# Written Public Comments

# IACC Full Committee Meeting

January 13, 2017

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Kerry Scott Lane, MD January 13, 2017

I would like to submit my US Patent "Methods of treatment for Autism" to IACC to archive and circulate.

Please post this everywhere, on FDA site. Tylenol depletes Glutathione, needed to metabolize the harmful metals in vaccines. Tylenol should have BLACK BOX WARNINGS ON THE PACKAGES. My patent is attached, please post it.

The entire world is watching...Including President Trump...

Please submit the following patent for the IACC Members entitled "Methods of treatment for Autism".

https://www.google.com/patents/US9442092

Mark Harrison January 13, 2017

My name is Mark Harrison and I am the father of a 6 year old diagnosed with ASD. I work for an employer who provides insurance coverage governed by ERISA. My employer has refused to cover ABA therapy using an exclusion for educational services as the reason. This is out dated language but I have not been successful in appealing the decision. How soon will families see a Federal Mandate that will eliminate these types of decision?

Toby Rogers January 13, 2017

#### Dear IACC:

I am writing to express my extreme displeasure at your decision to prevent Lisa Wiederlight, Executive Director of SafeMinds, from speaking at the upcoming quarterly meeting of the IACC. Your actions are an affront to democracy and a violation of open meetings laws. Autism represents a catastrophic failure on the part of HHS and the U.S. government to do its job to protect the American people. For nearly 30 years, HHS has a perfect record of failing to protect public health in connection with autism. Lisa Wiederlight is exactly the sort of outsider voice that is necessary to bring about a paradigm shift. The history of medicine from Jon Snow to Florence Nightingale to Robin Warren shows that outsiders are essential to producing paradigm shifts while insiders often block progress because they profit from the status quo. But of course, you don't want anyone to point out your failures, so you engage in censorship and the autism epidemic continues to ravage our country and the world.

One day history books will study your actions as examples of what NOT to do in public health while Lisa Wiederlight will be held up as a hero. I strongly urge you to reconsider your undemocratic actions. I have also copied my two Senators so that may also be aware of your extraordinary disregard for basic standards of fairness.

Sincerely, Toby

Toby Rogers
Ph.D. candidate, University of Sydney
MPP, University of California, Berkeley

Susan Reilly January 13, 2017

Please allow for Safe Minds to represent the voices of parents, caregivers and those who struggle with Autism. Limiting the information to the committee is not going to help anyone solve the puzzle. This type of behavior by the IACC is unacceptable.

sincerely ,
Susan Reilly
mother of a young adult on the spectrum and warrior for a cause

Marilyn Kissinger January 13, 2017

PLEASE READ....my case/argument/ah ha moment as it relates to infants and children's development issues after a horrible experience regarding an adult male cat I rescued Friday Nov. 4th, 2016 made me think about how many households with infants and children use over the counter flea and tick drops, collars and sprays on their indoor animals, changing them/using them throughout the year to prevent insects in their homes. I was a teacher in the public school system and became saddened by the fact of unusally high incidence of families' children affected by Autism disorder in the recent decade. I know this is long, but really would like to know from you if this research of a correlation has been studied..

This terribly thin and flea infested Turkish Van cat was abandoned and hanging around my back yard since I first saw it in August, 2016. At that time it was under a parked truck infested with over 100 fleas surrounding it's eyes and ears, appeared severely malnourished and dehydrated. I already have an indoor rescue dog and an indoor rescue kitten in an apartment. Our local animal control for the township has been rumored to euthanize any strays they are called to pick up, as Delaware County and many no kill shelters are so full they do not take these animals. So I did not want to call them to try to pick up this cat. On nov 4th I was able to capture and place this cat in my dog travel kennel; some minor fleas on him, and still mal-nourished, skin over bones. He did not try to claw, bite or get away and purred loudly when I held and pet him.

I immediately placed a Hartz Ultra Guard Plus Flea and Tick Collar for cats and kittens (7 month protection) on him and kept him outdoors until checked by a vet and or picked up by a rescue. tetrachlovinghos stated on box which is a cholinesterase inhibitor.

Saturday we took him to a local vet to see if he was microchipped and he was NOT, but was neutered. This vet recommended Frontline or Advantix . And since we did not have funds to pay \$70 for similar liquid three monthly treatments found at the local PetCo my daughter purchased ADVANTAGE treatment spray for CATS distributed by Bayer Healthcare LLC EPA Reg No 1021-1704-11556,EPA Est. no 11623-GA-384611638 V-05/2015 for \$14.95

Contains a combination of ingrdients;

Nylar

**Pyrethrins** 

3rd active ingrdient is NOT identified..simple one sentwence says"The third active ingredient ENHANCES the killling activity of Pyrethrins.

"This combination of ingredients in Advatage \*Treatment Spray foe CATS kills adult fleas, AND HATCHING FLEAS AND FLEA EGGS FOR 100 DAYS BEFORE THEY GROW UP TO BITE. NYLAR CONTINUES TO KILL HATCHING LEAS AND FLEA EGGS FOR 100 days by preventing their development into the adult stage.

On Saturday my daughter and I applied the spray wetting the cat and rubbing it against the grain of the fur as directed on Saturday afternoon and placed him back into a vacant bedroom to separate him from our household dog and kitten; we brought it inside as the night temperatures were in the 30's.

He smelled after the chemicals, kept shaking his head and then began licking himself where the spray was still wet. He began to drink inordinate amounts of water and ate sparingly Saturday night. He still had the Hartz FLEA COLLAR ON TOO!!

On Sunday he had diarrhia and vomiting in large amounts and began flicking his back legs out like he had

something on the pads of his feet. He became very lethargic, though was still able to walk, meow, use the litterbox and eating and drinking. He no longer was grooming himself.

On Monday I contacted 10 no skill shelters to no avail...no room at the INN.

On Monday and Tuesday he continued to vomit smaller clear liquid once or twice a day and continued to drink exceedingly large amounts of water. He began to look depressed and became inactive, just lying around and like he was in a fog by Wed, but continued to eat and walk around the apartment intermingling with our dog and kitten, (now 9 months old). He was not and never has been aggressive toward either one nor towards humans during those 5 days. After he vomited again late Wednesday night I finally had an AH HA moment...I suddenly knew he was being poisoned!!! I felt just awful, knowing WE HAD DONE THIS TOO HIM! I immediately removed the collar. I looked online doing research on these products and CLASS ACTION LAW SUITS, due to 44,000 deaths of pets from the toxic effects of these products in 2008 alone!

Our rescued cat is acting so much better since his bath AND HE HAS STOPPED DRINKING INORDINATE AMOUNTS OF WATER AND HAS STARTED GROOMING HIMSELF after stopping the first day of application. He is gaining weight, is playing with both the dog and the kitten, appears to have improved to normal behaviors with no vomiting nor diarrhia since the bath.

Today is MONDAY Nov. 14th. After reading the 7 sided information folder on the Advantage Spray and reading the EPA rulling on the 2008 lawsuit, I have this deep need to make the human medical community investigate IF THESE PET PRODUCTS dust, residue, liquids could infact be the cause of AUTISM spectrum, without any one thinking there could be a causal relationship.

If infants are crawling on these dust, debris floors of constantly treated household pets and or placing toys into their mouths, fingers into their mouths, after crawling on these contaminated areas could they not be ingesting by nose/mouth these high doses of toxic chemicals into their developmental physical bodies.

I and my daughter are horrified at how innocently we trusted to place these chemicals on a stray cat . And only after this research did I even recognize that my dogs constant scratching could also be a cause of the Harts Ultra GFuard Pro Flea and Tick Drops I have been using on her every single month for the past 18 months. I had used a Hartz pet collar on her for one week at the beginning of summer and she develped lesions around her neck... SHE IS A HOUSE DOG RUBBING AGAINST CARPETS< BEDDING< AND SOFAs to scratch the itch/or subside any pain. I went back to the drops.

Here are the ingredients:

Etofenprox 55%

Piperonyl Butoxide 10%

n-octyl bicycloheptene dicarboximide (MKG 264) 1%

Pyriproxyfen (NYLAR) 0.5%

S-Methoprene o.25%

OTHER INGRDIENTS 33.25% (not identified

Environmental Hazard...do not pour unused product down the drain or place filled container in recycle bins)

PLEASE conduct research if these everyday household use pet pesticides are causing the developmental neurological issues in our children!!!!

I will never use any over the counter insecticides or sprays on any of my pets, nor in my house where children visit from time to time.

CAN THE PEDIATRIC ASSOCIATION OF AMERICA STOP THIS RAMPANT POISON DISTRIBUTION INTO OUR HOMES???

Thank you for reading this all the way through...and a short reply would be appreciated with any helpful information.

I am outraged that consumer protection has not yet removed these toxins from the market. How many bottles do you believe have been poured down the drains, onto ground, and what if the plastic contains residules of the many toxic in reprocessing for use of human food products? Our rescue cat survived without known after affects; and I have thoroughly vacuumed every carpet and piece of furniture he may have lain on and rubbed up against in the 4 days the collar was on him as well as the spray liquid residue that may have dried into the cloth he lay on.

THESE ARE HOUSEHOLD PET PRODUCTS USED EVERY DAY, MONTH, YEAR IN OUR RESIDENTIAL ENVIRONMENT THAT ARE HARMING CHILDREN'S NEUROLOGICAL DEVELOPMENT WITH WORLD-WIDE PRODUCT DISTRIBUTION...

if not now--when??? WILL YOU GET THEM OFF THE MARKETS PERMANENTLY??

Mothers, fathers, grandparents trust the use of these toxic harmful chemicals and use them year after year on every single pet in their homes...carpets, bedding, pet fur on floors, hugs and pets by children, and over 44000 pet deaths each and every year from use of these products!!!

I am not a researcher, but will always be an educator ... I want the world to KNOW PET PESTICIDES ARE IN FACT HARMING OUR FUTURE GENERATIONS DEVELOPMENT.

Please respond and forward to researchers, pediatricians etc, as to if any research has been or is being conducted in this correlation regard.

Marilyn Kissinger, M. Ed retired 2009

Pam Rockwell January 13, 2017

Dear Director Gordon and members of the IACC,

Please accept this letter as a public comment to the Interagency Autism Coordinating Committee. In 2012 I spoke at the July IACC meeting about my concerns that influenza vaccine use in pregnancy could cause autism through the mechanism of maternal autoantibodies. In July 2014 I wrote to the IACC about my concerns that the FDA was expanding the number of vaccines that are used in pregnancy without doing any studies to determine if there are developmental effects. In 2015, I wrote IACC Director Insel about my concerns that the FDA was discussing how to delineate the safety criteria that it will use to approve vaccine use in pregnancy to prevent disease in newborns, and that drug companies did not want to evaluate long term safety issues that might require them to follow up for more than a year or two.

Vaccines in pregnancy are not tested for developmental effects. People who do not follow drug safety studies do not realize that vaccines are not usually tested in pregnant women, instead, after they have been approved for "all adults", the drug companies create pregnancy registries where side effects and pregnancy outcomes can be recorded. Using flu vaccine as an example, as people noticed the anecdotal connection between flu vaccine and miscarriage in early pregnancy, some safety studies were done to confirm flu vaccine safety — and indeed, flu vaccine in pregnancy is not associated with birth defects that are apparent at birth. But no studies were ever done to confirm that there were no developmental delay or cancer developed in the children exposed prenatally. The CDC Advisory Committee on Immunization Practices has the authority to put vaccines that have not been tested or approved by the FDA in specific high risk populations, and school districts and employers can legally require these vaccines based on the ACIP recommendation. Courts have upheld the firing of a nurse in Pennsylvania because she refused an influenza vaccine during her pregnancy because she was concerned that it might have been the cause of her previous miscarriage.

The only study of maternal influenza vaccine and autism showed an increased risk in the first trimester. In November 2016 the very first study published that evaluated whether there was a link between autism and maternal vaccination did indeed show a link between influenza vaccination in the first trimester and an increased autism risk of 4 cases in 1000 live births (a 20% increased risk):

Zerbo O, Qian Y, Yoshida C, Fireman BH, Klein NP, Croen LA.

Association Between Influenza Infection and Vaccination During Pregnancy and Risk of Autism Spectrum Disorder.

JAMA Pediatr. Published online November 28, 2016. doi:10.1001/jamapediatrics.2016.3609 https://www.ncbi.nlm.nih.gov/pubmed/27893896

"We found that influenza vaccination in the first trimester was associated, in an initial analysis unadjusted for multiple comparisons, with a slightly increased ASD risk after controlling for maternal allergy, asthma, autoimmune conditions, gestational diabetes, hypertension, age, education, race/ethnicity, child conception year, conception season, sex, and gestational age. However, adjusting for the multiplicity of hypotheses tested suggests that the results could be due to chance. If influenza vaccination during the first trimester of pregnancy causes ASD, our results suggest that it would amount to 4 additional ASD cases for every 1000 women vaccinated. Our finding of a possible association between maternal influenza vaccination in the first trimester and increased ASD risk parallels previous studies reporting an association between maternal viral infection or fever and increased ASD risk in the first trimester."

You may recall the maternal autoantibody theory of autism explains the gender bias in autism by supposing that female fetuses are more susceptible to these antibodies and are more likely to be reabsorbed (in mice) or spontaneously abort (in primates), and this is supported by their animal data. This is important because the CDC Advisory Committee on Immunization Practices (ACIP) has also been reviewing a Vaccine Safety Datalink study led by Dr. Jim Donahue, et al. at the Marshfield Clinic titled, "Evaluating the risk of spontaneous abortion following administration of influenza vaccines containing H1N1pdm09 and H3N2 viral antigens," which did show some correlation between first trimester flu vaccine and miscarriages. (The ACIP discounted this data because they felt that women who do not receive flu shots are less likely to seek medical attention for a miscarriage, even though there is no evidence to support this excuse to ignore the data.) The Zerbo study only evaluated full term pregnancies, so it would not have noticed if female fetuses were at increased risk of spontaneous abortion. The combination of increased numbers of males with autism in the Zerbo study and the increased miscarriages in the VSD study mirrors the animal models of the maternal autoantibody theory of autism.

**FDA** is about to delineate their safety criteria for vaccine use in pregnant women for the purpose of protecting the newborn. In addition to influenza and pertussis, dozens of vaccines will be evaluated and added to the vaccine schedule for pregnant women. Vaccine studies are usually done in poor countries — where they are really needed, but also where there are no regular developmental screenings, no provider diagnosis codes, no school special education services: no outside markers to use to assess developmental health milestones. And even if the drug companies invest the time and money to do their own developmental screenings, in these foreign cultures American developmental screening tools do not even work.

This is exactly the sort of internal government agency interaction that IACC was created to coordinate. The FDA Vaccine and Biologics division needs guidance about what sort of testing makes sense and they need feedback about what the information they gather means. 40% of pregnant women received flu vaccine during their pregnancies last year, and that is expected to go up this year. IACC should react to this new data. You should put this on the IACC agenda this coming January, 2017, or hold special meetings to address this study as soon as possible. IACC member Dr. David Amaral has personal research experience with the maternal autoimmune model of autism. FDA/IACC representative Dr. Tiffany Farchione can contact her counterpart in the FDA Department of Vaccine Research and Review, Dr. Marian Gruber to speak with the committee about vaccines in pregnancy and developmental assessments.

I think you should have speakers to bring the committee up to speed about this study and about the immunological links of autism. Certainly you want to hear from the author of the study, Dr. Zerbo, and from Dr. Gruber about the status of vaccines in pregnant women. Certainly you want to hear from the labs that study the links between maternal autoantibodies and autism, such as Dr. Amaral's colleagues Dr. Judy Van de Water and Dr. Melissa Bauman. You might also want to hear from the East coast maternal autoantibody group that looks at autism and learning disabilities from lupus, Dr. Betty Diamond and Dr. Lior Brimberg. You might also want to hear from Dr. Alan Brown from Columbia about the sort of studies he does linking maternal toxic exposures and offspring mental health.

It is time that vaccine safety in pregnancy was addressed by the autism community. You should get this on your next agenda, and make sure that you follow up. I know that it puts you in a bad position to be looking for a link between any vaccine and autism, but that is a much better position than missing the

chance to eliminate a risk factor for autism. The vaccine industry has a research budget 100 times larger than the research budget for autism. They should be proving their drugs do not cause harm, not expecting you to prove they do. Please get this on the agenda.

Thank	you,
Pam	

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Pam Rockwell Concord, Massachusetts Dwight Zahringer January 13, 2017

Dear Committee:

With your efforts of assigned studies and monies in the IACC, in the past 10 years has the IACCu found or identified any new treatments or causes of autism? What are your most successful projects where taxpayer monies were used, and how are you building upon that information and research?

I would like an open public answer to this questions above.

As requested in public comment in July 2016 I am again, requesting answers to the following:

- 1. Autism is an epidemic and the IACC needs real information and data from real people. I request that the IACC facilitates a survey the parents of ASD children in the United States. I request that this survey is over 50 but under 100 questions pertaining an ASD child and overseen and co-managed by a third party foundation, or organization for Autism that is recommended and voted on by the public. I request that the IACC proposes and allocates funding for this study in the fiscal year of 2016 to be published no later than the spring of 2017.
- 2. Autism is an epidemic and needs the attention from you, our Government and the media. I live in a community outside of Detroit, MI. Since I've been given the "gift" as a parent, I see ASD disorders in children more and more frequently. Recently while at a local park playground out of the 40-50 children there I came across not one other, not two, not three but four other children with moderate to severe autism.

Why is this happning?

The prevalence of autism in U.S. children has increased from 1-150 in 2000 to 1-68 in 2015. Autism is now the fastest-growing developmental disability in the United States.

I ask, as many have - why is this not being given the proper attention?

Can the IACC please answer this clearly to us parents and caregivers in the fiscal year of 2016?

## 3.) Glyphosate. What are the affects on the human brain? What are the affects on the human ASD brain?

Why would a 4-½ year old child on the spectrum whop was breast fed for two years and ate a natural, healthy diet have over 3x the normal levels of Glyphosate in his blood? We do not live near a farm, he does not work in produce, nor a processing plant. (ref: Glyphosate study on the human brain: http://drbogner.com/pesticides-autism/)

<u>Can the IACC to investigate how Glyphosate is affecting children with ASD vs. Non-ASD in the fiscal year of 2016?</u>

#### 4.) The IACC makes a formal request to Congress to subpoena Dr. William Thompson at the CDC.

Since his admission of falsifying tests, at the request of his superiors on how children receiving the MMR vaccine before 36 months were 340% more likely to receive an autism diagnosis or develop tics. Dr. Thompson made admissions to Biochemical Engineer Brian Hooker in a series of phone calls and not only gave specifics on how to obtain the correct data but also expressed remorse in his cover-up.

<u>I request that the IACC makes a public, formal request to Congress to subpoena Dr. William Thompson of the CDC.</u>

I request that the IACC makes a public, formal request to Nancy Messonnier, MD at the CDC for a full debriefing of the study to be included in the next IACC Summary of Advances in Autism Spectrum Disorder Research: Calendar Year 2016 that Dr. Thompson authored and the allegations of the link between autism and the MMR.

<u>I request that the IACC demand retraction of published study (PubMed 2004 Feb;113(2):259-66.) at the AAP of the MMR/Autism paper co-authored by Dr. DeStefano and Dr. Thompson.</u>

#### Note: Personally Identifiable Information (PII) has been redacted in this document

Christian Bogner, MD January 13, 2017

#### Dear Committee:

I am board certified physician from Michigan and speaker at multiple national autism conferences within the United States. I have researched autism for the last decade very extensively and hereby request you direct IACC efforts towards answering the following matters:

#### 1. Investigate glyphosate

Glyphosate (N-(phosphonomethyl)glycine) is a broad-spectrum systemic herbicide and crop desiccant. It is an organophosphorus compound, specifically a phosphonate. It is used to kill weeds, especially annual broadleaf weeds and grasses that compete with crops.

#### Here some concerning research data:

"Ingestion of >85 mL of the concentrated [glyphosate] formulation is likely to cause significant toxicity in adults. Gastrointestinal corrosive effects, renal and hepatic impairment are also frequent and usually reflect reduced organ perfusion."

-Bradberry SM et al; Toxicol Rev 23 (3): 159-67 (2004)

"Effects at 30,000 ppm included central lobular hepatocyte hypertrophy in males, central lobular hepatocyte necrosis in males, chronic interstitial nephritis in males, and proximal tubule epithelial basophilia and hypertrophy in females."

-California Environmental Protection Agency/Department of Pesticide Regulation

"The results/ suggest that acute toxicity at lethal doses may occur as a result of the uncoupling of oxidative phosphorylation."

-WHO/International Program on Chemical Safety; Environmental Health Criteria 159, Glyphosate, (1994).

"Taken together, these results demonstrated that Roundup might lead to excessive extracellular glutamate levels and consequently to glutamate excitotoxicity and oxidative stress in rat hippocampus." -Cattani D et al; Toxicology 320: 34-45 (2014)

Glyphosate has been demonstrated to be a contaminant in childhood vaccinations, including the Mumps-Measles-Rubella vaccine. MMR II (Merk) vaccine had 2.671 parts per billion (ppb) of glyphosate. [10] Glyphosate is a potent uncoupler of oxidative phosphorylation. [11] Results demonstrated that glyphosate might lead to excessive extracellular glutamate levels and consequently to glutamate excitotoxicity and oxidative stress in rat hippocampus. [12] Elevated levels of glyphosate have been reported in patients affected with autism. [13] Regardless of glyphosate pathophysiological involvement in autism spectrum disorders, contrast analyses demonstrated elevated levels of glutamate in children affected with ASD. [14]

In 2013, research from the Massachusetts Institute of Technology lead by Stephanie Seneff discovered that glyphosate <u>causes a disruption in the liver enzyme P450</u>. This enzyme detoxifies drugs and other toxins with which we come in contact with.

P450 is also involved in the production of an active form of vitamin D that stimulates your immune system to fight off disease-provoking proteins, which cause inflammation and auto-immune diseases. This compound formed is called globulin component macrophage-activating factor [GC-MAF]. Many labs dealing with synthetic GC-MAF were raided and shut down. In the presence of glyphosate, any immune system will have trouble producing this compound. GCMAF is believed to be one of the most powerful defense mechanisms in the human body and our bodies naturally produce it. But you need the P450 enzyme to do so. And again, this is the enzyme that is targeted by glyphosate.

Anandamide is one of several neurotransmitters. It is known as our own <a href="endocannabinoid">endocannabinoid</a>, as you produce it even as you read this article. It is highly expressed in 13 different regions of our brain. It is well recognized in its involvement with the neurotransmission processes in regards to pain, depression, appetite, memory, fertility and cognition. It binds tightly to a receptor called CB1 to execute those actions.

A recent discovery at the University of Michigan revealed that when our brains are under stress, *e.g. inflamed due to alcoholism*, the P450 enzyme in the brain is highly expressed in these 13 brain regions.

The reason for this "up-regulation" is that Anandamide is being converted into a very powerful antiinflammatory molecule called **5,6-EET-EAs** [epoxy-eico-satrienoic-acid-ethanolamides].

This compound literally acts as "super CBD", because it activates the CB2 receptor **300 more likely** than the CB1 receptor and it activates it **1000 times stronger** than CBD would. This is a groundbreaking discovery because we used to believe that P450 "detoxifies", e.g. breaks down molecules, whereas now we understand that the Anadamide-converted 5,6-EET-EAs are activating the CB2 receptors at a much higher rate.

CB2 receptor activation wakes up microglia, which are little "Pac Mans" that are activated by this super-CBD 5,6-EET-EAs. They start eating up the compound causing the inflammation in the first place (in autism, often times heavy metals such as copper, aluminum, mercury, etc.).

So now you can imagine what happens when a child is getting the MMR vaccine, filled with high concentrations of glyphosate and neurotoxins like aluminum. Remember that by injecting glyphosate, you bypass the liver and brain exposure is guaranteed, leading to destruction of the enzyme that makes this powerful antioxidant: 5,6-EET-EAs.

The brain is left defenseless against toxins causing the inflammation. This is why in autism, the brain is permanently bathed in heavy metals. Tests of autistic children's hair, plasma and urine show alarmingly higher-than-average levels of heavy metals. Incidentally, these tests are NOT recommended by the American Academy of Pediatrics. In fact, no blood testing is recommended by the American Academy of Pediatrics, as they claim autism is a neurodevelopmental disorder rather than an exposure-caused disorder.

The result of this glyphosate injection via CDC scheduled vaccines is activation of neurons and inflammation. Not only are the toxins not being cleared, but glyphosate by itself causes neuronal activation along with glutamate. They both act as neurotransmitters. Glyphosate is a glycine mimetic, meaning it can act like a neurotransmitter by itself. High amounts of glutamate can hence activate brain cells.

It is therefore prudent to immediately investigate all childhood vaccinations for glyphosate and immediately halt further injections of vaccines contamined with it. If we continue to inject this herbicide into children, we cause direct neurotoxic damage.

#### 2. Research the beneficial effects of phytocannabinoids

Cytokines are small secreted proteins released by cells that have a specific effect on the interactions and communications between cells. Pro-inflammatory cytokines are involved in the up-regulation of inflammatory reactions. [1] Elevated pro-inflammatory cytokine levels are associated with autism spectrum disorders (ASD). [1] In ASD, as well as a number of conditions, the expression level of CB2 receptors increases in response to the inflammatory nature of the condition. [2][3] Given that CB2 is up-regulated, and that it's believed to play a neuroprotective role, CB2 is being investigated as a potential target for treatment of ASD. [3] CB1 variations modulate the striatal function that underlies the perception of signals of social reward, such as happy faces. This suggests that CB1 is a key element in the molecular architecture of perception of certain basic emotions. This may have implications for understanding neurodevelopmental conditions marked by atypical eye contact and facial emotion processing, such as ASC. [4] Endocannabinoids are key modulators of synaptic function. [5] Endocannabinoids regulate stress responses, in part via the modulation of the 5-HT system. [6][7] Additional targets of endocannabinoids (and exogenous cannabinoids), PPARα, PPARγ, and GPR55 expression levels have shown reductions in a valproic acid model of autism in rats.[8]

No signs of toxicity or serious side effects have been observed following chronic administration of cannabidiol to healthy volunteers (Cunja et al., Pharmacology 21:175-185,1980), even in large acute doses of 700mg/day (Consroe et al., Pharmacol. Biochem. Behav. 40:701-708,1991) but cannabidiol is inactive at the NMDA receptor [9], indicating that THC is warranted. According to US patent 6630507, safety is demonstrated by stating that in the presence of glutamate alone, and in the presence of glutamate and cannabidiol (CBD) or THC, it was demonstrated that CBD and THC were similarly protective.

NMDA receptor antagonism can be achieved with a subset of cannabinoids. U.S. Pat. No. 5,538,993 (3S,4S-delta-6-tetrahydrocannabinol-7-oic acids), U.S. Pat. No. 5,521,215 (stereospecific (+) THC enantiomers), and U.S. Pat. No. 5,284,867 (dimethylheptyl benzopyrans) have reported that these cannabinoids are effective NMDA receptor blockers.

In addition, phytocannabinoids could be a potential replacement for depleted endocannabinoid CB1 agonists, which are utilized by P450D6 for 5,6EET-EAS and CB2 activation. CB1 agonist action is known to be responsible for mood, cognition, memory and learning as well as many other physiologic functions in the human body.

#### 3. Subpoena CDC employee Dr. William Thompson

#### The IACC makes a formal request to Congress to subpoena Dr. William Thompson at the CDC.

Since his admission of falsifying tests, at the request of his superiors on how children receiving the MMR vaccine before 36 months were 340% more likely to receive an autism diagnosis or develop tics. Dr. Thompson made admissions to Biochemical Engineer Brian Hooker in a series of phone calls and not only gave specifics on how to obtain the correct data but also expressed remorse in his cover-up.

# I request that the IACC makes a public, formal request to Congress to subpoena Dr. William Thompson of the CDC.

I request that the IACC makes a public, formal request to **Nancy Messonnier**, MD at the CDC for a full debriefing of the study to be included in the next IACC Summary of Advances in Autism Spectrum Disorder Research: Calendar Year 2016 that Dr. Thompson authored and the allegations of the link between autism and the MMR.

I request that the IACC demand retraction of published study (PubMed 2004 Feb;113(2):259-66.) at the AAP of the MMR/Autism paper co-authored by Dr. DeStefano and Dr. Thompson.

Thank you,

Christian Bogner, MD [PII redacted]

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- [19] Br J Pharmacol. 2009 Oct; 158(4): 1074–1087. Preventive and therapeutic anti-inflammatory properties of the sesquiterpene  $\alpha$ -humulene in experimental airways allergic inflammation

#### Note: Personally Identifiable Information (PII) has been redacted in this document

#### Eileen Nicole Simon, PhD, RN

January 13, 2017

Below are several points I want discussed by members of the IACC, and to be included in the Public Record.

Eileen Nicole Simon, PhD, RN
[PII redacted] Cambridge MA [PII redacted]

#### 1. New IACC Chairman

I hope Dr. Joshua Gordon, new chairman of the IACC, will schedule more time for public comments to be fully discussed at IACC meetings. It is not enough to just summarize or selectively choose a few submissions for consideration. Parents should be treated with more respect. We know our children better than erudite experts.

At the Autism Summit meeting of the IACC in November 2003, I was allowed a minute-and-a-half (and at the very end of the meeting) to ask members of the committee to discuss whether the protocol for clamping the umbilical cord immediately after birth might be contributing to the increased prevalence of autism.

Five years later in November 2008, I was allowed to make a 3-minute PowerPoint presentation. I am grateful that my PowerPoint slides remain online at <a href="https://iacc.hhs.gov/meetings/iacc-meetings/2008/full-committee-meeting/november21/slides\_eileen\_simon\_112108.pdf">https://iacc.hhs.gov/meetings/iacc-m

I have little more to add to that presentation. I will continue to ask members of the IACC to discuss my concern that immediate clamping of the umbilical cord at birth may cause asphyxia and damage within the brainstem auditory pathway.

#### 2. Causes of Autism?

What caused this to happen? What causes autism? What is causing the increased prevalence of autism? Wasn't this the reason for assembling an interagency committee, the Interagency Autism Coordinating Committee (IACC)?

The IACC was not intended to promote acceptance, early interventions, and lifespan care. The IACC was intended to be a collaborative effort to uncover and stop whatever is causing so many young children to have language problems, bizarre repetitive movements, lack of awareness, and seizures.

How bizarre to hear about an "elephant in the room" at the second IACC conference call on Question 3 of the IACC Strategic Plan (What Caused This to Happen?), whether any cause should be sought. Neurodiversity advocates appear to have dismantled the whole reason for having an interagency committee.

Would anyone have said no cause should be sought for the polio epidemic?

Heredity has long been the stigma associated with childhood mental afflictions. Now it's called genetics, and most demeaning is looking for "autistic traits" in parents and siblings. Attention is being deflected away from looking for causes of the increased prevalence of autism since the 1990s.

I hope Dr. Gordon, the new chairman of the IACC, will have more respect for parents and begin taking our comments more seriously.

#### 3. Brain Circuits

I was happy to read in the Simons Foundation Spectrum newsletter that Dr. Joshua Gordon plans to make circuit science a priority for research. For many years I have tried to point out that damage of auditory circuits might underlie language disorder and diminished level of awareness in autism.

The inferior colliculi in the midbrain auditory pathway receive higher blood flow than any other area of the brain. It has been suggested that the inferior colliculi may provide a vigilance function. The auditory system is always active, even during sleep. This is why we use alarm clocks. The inferior colliculi may provide signal gating within the auditory pathway. I discussed this in a paper on autism and Wernicke's encephalopathy. See <a href="https://www.ncbi.nlm.nih.gov/pubmed/2204786">https://www.ncbi.nlm.nih.gov/pubmed/2204786</a>.

Wernicke's encephalopathy affecting brainstem circuits was described 135 years ago. Wernicke's encephalopathy from alcohol abuse or thiamine deficiency progresses to Korsakoff dementia. Wernicke's encephalopathy should also be investigated as the neuropathology underlying Alzheimer's, addictions, autism, and schizophrenia. I have tried to bring this up for discussion at IACC meetings in the past.

#### 4. Brain Damage?

Since the Autism Summit in 2003, I have tried to request discussion of brain damage as the cause of (1) language disorder, (2) repetitive movements, and (3) diminished awareness in autistic children. Are these ideas silly? Please point out why?

Obstetric protocols adopted over the past 2 to 3 decades must be investigated for safety. Clamping the umbilical cord immediately after birth is wrong. This should be obvious. In 10th grade biology, learning that the anatomy of the heart must change at birth is one of my most vivid memories. How can this most important life event be overlooked by graduates of prestigious medical schools?

My comments to the IACC have been ignored over the past 13 years. Why? My autistic son is now 54 years old. I have been seeking to understand developmental language disorder for 52+ years. Once more I am asking: Can my ideas about vulnerability of the brainstem auditory pathway be discussed?

#### 5. Male Vulnerability

Shouldn't simple explanations in the medical literature be considered before suggesting elaborate new research proposals? I submitted the comment below for the IACC meeting in October on greater vulnerability of males. I am resubmitting it now for discussion at the January meeting:

Metabolism is higher in males than females. Muscle strength is greater in males than females. Women do not compete with men in most sports, and separate records are kept for running, swimming, and skiing competitions. Even events like figure skating, gymnastics, and springboard diving are separate for men and women.

During the process of birth, the aerobic needs of males are greater than females. I remember this being a topic of discussion at a meeting of the Fetal and Neonatal Physiological Society I attended in 2006, part of a discussion of cooling caps for infants who suffered anoxic-ischemic encephalopathy during birth.

What alternative ideas are there that might explain the 5:1 male to female ratio of children who develop autism?

Following are citations to the medical literature on this subject, including my own dissertation research back in 1976:

- [1] Dunn L et al. Gender specific intrapartum and neonatal outcomes for term babies. *Eur J Obstet Gynecol Reprod Biol*. 2015 Feb;185:19-22.
- [2] Diepeveen FB et al. Among perinatal factors, only the Apgar score is associated with specific language impairment. *Dev Med Child Neurol*. 2013 Jul;55(7):631-5.
- [3] Nagy E et al. Sex-differences in Apgar scores for full-term neonates. *Acta Paediatr*. 2009 May;98(5):898-900.
- [4] Simon N, Volicer L. Neonatal asphyxia in the rat: greater vulnerability of males and persistent effects on brain monoamine synthesis. *J Neurochem.* 1976 May;26(5):893-900.

#### 6. How It Feels

At an IMFAR meeting I heard one young researcher refer to autism as "an interesting mistake of nature."

I attended this meeting with someone who went howling out of a panel discussion on social disorder.

"These people love autism!" he yelled. "This is their bread and butter! They have no reason to find its cause."

I begin to feel like this during IACC meetings, especially now that "self-advocates" are driving so much of the discussion. Please return the focus to finding causes of autism, and how dangerous obstetric and neonatal practices can damage the brain.

Please pay attention to parents of severely affected children. Ignoring our comments is cruel.

#### 7. Diagnosis

"He will never be quite the person he would have been," Dr. Charles Barlow told me. "He has a mild form of cerebral palsy."

These words have echoed in my head now for 52+ years. My son had crawled under Dr. Barlow's big conference table, and was looking up at me. Did he recognize his mother's efforts to hold back tears? Could he in any way comprehend the future Dr. Barlow was predicting?

My grandmother had called Children's Hospital in Boston from Florida, and made the appointment with Dr. Barlow, chief of neurology. She was concerned that her first great-grandson was still not walking at 20 months of age. She was also angry that smiling pediatricians kept trying to tell us not to worry.

#### 8. Drugs in the brain

I attended a lecture given by Dr. Barlow on the blood-brain-barrier. Then I found and read an article he wrote "Drugs in the Brain" (Roth and Barlow, Science 1961 Jul 7;134:22-31). This paper made me aware of components in the brain that are specific for sensory experience, initiation of mental and motor responses, and the conscious state.

Drugs labeled with radioactive carbon atoms were injected into the bloodstream of mongrel (laboratory) cats. The cats were "sacrificed" after a few minutes and slices of their brains placed on photographic plates. Regions of dense radioactivity showed up as dark areas on the photographic plates. The plates were analyzed to determine what structures of the brain were sites where the labeled drug accumulated.

Some drugs were found to accumulate quickly in structures of highest blood flow. Roth and Barlow cited research by Seymour Kety on blood-flow in the brain. I then looked up articles by Seymour Kety,

#### 9. Blood flow in the brain

Seymour Kety was a true genius. He was also very kind and approachable. He wrote a seminal paper on blood flow in the brain which is free online at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1804882.

I went to a lecture he gave on monamines in the brain. Members of the "Mental Patients Liberation Front" also attended this lecture. Before he could begin to speak they stormed up to the front of the auditorium.

"Close the mental hospitals! No more snake pits! Shutter the asylums!" they shouted.

Gracious gentleman that he was, Dr. Kety asked these storm-troopers what they would do for mentally ill people. He pointed out that brain research could eventually make it possible to prevent or cure mental illnesses. Members of the disruptive group settled down. Sitting at his feet they listened quietly to his lecture on serotonin and dopamine.

In his paper on blood-flow Kety described the autoradiographic method that Roth and Barlow later used to investigate distribution of drugs in the brain.

Kety discovered highest blood flow in the auditory system, and reported this as a surprise.

#### 10. Asphyxia at birth

The October 1969 issue of the Scientific American appeared in my mailbox, and inside I found an article on asphyxia at birth, written by WF Windle.

Windle described experiments in which newborn monkeys were subjected to asphyxia (suffocation). Asphyxia had to be terminated after 6 to 8 minutes or the monkeys would die. This is what everyone learns now in CPR classes, and breathing must be re-established within 4 to 6 minutes to avoid brain damage.

Asphyxia was intended to create a primate model of cerebral palsy. But the monkeys did not develop cerebral palsy. They were delayed in motor development, and at first no damage was found in the brain at all.

Seymour Kety, based on his finding of highest blood-flow in the auditory system suggested looking for damage in the inferior colliculus (plural colliculi). These are very tiny relay centers in the midbrain. When looked for, that is where severe damage was found. Windle reported this in the Scientific American article, with pictures showing the damage, and location of the inferior colliculi in the roof of the midbrain.

#### 11. Who am I?

I attended the Boston University School of Medicine beginning in 1969. Professor Isaac Asimov spoke to our incoming class, and he asked why at that point in time any of us would choose medicine, rather than a career in the space program.

I had worked since 1960 in the satellite tracking program at the Harvard-Smithsonian Astrophysical Observatory. I was project leader and wrote much of the software for the Differential Orbit Improvement program. But I had two sons, born in 1962 and 1963, both diagnosed with autism.

When our pediatrician told me I did not have the technical competence to be reading the medical literature, I realized that I could not rely on the expertise of others for advice.

I am most grateful for the NIMH fellowships I was awarded. I received a PhD in biochemistry in 1975. I completed one year of post-doctoral research also funded by NIMH, but was unable to continue because of the high cost of day-care and after-school programs for my children. I returned to my former career in software engineering.

#### 12. Coming to NIMH

It is an emotional experience for me every time I come to NIMH for IACC meetings. After entering the Gateway Center and registering for the meeting, I place my knapsack and overnight bag on the AS&E baggage scanner.

AS&E (American Science and Engineering) was where I worked (from 1977 to 1979) developing software for the Medical MicroDose X-ray system, an adaptation of the AS&E baggage scanner. The prototype I worked on was tested at the University of Maryland Trauma Center in Baltimore. This machine may still be on display at the Walter Reed Army Hospital museum. The MicroDose scanner was later adapted for bone-density scanning.

Many IACC meetings are held in the C-wing 6th floor of Building 31. This was where I quickly whittled down my comment for a minute-and-a half presentation in 2003. By the time I got to speak many IACC members were putting on their coats and leaving.

#### 13. Comments to President-elect Donald Trump

I am among those asking President-elect Trump to initiate investigation of NIMH, the IACC, HHS, the CDC, the American College of Obstetrics and Gynecology (ACOG), and the American Medical Association (AMA). I hope the IACC will be retained, but required to focus on preventing all causes of brain injury that lead to autism.

Heredity (genetic defects) should not remain the primary focus of research. The intent in large part is to stigmatize parents, and dismiss their ideas about the cause of their child's disabilities. The concerns of parents (not just self-advocates) must be discussed, not just relegated to categories. Most unkind are attempts to promote the idea that we must be graciously accepting.

No! The autism epidemic is as serious as the polio epidemic was in the 20th century.

#### 14. First Comment to President-elect Donald Trump

Autism is my only concern. I hope you will make a strong effort to promote understanding all causes of encephalopathy (brain damage) that result in autism.

The obstetric protocol to clamp the umbilical cord immediately after birth must be recognized as a serious medical error, and it must be stopped. The protocol was adopted in the mid 1980s, which corresponds to the increased prevalence of autism since that time.

A lapse in respiration at birth injures the brainstem auditory pathway. This should be investigated as the cause of language problems in autistic children.

#### 15. Lifespan Outlook

My son is 54 years old. At age 40 (in 2003) he was discharged from Westborough State Hospital (in Massachusetts) to a "community" group home.

He was admitted to Westborough at age 29, after being brought there by the police. He lived at home after special education ended, but he wandered into trouble almost every day of this 7-year post-special-ed period.

During his 20's he frequently went missing. I became well-known for looking into dead-body reports in the news. Through all-points-bulletins (APBs) he was located in jails (Greenwich CT, Charles Street Boston, Billerica, Barnstable, and Berkshire in MA) or state hospitals (Northampton, Metropolitan, Bridgewater, Taunton, and Westborough).

Already in the 1980s the Mental Patients' Liberation Front had pushed through legislation that made it difficult for parents to locate a missing mentally ill person.

"Autism self-advocates" are currently creating trouble of the same kind. See their cruel effort to stop Avonte's Law at <a href="http://autisticadvocacy.tumblr.com/post/154264725937/urgent-call-your-senators-stop-avontes-law">http://autisticadvocacy.tumblr.com/post/154264725937/urgent-call-your-senators-stop-avontes-law</a>.

#### 16. Community Care?

My son has repeatedly run away from his group home. In 2009 he was missing for 7 weeks +2 days before being found. The police took him to the ER at Cambridge Hospital. They discharged him to the Quincy Mental Health Center (QMH) where he remained as an inpatient for several weeks. Then he was discharged back to the group home. QMH was closed shortly after that by the Massachusetts Department of Mental Health (DMH).

Last year my son ran away several times, but when found by police and taken to an emergency room he was asked if he were a danger to himself or others. When he responded no, he was immediately discharged to the street, without even any physical assessment.

I am most grateful to the police in Boston and Randolph MA, and the MA State Police at Logan Airport for helping me get to hospital emergency rooms ahead of my son's arrival. Still, special psychiatrists would take my son off behind a curtain, and discharge him. I am grateful also to security

guards at several hospitals for arranging practical matters like return of clothing and arranging midnight transportation (by ambulance) back to his group home.

#### 17. Who Cares?

I am allowed to pick my son up from his group home for weekend outings, and to drop him off afterwards. But I am not allowed to go inside his house. The staff treat me with great disdain. I am clearly a trouble-maker, even though I still try to apologize. I am sorry; working in a group home is difficult, often dangerous, and not well paid.

I have asked too often about whether job-training could be made a focus of my son's day-program. I have asked if learning to receive and send email could be included in his day-program, or even how to use Google. I am disdainfully told he has to ask for job training or to learn computer skills. They can't force him. Are these policies based on old laws pushed through by the Mental Patients' Liberation Front?

The only regularly scheduled activity at my son's group home, and his day program, is one-cigarette-every-hour-on-the-hour. This cigarette habit is so difficult to manage when I take him out on weekends. It severely limits things we can do. He loves taking train rides, but we are limited to trips that take no more than one hour. He would love to take the Down-Easter for a visit to Maine, but the trip is longer than an hour. It won't work. Stops are not long enough to get off the train for a cigarette break.

My husband and I are elderly now, and we fear for our son's future. Is there anything the IACC can do to improve lifespan care?

#### 18. Learning Differences?

A boys' choir visited our elders' community a few days ago to sing Christmas music for us. They were wonderful, and so young. Someone asked what their age-range is. The priest told us age 9 (fourth grade) to age 11 or 12. He told us boys' voices are changing earlier now than in the past, and that boys are reaching puberty earlier. He said this is probably caused by environmental pollution.

Premature puberty is something that should be a priority for research, along with childhood heart and pulmonary problems, asthma, and allergies, as well as increasing numbers of children with "learning differences." Clamping the umbilical cord immediately after birth should be stopped. There is no need for more randomized-controlled trials on this procedure. Research on umbilical cord clamping has not followed children into their school years.

Return to the traditional teaching to wait for placental blood flow to cease before tying or clamping the umbilical cord. Then see if there is a decline in heart problems, asthma, allergies, and learning differences.

#### 19. Placental Blood Flow

The American College of Obstetricians and Gynecologists (ACOG) has announced a new recommendation. A "delay" in umbilical cord clamping for at least 30-60 seconds is now encouraged, <a href="http://www.acog.org/About-ACOG/News-Room/News-Releases/2016/Delayed-Umbilical-Cord-Clamping-for-All-Healthy-Infants">http://www.acog.org/About-ACOG/News-Room/News-Releases/2016/Delayed-Umbilical-Cord-Clamping-for-All-Healthy-Infants</a>.

This is a step in the right direction, and comes two years after the same recommendation was made by the Royal College of Obstetricians and Gynaecologists (RCOG) in the UK. It would be better to return to the tradition of waiting for placental blood flow to cease.

After birth, fetal valves in the heart must close for blood to be fully redirected to the lungs rather than the placenta. Pulsations of the cord will then cease, the cord will go limp, and can easily be cut

without loss of any blood. Placental blood flow can continue for many minutes (up to half an hour) as documented in many research papers published in the late 19th to early 20th centuries.

Birth, the most momentous event in life, should not be hurried for anyone's convenience.

Lisa Wiederlight January 13, 2017

Dear Dr. Gordon:

I am writing to ask for a status report on the four workgroups that our organization has asked the IACC to convene since its November 2015 meeting. They are:

1. **Autism and Wandering/Elopement:** Each instance endangers the safety of the person with autism, and terrifies his/his caregivers.

- 2. **Environmental Factors Contributing to the Rise in Autism Prevalence**: Autism prevalence has increased from 1 in 2,000 before the 1980s, to 1 in 68 in 2016. There is no such thing as a genetic epidemic, and yet federal research funding on causation has been predominantly focused on genetics to date.
- 3. **Co-occurring Conditions:** Over 70 percent of people with autism have gastrointestinal issues. Additionally, up to 40 percent of people with autism have seizure disorders. Studies have also found that suicidality is also more common in the autism community. There are many other serious conditions that cause distress and danger every day—self injury, immune problems, tics, mitochondrial disorder, ADHD, and on and on.
- 4. **Caregiver Support**: If you want to help children with autism, you must also help their caregivers. There are few supports for the caregivers who must take care of their loved ones and themselves. This affects the caregivers' lives and the outcomes of those for whom they care. It is simply imperative that we provide the supports for caregivers as we focus on the person affected too.

A focus on the prevention of and treatments for the most severe cases of autism is merited based on their human and economic costs. We must work to prevent illness and increase the safety and independence of our most vulnerable populations.

Thank you,

Lisa Wiederlight
Executive Director

#### Note: Profanity redacted in this document

John Best January 13, 2017

In all the years you have been wasting time with this [profanity redacted], you have refused to tell the truth about autism. Go [profanity redacted] yourselves.

John Best

Londonderry, NH