costs for the ADHD cohort (US$729.3 million) accounted for 18.1% of the total costs for children enrolled in NYS Medicaid."

Citation: Guo *et al*. (2018). Treatment Patterns and Costs Among Children Aged 2 to 17 Years With ADHD in New York State Medicaid in 2013. *Journal of Attention Disorders* 1087054718816176. https://doi.org/10.1177/1087054718816176, (accessed May 1, 2020). See Exhibit 85.

(5) For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quotes from a review of *School Mental Health*:

> 1. "Results indicated that, as compared to students without ADHD, students with ADHD incurred a higher annual cost to the US Education system. Specifically, a student with ADHD incurred an average annual incremental cost to society of $5,007, as compared with $318 for students in the comparison group."
>
> 2. "Assuming a conservative prevalence rate of 5% for ADHD in childhood and adolescence, and extrapolating these results to the U.S. population between the ages of 5-18 (U.S. Census Bureau, 2009), the estimated annual costs associated with ADHD total $13.4 billion to the U.S. Education System. Thus, the incremental lifetime cost of educating the population of children with ADHD is approximately $174 billion over 13 years of education."

Citation: Robb *et al*. (2011). The Estimated Annual Cost of ADHD to the U.S. Education System. *School Mental Health* 3(3):169-177. https://doi.org/10.1007/s12310-011-9057-6, (accessed May 1, 2020). See Exhibit 86.

9. Learning disorders/disabilities

A. Definition

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following description of 'learning disorders' from the Centers for Disease Control and Prevention website: "Having a learning disorder means that a child has difficulty in one or more areas of learning, even when overall intelligence or motivation is not affected…. Examples of Learning Disorders include: Dyslexia – difficulty with reading; Dyscalculia – difficulty with math; Dysgraphia – difficulty with writing."

Citation: Centers for Disease Control and Prevention, *Learning Disorders in Children*. https://www.cdc.gov/ncbddd/childdevelopment/learning-disorder.html, (accessed on July 1, 2020). See Exhibit 87.

B. Prevalence of learning disabilities

(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 a chapter in *Mental Disorders and Disabilities Among Low-Income Children*:

> "The estimate for current learning disabilities among children of ages 3–17 years in 2007 was 7.8 percent, with 3.7 percent rated as mild and 4.0 percent rated as moderate or severe (NSCH, 2007a,b). The estimate for learning disabilities in 2011–2012 was 8.0 percent for children of ages 3–17, with 4 percent rated as mild and 4 percent rated as moderate or severe (NSCH, 2012a)."

Citation: Boat TF, Wu JT, eds. Washington (DC): National Academies Press (US); 2015. *Mental Disorders and Disabilities Among Low-Income Children*. https://www.ncbi.nlm.nih.gov/books/NBK332880/, (accessed on May 8, 2020). See Exhibit 88.

(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 National Institute on Deafness and Other Communication Disorders (NIDCD) website:

> "Nearly 1 in 12 (7.7 percent) U.S. children ages 3-17 has had a disorder related to voice, speech, language, or swallowing in the past 12 months. Among children who have a voice, speech, language, or swallowing disorder, 34 percent of those ages 3-10 have multiple communication or swallowing disorders, while 25.4 percent of those ages 11-17 have multiple disorders. Boys ages 3-17 are more likely than girls to have a voice, speech, language, or swallowing disorder (9.6 percent compared to 5.7 percent)."

Citation: National Institutes of Health, National Institute on Deafness and Other Communication Disorders, *Quick Statistics About Voice, Speech, Language.* https://www.nidcd.nih.gov/health/statistics/quick-statistics-voice-speech-language, (accessed May 6, 2020). See Exhibit 89.

10. Epilepsy

A. Definition

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'epilepsy' from the Mayo Clinic website: "Epilepsy is a central nervous system (neurological) disorder in which brain activity becomes abnormal, causing seizures or periods of unusual behavior, sensations, and sometimes loss of awareness."

Citation: Mayo Clinic, *Epilepsy*, https://www.mayoclinic.org/diseases-conditions/epilepsy/symptoms-causes/syc-20350093, (accessed July 1, 2020). See Exhibit 90.

B. Prevalence of Epilepsy

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 Centers for Disease Control and Prevention website: "In 2015, 1.2% of the US population had active epilepsy. This is about 3.4 million people with epilepsy nationwide: 3 million adults and 470,000 children."

Citation: Centers for Disease Control and Prevention, *Epilepsy Data and Statistics.* https://www.cdc.gov/epilepsy/data/index.html, (accessed July 1, 2020). See Exhibit 91.

C. Increasing Prevalence of Epilepsy

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 Centers for Disease Control and Prevention website: "The number of adults with active epilepsy rose from 2.3 million in 2010 to 3 million in 2015. The number of children with the condition increased from 450,000 in 2007 to 470,000 in 2015."

Citation: Centers for Disease Control and Prevention, *More Americans have epilepsy than ever before.* https://www.cdc.gov/media/releases/2017/p0810-epilepsy-prevalence.html, (accessed July 1, 2020). See Exhibit 92.

11. Febrile seizures

A. Definition and Prevalence

(1) For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following description of 'febrile seizures' from the Centers for Disease Control and Prevention: "Sometimes, fevers can cause a child to experience spasms or jerky movements called seizures. Seizures caused by fever are called 'febrile seizures'."

Citation: Centers for Disease Control and Prevention, *Childhood Vaccines and Febrile Seizures*. https://www.cdc.gov/vaccinesafety/concerns/febrile-seizures.html, (accessed July 1, 2020). See Exhibit 93.

(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 Centers for Disease Control and Prevention website:

> "Up to 5% of young children will have a febrile seizure at some time in their life. Febrile seizures happen in children between the ages of 6 months and 5 years, with most occurring between 14–18 months of age. About 1 out of every 3 children who have a febrile seizure will have at least one more during childhood."

Citation: Centers for Disease Control and Prevention, *Childhood Vaccines and Febrile Seizures*. https://www.cdc.gov/vaccinesafety/concerns/febrile-seizures.html, (accessed July 1, 2020). See Exhibit 93.

B. Vaccination is a probable suspect in etiology of febrile seizures

(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 Centers for Disease Control and Prevention website: 1 ."Studies have shown that for children younger than 7 years old, there is a very small increased risk of febrile seizures approximately 6 to 14 days after MMR vaccination; this happens in about 1 in 3,000 to 4,000 children."

Citation: Centers for Disease Control and Prevention, *Measles, Mumps, Rubella (MMR) Vaccine, Safety Information.* https://www.cdc.gov/vaccinesafety/vaccines/mmr-vaccine.html, (accessed July 1, 2020). See Exhibit 94.

(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 Centers for Disease Control and Prevention website:

> "There is a small increased risk for febrile seizures when inactivated influenza vaccine (flu shot) is given at the same doctor visit as either the PCV13 (pneumococcal) vaccine or the DTaP vaccine…. There may be a small increase in the risk of febrile seizure when PCV13 (pneumococcal) vaccine is given by itself."

Citation: Centers for Disease Control and Prevention, *Childhood Vaccines and Febrile Seizures*. https://www.cdc.gov/vaccinesafety/concerns/febrile-seizures.html, (accessed July 1, 2020). See Exhibit 93.

C. Prevalence of febrile seizures

Citation: Centers for Disease Control and Prevention, *Childhood Vaccines and Febrile Seizures*. https://www.cdc.gov/vaccinesafety/concerns/febrile-seizures.html, (accessed July 1, 2020). See Exhibit 93.

12. Tourette syndrome (TS)

A. Definition

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'Tourette syndrome' from the U.S. National Library of Medicine: "Tourette syndrome is a complex disorder characterized by repetitive, sudden, and involuntary movements or noises called tics. Tics usually appear in childhood, and their severity varies over time."

Citation: U.S. National Library of Medicine, Genetics Home Reference. *Tourette Syndrome* (accessed on June 25, 2020). See Exhibit 95.

B. Prevalence of TS

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 Centers for Disease Control and Prevention website: "Studies that included children with diagnosed and undiagnosed TS [Tourette syndrome] have estimated that 1 of every 162 children (0.6%) have TS."

Citation: Centers for Disease Control and Prevention, *Data & Statistics on Tourette Syndrome*. https://www.cdc.gov/ncbddd/tourette/data.html, (accessed July 1, 2020). See Exhibit 96.

C. Etiology of TS

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 Centers for Disease Control and Prevention website: 1. "The causes of TS and other tic disorders are not well understood." 2. "Some research has shown that TS is a genetically complex disorder that likely occurs as a result of the effects of multiple genes interacting with other factors in the environment. Scientists are studying other possible causes and environmental risk factors that might contribute to TS."

Citation: Centers for Disease Control and Prevention, *Risk Factors and Causes for Tourette Syndrome*. https://www.cdc.gov/ncbddd/tourette/riskfactors.html, (accessed July 1, 2020). See Exhibit 97.

D. Comorbid conditions

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 Centers for Disease Control and Prevention website:

> "Among children diagnosed with TS, 86% also have been diagnosed with at least one additional mental, behavioral, or developmental disorder, such as: 63% had ADHD. 26% had behavioral problems, such as oppositional defiant disorder (ODD) or conduct disorder (CD). 49% had anxiety problems. 25% had depression. 35% had autism spectrum disorder. 47% had learning disabilities. 29% had speech or language problems. 30% had developmental delays. 12% had intellectual disabilities. More than one-third of people with TS also have obsessive-compulsive disorder. 42.6% have at least one co-occurring chronic health condition."

Citation: Centers for Disease Control and Prevention, *Data & Statistics on Tourette Syndrome*. https://www.cdc.gov/ncbddd/tourette/data.html, (accessed July 1, 2020). See Exhibit 96.

13. Mental Illness/Disorder

A. Any Mental Illness (AMI) and Serious Mental Illness (SMI)

(1) For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'any mental illness' from the National Institute of Mental Health website: "Any mental illness (AMI) is defined as a mental, behavioral, or emotional disorder. AMI can vary in impact, ranging from no impairment to mild, moderate, and even severe impairment (e.g., individuals with serious mental illness as defined below)."

Citation: National Institute of Mental Health, *Mental Illness*. https://www.nimh.nih.gov/health/statistics/mental-illness.shtml, (accessed July 1, 2020). See Exhibit 98.

(2) For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'serious mental illness' from

the National Institute of Mental Health website: "Serious mental illness (SMI) is defined as a mental, behavioral, or emotional disorder resulting in serious functional impairment, which substantially interferes with or limits one or more major life activities. The burden of mental illnesses is particularly concentrated among those who experience disability due to SMI."

Citation: National Institute of Mental Health, *Mental Illness*. https://www.nimh.nih.gov/health/statistics/mental-illness.shtml, (accessed July 1, 2020). See Exhibit 98.

(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 National Institute of Mental Health website: "In 2017, there were an estimated 46.6 million adults aged 18 or older in the United States with AMI. This number represented 18.9% of all U.S. adults."

Citation: National Institute of Mental Health, *Mental Illness*. https://www.nimh.nih.gov/health/statistics/mental-illness.shtml, (accessed July 1, 2020). See Exhibit 98.

(4) 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 Institute of Mental Health website: "In 2017, there were an estimated 11.2 million adults aged 18 or older in the United States with SMI. This number represented 4.5% of all U.S. adults."

Citation: National Institute of Mental Health, *Mental Illness*. https://www.nimh.nih.gov/health/statistics/mental-illness.shtml, (accessed July 1, 2020). See Exhibit 98.

(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 the National Institute of Mental Health website: "An estimated 49.5% of adolescents [aged 13-18] had any mental disorder. Of adolescents with any mental disorder, an estimated 22.2% had severe impairment."

Citation: National Institute of Mental Health, *Mental Illness*. https://www.nimh.nih.gov/health/statistics/mental-illness.shtml, (accessed July 1, 2020). See Exhibit 98.

B. Children's mental disorders

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote of 'children's mental disorders' from the Centers for Disease Control and Prevention website: "Mental disorders among children are described as serious changes in the way children typically learn, behave, or handle their emotions, which cause distress and problems getting through the day."

Citation: Centers for Disease Control and Prevention, *Children's Mental Disorders*. https://www.cdc.gov/childrensmentalhealth/symptoms.html (accessed July 1, 2020). See Exhibit 99.

C. Prevalence and economic burden of mental disorders in young children

(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 Child Mind Institute report: "Mental health disorders are the most common health issues faced by our nation's school-aged children. One in five children suffers from a mental health or learning disorder, and 80% of chronic mental disorders begin in childhood."

Citation: Child Mind Institute, *2016 Child Mind Institute Children's Mental Health Report*. https://childmind.org/downloads/2016%20Childrens%20Mental%20Health%20Report.pdf, (accessed May 6, 2020). See Exhibit 100.

(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 Centers for Disease Control and Prevention website: "It is estimated that as many as 1 out of 5 children experience a mental disorder in a given year, and an estimated $247 billion is spent each year on treatment and management of childhood mental disorders."

Citation: United States Centers for Disease Control and Prevention, *Improving Children's Behavioral Health*. https://www.cdc.gov/childrensmentalhealth/features/child-mental-health.html, (accessed July 1, 2020). See Exhibit 101.

D. Vaccination is a probable suspect in etiology of mental disorders

(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 a study published in *Frontiers in Psychiatry*:

> "Subjects with newly diagnosed AN [anorexia nervosa] were more likely than controls to have had any vaccination in the previous 3 months. Influenza vaccinations during the prior 3, 6, and 12 months were also associated with incident diagnoses of AN, OCD, and an anxiety disorder. Several other associations were also significant with HRs greater than 1.40 (hepatitis A with OCD and AN; hepatitis B with AN; and meningitis with AN and chronic tic disorder)."

Citation: Leslie *et al*. (2017). Temporal Association of Certain Neuropsychiatric Disorders Following Vaccination of Children and Adolescents: A Pilot Case-Control Study. *Frontiers in Psychiatry* 8:3. https://doi.org/10.3389/fpsyt.2017.00003, (accessed May 13, 2020). See Exhibit 102.

(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 a study published in *Brain, Behavior, and Immunity*: "Greater increases in IL-6 were associated with greater mood disturbance on post-vaccine days, specifically depressed mood and cognitive symptoms."

Citation: Kuhlman *et al.* (2018). Within-subject associations between inflammation and features of depression: Using the flu vaccine as a mild inflammatory stimulus. *Brain, Behavior, and Immunity* 69:540-547. https://doi.org/10.1016/j.bbi.2018.02.001, (accessed May 13, 2020). See Exhibit 103.

14. Depression

A. Definition

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'depression' from the National Institute of Mental Health website: "Depression (major depressive disorder or clinical depression) is a common but serious mood disorder. It causes severe symptoms that affect how you feel, think, and handle daily activities, such as sleeping, eating, or working."

Citation: National Institute of Mental Health, *Depression*. https://www.nimh.nih.gov/health/topics/depression/index.shtml (accessed July 1, 2020). See Exhibit 104.

B. Prevalence of depression in children

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 Centers of Disease Control and Prevention website: "3.2% of children aged 3-17 years (approximately 1.9 million) have diagnosed depression."

Citation: Centers for Disease Control and Prevention, *Anxiety and depression in children: Get the facts.* https://www.cdc.gov/childrensmentalhealth/features/anxiety-depression-children.html, (accessed July 1, 2020). See Exhibit 105.

C. Prevalence of depression in adults

(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 Centers of Disease Control and Prevention website: "During 2013–2016, 8.1% of American adults aged 20 and over had depression in a given 2-week period."

Citation: Centers for Disease Control and Prevention, National Center for Health Statistics, *Prevalence of Depression Among Adults Aged 20 and Over: United States, 2013–2016*, NCHS Data Brief No. 303, February 2018. https://www.cdc.gov/nchs/data/databriefs/db303.pdf, accessed May 5, 2020). See Exhibit 106.

(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 U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA): "The percentage of adolescents aged 12 to 17 in 2018 who had a past year MDE [major depressive episode] was higher than the percentages in 2004 to 2017."

Citation: Department of Health and Human Services (HHS), Substance Abuse and Mental Health Services Administration (SAMHSA), *Key Substance Use and Mental Health Indicators in the United States: Results from the 2018 National Survey on Drug Use and Health.*

https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHNationalFindingsReport2018/NSDUHNationalFindingsReport2018.pdf, (accessed July 5, 2020). See Exhibit 107.

15. Anxiety Disorders

A. Definition and prevalence in children

(1) For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'anxiety disorders' from the National Institute of Mental Health website: "anxiety disorders involve more than temporary worry or fear. For a person with an anxiety disorder, the anxiety does not go away and can get worse over time. The symptoms can interfere with daily activities such as job performance, school work, and relationships."

Citation: National Institute of Mental Health, *Anxiety Disorders*, https://www.nimh.nih.gov/health/topics/anxiety-disorders/index.shtml, (accessed July 1, 2020). See Exhibit 108.

(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 Centers for Disease Control and Prevention: "7.1% of children aged 3-17 years (approximately 4.4 million) have diagnosed anxiety."

Citation: Centers for Disease Control and Prevention, *Anxiety and depression in children: Get the facts.* https://www.cdc.gov/childrensmentalhealth/features/anxiety-depression-children.html (accessed July 1, 2020). See Exhibit 105.

B. Prevalence of anxiety disorders in adults, and Impact

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from Anxiety and Depression Association of America (ADAA):

> "Anxiety disorders are the most common mental illness in the U.S., affecting 40 million adults in the United States age 18 and older, or 18.1% of the population every year…. People with an anxiety disorder are three to five times more likely

to go to the doctor and six times more likely to be hospitalized for psychiatric disorders than those who do not suffer from anxiety disorders."

Citation: Anxiety and Depression Association of America, *Fact and Statistics*. https://adaa.org/about-adaa/press-room/facts-statistics, (accessed July 1, 2020). See Exhibit 109.

16. Obsessive-compulsive disorder (OCD)

A. Definition

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'obsessive-compulsive disorder' from the National Institute of Mental Health website: "Obsessive-Compulsive Disorder (OCD) is a common, chronic, and long-lasting disorder in which a person has uncontrollable, reoccurring thoughts (obsessions) and/or behaviors (compulsions) that he or she feels the urge to repeat over and over."

Citation: National Institute of Mental Health. *Obsessive Compulsive Disorder.* https://www.nimh.nih.gov/health/topics/obsessive-compulsive-disorder-ocd/index.shtml, (accessed July 1, 2020). See Exhibit 110.

B. Prevalence of OCD

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from a study published in *Archives of Disease in Childhood*: "Once considered to be rare in youth, epidemiological studies have found an estimated prevalence [of OCD] of 0.25%–4% among children and adolescents."

Citation: Krebs & Heyman (2015). Obsessive-compulsive disorder in children and adolescents. *Archives of Disease in Childhood* 100(5):495-499. https://doi.org/10.1136/archdischild-2014-306934, (accessed May 7, 2020). See Exhibit 111.

C. Etiology of OCD

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 Centers for Disease Control and Prevention website:

> "It is not known exactly why some children develop OCD. There is likely to be a biological and neurological component, and some children with OCD also have Tourette syndrome or other tic disorders. There are some studies that suggest that health problems during pregnancy and birth may make OCD more likely, which is one of many important reasons to support the health of women during pregnancy."

Citation: Centers for Disease Control and Prevention, *Obsessive-Compulsive Disorder in Children.* https://www.cdc.gov/childrensmentalhealth/ocd.html, (accessed July 1, 2020). See Exhibit 112.

17. Suicide and self-harm

A. Increased rate of suicide

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 Centers for Disease Control and Prevention website: "From 1999 through 2017, the age-adjusted suicide rate increased 33% from 10.5 to 14.0 per 100,000."

Citation: Centers for Disease Control and Prevention, National Center for Health Statistics Data Brief No. 330, November, 2108. *Suicide Mortality in the United States, 1999–2017*, https://www.cdc.gov/nchs/products/databriefs/db330.htm, (accessed May 13, 2020). See Exhibit 113.

B. Increased hospital visits for self-harming behavior

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from a study published in *Journal of the American Medical Association (JAMA)*: "Youth self-inflicted injury Emergency Department (ED) visit rates were relatively stable before 2008. However, rates among females significantly increased thereafter—particularly among females aged 10 to 14 years, who experienced an 18.8% annual increase from 2009 to 2015."

Citation: Mercado *et al*. (2017). Trends in Emergency Department Visits for Nonfatal Self-inflicted Injuries Among Youth Aged 10 to 24 Years in the United States, 2001-2015. *JAMA* 318(19):1931–1933. https://doi.org/10.1001/jama.2017.13317, (accessed May 13, 2020). See Exhibit 114.

18. Diabetes

A. Definition

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'diabetes' from the National Institute of Diabetes and Digestive and Kidney Diseases: "Diabetes is a disease that occurs when your blood glucose, also called blood sugar, is too high."

Citation: National Institute of Diabetes and Digestive and Kidney Diseases, *What is Diabetes?* https://www.niddk.nih.gov/health-information/diabetes/overview/what-is-diabetes, (accessed July 1, 2020). See Exhibit.

B. Prevalence of diabetes

(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 Diabetes Association website: "In 2018, 34.2 million Americans, or 10.5% of the population, had diabetes."

Citation: The American Diabetes Association, *Statistics About Diabetes*. https://www.diabetes.org/resources/statistics/statistics-about-diabetes, (accessed July 1, 2020). See Exhibit 116.

(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 American Diabetes Association website: "About 210,000 Americans under age 20 are estimated to have diagnosed diabetes, approximately 0.25% of that population."

Citation: The American Diabetes Association, *Statistics About Diabetes*. https://www.diabetes.org/resources/statistics/statistics-about-diabetes, (accessed July 1, 2020). See Exhibit 116.

C. Increasing prevalence of diabetes

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from a study published in *Journal of the American Medical Association (JAMA): "*Between 2001 and 2009 in 5 areas of the United States, the prevalence of both type 1 and type 2 diabetes among children and adolescents increased."

Citation: Dabelea *et al*. (2014). Prevalence of type 1 and type 2 diabetes among children and adolescents from 2001 to 2009. *JAMA* 311(17):1778-1786. https://doi.org/10.1001/jama.2014.3201, (accessed May 13, 2020). See Exhibit 117.

D. Economic burden of diabetes

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

> "The total estimated cost of diagnosed diabetes in 2017 is $327 billion, including $237 billion in direct medical costs and $90 billion in reduced productivity. For the cost categories analyzed, care for people with diagnosed diabetes accounts for 1 in 4 health care dollars in the U.S., and more than half of that expenditure is directly attributable to diabetes. People with diagnosed diabetes incur average medical expenditures of ~$16,750 per year, of which ~$9,600 is attributed to diabetes. People with diagnosed diabetes, on average, have medical expenditures ~2.3 times higher than what expenditures would be in the absence of diabetes. Indirect costs include increased absenteeism ($3.3 billion) and reduced productivity while at work ($26.9 billion) for the employed population, reduced productivity for those not in the labor force ($2.3 billion), inability towork because of disease-related disability ($37.5 billion), and lost productivity due to 277,000 premature deaths attributed to diabetes ($19.9 billion)."

Citation: The American Diabetes Association (2018). Economic Costs of Diabetes in the U.S. in 2017. *Diabetes Care* dci180007. https://doi.org/10.2337/dci18-0007, (accessed May 13, 2020). See Exhibit 118.

19. <u>Type 1 Diabetes (T1D)/ Juvenile Diabetes</u>

A. Definition and Prevalence of T1D

(1) For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'type 1 diabetes/ juvenile diabetes' from the Mayo Clinic: "Type 1 diabetes, once known as juvenile diabetes or insulin-dependent diabetes, is a chronic condition in which the pancreas produces little or no insulin. Insulin is a hormone needed to allow sugar (glucose) to enter cells to produce energy."

Citation: Mayo Clinic, *Type 1 Diabetes*. https://www.mayoclinic.org/diseases-conditions/type-1-diabetes/symptoms-causes/syc-20353011 (accessed July 1, 2020). See Exhibit 119.

(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 American Diabetes Association: "Nearly 1.6 million Americans have type 1 diabetes, including about 187,000 children and adolescents."

Citation: The American Diabetes Association, *Statistics About Diabetes*. https://www.diabetes.org/resources/statistics/statistics-about-diabetes, (accessed July 1, 2020). See Exhibit 116.

B. Growing prevalence of T1D

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from a study published in *Journal of the American Medical Association (JAMA):* "type 1 diabetes increased between 2001 and 2009 in all sex, age, and race/ethnic subgroups except for those with the lowest prevalence (age 0–4 years and American Indians). Adjusted for completeness of ascertainment, there was a 21.1% (95% CI, 15.6%–27.0%) increase in type 1 diabetes over 8 years."

Citation: Dabelea *et al*. (2014). Prevalence of type 1 and type 2 diabetes among children and adolescents from 2001 to 2009. *JAMA* 311(17):1778-1786. https://doi.org/10.1001/jama.2014.3201, (accessed May 13, 2020). See Exhibit 117.

20. Cancer

A. Definition

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'cancer' from the National Cancer Institute website: "a term for diseases in which abnormal cells divide without control and can invade nearby tissues."

Citation: National Cancer Institute, *NCI Dictionary of Cancer Terms*. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/cancer, (accessed July 1, 2020). See Exhibit 121.

B. Common types of childhood cancer

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 Cancer Institute website:

> "Overall, among children and adolescents (ages 0 to 19) in the United States, the most common types of cancer are leukemias, brain and central nervous system tumors, and lymphomas. Among children (ages 0 to 14 years), the most common types of cancer are leukemias, followed by brain and other central nervous system tumors, lymphomas, soft tissue sarcomas (of which half are rhabdomyosarcoma), neuroblastoma, and kidney tumors. Among adolescents (ages 15 to 19 years), the most common types of cancer are brain and other central nervous system tumors and lymphomas, followed by leukemias, gonadal (testicular and ovarian) germ cell tumors, thyroid cancer, and melanoma."

Citation: National Cancer Institute, *Child and Adolescent Cancers Fact Sheet*. https://www.cancer.gov/types/childhood-cancers/child-adolescent-cancers-fact-sheet, (accessed July 1, 2020). See Exhibit.

C. Childhood cancer statistics

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 Cancer Society website:

> "About 11,050 children in the United States under the age of 15 will be diagnosed with cancer in 2020…. Childhood cancer rates have been rising slightly for the past few decades…. After accidents, cancer is the second leading cause of death in children ages 1 to 14. About 1,190 children under the age of 15 are expected to die from cancer in 2020."

Citation: American Cancer Society, *Key Statistics for Childhood Cancers.* https://www.cancer.org/cancer/cancer-in-children/key-statistics.html, (accessed July 1, 2020). See Exhibit 123.

D. Growing rates of colorectal cancer among young adults

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from a study published in *Journal of the National Cancer Institute*: "Compared with adults born circa 1950, those born circa 1990 have

double the risk of colon cancer (IRR = 2.40, 95% CI = 1.11 to 5.19) and quadruple the risk of rectal cancer (IRR = 4.32, 95% CI = 2.19 to 8.51)."

Citation: Siegel *et al*. (2017). Colorectal Cancer Incidence Patterns in the United States, 1974–2013. *Journal of the National Cancer Institute* 109(8):djw322. https://doi.org/10.1093/jnci/djw322, (accessed May 13, 2020). See Exhibit 124.

21. Infertility

A. Definitions

Infertility

(1) For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'infertility' from the Centers for Disease Control and Prevention website: "In general, infertility is defined as not being able to get pregnant (conceive) after one year (or longer) of unprotected sex."

Citation: Centers for Disease Control and Prevention, *Infertility FAQs*. https://www.cdc.gov/reproductivehealth/infertility/index.htm, (accessed May 13, 2020). See Exhibit 125.

Impaired fecundity

(2) For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'impaired fecundity' from the Centers for Disease Control and Prevention website: "Impaired fecundity is a condition related to infertility and refers to women who have difficulty getting pregnant or carrying a pregnancy to term."

Citation: Centers for Disease Control and Prevention, *Infertility FAQs*. https://www.cdc.gov/reproductivehealth/infertility/index.htm, (accessed July 1, 2020). See Exhibit 125.

B. Prevalence of infertility and impaired fecundity

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 Centers for Disease Control and Prevention website:

> "About 6% of married women aged 15 to 44 years in the United States are unable to get pregnant after one year of trying (infertility). Also, about 12% of women aged 15 to 44 years in the United States have difficulty getting pregnant or carrying a pregnancy to term, regardless of marital status (impaired fecundity)."

Citation: Centers for Disease Control and Prevention, *Infertility FAQs*. https://www.cdc.gov/reproductivehealth/infertility/index.htm, (accessed July 1, 2020). See Exhibit 125.

22. Allergy

A. Definitions

Allergy

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'allergy' from *Farlex Partner Medical Dictionary*: 'allergy is "hypersensitivity caused by exposure to a particular antigen (allergen) resulting in a marked increase in reactivity to that antigen on subsequent exposure, sometimes resulting in harmful immunologic consequences." '

Citation: *Farlex Partner Medical Dictionary*. (2012). https://medical-dictionary.thefreedictionary.com/allergy, (accessed July 1, 2020). See Exhibit 126.

Allergic rhinitis/ hay fever

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'allergic rhinitis' from *Gale Encyclopedia of Medicine:* "Allergic rhinitis, more commonly referred to as hay fever, is an inflammation of the nasal passages caused by allergic reaction to airborne substances."

Citation: *Gale Encyclopedia of Medicine*. (2008). https://medical-dictionary.thefreedictionary.com/allergic+rhinitis, (accessed October 18, 2020). See Exhibit 127.

Food allergy

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'food allergy' from *Collins Dictionary of Medicine*: 'food allergy is "sensitivity to one or more of the components of normal diets."

Citation: *Collins Dictionary of Medicine*. (2004, 2005). https://medical-dictionary.thefreedictionary.com/food+allergy, (accessed July 1, 2020). See Exhibit 128.

Atopic dermatitis (AD) / eczema

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'atopic dermatitis' from *Gale Encyclopedia of Medicine*: "Atopic dermatitis, a form of eczema, is a non-contagious disorder characterized by chronically inflamed skin and sometimes intolerable itching."

Citation: *Gale Encyclopedia of Medicine*. (2008). https://medical-dictionary.thefreedictionary.com/atopic+dermatitis, (accessed July 1, 2020). See Exhibit 129.

Anaphylaxis

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'anaphylaxis' from *Gale Encyclopedia of Medicine:* "Anaphylaxis is a rapidly progressing, life-threatening allergic reaction."

Citation: *Gale Encyclopedia of Medicine*. (2008). https://medical-dictionary.thefreedictionary.com/anaphylaxis, (accessed July 1, 2020). See Exhibit 130.

B. Prevalence of allergy

(1) 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 Asthma and Allergy Foundation of America website: 1. "More than 50 million Americans have experienced various types of allergies each year." 2. "Allergic conditions are the most common health issues affecting children in the U.S. In 2015, 8.2 percent of adults and 8.4 percent of children were diagnosed with hay fever."

Citation: Asthma and Allergy Foundation of America, *Allergy Facts and Figures.* https://www.aafa.org/allergy-facts/, (accessed July 1, 2020). See Exhibit 131.

(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 Centers for Disease Control and Prevention: 'for "children under 18 years,

A. Number with reported hay fever in the past 12 months: 5.2 million

B. Percent with reported hay fever in the past 12 months: 7.2%

C. Number with reported respiratory allergies in the past 12 months: 7.1 million

D. Percent with reported respiratory allergies in the past 12 months: 9.6%

E. Number with reported food allergies in the past 12 months: 4.8 million

F. Percent with reported food allergies in the past 12 months: 6.5%

G. Number with reported skin allergies in the past 12 months: 9.2 million

H. Percent with reported skin allergies in the past 12 months: 12.6%"

For "adults aged 18 and over,

I. Number with diagnosed hay fever in the past 12 months: 19.2 million

J. Percent with diagnosed hay fever in the past 12 months: 7.7%" '

Citation: Centers for Disease Control and Prevention, *Allergies and Hay Fever.* https://www.cdc.gov/nchs/fastats/allergies.htm, (accessed July 1, 2020). See Exhibit 132.

C. Prevalence of food allergy

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 Food Allergy Research and Education (FARE) website:

> "Approximately 32 million people in the United States have food allergies. Nearly 11 percent of people age 18 or older – more than 26 million adults – have food allergies. Results from a 2015-2016 survey of more than 38,000 children indicate that 5.6 million children, or nearly 8 percent, have food allergies. That's one in 13 children, or roughly two in every classroom." Specific food allergies affecting Americans include: shellfish: 8.2 million, milk: 6.1 million, peanut: 6.1 million, tree nuts: 3.9 million, egg: 2.6 million, fin fish: 2.6 million, wheat: 2.4 million, soy: 1.9 million, sesame: 0.7 million. About 40 percent of children with food allergies are allergic to more than one food."

Citation: Food Allergy Research and Education, *Fact and Statistics.* https://www.foodallergy.org/resources/facts-and-statistics, (accessed May 12, 2020). See Exhibit 133.

D. Prevalence of respiratory allergy in children and Increase in prevalence of allergy

(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 Centers for Disease Control and Prevention website: "Respiratory allergy prevalence increased with the increase of age (10.8% among 0–4 years, 17.4% among 5–9 years, and 20.8% among 10–17 years).

Citation: Centers for Disease Control and Prevention, National Center for Health Statistics, Data Brief No. 121, 2013. *Trends in Allergic Conditions Among Children: United States, 1997–2011*. https://www.cdc.gov/nchs/data/databriefs/db121.pdf, (accessed April 29, 2020). See Exhibit 134.

(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 Centers for Disease Control and Prevention Data Brief: "Among children aged 0–17 years, the prevalence of food allergies increased from 3.4% in 1997–1999 to 5.1% in 2009–2011. The prevalence of skin allergies increased from 7.4% in 1997–1999 to 12.5% in 2009–2011."

Citation: Centers for Disease Control and Prevention, *National Children's Health Survey Data Brief No. 121, 2013. Trends in Allergic Conditions Among Children: United States, 1997–2011*. https://www.cdc.gov/nchs/data/databriefs/db121.pdf, (accessed May 12, 2020). See Exhibit 134.

E. Increase in prevalence of anaphylaxis

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from a study published in *Current Allergy and Asthma Reports*: "The occurrence of anaphylaxis is increasing across all ages in the United States, with increased risk of worse outcome in teenagers/young adults and in those with comorbid conditions such as asthma."

Citation: Dinakar (2012). Anaphylaxis in children: current understanding and key issues in diagnosis and treatment. *Current Allergy and Asthma Reports* 12(6):641-649. https://doi.org/10.1007/s11882-012-0284-1, (accessed May 12, 2020). See Exhibit 135.

F. Medical and economic burden of food allergy

(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 a study published in *JAMA Pediatrics:* "Food allergies cost about $24.8 Billion per year."

Citation: Gupta *et al*. (2013). The economic impact of childhood food allergy in the United States. *JAMA Pediatrics* 167(110):1026-1031. https://doi.org/10.1001/jamapediatrics.2013.2376, (accessed May 12, 2020). See Exhibit 136.

(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 Food Allergy Research and Education (FARE) website*:* "Each year in the U.S., 200,000 people require emergency medical care for allergic reactions to food. Pediatric hospitalizations for food allergy tripled between the late 1990s and the mid-2000s. Between 2004 and 2006, an average of 9,500 children received in-patient hospital care for food allergies each year."

Citation: Food Allergy Research and Education: *Fact and Statistics.* https://www.foodallergy.org/resources/facts-and-statistics, (accessed May 12, 2020). See Exhibit 133.

G. Aluminum adjuvant is a reasonable suspect in etiology of allergy

(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 a study published in *Genetics and Molecular Research*: "This study evaluated different dosage forms of aluminum adjuvant in generating allergic rhinitis animal models."

Citation: Xi *et al*. (2014). Role of aluminum adjuvant in producing an allergic rhinitis animal model. *Genetics and Molecular Research* 13(3):5173-5181. https://doi.org/10.4238/2014.July.7.10, (accessed May 12, 2020). See Exhibit 137.

(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 a study published in *International Archives of Allergy and Immunology:* "Brown Norway rats were sensitized to protein extracts (RuBisCO, apple, soy, peanut, garden pea) or ovalbumin (OVA) combined with *Bordetella pertussis* and aluminum hydroxide, followed by oral allergen challenges."

Citation: Ahrens *et al*. (2014). Development of an animal model to evaluate the allergenicity of food allergens. *International Archives of Allergy and Immunology* 164(2):89-96. https://doi.org/10.1159/000363109, (accessed May 12, 2020). See Exhibit 138.

23. Asthma

A. Definition

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'asthma' from *Gale Encyclopedia of Medicine*:

> "Asthma is a chronic (long-lasting) inflammatory disease of the airways. In those susceptible to asthma, this inflammation causes the airways to spasm and swell periodically so that the airways narrow. The individual then must wheeze or gasp for air. Obstruction to air flow either resolves spontaneously or responds to a wide range of treatments, but continuing inflammation makes the airways hyper-responsive to stimuli such as cold air, exercise, dust mites, pollutants in the air, and even stress and anxiety."

Citation: *Gale Encyclopedia of Medicine*. (2008). https://medical-dictionary.thefreedictionary.com/asthma, (accessed July 1, 2020). See Exhibit 139.

B. Prevalence of asthma

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following figures from the Centers of Disease Control and Prevention website: 'Asthma affects over 24 million people (2018) , including over 5 million children under age 18 (2018)…"

Citation: Centers for Disease Control and Prevention, *Most Recent National Asthma Data.* https://www.cdc.gov/asthma/most_recent_national_asthma_data.htm, (accessed July 1, 2020). See Exhibit 140.

C. Increasing prevalence of asthma

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following figures from the Centers of Disease Control and Prevention website: "Asthma is increasing every year in the US. Too many people have asthma.

The number of people with asthma continues to grow. One in 12 people (about 25 million, or 8% of the population) had asthma in 2009, compared with 1 in 14 (about 20 million, or 7%) in 2001."

Citation: Centers for Disease Control and Prevention, *Asthma in the US.* https://www.cdc.gov/vitalsigns/asthma/index.html, (accessed July 1, 2020). See Exhibit 141.

D. Economic burden of asthma

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from a paper published in *Annals of Global Health*: "In the United States, asthma cost about $3,300 per patient each year in medical expenses. Medical costs associated with asthma increased from $48.6 billion in 2002 to $50.1 billion in 2007, and will likely keep growing."

Citation: Serebrisky & Wiznia (2019). Pediatric Asthma: A Global Epidemic. *Ann Glob Health* 85(1):6. https://doi.org/10.5334/aogh.2416, (accessed May 12, 2020). See Exhibit 142.

E. Etiology of asthma

(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 Centers of Disease Control and Prevention website: "In most cases, we don't know the exact causes of asthma and we don't know how to cure it."

Citation: Centers for Disease Control and Prevention, *You Can Control Your Asthma.* https://www.cdc.gov/nceh/features/asthmaawareness/index.html, (accessed July 1, 2020). See Exhibit 143.

(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 a review published in *Expert Review of Clinical Immunology*: "Asthma is generally believed to result from gene-environment interactions."

Citation: Propp & Becker (2013). Prevention of asthma: where are we in the 21st century? *Expert Review of Clinical Immunology* 9(12):1267–1278. https://doi.org/10.1586/1744666x.2013.858601, (accessed July 1, 2020). See Exhibit 144.

F. Aluminum adjuvant is a reasonable suspect in etiology of asthma

(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 a review published in *American Journal of Physiology - Lung Cellular and Molecular Physiology*:

> "Allergic mouse models of asthma are generated by first sensitizing an animal to a foreign protein, most commonly ovalbumin. This is typically done by injecting the protein intraperitoneally along with an adjuvant, typically aluminum hydroxide, that serves to enhance the protein's immunogenicity for reasons that are complex and not entirely understood."

Citation: Bates *et al*. (2009). Animal models of asthma. *American Journal of Physiology - Lung Cellular and Molecular Physiology* 297(3):L401-L410. https://doi.org/10.1152/ajplung.00027.2009, (accessed May 12, 2020). See Exhibit 145.

(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 a study published in *Vaccine*:

> "The global expression of immune response genes in infants after vaccination and their role in asthma and allergy is not clearly understood... Here, array technology was used to assess the expression kinetics of immune response genes with association to asthma and allergy in peripheral blood mononuclear cells (PBMC) of five healthy infants after vaccination with Infanrix-Polio + Hib. At 12 h after in vitro re-stimulation of the PBMC with pertussis toxin (PT) antigen, 14 immune response pathways, 33 allergy-related and 66 asthma-related genes were found activated."

Citation: Lahdenperäa *et al*. (2008). Kinetics of asthma- and allergy-associated immune response gene expression in peripheral blood mononuclear cells from vaccinated infants after in vitro re-stimulation with vaccine antigen. *Vaccine* 26(14):1725-1730. https://doi.org/10.1016/j.vaccine.2008.01.041, (accessed May 12, 2020). See Exhibit 146.

24. Erythema multiforme (EM)/ Stevens Johnson syndrome (SJS) / Toxic epidermal necrolysis (TEN)

A. Definitions

(1) **Erythema Multiforme/Stevens Johnson Syndrome(EM/SJS)**

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'erythema multiforme' from *Gale Encyclopedia of Medicine:*

> "Erythema multiforme is a skin disease that causes lesions and redness around the lesions. Erythema multiforme appears on the skin and the mucous membranes (the lining of the mouth, digestive tract, vagina, and other organs). Large, symmetrical red blotches appear all over the skin in a circular pattern. On mucous membranes, it begins as blisters and progresses to ulcers. A more advanced form, called Stevens-Johnson syndrome, can be severe and even fatal."

Citation: *Gale Encyclopedia of Medicine*. (2008). https://medical-dictionary.thefreedictionary.com/erythema+multiforme, (accessed July 1, 2020). See Exhibit 147.

(2) **Toxic epidermal necrolysis (TEN)**

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'toxic epidermal necrolysis' from *Gale Encyclopedia of Medicine:* "Toxic epidermal necrolysis is a rare condition that causes large portions of the epidermis, the skin's outermost layer, to detach from the layers of skin below."

Citation: *Gale Encyclopedia of Medicine*. (2008). https://medical-dictionary.thefreedictionary.com/toxic+epidermal+necrolysis (accessed July 1, 2020). See Exhibit 148.

B. Vaccination is a reasonable suspect in etiology of EM/SJS/TEN

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

> 1. "Most reports of EM/SJS/TEN described onset of symptoms within 14 days of vaccination; for cases of SJS with known time to onset, 71% described onset of symptoms within 3 days of vaccination."

> 2. "Of 466,027 reports to VAERS during 1999-2017, we identified 984 reports of EM, 89 reports of SJS, 6 reports of SJS/TEN, and 7 reports of TEN. Few reports of EM (9%), and most reports of SJS (52%), SJS/TEN (100%), and TEN (100%) were serious. Overall, 55% of reports described males, 48% described children aged < 4 years; 58% of EM/SJS/TEN occurred ≤ 7 days after vaccination…Overall, childhood vaccines (e.g., combined measles, mumps, and rubella vaccine) were most commonly reported."

Citation: Su *et al*. (2020). Erythema multiforme, Stevens Johnson syndrome, and toxic epidermal necrolysis reported after vaccination, 1999-2017. *Vaccine* 38(7):1746-1752. https://doi.org/10.1016/j.vaccine.2019.12.028, accessed May 12, 2020). See Exhibit 149.

25. Autoimmune disorders

A. Definition

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'autoimmune disorder' from *Gale Encyclopedia of Medicine:* 'autoimmune disorder is "a disorder caused by a reaction of an individual's immune system against the organs or tissues of the body. Autoimmune processes can have different results: slow destruction of a particular type of cell or tissue, stimulation of an organ into excessive growth, or interference in function." '

Citation: *Gale Encyclopedia of Medicine*. (2008). https://medical-dictionary.thefreedictionary.com/Autoimmune+disorder (accessed July 1, 2020). See Exhibit 150.

B. Types of autoimmune disorders

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 Institute of Allergy and Infectious Diseases website: "More than 80 diseases occur as a result of the immune system attacking the body's own organs, tissues, and cells. Some of the more common autoimmune diseases include type 1 diabetes, rheumatoid arthritis, systemic lupus erythematosus, and inflammatory bowel disease."

Citation: National Institute of Allergy and Infectious Diseases, *Autoimmune Diseases*. https://www.niaid.nih.gov/diseases-conditions/autoimmune-diseases, (accessed July 1, 2020). See Exhibit 151.

C. Prevalence of autoimmune disorders

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from a study published in *International Journal of Molecular Sciences:* "Of the 80 individual autoimmune diseases, common examples include rheumatoid arthritis (RA), Type 1 Diabetes (T1D), and the autoimmune thyroid diseases; others may be rarer, but as a group afflict 5%–9% of the U.S. population."

Citation: Parks *et al*. (2014). Expert panel workshop consensus statement on the role of the environment in the development of autoimmune disease. *International Journal of Molecular Sciences* 15(8):14269-14297. https://doi.org/10.3390/ijms150814269, (accessed May 12, 2020). See Exhibit 152.

D. Growing prevalence of autoimmune disorders

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from a study published in *International Journal of Celiac Disease*: "Epidemiological data provide evidence of a steady rise in autoimmune disease throughout Westernized societies over the last decades... Rheumatic, endocrinological, gastrointestinal and neurological autoimmune diseases revealed the following annual % increases per year: 7.1, 6.3, 6.2, and 3.7, respectively."

Citation: Lerner *et al*. (2015). The World Incidence and Prevalence of Autoimmune Diseases is Increasing. *International Journal of Celiac Disease* 3(4):151-155. https://doi.org/10.12691/ijcd-3-4-8, (accessed May 12, 2020). See Exhibit 153.

26. Myalgic encephalomyelitis/ chronic fatigue syndrome (ME/CFS)

A. Definition

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'chronic fatigue syndrome' from a review published in *Clinical Immunology:* 'chronic fatigue syndrome,

> "which is also known as myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS), is a complex disease which presents with pronounced disabling fatigue, mental and physical post-exertional malaise, pain, sleep disturbances and cognitive impairment. Diagnostic criteria additionally emphasize symptoms of immune system dysregulation, autonomic nervous system dysfunction and metabolic disturbance."

Citation: Shoenfeld *et al*. (2020). Complex syndromes of chronic pain, fatigue and cognitive impairment linked to autoimmune dysautonomia and small fiber neuropathy. *Clinical Immunology* 214:108384, https://doi.org/10.1016/j.clim.2020.108384, (accessed May 12, 2020). See Exhibit 154.

B. Prevalence of ME/CFS and Economic burden of ME/CFS

(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 Centers of Disease

Control and Prevention website: "An estimated 836,000 to 2.5 million Americans suffer from ME/CFS. About 90 percent of people with ME/CFS have not been diagnosed."

Citation: Centers for Disease Control and Prevention, *Myalgic Encephalomyelitis/Chronic Fatigue Syndrome.* https://www.cdc.gov/me-cfs/about/index.html, (accessed July 1, 2020). See Exhibit 155.

(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 Centers of Disease Control and Prevention website: "ME/CFS costs the U.S. economy about $17 to $24 billion annually in medical bills and lost incomes."

Citation: Centers for Disease Control and Prevention, *Myalgic Encephalomyelitis/Chronic Fatigue Syndrome.* https://www.cdc.gov/me-cfs/about/index.html, (accessed July 1, 2020). See Exhibit 155.

C. Vaccination is a reasonable suspect in etiology of ME/CFS

(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 a review published in *Autoimmunity Reviews*: "Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) is a multifactorial and poorly understood disabling disease. We present epidemiological, clinical and experimental evidence that ME/CFS constitutes a major type of adverse effect of vaccines, especially those containing poorly degradable particulate aluminum adjuvants."

Citation: Gherardi *et al*. (2019). Myalgia and chronic fatigue syndrome following immunization: macrophagic myofasciitis and animal studies support linkage to aluminum adjuvant persistency and diffusion in the immune system. *Autoimmunity Reviews* 18(7):691-705. https://doi.org/10.1016/j.autrev.2019.05.006, (accessed May 12, 2020). See Exhibit 156.

(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 a chapter in *Vaccines and Autoimmunity:* "CFS has been reported to emerge following vaccination in several reports, including after measles, mumps and rubella (MMR), Pneumovax, influenza, hepatitis B virus

(HBV), tetanus, typhoid and poliovirus vaccines… Such reports have made researchers concerned regarding the role of vaccinations in the onset of CFS and the safety of their use in CFS patients."

Citation: Shoenfeld *et al*., *Chapter 36. "Infections, Vaccinations and Chronic Fatigue Syndrome."* In: Shoenfeld Y, Agmon-Levin N, and Tomljenovic L eds. *Vaccines and Autoimmunity*, Wiley-Blackwell, 2015, pp. 345-348. See Exhibit 157.

27. Guillain-Barré syndrome (GBS)

A. Definition and Annual incidence of GBS

(1) For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'Guillain-Barré syndrome' from the Centers for Disease Control and Prevention: "Guillain-Barré syndrome (GBS) is a rare disorder where the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis."

Citation: Centers for Disease Control and Prevention, *Guillain-Barré Syndrome*. https://www.cdc.gov/vaccinesafety/concerns/guillain-barre-syndrome.html, (accessed July 1, 2020). See Exhibit 158.

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 Centers for Disease Control and Prevention: "Each year in the United States, an estimated 3,000 to 6,000 people develop GBS. Most people fully recover from GBS, but some have permanent nerve damage."

(2) Citation: Centers for Disease Control and Prevention, *Guillain-Barré Syndrome*. https://www.cdc.gov/vaccinesafety/concerns/guillain-barre-syndrome.html, (accessed May 12, 2020). See Exhibit 158.

B. Vaccination is a reasonable suspect in etiology of GBS

(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 a study published in *Vaccine*: "Using data from Vaccine Adverse Event Reporting System, we identified 69 reports of Guillain–Barré Syndrome (GBS) after Gardasil vaccination that occurred in the United States between 2006 and 2009. The onset of symptoms was within 6 weeks after vaccination in 70% of the patients in

whom the date of vaccination was known. The estimated weekly reporting rate of post-Gardasil GBS within the first 6 weeks (6.6 per 10,000,000) was higher than that of the general population, and higher than post-Menactra and post-influenza vaccinations."

Citation: Souayah *et al*. (2011). Guillain–Barré syndrome after Gardasil vaccination: Data from Vaccine Adverse Event Reporting System 2006–2009. *Vaccine* 29(5):886-889. https://doi.org/10.1016/j.vaccine.2010.09.020, (accessed May 12, 2020). See Exhibit 159.

(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 a study published in *Journal of Clinical Neuromuscular Disease: "*There were 1000 cases (mean age, 47 years) of GBS reported after vaccination in the United States between 1990 and 2005. The onset of GBS was within 6 weeks in 774 cases, >6 weeks in 101, and unknown in 125. Death and disability after the event occurred in 32 (3.2%) and 167 (16.7%) subjects, respectively. The highest number (n = 632) of GBS cases was observed in subjects receiving influenza vaccine followed by hepatitis B vaccine (n = 94). Other vaccines or combinations of vaccines were associated with 274 cases of GBS… Our results suggest that vaccines other than influenza vaccine can be associated with GBS."

Citation: Souayah *et al*. (2009). Guillain-Barré syndrome after vaccination in United States: data from the Centers for Disease Control and Prevention/Food and Drug Administration Vaccine Adverse Event Reporting System (1990-2005). *Journal of Clinical Neuromuscular Disease* 11(1):1-6. https://doi.org/10.1097/CND.0b013e3181aaa968, (accessed May 12, 2020). See Exhibit 160.

(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 Centers for Disease Control and Prevention:

> "In 1976, there was a small increased risk of GBS after swine flu vaccination, which was a special flu vaccine for a potential pandemic strain of flu virus. The National Academy of Medicine, formerly known as Institute of Medicine, conducted a scientific review of this issue in 2003 and found that people who received the 1976 swine flu vaccine had an increased risk for developing GBS. The increased risk was approximately one additional case of GBS for every 100,000 people who got the swine flu vaccine. Scientists have several theories about the cause, but the exact reason for this link remains unknown. There have been several studies of the risk of GBS after flu vaccine and CDC monitors for GBS during each flu season. The data on an association between seasonal influenza vaccine and GBS have been variable from season-to-season. When there has been an increased risk,

it has consistently been in the range of 1-2 additional GBS cases per million flu vaccine doses administered."

Citation: Centers for Disease Control and Prevention, *Guillain-Barré Syndrome*. https://www.cdc.gov/vaccinesafety/concerns/guillain-barre-syndrome.html, (accessed May 12, 2020). See Exhibit 158.

28. Multiple sclerosis (MS)

A. Definition

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following description of 'multiple sclerosis' from the Mayo Clinic website: "Multiple sclerosis (MS) is a potentially disabling disease of the brain and spinal cord (central nervous system). In MS, the immune system attacks the protective sheath (myelin) that covers nerve fibers and causes communication problems between your brain and the rest of your body. Eventually, the disease can cause permanent damage or deterioration of the nerves."

Citation: Mayo Clinic, *Multiple Sclerosis*. https://www.mayoclinic.org/diseases-conditions/multiple-sclerosis/symptoms-causes/syc-20350269, (accessed July 1, 2020). See Exhibit 161.

B. Increasing prevalence of MS

(1) For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quotes from a study published in *Neurology*:

a. "The estimated 2010 prevalence of MS in the US adult population cumulated over 10 years was 309.2 per 100,000 (95% confidence interval [CI] 308.1–310.1), representing 727,344 cases."

b. "On the basis of observed increases in prevalence with our VA and Intercontinental Marketing Services datasets after 2010, we estimated that the prevalence of MS in 2017 cumulated over 17 years would range from 337.9 per 100,000 population (n = 851,749 persons with MS) to 362.6 per 100,000 population (n = 913,925 persons with MS)."

Citation: Wallin *et al*. (2019). The prevalence of MS in the United States: A population-based estimate using health claims data. *Neurology* 92(10). https://doi.org/10.1212/WNL.0000000000007035, (accessed May 12, 2020). See Exhibit 162.

(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 MultipleSclerosis.net: "The rates of MS have increased worldwide since 1955. The first report of MS in the U.S. was published in 1976 and found 123,000 cases. A study from 1990 found 300,000 cases of MS. This compares to the estimated 750,000 to 1 million cases in 2019. Another study found that rates of MS increased by about 10 percent between 1990 and 2016."

Citation: MultipleSclerosis.net, *MS Statistics*. https://multiplesclerosis.net/what-is-ms/statistics/, (accessed May 12, 2020). See Exhibit 163.

29. Acute disseminated encephalomyelitis (ADEM)

A. Definition

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following description of 'acute disseminated encephalomyelitis' from a study published in *Neurology*:

> "Acute disseminated encephalomyelitis (ADEM) is an immune-mediated inflammatory disorder of the CNS [central nervous system] characterized by a widespread demyelination that predominantly involves the white matter of the brain and spinal cord. The condition is usually precipitated by a viral infection or vaccination. The presenting features include an acute encephalopathy with multifocal neurologic signs and deficits. Children are preferentially affected."

Citation: Tenembaum *et al*. (2007). International Pediatric MS Study Group. Acute disseminated encephalomyelitis. *Neurology* 68(16 Suppl 2):S23-S36. https://doi.org.10.1212/01.wnl.0000259404.51352.7f, (accessed May 12, 2020). See Exhibit 164.

B. Vaccination is a reasonable suspect in etiology of ADEM

(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 a study published in *Clinical Neuroscience*: "Post-vaccination ADEM has been associated with several vaccines such as rabies,

diphtheria–tetanus–polio, smallpox, measles, mumps, rubella, Japanese B encephalitis, pertussis, influenza, hepatitis B, and the Hog vaccine."

Citation: Huynh *et al*. (2008). *Post-vaccination encephalomyelitis: literature review and illustrative case. Clinical Neuroscience* 15(12):1315-1322. https://doi.org/10.1016/j.jocn.2008.05.002, (accessed May 12, 2020). See Exhibit 165.

(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 a review published in *Autoimmunity Reviews:*

> "A wide variety of inflammatory diseases temporally associated with the administration of various vaccines, has been reported in the literature. A PubMed search from 1979 to 2013 revealed seventy one (71) documented cases. The most commonly reported vaccinations that were associated with CNS demyelinating diseases included influenza (21 cases), human papilloma virus (HPV) (9 cases), hepatitis A or B (8 cases), rabies (5 cases), measles (5 cases), rubella (5 cases), yellow fever (3 cases), anthrax (2 cases), meningococcus (2 cases) and tetanus (2 cases)."

Citation: Karussis & Petrou (2013). The spectrum of post-vaccination inflammatory CNS demyelinating syndromes. *Autoimmunity Reviews* 13(3):215-224. https://doi.org.10.1016/j.autrev.2013.10.003, (accessed May 12, 2020). See Exhibit 166.

30. Myasthenia gravis (MG)

A. Definition

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'myasthenia gravis' from the National Institute of Neurological Disorders and Stroke website: "Myasthenia gravis is a chronic autoimmune, neuromuscular disease that causes weakness in the skeletal muscles that worsens after periods of activity and improves after periods of rest. These muscles are responsible for functions involving breathing and moving parts of the body, including the arms and legs."

Citation: National Institute of Neurological Disorders and Stroke, *Myasthenia Gravis Fact Sheet*. https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Myasthenia-Gravis-Fact-Sheet, (accessed July 1, 2020). See Exhibit 167.

B. Vaccination is a reasonable suspect in etiology of MG

(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 a study published in *BMC Neurology:* "HPV vaccination may cause MG owing to unexpected abnormal autoimmune responses."

Citation: Chung *et al*. (2018). Myasthenia gravis following human papillomavirus vaccination: a case report. *BMC Neurology* 18(1):222. https://doi.org/10.1186/s12883-018-1233-y, (accessed May 12, 2020). See Exhibit 168.

(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 a study published in *Journal of the Neurological Sciences*: "case histories and series hint at a temporal association between hepatitis B vaccines and the development of various neuropathy syndromes, polyarteritis nodosa complicated by vasculitic neuropathy, myasthenia gravis and dermatomyositis. Conceivably, the hepatitis B vaccines have a potential to occasionally trigger the onset of immune diseases in individuals with an underlying genetic or immunological susceptibility."

Citation: Stübgen (2010). Neuromuscular disorders associated with hepatitis B vaccination. *Journal of the Neurological Sciences* 292(1–2):1–4. https://doi.org/10.1016/j.jns.2010.02.016, (accessed May 12, 2020). See Exhibit 169.

31. Narcolepsy

A. Definition and Prevalence

(1) For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'narcolepsy' from the National Institute of Neurological Disorders and Stroke website: "Narcolepsy is a chronic neurological disorder that affects the brain's ability to control sleep-wake cycles."

Citation: National Institute of Neurological Disorders and Stroke, *Narcolepsy Fact Sheet.* https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Narcolepsy-Fact-Sheet#3201_1, (accessed July 1, 2020). See Exhibit 170.

(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 National Institute of Neurological Disorders and Stroke website:

> "When cataplexy is present, the cause is most often the loss of brain cells that produce hypocretin. Although the reason for this cell loss is unknown, it appears to be linked to abnormalities in the immune system... Researchers believe that in individuals with narcolepsy, the body's immune system selectively attacks the hypocretin-containing brain cells because of a combination of genetic and environmental factors."

Citation: National Institute of Neurological Disorders and Stroke, *Narcolepsy Fact Sheet.* https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Narcolepsy-Fact-Sheet#3201_1, (accessed July 1, 2020). See Exhibit 170.

(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 National Institute of Neurological Disorders and Stroke website: "Anywhere from 135,000 to 200,000 people in the United States have narcolepsy. However, since this condition often goes undiagnosed, the number may be higher."

Citation: National Institute of Neurological Disorders and Stroke, *Narcolepsy Fact Sheet.* https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Narcolepsy-Fact-Sheet#3201_1, (accessed July 1, 2020). See Exhibit 170.

B. Vaccination is a reasonable suspect in the etiology of narcolepsy

(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 a study published in *PLoS One*: "The incidence of narcolepsy was 9.0 in the vaccinated as compared to 0.7/100,000 person years in the unvaccinated individuals, the rate ratio being 12.7 (95% confidence interval 6.1-30.8). The vaccine-attributable risk of developing narcolepsy was 1:16,000 vaccinated 4 to 19-year-olds (95% confidence interval 1:13,000-1:21,000)."

Citation: Nohynek *et al*. (2012). AS03 adjuvanted AH1N1 vaccine associated with an abrupt increase in the incidence of childhood narcolepsy in Finland. *PLoS One* 7(3):e33536. https://doi.org/10.1371/journal.pone.0033536, (accessed May 12, 2020). See Exhibit 171.

(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 a study published in *Brain:* "H1N1 vaccination was associated with narcolepsy-cataplexy with an odds ratio of 6.5 (2.1-19.9) in subjects aged<18 years, and 4.7 (1.6-13.9) in those aged 18 and over."

Citation: Dauvilliers *et al*. (2013). Increased risk of narcolepsy in children and adults after pandemic H1N1 vaccination in France. *Brain* 136(Pt 8):2486-2496. https://doi.org/10.1093/brain/awt187, (accessed May 12, 2020). See Exhibit 172.

(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 a study published in *BMJ*: "The increased risk of narcolepsy after vaccination with ASO3 adjuvanted pandemic A/H1N1 2009 vaccine indicates a causal association."

Citation: Miller *et al*. (2013). Risk of narcolepsy in children and young people receiving AS03 adjuvanted pandemic A/H1N1 2009 influenza vaccine: retrospective analysis. *BMJ* 346:f794. https://doi.org/10.1136/bmj.f794, (accessed June 6, 2020). See Exhibit 173.

(4) For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from a study published in *Sleep*: "We found a significantly increased risk of narcolepsy in adults following Pandemrix vaccination in England."

Citation: Stowe *et al*. (2016). Risk of Narcolepsy after AS03 Adjuvanted Pandemic A/H1N1 2009 Influenza Vaccine in Adults: A Case-Coverage Study in England. *Sleep* 39(5):1051-1057. https://doi:10.5665/sleep.5752, (accessed May 12, 2020). See Exhibit 174.

32. Rheumatoid arthritis (RA)

A. Definition

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following description of 'rheumatoid arthritis' from the Centers of Disease Control and Prevention website: "Rheumatoid arthritis, or RA, is an autoimmune and inflammatory disease, which means that your immune system attacks healthy cells in your body

by mistake, causing inflammation (painful swelling) in the affected parts of the body. RA mainly attacks the joints, usually many joints at once."

Citation: Centers for Disease Control and Prevention, *Rheumatoid Arthritis*. https://www.cdc.gov/arthritis/basics/rheumatoid-arthritis.html, (accessed July 1, 2020). See Exhibit 175.

B. Prevalence of RA

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 Centers of Disease Control and Prevention website: "From 2013–2015, an estimated 54.4 million US adults (22.7%) annually had ever been told by a doctor that they had some form of arthritis, rheumatoid arthritis, gout, lupus, or fibromyalgia."

Citation: Centers for Disease Control and Prevention, *Arthritis-Related Statistics*. https://www.cdc.gov/arthritis/data_statistics/arthritis-related-stats.htm, (accessed July 1, 2020). See Exhibit 176.

C. Growing prevalence of RA

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

> "Analysis of data from the two databases indicated that the RA prevalence rate in commercially insured adult US population ranged from 0.41 to 0.54% from 2004 to 2014. The prevalence varied substantially by gender and age in each year and increased gradually across the years for most subgroups… The prevalence of RA in the US appeared to increase during the period from 2004 to 2014, affecting a conservative estimate of 1.28-1.36 million adults in 2014."

Citation: Hunter *et al*. (2017). Prevalence of Rheumatoid Arthritis in the United States Adult Population in Healthcare Claims Databases, 2004-2014. *Rheumatology International* 37(9):1551-1557. https://doi.org/10.1007/s00296-017-3726-1, (accessed May 12, 2020). See Exhibit 177.

D. Vaccination is a reasonable suspect in etiology of RA

(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 a review published in

Immunopharmacology & Immunotoxicology: "The animal models of RA with a proven track record of predictability for efficacy in humans include: collagen type II induced arthritis in rats as well as mice, adjuvant induced arthritis in rats and antigen induced arthritis in several species."

Citation: Choudhary *et al*. (2018). Experimental animal models for rheumatoid arthritis. *Immunopharmacology & Immunotoxicology* 40(3):193-200. https://doi.org/10.1080/08923973.2018.1434793, (accessed May 12, 2020). See Exhibit 178.

(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 a study published in *Infection & Immunity:* "When the canine rOspA vaccine was combined with aluminum hydroxide, all vaccinated hamsters developed arthritis after challenge with *B. burgdorferi* sensu stricto."

Citation: Croke *et al*. (2000). Occurrence of Severe Destructive Lyme Arthritis in Hamsters Vaccinated With Outer Surface Protein A and Challenged With Borrelia Burgdorferi. *Infection & Immunity* 68(2):658-663. https://doi.org/10.1128/iai.68.2.658-663.2000, (accessed May 12, 2020). See Exhibit 179.

(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 a study published in *Autoimmunity Reviews*: "there was an obvious association between vaccinations and increased risk of RA."

Citation: Wang *et al*. (2017). Vaccinations and risk of systemic lupus erythematosus and rheumatoid arthritis: A systematic review and meta-analysis. *Autoimmunity Reviews* 16 (7):756-765. https://doi.org/10.1016/j.autrev.2017.05.012, (accessed July 1, 2020). See Exhibit 180.

33. Juvenile idiopathic arthritis (JIA)

A. Definition

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following description of 'juvenile idiopathic arthritis' from the Mayo Clinic website:

> "Juvenile idiopathic arthritis, formerly known as juvenile rheumatoid arthritis, is the most common type of arthritis in children under the age of 16. Juvenile

> idiopathic arthritis can cause persistent joint pain, swelling and stiffness. Some children may experience symptoms for only a few months, while others have symptoms for the rest of their lives."

Citation: Mayo Clinic, *Juvenile Idiopathic Arthritis*. https://www.mayoclinic.org/diseases-conditions/juvenile-idiopathic-arthritis/symptoms-causes/syc-20374082, (accessed July 1, 2020). See Exhibit 181.

B. Prevalence of JIA

(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 Genetics Home Reference website: "One in 1,000, or approximately 294,000, children in the United States are affected [by JIA]."

Citation: Genetics Home Reference, U.S. National Library of Medicine, *Juvenile Idiopathic Arthritis*. https://ghr.nlm.nih.gov/condition/juvenile-idiopathic-arthritis#statistics, (accessed July 1, 2020). See Exhibit 182.

(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 a study published in *The Journal of Rheumatology*: "The prevalence of JIA per 100,000 persons was 44.7 (95% CI 39.1–50.2) on December 31, 2009."

Citation: Harrold *et al*. (2013). Incidence and prevalence of juvenile idiopathic arthritis among children in a managed care population, 1996-2009. *The Journal of Rheumatology* 40(7):1218–1225. https://doi.org/10.3899/jrheum.120661, (accessed July 1, 2020). See Exhibit 183.

C. Growing medical burden of JIA and other rheumatologic conditions

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from a study published in *Arthritis Care & Research*:

> "The number of ambulatory care visits for SPARC [significant pediatric arthritis and other rheumatologic conditions] increased from 665,000 in 2001 to 813,000 in 2002 to 828,000 in 2003 to 1,000,000 in 2004 for an average annualized estimate of 827,000 visits (95% CI 609,000–1,044,000) including an average

annualized estimate of 83,000 ED visits."

Citation: Sacks *et al*. (2007). Prevalence of and annual ambulatory health care visits for pediatric arthritis and other rheumatologic conditions in the United States in 2001–2004. *Arthritis Care & Research* 57(8):1439-1445. https://doi.org/10.1002/art.23087, (accessed May 12, 2020). See Exhibit 184.

D. Etiology of childhood arthritis

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 Centers for Disease Control and Prevention website: "The exact cause of childhood arthritis is unknown. In childhood arthritis the immune system may not work right which causes the inflammation in the joints and other body systems."

Citation: Centers for Disease Control and Prevention, *Childhood Arthritis*. https://www.cdc.gov/arthritis/basics/childhood.htm, (accessed July 1, 2020). See Exhibit 185.

34. Systemic lupus erythematosus (SLE)

A. Definition

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'systemic lupus erythematosus" from the Merck Manual: "Systemic lupus erythematosus is a chronic autoimmune inflammatory connective tissue disorder that can involve joints, kidneys, skin, mucous membranes, and blood vessel walls."

Citation: Merck Manual Consumer Version, *Systemic Lupus Erythematosus (SLE), (Disseminated Lupus Erythematosus or Lupus), by Alana M. Nevares, MD, The University of Vermont Medical Center, Last full review/revision Apr 2020*. https://www.merckmanuals.com/home/bone,-joint,-and-muscle-disorders/autoimmune-disorders-of-connective-tissue/systemic-lupus-erythematosus-sle, (accessed July 1, 2020). See Exhibit 186.

B. Prevalence of SLE

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 Centers for Disease Control and

Prevention website: "A conservative estimate suggests a [national] prevalence of 161,000 with definite SLE and 322,000 with definite or probable SLE."

Citation: Centers for Disease Control and Prevention, *Systemic Lupus Erythematosus*. https://www.cdc.gov/lupus/facts/detailed.html#prevalence, (accessed July 1, 2020). See Exhibit 187.

C. SLE mortality

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

> "During 2000–2015, there were 28,411 deaths of females with SLE recorded as an underlying or contributing cause of death. SLE ranked among the top 20 leading causes of death in females between 5 and 64 years of age. SLE ranked tenth among those ages 15–24 years, fourteenth among those ages 25–34 years and 35–44 years, and fifteenth among those ages 10–14 years."

Citation: Yen & Singh (2018). Brief Report: Lupus—An Unrecognized Leading Cause of Death in Young Females: A Population-Based Study Using Nationwide Death Certificates, 2000–2015. *Arthritis & Rheumatology* 70(8):1251-1255. https://doi.org/10.1002/art.40512, (accessed May 12, 2020). See Exhibit 188.

D. Vaccination is a reasonable suspect in etiology of SLE

(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 a study published in *Clinical Rheumatology*: "In the current study, a temporal association between immunization with HPV vaccine and the appearance of a spectrum of SLE-like conditions is reported. Additionally, among the patients described, several common features were observed that may enable better identification of subjects at risk."

Citation: Gatto *et al*. (2013). Human papillomavirus vaccine and systemic lupus erythematosus. *Clinical Rheumatology* 32:1301–1307. https://doi.org/10.1007/s10067-013-2266-7 (accessed May 12, 2020). See Exhibit 189.

(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 a study published in *PLoS One*: "Repeated immunization with antigen causes systemic autoimmunity in mice otherwise not prone to spontaneous autoimmune diseases… akin to systemic lupus erythematosus (SLE)."

Citation: Tsumiyama *et al*. (2009). Self-organized criticality theory of autoimmunity. *PLoS One* 4(12):e8382. https://doi.org/10.1371/journal.pone.0008382, (accessed May 12, 2020). See Exhibit 190.

(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 a study published in *Autoimmunity Reviews*: "The pooled findings suggested that vaccinations significantly increased risk of SLE."

Citation: Wang *et al*. (2017). Vaccinations and risk of systemic lupus erythematosus and rheumatoid arthritis: A systematic review and meta-analysis. *Autoimmunity Reviews* 16 (7):756-765. https://doi.org/10.1016/j.autrev.2017.05.012, (accessed July 1, 2020). See Exhibit 180.

35. Sjögren's syndrome (SjS)

A. Definition

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following description of 'Sjögren's syndrome' from the National Institutes of Arthritis and Musculoskeletal and Skin Diseases website: "Sjögren's syndrome is an autoimmune disease. In Sjögren's syndrome, your immune system attacks the glands that make tears and saliva….It most often causes dryness in the mouth and eyes. It can also lead to dryness in other places that need moisture, such as the nose, throat, and skin."

Citation: National Institutes of Arthritis and Muskuloskeletal and Skin Diseases, *Sjögren's Syndrome*. https://www.niams.nih.gov/health-topics/sjogrens-syndrome, (accessed July 1, 2020). See Exhibit 191.

B. Prevalence of SjS

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

Rheumatology website: "Between 400,000 and 3.1 million adults have Sjögren's syndrome. This condition can affect people of any age, but symptoms usually appear between the ages of 45 and 55. It affects ten times as many women as men. About half of patients also have rheumatoid arthritis or other connective tissue diseases, such as lupus."

Citation: American College of Rheumatology, *Sjögren's Syndrome*. https://www.rheumatology.org/I-Am-A/Patient-Caregiver/Diseases-Conditions/Sjogrens-Syndrome, (accessed July 1, 2020). See Exhibit 192.

C. Vaccination is a reasonable suspect in etiology of SjS

(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 a study published in *Clinical and Experimental Rheumatology:* "In the NZM2758 mice, alum induces a Sjögren's syndrome-like disorder that is characterized by chronic salivary gland dysfunction and the presence of lymphocytic infiltrates within the salivary glands. Thus, the potential of aluminum based adjuvants for induction of autoimmunity should be closely monitored in individuals genetically susceptible to developing autoimmune disorders."

Citation: Bagavant *et al*. (2014). Alum, an aluminum-based adjuvant, induces Sjögren's syndrome-like disorder in mice. *Clinical and Experimental Rheumatology* 32(2):251-255. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3990870/, (accessed May 12, 2020). See Exhibit 193.

(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 a study published in *The Israel Medical Association Journal:* "the administration of vaccines containing *Saccharomyces cerevisiae* should be carefully evaluated in patients with SjS since there is the possibility that such vaccines may elicit the production of autoantibodies in these patients. Moreover, the question whether vaccines may cause an autoimmune disease in otherwise healthy subjects is still unanswered…the possible association between vaccination and autoimmune diseases, including SjS, is a matter of which physicians should be aware of."

Citation: Colafrancesco et al. (2014) Sjögren's syndrome: Another facet of the autoimmune/inflammatory syndrome induced by adjuvants (ASIA). *Journal of Autoimmunity.* 51: 10-16. See Exhibit 194.

(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 a study published in *The Israel Medical Association Journal:* "several case reports have suggested that both vaccines and silicone may trigger the development of SS."

Citation: Colafrancesco *et al*. (2016). Autoimmune/Inflammatory Syndrome Induced by Adjuvants and Sjögren's Syndrome. *The Israel Medical Association Journal* 18(3-4):150–153. https://pubmed.ncbi.nlm.nih.gov/27228631, (accessed July 1, 2020). See Exhibit 195.

36. Celiac Disease (CD)

A. Definition

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following description of 'celiac disease' from a study published in *The American Journal of Gastroenterology*: "Celiac disease is a chronic immune-mediated disease characterized by small intestinal inflammation. Triggered by gluten exposure in genetically sensitive individuals, this disease is associated with excess mortality as well as a number of complications, including type 1 diabetes and lymphoproliferative disease."

Citation: Ludvigsson *et al*. (2013). Increasing incidence of celiac disease in a North American population. *The American Journal of Gastroenterology* 108(5):818–824. https://doi.org/10.1038/ajg.2013.60, (accessed May 12, 2020). See Exhibit 196.

B. Rising Annual Incidence of CD

(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 a study published in *Clinical Gastroenterology and Hepatology*: "The overall annual incidence of celiac disease was 2.1 per 100,000 (95% confidence interval [CI], 1.7–2.6) but increased from 0.9 per 100,000 (CI, 0.5–1.2) in 1950–1989 to 3.3 per 100,000 (95% CI, 2.2–4.4) in the 1990s. The incidence was 9.1 per 100,000 (95% CI, 5.2–13.0) in the final 2 years of the study."

Citation: Murray *et al*. (2003). Trends in the identification and clinical features of celiac disease in a North American community, 1950-2001. *Clinical Gastroenterology and Hepatology* 1(1):19-27. https://doi.org/10.1053/jcgh.2003.50004, (accessed May 12, 2020). See Exhibit 197.

(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 a study published in *The American Journal of Gastroenterology*: "The overall age- and sex-adjusted incidence of CD in the study period was 17.4 (95% confidence interval [CI] = 15.2–19.6) per 100,000 person-years, increasing from 11.1 (95% CI=6.8–15.5) in 2000–2001 to 17.3 (95% CI=13.3–21.3) in 2008–2010."

Citation: Ludvigsson *et al*. (2013). Increasing incidence of celiac disease in a North American population. *The American Journal of Gastroenterology* 108(5):818–824. https://doi.org/10.1038/ajg.2013.60, (accessed May 12, 2020). See Exhibit 196.

C. Economic burden of CD

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from a study published in *Alimentary Pharmacology & Therapeutics*: "Over a 4-year period, coeliac disease cases experienced higher out-patient costs (mean difference of $1457; P = 0.016) and higher total costs than controls (mean difference of $3964; P = 0.053)."

Citation: Long *et al*. (2010). The economics of coeliac disease: a population-based study. *Alimentary Pharmacology & Therapeutics*, 32: 261-269. https://doi.org/10.1111/j.1365-2036.2010.04327.x, (accessed May 12, 2020). See Exhibit 198.

D. Vaccination is a reasonable suspect in etiology of CD

(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 a study published in *The American Journal of Gastroenterology*: "The high CD incidence (17 per 100,000 p-y in the past decade) points towards a change in environmental exposures, potentially responsible for triggering CD not only in children but also, and particularly, in adults."

Citation: Ludvigsson *et al*. (2013). Increasing incidence of celiac disease in a North American population. *The American Journal of Gastroenterology* 108(5):818–824. https://doi.org/10.1038/ajg.2013.60, (accessed May 12, 2020). See Exhibit 196.

(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 a study published in *Journal of Internal Medicine*: "The observed association of a 56% increased risk of coeliac disease after qHPV [quadrivalent human papillomavirus] vaccination was strong, and the increase was strikingly similar in both risk periods after vaccination."

Citation: Hviid *et al*. (2018). Human papillomavirus vaccination of adult women and risk of autoimmune and neurological diseases. *Journal of Internal Medicine* 283(2):154-65, https://doi.org/10.1111/joim.12694, (accessed May 12, 2020). See Exhibit 199.

37. Inflammatory Bowel Disease (IBD)

A. Definition

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following description of 'inflammatory bowel disease' from the Centers of Disease Control and Prevention website:

> "Inflammatory Bowel Disease (IBD) is a broad term that describes conditions characterized by chronic inflammation of the gastrointestinal tract. The two most common inflammatory bowel diseases are ulcerative colitis and Crohn's disease. Inflammation affects the entire digestive tract in Crohn's disease and only the large intestine (also called the colon) in ulcerative colitis. Both illnesses involved an abnormal response to the body's immune system."

Citation: Centers for Disease Control and Prevention, Inflammatory bowel disease (IBD). https://www.cdc.gov/ibd/index.htm, (accessed July 1, 2020). See Exhibit 200.

B. Prevalence of IBD

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 Centers of Disease Control and Prevention website: "In 2015, an estimated 1.3% of US adults (3 million) reported being diagnosed with IBD (either Crohn's disease or ulcerative colitis). This was a large increase from 1999 (0.9% or 2 million adults)."

Citation: Centers for Disease Control and Prevention, Inflammatory bowel disease (IBD), *Data and Statistics.* https://www.cdc.gov/ibd/data-statistics.htm#2, (accessed July 1, 2020). See Exhibit 201.

C. Pediatric incidence and prevalence of IBD

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from a study published in *JAMA Pediatrics*: "The incidence of pediatric IBD is approximately 10 per 100 000 children in the United States and Canada and is rising. With a prevalence of 100 to 200 per 100 000 children in the United States (and an estimated total of 70 000), most pediatricians will treat children with IBD in their practices."

Citation: Rosen *et al*. (2015). Inflammatory Bowel Disease in Children and Adolescents. *JAMA Pediatrics* 169(11):1053–1060. https://doi.org/10.1001/jamapediatrics.2015.1982, (accessed May 12, 2020). See Exhibit 202.

D. Etiology of IBD

(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 Centers of Disease Control and Prevention website:

> "The exact cause of IBD is unknown, but IBD is the result of a defective immune system. A properly functioning immune system attacks foreign organisms, such as viruses and bacteria, to protect the body. In IBD, the immune system responds incorrectly to environmental triggers, which causes inflammation of the gastrointestinal tract. There also appears to be a genetic component—someone with a family history of IBD is more likely to develop this inappropriate immune response."

Citation: Centers for Disease Control and Prevention, *What is inflammatory bowel disease (IBD)?* https://www.cdc.gov/ibd/what-is-IBD.htm, (accessed May 12, 2020). See Exhibit 203.

(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 a study published in *World Journal of Gastroenterology:*

> "Environmental factors may also directly act on the intestinal mucosa and alter immune function and gene expression. This can be due to a change in intestinal permeability or an alteration in host gene expression by epigenetic modification or other mechanisms. The end result is an abnormal host immune function and chronic inflammation in the gut."

Citation: Dutta & Chacko (2016). Influence of environmental factors on the onset and course of inflammatory bowel disease. *World Journal of Gastroenterology* 22(3):1088-1100. https://doi.org/10.3748/wjg.v22.i3.1088, (accessed May 12, 2020). See Exhibit 204.

(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 a study published in *JAMA Pediatrics*: "early-life environmental factors associated with a Western lifestyle may predispose to IBD."

Citation: Rosen *et al*. (2015). Inflammatory Bowel Disease in Children and Adolescents. *JAMA Pediatrics* 169(11):1053–1060. https://doi.org/10.1001/jamapediatrics.2015.1982, (accessed May 12, 2020). See Exhibit 202.

E. Vaccination is a reasonable suspect in etiology of IBD

(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 a review published in *Clinical Reviews in Allergy & Immunology*:

> "*Saccharomyces cerevisiae* is best known as the baker's and brewer's yeast, but its residual traces are also frequent excipients in some vaccines. Although anti-S. cerevisiae autoantibodies (ASCAs) are considered specific for Crohn's disease, a growing number of studies have detected high levels of ASCAs in patients affected with autoimmune diseases as compared with healthy controls, including antiphospholipid syndrome, systemic lupus erythematosus, type 1 diabetes mellitus, and rheumatoid arthritis… Furthermore, ASCAs may be present years before the diagnosis of some associated autoimmune diseases as they were retrospectively found in the preserved blood samples of soldiers who became affected by Crohn's disease years later. Our results strongly suggest that ASCAs' role in clinical practice should be better addressed in order to evaluate their predictive or prognostic relevance."

Citation: Rinaldi *et al*. (2013). Anti-Saccharomyces cerevisiae Autoantibodies in Autoimmune Diseases: from Bread Baking to Autoimmunity. *Clinical Reviews in Allergy &*

Immunology 45:152–161. https://doi.org/10.1007/s12016-012-8344-9, (accessed June 26, 2020). See Exhibit 205.

(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 a study published in *Clinical Gastroenterology and Hepatology:* "Subgroup analysis for Crohn's disease (CD) and ulcerative colitis (UC) found an association between the poliomyelitis vaccine and risk for developing CD (RR, 2.28; 95% CI, 1.12–4.63) or UC (RR, 3.48; 95%CI, 1.2–9.71)."

Citation: Pineton de Chambrun *et al*. (2015). Vaccination and Risk for Developing Inflammatory Bowel Disease: A Meta-Analysis of Case–Control and Cohort Studies *Clinical Gastroenterology and Hepatology* 13:1405–1415. https://doi.org/10.1016/j.cgh.2015.04.179, (accessed May 12, 2020). See Exhibit 206.

38. Immune thrombocytopenia (ITP)

A. Definition and Incidence and prevalence of ITP

(1) For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following description of 'immune thrombocytopenia' from the National Organization for Rare Disorders (NORD) website:

> "Immune thrombocytopenia (ITP) is an autoimmune bleeding disorder characterized by abnormally low levels of blood cells called platelets, a situation which is referred to as thrombocytopenia. Platelets are specialized blood cells that help maintain the integrity of the walls of our blood vessels and help prevent and stop bleeding by accelerating clotting."

Citation: National Organization for Rare Disorders, *Immune Thrombocytopenia*. https://rarediseases.org/rare-diseases/immune-thrombocytopenia, (accessed July 1, 2020). See Exhibit 207.

(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 National Organization for Rare Disorders (NORD) website: "The incidence (how many people are diagnosed each year) of ITP among adults in the USA is estimated to be 3.3 per 100,000 adults/year. The prevalence (how

many adults have ITP at any time) is 9.5 cases per 100,000. The annual prevalence is estimated at 5.3 per 100,000 among children."

Citation: National Organization for Rare Disorders, *Immune Thrombocytopenia*. https://rarediseases.org/rare-diseases/immune-thrombocytopenia, (accessed May 12, 2020). See Exhibit 207.

B. Vaccination as reasonable suspect in etiology of ITP

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 Centers of Disease Control and Prevention website: "The risk of ITP has been shown to be increased in the six weeks following an MMR vaccination, with one study estimating 1 case per 40,000 vaccinated children."

Citation: Centers for Disease Control and Prevention, *Measles, Mumps, Rubella (MMR) Vaccine, Safety Information.* https://www.cdc.gov/vaccinesafety/vaccines/mmr-vaccine.html, (accessed May 12, 2020). See Exhibit 94.

39. Alopecia areata (AA)

A. Definition and Prevalence of AA

(1) For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following description of 'alopecia areata' from the National Alopecia Areata Foundation website: "Alopecia areata is a common autoimmune skin disease, causing hair loss on the scalp, face and sometimes on other areas of the body. It affects as many as 6.8 million people in the U.S. with a lifetime risk of 2.1%."

Citation: National Alopecia Areata Foundation, *What You Need to Know About Alopecia Areata.* https://www.naaf.org/alopecia-areata, (accessed July 1, 2020). See Exhibit 208.

B. Vaccination is a reasonable suspect in etiology of AA

(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 a 1997 study published in "After reviewing 60 case reports, we believe that immunizations warrant consideration among potential causes of hair loss."

Citation: Wise. R *et al.* (1997). Hair Loss After Routine Immunizations. *JAMA* 278 (14): 1176-1178. See Exhibit 209.

(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 a case report published in *Pediatric Dermatology:*

> "Alopecia areata (AA) is the most common form of hair loss in children. We report the case of a child who had two episodes of AA after two different vaccines with complete hair regrowth between the episodes. This case supports the concept that vaccination might be a trigger for the development of AA in genetically predisposed children."

Citation: Chu *et al*. (2016). Alopecia Areata After Vaccination: Recurrence with Rechallenge. *Pediatric Dermatology* 33(3):e218–219. https://doi.org/10.1111/pde.12849, (accessed May 12, 2020). See Exhibit 210.

40. Bullous Dermatoses

A. Definition

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following description of 'bullous dermatoses' from a review published in *Annals of the New York Academy of Sciences:* "Bullous dermatoses are a variety of autoimmune skin diseases that are characterized by the presence of bullae or blisters. Most of these diseases are associated with substantial morbidity, and a few may result in death."

Citation: Patrício *et al*. (2009). Autoimmune bullous dermatoses: a review. *Annals of the New York Academy of Sciences* 1173:203–210. https://doi.org/10.1111/j.1749-6632.2009.04737.x, (accessed May 12, 2020). See Exhibit 211.

B. Growing incidence of Bullous Pemphigoid (BP) in infants

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

> "Bullous pemphigoid is an acquired autoimmune disorder presenting with subepidermal blistering, eosinophilia, and severe itch. Its incidence is increasing and it mostly affects the elderly; it is considered rare in children. The first case of

> BP in a child was described in 1970 based on immunofluorescence diagnosis; the first case of BP in an infant was described in 1977. Since then, the number of reported pediatric cases has steadily increased… the majority of cases of childhood BP occurred in small children under the age of 12 months."

Citation: Schwieger-Briel *et al.* (2014). Bullous pemphigoid in infants: characteristics, diagnosis and treatment. *Orphanet Journal of Rare Diseases* 9:185. https://doi.org/10.1186/s13023-014-0185-6, (accessed October 17, 2020). See Exhibit 212.

C. Vaccination is a reasonable suspect in etiology of BP in infants

(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 a study published in *Pediatric Dermatology:*

> "Bullous pemphigoid (BP) is an acquired autoimmune blistering disorder of unknown etiology uncommon in childhood… We report three infants with infantile BP presenting shortly after vaccination for diphtheria, pertussis, tetanus, poliomyelitis, hepatitis B, Haemophilus influenzae B, and meningococcus C. Our cases further reinforce the causal association between childhood BP and vaccination."

Citation: de la Fuente *et al*. (2013). Postvaccination bullous pemphigoid in infancy: report of three new cases and literature review. *Pediatric Dermatology 30*(6):741–744. https://doi.org/10.1111/pde.12231, (accessed May 12, 2020). See Exhibit 213.

(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 a study published in BMC Pediatrics: "Here we describe three cases of BP which were referred to our department in the last 15 years. Two of them developed an eruption of bullous lesions just a few days after vaccination for diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B and *Haemophilus influenzae* B."

Citations: Baroero *et al*. (2017). Three case reports of post immunization and post viral Bullous Pemphigoid: looking for the right trigger. *BMC Pediatrics* 17(1):60. https://doi.org/10.1186/s12887-017-0813-0, (accessed May 12, 2020). See Exhibit 214.

41. Otitis Media

A. Definitions

(1) Otitis media

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following definition of 'otitis media' from MedicineNet: '*otitis media* is "inflammation of the middle ear characterized by the accumulation of infected fluid in the middle ear, bulging of the eardrum, pain in the ear and, if eardrum is perforated, drainage of purulent material (pus) into the ear canal." '

Citation: MedicineNet, *Medical Definition of Otitis Media, Medical Author: William C. Shiel Jr., MD, FACP, FACR.* https://www.medicinenet.com/script/main/art.asp?articlekey=8912, (accessed July 1, 2020). See Exhibit 215.

(2) Acute otitis media (AOM)

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following description of 'acute otitis media' from the National Institute on Deafness and Other Communication Disorders (NIDOCD) website: "Acute otitis media (AOM) is the most common ear infection. Parts of the middle ear are infected and swollen and fluid is trapped behind the eardrum. This causes pain in the ear—commonly called an earache."

Citation: National Institute on Deafness and Other Communication Disorders, *NIDCD Fact Sheet: Ear Infections in Children*. https://www.nidcd.nih.gov/sites/default/files/Documents/health/hearing/NIDCD-Ear-Infections-In-Children.pdf, (accessed June 9, 2020). See Exhibit 216.

B. Prevalence of AOM

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

> "In the United States, 70% of all children experience one or more attacks of AOM before their second birthday. A study from Pittsburgh that prospectively followed urban and rural children for the first 2 years of life determined that the incidence of middle ear effusion episodes is approximately 48% at age 6 months, 79% at age 1 year, and 91% at age 2 years."

Citation: Medscape, *What is the incidence and prevalence of acute otitis media (AOM) in the US? Author: John D Donaldson, MD, FRCSC, FACS.*

https://www.medscape.com/answers/859316-30596/what-is-the-incidence-and-prevalence-of-acute-otitis-media-aom-in-the-us, (accessed June 26, 2020). See Exhibit 217.

C. Economic burden of AOM

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 Infection Control Today website: "The findings show that AOM is associated with significant increases in direct costs incurred by consumers and the healthcare system. With its high prevalence across the U.S., pediatric AOM accounts for approximately $2.88 billion in added healthcare expenses annually and is a significant healthcare utilization concern."

Citation: Infection Control Today, *Kids' Ear Infections Cost Healthcare System Nearly $3 Billion Annually,* January 10, 2014. https://www.infectioncontroltoday.com/infections/kids-ear-infections-cost-healthcare-system-nearly-3-billion-annually, (accessed June 9, 2020). See Exhibit 218.

D. Immunologic deficits in etiology of otitis media

For recognition of a commonly known fact to public health officials familiar with the matter, Petitioners request judicial notice of the following quote from a review published in *The Journal of Infection:* "Immunologic deficits in otitis prone children cause them to be unusually vulnerable to viral upper respiratory infections and respond inadequately to routine pediatric vaccines."

Citation: Pichichero (2020). Immunologic dysfunction contributes to the otitis prone condition. *The Journal of Infection* 80(6): 614–622. https://doi.org/10.1016/j.jinf.2020.03.017, (accessed June 9, 2020). See Exhibit 219.

CONCLUSION

Petitioners hereby request judicial notice of the foregoing facts.

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ATTORNEYS FOR PETITIONERS

Date: 12-6-20

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