State Board of Health – Nominating Committee  
June 15, 2023 - 9:00am  
Perimeter Center, Boardroom 2  

Members Present: Lee Jones, DMD; Maribel Ramos; Stacey Swartz, PharmD, Chair.

VDH Staff Present: Alexandra Jansson, Staff to the State Board of Health

Dr. Swartz gavelled the meeting to order at 8:30am.

There were no persons signed up for public comment.

Dr. Jones moved to nominate the following slate: Gary Critzer – Chair; Patricia Kinser, PhD – Vice Chair; Anna Jeng, ScD and Michael Desjadon – Executive Committee members. The motion was seconded by Ms. Ramos. The motion was approved by unanimous voice vote.

The meeting adjourned at 8:34am.

State Board of Health  
June 15, 2023 - 9:00am  
Perimeter Center, Boardroom 2

Members Present: Gary Critzer, Chair; Michael Desjadon; Melissa Green; Elizabeth Ruffin Harrison; Anna Jeng, ScD; Lee Jones, DMD; Patricia Kinser, PhD; Wendy Klein, MD, Vice Chair; Patricia O’Bannon; Holly Puritz, MD; Maribel Ramos; Stacey Swartz, PharmD; Ann B.R. Vaughters, MD; and Mary Margaret Whipple

Members Absent: Jim Shuler, DVM.

Ms. Green participated virtually from her home in Bath County due to a temporary medical condition.

Dr. Klein participated virtually from Rhode Island for personal reasons involving pre-existing travel.

VDH Staff Present: Michael Capps, Senior Policy Analyst; Tiffany Ford, Deputy Commissioner for Administration; Laurie Forlano, State Epidemiologist; Robert Hicks, Deputy Commissioner of Public Health & Preparedness; Joe Hilbert, Deputy Commissioner for Governmental and Regulatory Affairs; Alexandra Jansson, Senior Policy Analyst; Christopher Lindsay, Chief Operating Officer; Maria Reppas, Director, Office of Communications; Anthony Salgado, Medical Reserve Corps Coordinator; Karen Shelton, State Health Commissioner; and Sirah Yoo, Senior Graphic Designer.

Other Staff Present: Robin Kurz, JD, Senior Assistant Attorney General; Allyson Tysinger, Senior Assistant Attorney General/Section Chief; and James Williams, Deputy Secretary for Health and Human Resources.
Ms. Harrison arrived at 9:19 am. Dr. Klein joined the meeting at 9:30 am.

Call to Order
Mr. Critzer called the meeting to order at 9:02 am.

Introductions
Mr. Critzer welcomed those in attendance to the meeting. Mr. Critzer then started the introductions of the Board members and VDH staff present.

Review of Agenda
Ms. Jansson reviewed the agenda and the items contained in the Board’s binder.

Approval of March 23rd, 2023 Minutes
The minutes from the March 23 meeting were adopted by unanimous consent, with Mrs. O’Bannon abstaining.

Commissioner’s Report
Dr. Shelton provided the Commissioner’s Report to the Board. She updated the Board on key issues and projects VDH is engaged in including:

- Agency Stars
- Maternal Health
- Substance Misuse Including EO26/Fentanyl Response
- Partnership for Petersburg
- Projects Funded by the American Rescue Plan Act (ARPA)
- Public Health Infrastructure Grant
- Emergency Preparedness/Hurricane Season
- Public Health Policy Fellows Program
- VDH Follow-up to Joint Commission on Health Care Study of Structure and Financing of Local Health Departments
- Public Health Policy Agenda Development Process

There was discussion regarding maternal mental health screening data, Virginia’s national standing as it relates to maternal health and perinatal policy, the methodology associated with the maternal mental health data, and the industry practice of post-partum depression screening, the Board’s involvement with the VDH Policy Agenda, the Opioid Impact Reduction Registry, and the Electronic Health Record data system and how that would operate in conjunction with the new Opioid Registry.

Regulatory Action Update
Mr. Capps reviewed the summary of all pending VDH regulatory actions.

Since the March 2023 meeting, the Commissioner approved 3 regulatory actions on behalf of the Board while the Board was not in session. All three approved actions for the results of periodic review. The first 2 Periodic Review results for the Commonwealth of Virginia Sanitary Regulations for Marinas and Boat Moorings (12VAC5-570) and the Regulations Implementing the Virginia Donor Registry (12VAC5-475) resulted in “Amend” decision. The third Periodic
Review Result for the Regulations for the Immunization of School Children (12VAC5-110) resulted in a “Retain as is” decision. The Periodic Review Results for 12VAC5-570 were approved by Parham Jaberi, MD during his time as “Acting” Commissioner, while 12VAC5-475 and 12VAC5-110 were approved by Karen Shelton, MD after her appointment as the Virginia State Health Commissioner.

Since the March 2023 meeting the Commissioner has not taken any non-regulatory action on behalf of the Board while the Board was not in session.

Mr. Capps advised the Board that there are 20 periodic reviews in progress:
- 12 VAC 5-67 Advance Health Care Directive Registry
- 12 VAC 5-125 Regulations for Bedding and Upholstered Furniture Inspection Program
- 12 VAC 5-215 Rules and Regulations Governing Health Data Reporting
- 12 VAC 5-216 Methodology to Measure Efficiency and Productivity of Health Care Institutions
- 12 VAC 5-217 Regulations of the Patient Level Data System
- 12 VAC 5-220 Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations
- 12 VAC 5-221 Virginia’s Rules and Regulations Governing Cooperative Agreements
- 12 VAC 5-381 Home Care Organization Regulations
- 12 VAC 5-405 Rules Governing Private Review Agents
- 12 VAC 5-407 Regulations for the Submission of Health Maintenance Organization Quality of Care Performance Information
- 12 VAC 5-507 Guidelines for General Assembly Nursing Scholarships and Loan Repayment Program Requiring Service in a Long-Term-Care Facility
- 12 VAC 5-520 Regulations Governing the State Dental Program Scholarship Program
- 12 VAC 5-530 Regulations Governing the Virginia Medical Scholarship Program
- 12 VAC 5-542 Rules and Regulations Governing the Virginia Nurse Practitioner / Nurse Midwife Scholarship Program
- 12 VAC 5-545 Guidelines for the Nurse Educator Scholarship
- 12 VAC 5-590 Waterworks Regulations
- 12 VAC 5-613 Regulations for Alternative Onsite Sewage Systems
- 12 VAC 5-620 Regulations Governing Application Fees for Construction Permits for Onsite Sewage Disposal Systems and Private Wells
- 12 VAC 5-640 Alternative Discharging Sewage Treatment Regulations for Individual Single Family Dwellings
- 12 VAC 5-650 Schedule of Civil Penalties

There was discussion regarding the regulatory matrix containing all 46 of VDH’s current regulatory actions.

**Public Comment Period**

There were 13 persons signed up for the public comment period. The Board’s public comment period allows for a 20 minute period with 2 minutes per person. A motion to extend the public comment period by 6 minutes was made by Mr. Desjadon and seconded by Dr. Puritz. The
motion was passed by unanimous voice vote.


**Fast Track Amendments to Regulations Governing Vital Records 12 VAC 5-550**

Mr. Seth Austin presented the Fast Track Amendments to the Regulations Governing Vital Records. The purpose of the amendments is to reflect several recent changes in the Code of Virginia, including changes to §§ 32.1-258.1, 32.1-269.1, 32.1-261, and 32.1-267. Several sections will be repealed, as these sections are not regulatory in nature.

Chapter 171 (2022) removed the authority to charge a fee to obtain a stillbirth certificate for unintended, intrauterine fetal deaths. Chapters 209, 210, and 211 (2020) removed race from the data to be collected regarding marriages, divorces, and annulments. Chapters 465 and 466 (2020) amended the process to change one’s sex on a birth certificate. Chapters 116 and 117 (2022) changed the process and timelines associated with amending a death certificate. Additionally, sections 20, 30, 50, and 60 will be repealed because the provisions do not meet the statutory definition of a “regulation” in § 2.2-4001.

The rulemaking is expected to be non-controversial because the substantive changes being made are to comply with changes to the Code of Virginia. Additionally, the style and form changes are not substantive but will make the regulations clearer and more readable for both the public and agency staff.

There was discussion regarding the processes and language related to amending sex on a birth certificate.

Dr. Swartz made a motion to approve the fast-track regulations with Dr. Puritz seconding. The motion passed unanimously by voice vote.

**Proposed Amendments to Waterworks Operation Fee 12 VAC 5-600**

Mr. Dwayne Roadcap presented the Proposed Amendments to the Waterworks Operation Fee Regulations (12VAC5-600). The regulations codify how the Office of Drinking Water (ODW) generates revenue from fees charged to the waterworks that are regulated by the ODW under the federal Safe Drinking Water Act (SDWA) and the Virginia Waterworks Regulations (12VAC5-590). While the regulations have not been amended at all since 2014, there are portions of the regulations, such as the fee assessed for nontransient noncommunity waterworks, which have not changed since the regulations were first promulgated in 1993. In addition to modifying the fee for nontransient noncommunity waterworks and clarifying the method by which operation fees are calculated, the amendments seek to add categories of waterworks, not previously charged a fee, into the regulations. Specifically, transient noncommunity waterworks and wholesale waterworks are proposed to be added to the list of categories of waterworks that are charged a fee for the technical assistance and compliance oversight provided by ODW.
There was discussion regarding the time requirements faced by ODW as it relates to the various waterworks operators, how equity is implemented in the regulations, an overview of the new fee changes, and the potential impacts to localities.

Dr. Jones made a motion to approve the proposed amendments with Ms. Whipple seconding. The motion passed unanimously by voice vote.

**Fast Track Amendments to the Regulations for the Patient Level Data System 12 VAC 5-217**

Mr. Suresh Soundararajan presented the Fast Track Amendments to the Regulations of the Patient Level Data System. These amendments seek to permanently adopt the emergency regulation promulgated in January 2022 and update the language to reflect current inpatient data reporting practices. Item 307 (D1) of Chapter 552 of the 2021 Acts of Assembly Special Session I (“2021 Appropriation Act”) requires inpatient hospitals to report to the Board the admission source of any individuals meeting the criteria for voluntary or involuntary psychiatric commitment. To conform to this mandate, the emergency regulation was promulgated effective January 17, 2022.

Additional amendments are proposed to conform the regulations to reflect the data reporting elements currently submitted by inpatient hospitals to Virginia Health Information (VHI). Non-regulatory language is also being removed from 12VAC5-217-20 to conform to the Form and Style Requirements set forth by the Virginia Registrar of Regulations.

Dr. Kinser made a motion to approve the Fast Track with Dr. Vaughters seconding. The motion passed unanimously by voice vote.

**Final Exempt Amendments to the Regulations for the Licensure of Hospitals in Virginia 12 VAC 5-410**

Ms. Rebekah E. Allen presented the Final Exempt Amendments to the Regulations for the Licensure of Hospitals in Virginia. Chapter 417 of the 2023 Acts of Assembly requires the State Board of Health to amend its hospital regulations to require hospitals with emergency departments “to establish a security plan…using standards established by the International Association for Healthcare Security and Safety or other industry standard” and that is “based on the results of a security risk assessment of each emergency department location of the hospital.” This security plan must “include the presence of at least one off-duty law-enforcement officer or trained security personnel who is present in the emergency department at all times as indicated to be necessary and appropriate by the security risk assessment.” Chapter 417 further enumerates what identified risks that hospitals must consider when developing security plans and training requirements for security personnel. Chapter 417 authorizes the State Health Commissioner to “provide a waiver from the requirement that at least one off-duty law-enforcement officer or trained security personnel be present at all times in the emergency department if the hospital demonstrates that a different level of security is necessary and appropriate for any of its emergency departments based upon findings in the security risk assessment.”

The second enactment clause of Chapter 417 exempts this regulatory action from the
Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia), provided that the State Board of Health gives an opportunity for public comment prior to adoption. The State Board of Health published a general notice in The Virginia Register of Regulations on April 10, 2023 containing the proposed regulatory text; this general notice had a 30-day public comment period during which three comments were received. Outside of the public comment period, two written comments were received related to this action for this meeting – they are included at the end of the minutes document.

There was discussion regarding the legal interpretation and intent of the statutory language, security protocols, and liability associated with waivers.

Dr. Kinser made a motion to approve the Final Exempt Amendments with Dr. Vaughters seconding. The motion passed unanimously by voice vote.

Report of the Nominating Committee
Dr. Swartz presented the report of the Nominating Committee. The committee nominated Gary Critzer to continue serving as the chairman of the Board, Patricia Kinser as the Vice Chair of the Board, and Anna Jeng and Michael Desjadon as the Executive Committee members.

Dr. Puritz made a motion to approve the nominations with Ms. Harrison seconding that motion. The motion passed unanimously by voice vote.

Board Bylaws Review
Ms. Jansson reviewed the Board Bylaws to the members as required every four years. Ms. Jansson reviewed the general sections for the bylaws relating to applicability and purpose of the Board, membership, committees, meetings, and elections of members.

There was discussion regarding the Board’s involvement in policy work in conjunction with VDH, and how establishing committees to focus on specific topics would occur.

Ms. Whipple made a motion to approve the bylaws as presented with Dr. Swartz seconding that meeting. The motion was passed unanimously by voice vote.

Other Business
Mr. Critzer updated the Board on the progress of the Office of Emergency Medical Services and their study of the Emergency Department off-loading practices. A full report is anticipated at the September meeting.

Mr. Critzer also recommended the creation of a policy committee comprised of interested Board members not to exceed 4 members to communicate policy interests and recommendations to the Agency on behalf of the Board. The members selected at the meeting were Dr. Kinser, Mr. Desjadon, and Ms. Ramos. Mr. Critzer made a motion to approve committee creation. The motion was passed unanimously by voice vote. The group plans to meet prior to the start of the September Board meeting.

Mr. Critzer proposed hosting one of the quarterly meetings per year at a different location than
Richmond. The Board recommended VDH investigate the feasibility of this and to report the findings of this investigation to the Board at the September meeting.

There was discussion regarding the “Right Help Right Now” bills recently signed by Governor Youngkin and how those may impact the current Emergency Department Diversions, the financial costs and budgeting needed to host a meeting in a different area of the State, and the logistics of the presentations at a moving Board meeting and what they may involve.

**Adjourn**
The meeting adjourned at 12:33pm.
VHHA Public Comment - June 15, 2023 Board of Health

Rawlings, Brent <brawlings@vhha.com>
Tue 6/13/2023 4:23 PM
To: State Board of Health (VDH) <boardofhealth@vdh.virginia.gov>
Cc: Allen, Rebekah (VDH) <Rebekah.Allen@vdh.virginia.gov>; Dime, Julie <jdime@vhha.com>

1 attachments (212 KB)
VHHA Comments - Emergency Department Security (SB 827) Response.pdf;

Please accept the attached public comment on behalf of Virginia Hospital & Healthcare Association to be submitted to the Board of Health in advance of its June 15, 2023, quarterly meeting. This pertains to the agenda item seeking Board approval for Draft Amendments for 12VAC5-410-10 et seq. to Implement SB 827 from 2023 Regular Session (Emergency Department Security).

Please let me know if you have any questions or if you require further information.

Sincerely,

Brent

R. Brent Rawlings
Senior Vice President and General Counsel
Virginia Hospital & Healthcare Association
4200 Innslake Drive, Suite 203
P.O. Box 31394, Richmond, VA 23294
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[Image of 2023 Virginia Behavioral Health Summit]
June 13, 2023

Ms. Rebekah E. Allen, J.D.
Senior Policy Analyst
Virginia Department of Health
Office of Licensure and Certification
9960 Mayland Drive, Suite 401
Henrico, Virginia 23233

RE: Public Comment on Draft Amendments for 12VAC5-410-10 et seq. to Implement SB 827 from 2023 Regular Session

Dear Ms. Allen,

On behalf of the Virginia Hospital & Healthcare Association (VHHA) and its hospital and health system members across the Commonwealth, please accept these additional comments on draft amendments for 12VAC5-410-10 et seq. to implement SB 827 from the 2023 Regular Session for submission to the Board of Health prior to its meeting on June 15, 2023. VHHA previously submitted public comments in response to the notice of public comment on the draft amendments. Those public comments were included in the Agency Background Document for this action prepared by the Virginia Department of Health (VDH) on May 11, 2023.

In its Agency Background Document, VDH provided a response to each of the comments raised by VHHA. We are very appreciative of VDH’s thoughtful and thorough analysis and willingness to include modifications to the regulations in certain areas.

One area where we remain in disagreement, however, relates to the security personnel requirement at 12VAC5-410-280.1.3. SB 827 states that any security plan “shall include the presence of at least one off-duty law-enforcement officer or trained security personnel who is present in the emergency department at all times “as indicated to be necessary and appropriate by the security risk assessment.” VHHA was very careful to include this phrase in its negotiations with stakeholders to reach consensus on the legislation. The intent of this phrase was to recognize that there could be instances where the security risk assessment indicates that the presence of at least one trained security personnel is not necessary and appropriate, and in such instances, a different security standard could be applied, without obtaining any waiver from the Commissioner.

To apply the statute otherwise creates a presumption that every security risk assessment for every location of every emergency department in Virginia will indicate that the presence of at least one off-duty law-enforcement officer or trained security personnel who is present in the emergency department at all times is necessary and appropriate. This cannot be presumed and the very purpose of requiring the security risk assessment was to insert an objective model for determining whether the presence of security personnel is necessary and appropriate. To apply the statute in this manner would effectively nullify and treat as surplusage the first use of the words “as indicated to be necessary and appropriate by the security risk assessment.” Such a determination is inconsistent with the rules of statutory
construction — every part of a statute is presumed to have some meaning and can be rejected as surplusage only if inserted inadvertently or by mistake.

There are plausible reasons why a waiver would be required even where the presence of at least one off-duty law-enforcement officer or trained security personnel who is present in the emergency department at all times is “indicated to be necessary and appropriate by the security risk assessment.” For example, in a small critical access hospital, the security plan provides for security personnel to be located within the hospital in some location other than the emergency department. Because of the small size of the facility and concern for threats in other parts of the hospital, the hospital desires not to require a security post in the emergency department, but instead for it to be located in some centralized area that is adjacent to the emergency department. This could effectively be determined by the Commissioner to provide the same level of security as might be available in the emergency department of a larger urban hospital, although it does not meet the technical requirement, making a waiver necessary.

Applying the statute in this manner would not remove the agency’s authority to challenge a hospital’s determination of whether a security risk assessment does or does not indicate that the presence of at least one off-duty law-enforcement officer or trained security personnel who is present in the emergency department at all times is necessary and appropriate. Just as with any other licensure requirement, the agency would retain the ability to enforce compliance through the licensure process, including requesting to review security plans or security risk assessments for the emergency department as part of inspection or in response to a complaint. So the hospital would remain subject to scrutiny for compliance with the security requirements as a matter of law.

This is not an alternative interpretation and we do not regard it as a “watering down” of the statute as it has been characterized by other stakeholders. Other stakeholders have also suggested that our public comments constituted newly expressed concerns not raised in discussion regarding the legislation. VHHA repeatedly expressed its concerns about the full-time presence of security personnel in emergency departments in its discussions with the patron and all stakeholders. We conveyed concerns over disparate impacts noting that the statute would apply to small rural and critical access hospitals, as well as freestanding emergency departments, in the same manner as it would apply to much larger mid-sized suburban and urban hospitals with much higher volumes and risk profiles. We expressed concerns about existing workforce challenges with security personnel who are already being tasked with managing security details in other parts of the hospital outside of the emergency department. We expressed concerns about the significant costs of the full-time presence of security personnel in emergency departments, which the agency estimates to amount to over $24 million in annual direct and indirect costs. This is in addition to other costs associated with compliance, which the agency estimates to amount to over $117 million in direct and indirect costs for hospitals in total.

It is for these reasons that VHHA was careful to include the phrase “as indicated to be necessary and appropriate by the security risk assessment” seeking to reduce regulatory burden involved in requesting waivers – both on behalf of providers and the agency. The safety and security of patients, staff, and the public is of paramount concern for hospitals, but this regulation represents a significant regulatory change bringing with it significant direct and indirect costs that need to be taken into account. This further highlights the importance of ensuring that implementing regulations provide needed flexibility for different levels of risk at various emergency departments across the Commonwealth and avoid imposing unnecessary regulatory burden on hospitals.
We again thank VDH for its thoughtful and thorough analysis and appreciate further consideration of these comments by the Board of Health in its deliberations. Please let us know if we can provide you with any further information on this matter.

Sincerely,

[Signature]

R. Brent Rawlings
Senior Vice President and General Counsel

cc: Ms. Julie M. Dime, Vice President of Government Affairs
With respect to 12VACS-410-10 et seq. to implement SB 827 from the 2023 legislative session, and in response to the public comment submitted by the Virginia Hospital and Healthcare Association (VHHA):

The Virginia Nurses Association agrees that the decision to embed security personnel in healthcare settings is one that requires careful consideration of a number of factors, including the level of risk, legal and regulatory limitations, and community response. In contrast to the VHHA, the Virginia Nurses Association believes that the best way to ensure adequate consideration of these factors is to maintain regulatory oversight of hospital-generated security risk assessments and safety plans for each emergency department location of a hospital. It is our expectation, in accordance with Virginia law, that safety plans include the presence of at least one off-duty law enforcement officer or trained security personnel who is present in the emergency department at all times. If a security risk assessment clearly demonstrates that security personnel are not necessary to ensure the safety of patients and staff, the hospital should submit the risk assessment and supporting documentation for consideration of a waiver of this obligation. Waivers should be issued only with appropriate regulatory oversight, at the discretion of the Commissioner of Health. Our position is directly aligned with both the language and intent of SB 827, which passed both chambers of the Virginia General Assembly unanimously with the full support of the Virginia Hospital and Healthcare Association, the Virginia Nurses Association, the Virginia College of Emergency Physicians, The Medical Society of Virginia, and numerous other stakeholders.

While the physical presence of security personnel is just one component of hospital security, it’s a highly effective intervention to reduce the incidence of violence and maintain the safety of patients and staff in the emergency setting. Federal regulations and accrediting bodies have long required hospitals to maintain all-hazards security plans and train staff on violence prevention and de-escalation techniques- and hospitals have long been given autonomy and flexibility to perform safety risk assessments and implement safety plans that meet the industry standard without significant regulatory oversight or approval requirements; Unfortunately, that approach has not adequately protected the healthcare workforce. In 2018, 70% of emergency department nurses and 47% of emergency physicians reported being physically assaulted while on the job (American College of Emergency Physicians, Emergency Nurses Association), and that was before the added stressors brought about by the COVID-19 pandemic. It’s clear that additional regulation is required, which is precisely why SB 827 garnered widespread support and received swift legislative and executive approval in 2023.

The Virginia Nurses Association agrees that the security personnel requirement set forth in SB 827 carries substantial financial and workforce implications. The COVID-19 pandemic has exacerbated long-standing problems in hospitals across the United States, resulting in increased violence against healthcare workers and an exodus from the nursing profession. If nurses don’t feel safe at work, they will continue to leave the bedside and patient care will suffer. The requirement for security personnel in all emergency departments is not intended to inflict an “administrative burden” on Virginia hospitals- it’s meant to reduce the burden of violence against caregivers and the patients we serve. We literally cannot afford to lose any more of our workforce.

The Virginia Nurses Association asks the Board of Health to respect the spirit and intent of SB 827 and put in place robust regulatory oversight to ensure the safety of nurses and patients in the Commonwealth.
Ashley Apple, DNP, RN, FNP-BC
Commissioner on Government Relations
Virginia Nurses Association
COMMENTS OF JIM EDMONDSON TO VIRGINIA BOARD OF HEALTH
JUNE 15, 2023

MY NAME IS JIM EDMONDSON, A RESIDENT OF FAIRFAX COUNTY AND A 13-
YEAR BOH MEMBER. AT MY LAST MEETING A YEAR AGO THE BOARD VOTED
UNANIMOUSLY TO REJECT THE IDEA THAT HEALTH DISPARITIES IN THE
COMMONWEALTH, PARTICULARLY FOR AFRICAN-AMERICAN AND OTHER
MINORITY AND LOW-INCOME COMMUNITIES, WERE SUBJECTS NOT TO BE
DISCUSSED OR TO BE AGGRESSIVELY REDUCED. EVENTUALLY THE VOICE OF
THIS REPUGNANT ATTITUDE, WHICH SEEMS TO HAVE BEEN A REFLECTION OF
THE GOVERNOR'S VIEWS, WAS DENIED APPROVAL OF PERMANENT OFFICE AS
THE COMMISSIONER OF HEALTH. UNFORTUNATELY FOR THE CITIZENS OF THE
COMMONWEALTH, THE "DEPOSED" COMMISSIONER, DR. COLIN GREENE, NOW
HAS A ROLE THAT IS SUPPOSED TO REDUCE THE DAMAGE INFLECTED BY THE
OPIOID EPIDEMIC. I CAN ONLY WONDER WHAT TYPES OF DAMAGE MIGHT GO
UNADRESSED IN THIS WORTHY EFFORT BECAUSE SOMEHOW THE WHITE
CITIZENS OF VIRGINIA OR OTHERS, WHO DO NOT SUFFER FROM OPIOID
ADDICTION, MIGHT BE OFFENDED BY POINTING OUT THAT SOME GROUPS –
BLACKS OR RESIDENTS OF APPALACHIA OR POOR WHITES – ARE MORE
LIKELY TO BE AFFECTED.

AS WE LOOK BACK ON THE COVID PANDEMIC AND SEE HOW MINORITIES
WERE MUCH MORE LIKELY TO HAVE SUFFERED FROM THE DISEASE AND
DEATH FROM IT, WHAT BETTER EXAMPLE FOR THE TRUTH OF THE EXISTENCE
OF DISPARITIES IS REQUIRED? THE PREVIOUS COMMISSIONERS AND THIS
BOARD HAVE STUDIED, REPORTED ON, AND FULLY APPRECIATED THE
REALITY OF DISPARITIES IN HEALTH ACCESS AND OUTCOMES ACROSS A
BROAD RANGE OF DISEASES AND CONDITIONS. THE OTHER MOST OBVIOUS
DISPARITIES INVOLVE MATERNAL HEALTH, PREGNANCIES AND BIRTHS. HOW
CAN ANYONE OF GOOD CONSCIENCE CONTINUE TO HOLD THE VIEWS OF THE
GOVERNOR AND THE PREVIOUS, REJECTED COMMISSIONER? MY
CHALLENGES TO THIS BOARD, INCLUDING THOSE MEMBERS APPOINTED BY
GOV. YOUNGKIN, ARE THESE: 1) TO MAKE SURE, AS LONG AS SHE HOLDS THE
POSITION, THAT THE COMMISSIONER'S ACTIONS DO NOT CONTINUE TO
CAUSE THE PUBLIC HEALTH OF VIRGINIANS TO DETERIORATE; AND 2) THAT
THE BOARD WILL DIRECT HER TO TAKE ACTIONS THAT REDUCE DISPARITIES
AND IMPROVE THE EQUALITY OF ACCESS TO CARE AND THE OUTCOMES OF
CARE TO ALL VIRGINIANS.

ADDITIONAL COMMENTS NOT MADE DURING THE PUBLIC COMMENT PERIOD:

I and other Board members, especially Anna Jing, were deeply involved in fighting the
regulations drafted by former AG Ken Cuccinelli that were intended to shut all women's
health clinics that offered abortion care. After the victories of Terry McAuliffe and Mark
Herring in the election of 2013, those indefensible regulations, which had been in effect
for approximately one year, were overturned. The Commonwealth lost approximately
seven clinics as a result of the TRAP regulations, but the leadership of three Commissioners, Drs. Karen Remley, Marissa Levine and Norm Oliver, prevented there being a greater loss. Now, the treatment of abortion clinics as hospitals or outpatient surgery clinics is not permitted under state law, and we hope it remains that way. Many of the former members of the BOH, and perhaps some current members, do not object to the regulation of abortion clinics, nor do all support abortion access during the very late term. We did, and I hope you still do, object strongly to ignoring the precedent of applying regulations to operating clinics rather than imposing them only when new clinics are constructed or substantially renovated....and that you would apply logic to any regulations you may impose in the future -- for example, making parking places a criterion for the granting of permission to operate or requiring that medical abortions be treated exactly as surgical abortions. I remind you that both surgical and medical abortions are safer than giving birth.

Even if the current Attorney General were to draft regulations comparable to the Cuccinelli regulations, the Board has the power to reject them. Mr. Cuccinelli threatened not to represent any Board members who voted to reject his regs, if they were sued by anti-abortion advocates, a clear violation of his duties under the Administrative Procedures law. Enough of the members of the Board in 2012 were intimidated by his threat that, when presented to the Board a second time, those regs were adopted, with only a few holdouts such as Anna and me. If the opportunity to defy the AG occurs again (and I hope it doesn't), be strong and take the position of a vast majority of Virginians -- abortion access is a basic right.
Ruth Machen, Mathews. I come before you today to ask that you not recommend the Covid jab for children. There are thousands of stories like this one that I am about to share written by Maddie’s mother.

“Maddie de Garay was a healthy and vibrant 12-year-old. She was a normal pre-teen who loved dancing and spending time with friends. Maddie’s life changed forever when she received her second dose of the Pfizer Covid vaccine in January 2021 while participating in the trial for 12-15-year-olds.

In less than 24 hours of her second dose, Maddie had a severe systemic adverse reaction. She developed crippling body pain, her fingers and toes ice cold and turned white and she said she felt like someone was “ripping her heart out though her neck.”

A life of soccer games and school was replaced with 11 ER trips totaling more than 65 days. Maddie has suffered numerous systemic injuries, she is still in a wheelchair, receives all her nutrition and medicine through a feeding tube, cannot control her neck, has constant stomach, back, neck and body pain, vision problems, tinnitus, can’t feel from the waist down, allergic reactions, and more. She’s not improving but declining.

After reporting everything to the Pfizer clinical trial Principal Investigator and being brushed aside, we started documenting Maddie’s injury. Cincinnati Children’s first tried to treat Maddie as “a mental patient,” telling us it was anxiety and it was all in Maddie’s head. Pfizer listed her traumatic systemic adverse reaction as “functional abdominal pain” when reporting to the FDA. A day before Pfizer submitted their request for emergency approval for the Covid vaccine for 12-15-year-olds and before necessary testing was done, they put Functional Neurological Disorder as a diagnosis in her chart.

It’s been over two years and a half, time and options are running out for Maddie. I can’t even explain how hard it is to see your child suffer while watching doctor after doctor refuse to help her. We have exhausted all options available through insurance. Pfizer has zero financial obligation for Maddie’s injury and they have not offered any assistance. Despite all that she has been through, she has remained strong and optimistic. We trust God and know that he will heal Maddie, he chose her for a reason and will continue to give her strength.”
Dear Members of the Board,

Peter Machen, Mathews, VA

I am here today to speak against adding the Covid-19 shot to the schedule. Here is the updated VAERS data:

35,347 DEATHS
17,048 BELL'S PALSY
5,009 Miscarriages
19,915 Heart Attacks
27,113 Myocarditis
66,462 Permanently Disabled
37,785 Life Threatening
15,751 Shingles

Total two and a half million adverse events.

I would like you leave you with a few question, how many more people have to die before you stop recommending the Covid-19 shot? Do any of your close family members have to die before you stop? How much lower does the torch of freedom have to burn before you act to save my generation, or will you wait until the torch of freedom is completely extinguished and you yourself has no freedom either? One of our founding fathers John Adams said: “Freedom once lost, is lost forever.” So either you can defend our rights or you can blow out the torch forever. Thank you
Dear Members of the Board,

I am Donna Machen of Mathews, Virginia, and I am concerned about the adverse effects of technology on my body. 5G has rolled out in my community, and Miss Judy Rowe has vowed that she will reach every person in Mathews with it, like it or not. Smart meters have rolled out into my neighborhood, and Dominion has vowed to upgrade every meter, like it or not. I have done my homework and learned that with 5G and smart meters, surveillance in my home will be an invasion of my privacy at the cost of my health. Not only that, it will be a violation of my fourth amendment right against searches and seizures. I urge you to do everything within your power to educate yourself and others on the dangers of technology and on ways to limit the danger for the sake of all Virginians. The effects include increased risk of cancer. How many people do you know or have you known with cancer? My husband has cancer. My mother has cancer. My father-in-law was diagnosed with cancer and put on hospice this week. My mother-in-law died from cancer. My deceased father had cancer. My neighbor, Miss Joan, has cancer and her deceased husband did, too. Will you pay attention? Will you listen? Will you do the right thing? Will you take action? Will you verify whether or not this technology is safe? Please face this, like it or not.
Good morning. I am Susan Franz and I'm from Williamsburg Virginia. The VDH continues to promote the Covid injection as safe and effective for pregnant women. I assume that as a public health board you are aware of Pfizer's own data demonstrating the injection is not safe for pregnant women or their babies. In their own document titled “cumulative analysis of adverse event reports,” 5.3.6 page 12, they demonstrate an 80 percent miscarriage rate in injection recipients. This study was conducted from Dec 2021 to Feb 2021. This one piece of information alone should cause the VDH to stop promoting this vaccine as safe and effective for pregnant women. Are you even aware of this information? If not, why not? It is your job to know the data that affects the decisions you make. Additional data is available that clearly demonstrates fetal death, malformation, blood clots and heart attacks in babies. Apparently you choose not to look at it. Worse, you know the truth and you choose not to act. It is pure evil to continue to promote this injection. I am calling for you, the VDH, to take a stand and stop promoting this injection as safe and effective. It clearly is not. The public is not stupid. We know when we have been lied to. We have lost complete faith and trust in those charged with keeping us safe and healthy. You have a chance to redeem your reputation by stopping this injection from being administered to anyone.

I am leaving you with a copy of the Pfizer results to review for yourselves.
5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021

Report Prepared by:
Worldwide Safety
Pfizer

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Table 6. Description of Missing Information

<table>
<thead>
<tr>
<th>Missing Information</th>
<th>Description</th>
</tr>
</thead>
</table>
| Use in Pregnancy and lactation | - Number of cases: 413* (0.98% of the total FM dataset); 84 serious and 329 non-serious:  
- Country of incidence: US (205), UK (64), Canada (31), Germany (30), Poland (13), Israel (11); Italy (9), Portugal (8), Mexico (6), Estonia, Hungary and Ireland, (5 each); Romania (4); Spain (3). Czech Republic and France (2 each), the remaining 10 cases were distributed among 10 other countries.  
- Pregnancy cases: 274 cases including:  
  - 270 mother cases and 4 focus/baby cases representing 270 unique pregnancies (the 4 focus/baby cases were linked to 3 mother cases: 1 mother case involved twins).  
  - Pregnancy outcomes for the 270 pregnancies were reported as spontaneous abortion (23), outcome pending (5), premature birth with neonatal death, spontaneous abortion with intrauterine death (2 each), spontaneous abortion with neonatal death, and normal outcome (1 each). No outcome was provided for 238 pregnancies (note that 2 different outcomes were reported for each twin, and both were counted).  
  - 146 non-serious mother cases reported exposure to vaccine in utero without the occurrence of any clinical adverse event. The exposure PTs coded to the PTs Maternal exposure during pregnancy (111). Exposure during pregnancy (29) and Maternal exposure timing unspecified (6). Trimester of exposure was reported in 21 of these cases: 1st trimester (15 cases), 2nd trimester (7) and 3rd trimester (2).  
  - 124 mother cases, 49 non-serious and 75 serious, reported clinical events, which occurred in the vaccinated mothers. Pregnancy-related events reported in these cases coded to the PTs Abortion spontaneous (23), Uterine contraction during pregnancy, Premature rupture of membranes. Abortion, Abortion missed, and Foetal death (1 each). Other clinical events which occurred in more than 5 cases coded to the PTs Headache (35), Vaccination site pain (24), Pain in extremity and fatigue (22 each), Myalgia and Pyrexia (16 each), Chills (13) Nausea (12), Pain (11), Arthralgia (9), Lymphadenopathy and Drug ineffective (7 each), Chest pain, Dizziness and Asthenia (6 each), Malaise and COVID-19 (5 each). Trimester of exposure was reported in 22 of these cases: 1st trimester (19 cases), 2nd trimester (1 case), 3rd trimester (2 cases).  
  - 4 serious focus/baby cases reported the PTs Exposure during pregnancy, Foetal growth restriction, Maternal exposure during pregnancy: Premature baby (2 each), and Death neonatal (1). Trimester of exposure was reported for 2 cases (twins) as occurring during the 1st trimester.  
| Breast feeding baby cases: 133, of which: |  
| - 116 cases reported exposure to vaccine during breastfeeding (PT Exposure via breast milk) without the occurrence of any clinical adverse events:  
| - 17 cases, 3 serious and 14 non-serious, reported the following clinical events that occurred in the infant/child exposed to vaccine via breastfeeding: Pyrexia (5), Rash (4), Infant irritability (3), Infanticile vomiting, Diarrhoea, Insomnia, and illness (2 each). Poor feeding infant. Lethargy, Abdominal discomfort, Vomiting. Allergy to vaccine, Increased appetite. Anxiety. Crying. Poor quality sleep, Enuresis, Agitation. Pain and Urticaria (1 each).  
| Breast feeding mother cases (6): |  
| - 1 serious case reported 3 clinical events that occurred in a mother during breastfeeding (PT Maternal exposure during breast feeding); these events coded to the PTs Chills, Malaise, and Pyrexia  
| - 1 non-serious case reported with very limited information and without associated AEs. |
Horowitz: Confidential Pfizer document shows the company observed 1.6 million adverse events covering nearly every organ system

Over 10,000 categories of nearly 1.6 million adverse events – many of them serious and debilitating – brought to you by Pfizer!

You might not have heard it in the news, but in recent months, Pfizer’s pharmacovigilance documents requested by the European Union’s drug regulator, the European Medicines Agency, have been released. They show that Pfizer knew about a sickening level of injury early on. An August 2022 document shows that the company already had observed the following scope of vaccine injury:

- 508,351 individual case reports of adverse events containing 1,597,673 events;
- One-third of the AEs were classified as serious, well above the standard for safety signals usually pegged at 15%;
- Women reported AEs at three times the rate of men;
- 60% of cases were reported with either “outcome unknown” or “not recovered,” so many of the injuries were not transient;

Highest number of cases occurred in the 31-50 year age group, and 92% did not have any comorbidities, which makes it very likely it was the vaccine causing such widespread, sudden injury.
These numbers alone suggest that all COVID shots should be defunded and Congress must immediately remove liability protections from the manufacturers. But a more recent document released by the Europeans is even more devastating, because it breaks down the 1.6 million adverse events observed by Pfizer by category and subcategory of ailment and injury.

The 393-page confidential Pfizer document, dated Aug. 19, 2022, shows that Pfizer observed over 10,000 categories of diagnosis, many of them very severe and very rare. For example:

- Pfizer was aware of 73,542 cases of 264 categories of vascular disorders from the shots. Many of them are rare conditions.
- There were hundreds of categories of nervous system disorders, totaling 696,508 cases.
- There were 61,518 AEs from well over 100 categories of eye disorders, which is unusual for a vaccine injury.
- Likewise, there were over 47,000 ear disorders, including almost 16,000 cases of tinnitus, which even Mayo Clinic researchers observed as a common but often devastating side effect early on.
- There were roughly 225,000 cases of skin and tissue disorders.
- There were roughly 190,000 cases of respiratory disorders.
- Disturbingly, there were over 178,000 cases of reproductive or breast disorders, including disorders you wouldn't expect, such as 506 cases of erectile dysfunction in men.
• Very disturbingly, there were over 77,000 psychiatric disorders observed following the shots, lending credence to Dr. Peter McCullough's research observing case studies showing psychosis correlating with vaccination.

• 3,711 cases of tumors – benign and malignant

• Of course, there were almost 127,000 cardiac disorders, running the gamut of about 270 categories of heart damage, including many rare disorders, in addition to myocarditis.

• There were over 100,000 blood and lymphatic disorders, for both of which there’s a wealth of literature linking them to the spike protein.

When reading what Pfizer knew early on juxtaposed to independent studies, it’s clear that nobody could have mistaken most of these AEs for mere incidental ailments. Here is a list of 3,129 case studies chronicling vaccine injury in every organ system observed in this Pfizer document.

What is so jarring is that there are hundreds of very rare neurological disorders that reflect something so systemically wrong with the shots, a reality that was clearly of no concern to the manufacturers and regulators alike. One of the infamous cases of vaccine injury was Maddie de Garay, an Ohio teen who became disabled for life immediately after participating in the Pfizer clinical trial. Her story is chronicled in chapter 16 of my book. I checked this confidential document and found that they knew of 68 cases of her rare diagnosis, chronic inflammatory demyelinating polyneuropathy.
<table>
<thead>
<tr>
<th>Preferred Term</th>
<th>Total # of Spontaneous AE</th>
<th>I</th>
<th>C</th>
<th>I</th>
<th>C</th>
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<td>Cervicogenic vertigo</td>
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<td>Change in seizure presentation</td>
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<td>32</td>
<td>8</td>
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<td>Chronic inflammatory involvement of pterygium</td>
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<td>Chronic pancytopenia</td>
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<td>4</td>
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<td>Clauder's syndrome</td>
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<td>3</td>
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<td>Clinically isolated syndrome</td>
<td>18</td>
<td>6</td>
<td>18</td>
<td></td>
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</tbody>
</table>

* Interacted, Onset/Duration
* Associated Term
* Multiple adverse events coding in the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

The broad scope of injuries affecting every single organ system is simply extraordinary. Yet to this day, the FDA continues to criminally label the Pfizer shot as safe and effective. To this day, the label indicates the shot is a fully protective vaccine and also fails to mention all of these side effects, as required by law.

Recently, Peter Doshi, editor of the British Medical Journal, wrote a letter to the FDA requesting that the agency update its labeling to reflect the reality of what we've learned about the shots. Specifically, he asked that they include the following side effects on the label: multisystem inflammatory syndrome in children, pulmonary embolism, sudden cardiac death, neuropathic and autonomic disorders, decreased sperm concentration, heavy menstrual bleeding, and detection of vaccine mRNA in breast milk. The
causal relationship of all these AEs to the vaccine is backed by substantial research, surveys, and adverse event reporting systems.

Unfortunately, the FDA denied the causal relationship between any of these side effects and the COVID shots. Even with regard to the request that officials clarify on the label that the shots don’t stop transmission, the FDA replied, “We are not convinced that there is any widespread misconception about this.”

“Product labeling should be informative and accurate, not promotional. The law requires it, and following the law shouldn’t be optional,” bemoaned Doshi and the other authors in a piece at TheHill.com.

The question is whether Republicans in the House will force the FDA to comply with the law by using the leverage of the appropriations bills for the FDA and HHS. So far, there has been no reckoning for their false marketing and the devastating human toll it has cost. Oh, and that is just the short-term human toll.
TURTLES ALL THE WAY DOWN
Vaccine Science and Myth

FOREWORD BY MARY HOLLAND, J.D.
EDITED BY ZOEY O'TOOLE AND MARY HOLLAND
Information for Administrators

Legal Responsibility of School Administrators - Multiple state and federal laws confer legal responsibility on school administrators to ensure a safe and healthy learning environment for all students and staff. Understanding the risks of radiofrequency (RF) radiation and knowing exposure levels in classrooms is part of that legal responsibility. For more information, visit the Legal tab on our website.

Emerging Science on RF Radiation Exposure - Recent studies document serious biological harm from RF radiation at levels below current FCC safety guidelines. Exposure is cumulative and additive. Children and developing fetuses are at increased risk due to their unique physiologic vulnerability. To learn more, visit the Science tab on our website.

Three Easy Ways to Reduce Exposures

1. Have classrooms tested to determine RF radiation exposure levels. Test at task level with all devices operating.

2. Ask IT staff to reduce output power levels and adjust beacon frequency of routers and access points to reduce exposure levels.

3. Stop all purchases of wireless technology pending new exposure level recommendations from federal agencies.

For more ways to reduce radiation levels in classrooms, please visit the Mitigation tab on our website.

"We wired all our classrooms with Ethernet, and were able to reduce the power output of our few wireless access points by 75% without any noticeable impact on performance. From our perspective, even though we don't have all the answers, it's much better to take precautionary measures than to take the risk, especially when it comes to our students."

- Frances Cameron, Head of School, The Hartsbrook School, Hadley, MA

www.TechSafeSchools.org
# Children’s Radiofrequency (RF) Radiation Health Survey

**Child’s Age:** _____  
**Known Health Conditions Prior to Exposure:** ________________________________________

### Symptoms

<table>
<thead>
<tr>
<th>Cardiovascular Problems</th>
<th>Duration</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arrhythmia</td>
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<tr>
<td>Blood Pressure Abnormalities</td>
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<tr>
<td>Heart Palpitations</td>
<td></td>
<td></td>
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<tr>
<td>Eye Pain, Pressure or Visual Disturbances</td>
<td></td>
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<tr>
<td>Fatigue</td>
<td></td>
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<tr>
<td>Hearing Loss, Ear Pain or Ringing in the Ears</td>
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<tr>
<td>Nausea</td>
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</table>

### Neurological Problems

| Anxiety                          |          |          |
| Behavioral Problems              |          |          |
| Concentration and Memory Problems|          |          |
| Dizziness                        |          |          |
| Headaches                        |          |          |
| Hyperactivity                    |          |          |

### Nose Bleeds

| Seizures                          |          |          |
| Skin Rashes                       |          |          |
| Sleep Problems                    |          |          |
| Tingling or Burning Sensations of the Skin |      |          |
| Other                             |          |          |

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Children's Radiofrequency (RF) Radiation Health Survey

**Child's Age:** ____

**Known Health Conditions Prior to Exposure:** ________________________________

<table>
<thead>
<tr>
<th>Symptoms</th>
<th><strong>Duration</strong></th>
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<tr>
<td><strong>Cardiovascular Problems</strong></td>
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<td><strong>Nausea</strong></td>
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<tr>
<td><strong>Neurological Problems</strong></td>
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<tr>
<td>Anxiety</td>
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<tr>
<td>Behavioral Problems</td>
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<td>Concentration and Memory Problems</td>
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<td>Dizziness</td>
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<td>Headaches</td>
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<tr>
<td>Hyperactivity</td>
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<tr>
<td><strong>Nose Bleeds</strong></td>
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<tr>
<td><strong>Seizures</strong></td>
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<tr>
<td><strong>Skin Rashes</strong></td>
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<td><strong>Sleep Problems</strong></td>
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<tr>
<td>Tingling or Burning Sensations of the Skin</td>
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<tr>
<td><strong>Other</strong></td>
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</table>

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Children's Radiofrequency (RF) Radiation Health Survey

**Cancer**
- Adrenal Gland
- Brain
- Breast
- Heart
- Parotid Gland
- Testicular
- Thyroid
- Vestibular

**Exposures**
- Alexa/Google/Siri
- Baby Monitors and Accessories
- Cell Phone
- Cell Tower
- Computer/Computer Components
- Cordless or DECT Phone
- Small Cell Antenna
- Smart Home Fixtures/Appliances
- Tablet
- Utility Smart Meter
- VR Headsets
- Wi-Fi Router
- Wireless Games/Toys
- Wireless Wearables (Smart Watches/Earbuds)
# EMF Points of Confusion vs. Fact

Many are surprised to learn the electromagnetic fields (EMFs) emitted by wireless technology are biologically hazardous, and one often gets pushback when they open the conversation. This fact sheet provides information to help sort fact from misinformation and identifies solutions for safer technology use. For those reading this in print format, please see [https://sites.google.com/site/understandingemfs/ma-emf-bills](https://sites.google.com/site/understandingemfs/ma-emf-bills) for an electronic copy to access the links below.

<table>
<thead>
<tr>
<th>Point of Confusion</th>
<th>FACT</th>
</tr>
</thead>
<tbody>
<tr>
<td>The FCC says wi-fi is fine.</td>
<td>FCC guidelines are outdated. The <a href="https://www.gao.gov">U.S. Government Accountability Office</a> in 2012 instructed the FCC to bring their public radiation exposure limits in line with current science. Hundreds of formal comments were submitted to the FCC by EMF scientists, doctors and the <a href="https://aap.org">American Academy of Pediatrics</a>. The FCC has failed to respond and continues to promote wireless technology. See Harvard's <a href="https://www.citizenwireless.com">Captured Agency: How the Federal Communications Commission is Dominated by the Industries it Presumably Regulates</a>. They appear to be using the tobacco industry playbook. See also the <a href="https://www.mch.org">Mobile Communications and Health</a> study by T-Mobil.</td>
</tr>
<tr>
<td>The manufacturers make it look like all wi-fi all the time is the way to go.</td>
<td>Most consumers, and even many who work in the industry, are unaware of the manufacturers’ <a href="https://www.fcc.gov">fine print</a> that comes with each device indicating one should never keep an active device on one’s body or radiation exposure may exceed even the FCC’s outdated non-protective guidelines. Additionally, science indicates we should have invoked the <a href="https://www.precautionaryprinciple.org">Precautionary Principle</a> decades ago when evidence of harm was first found, and not exposed the public until proven safe. We have not done this in the U.S. but <a href="https://www.who.int">other countries</a> have. This <a href="https://www.ncbi.nlm.nih.gov">table</a> illustrates the disparity in allowable public radiation exposure levels.</td>
</tr>
<tr>
<td>There are studies showing no evidence of harm.</td>
<td>No evidence of harm is not the same as safe. This technology was brought to market with no safety testing and a safe level of microwave radiation has never been identified. The telecommunications industry produces its own scientific studies designed to show no evidence of harm. This creates doubt among consumers so they will continue to purchase wireless products. Dr. Henry Lai provides insights <a href="https://www.betterhealth.vic.gov.au/">here</a>, in 2018 the <a href="https://www.nih.gov">U.S. National Institutes of Health</a> found clear evidence of cancer, as did a large <a href="https://www.ncbi.nlm.nih.gov">Italian study</a> at the Ramazzini Institute.</td>
</tr>
<tr>
<td>There are not many studies done on wi-fi.</td>
<td>There didn’t used to be, but there are now. See this 2018 <a href="https://www.ncbi.nlm.nih.gov">meta-study on Wi-Fi</a> by Dr. Martin Pall. Cell phones came first so that is why the majority of studies, which can take years to complete, use cell phones. However, all wireless operates in the biologically hazardous microwave segment of the <a href="https://www.epa.gov/">electromagnetic radiation spectrum</a>. So, what cell phone studies reveal holds true for 2G, 3G, 4G, 5G, wi-Fi and the Internet of Things too. We have <a href="https://www.ncbi.nlm.nih.gov">thousands of studies</a> showing man-made EMFs are hazardous to all biological species—humans, plants, animals, and insects— including the <a href="https://www.pollinator.org">pollinators</a> needed to grow our food.</td>
</tr>
<tr>
<td>Point of Confusion</td>
<td>FACT</td>
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<td>----------------------------------------------------------------------------------</td>
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<td>Surely we would know if this were an issue.</td>
<td>Advertising dollars influence media content, and telecommunications, energy and technology companies are among the top advertisers. Media executives will not allow true investigative journalism into this issue or their revenues will drop so we rarely hear of wi-fi harm in mainstream media. When there is coverage, they typically say more research is needed, which appeases industry advertisers and keeps consumers buying their toxic products. Industry influence on public servants can also be a factor. In 2017, it took a lawsuit for the California Department of Public Health to finally release a long-suppressed fact sheet on cell phone radiation.</td>
</tr>
<tr>
<td>Our education agencies do not see this as an issue.</td>
<td>Few agencies have investigated because the industry has been so effective at suppressing evidence of harm while offering financial incentives to adopt EMF products and infrastructure. In our top-down education system, local schools often do not feel empowered to act. However, legal precedents are being set that leave schools, public agencies and companies at risk. The insurance industry has identified EMFs as one of the top emerging hazards. Lloyds of London and other insurers do not cover EMF damages so schools and businesses can be held directly responsible for harm. Workers compensation cases have also been awarded for EMF damages in the workplace, and teachers unions are beginning to request hard-wired work environments. Click here for additional information. Ashland Public Schools, MA has become the first in the nation to adopt Best Practices for Mobile Devices and Maryland is the first state to recommend hard-wiring in schools with wi-fi off.</td>
</tr>
<tr>
<td>We need wireless for the 21st century classroom.</td>
<td>The industry identified children as an untapped market and began their 21st Century Classroom campaign to put a wireless device in the hands of every child. In addition to biological harm from wi-fi, studies are showing excessive screen time is harming neurological brain development. This is causing impaired social and emotional skills, digital addiction and poorer educational outcomes. See the Reykjavik Appeal.</td>
</tr>
<tr>
<td>Some say electrosensitivity doesn't exist.</td>
<td>The United States Access Board's IEQ Indoor Environmental Quality Project indicates electromagnetic sensitivities may be considered disabilities under the ADA and recommends accommodations. Just as Lyme Disease was dismissed by medical practitioners before it was widely understood, today’s doctors, nurses, psychologists and social workers in many countries have yet to be trained to diagnose and treat electrosensitivity (ES). School nursing records often indicate an increase in one or more common symptoms among students and staff following the installation of wireless systems: headaches, tachycardia, bloody noses, ear bleeds, skin rashes, nausea, tinnitus (loud ringing in the ears), vertigo, inability to concentrate, depression, anxiety, insomnia. See also the EUROPAEM EMF Guideline 2016 for the prevention, diagnosis and treatment of EMF-related health problems and illnesses and the Guideline of the Austrian Medical Association for the diagnosis and treatment of EMF related health problems and illnesses (EMF syndrome).</td>
</tr>
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https://sites.google.com/site/understandingemfs/ma-emf-bills

Contact Cece Doucette, c2douce@gmail.com
<table>
<thead>
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<th>Point of Confusion</th>
<th>FACT</th>
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<tr>
<td>The radiation drops off with distance.</td>
<td>This is true, in physics the inverse-square law states the intensity is inversely proportional to the square of the distance from the source of that physical quantity. However, it is the pulsed, spiked, erratic signal that causes biological damage. Many routers and cell antennas send and receive data at long distances, and those erratic pulses, though spread out with distance, hit our bodies as they go through buildings, walls, ceilings, etc. Further, if not stopped, the industry will put cell antennas right in our neighborhoods every 2-12 houses for 5G and the Internet of Things. These will pulse close range toxic radiation at our families 24x7.</td>
</tr>
<tr>
<td>Respected engineers, physicists, medical professionals and technologists in our community want our children to have wi-fi in schools.</td>
<td>Most professionals were taught in school and in their work that there must be enough heat from a wireless device to raise the temperature of skin tissue in order to cause harm. Non-industry funded science has now proven this thermal effect premise is false. Thousands of studies show biological effects at the non-thermal, non-ionizing level; most recently the U.S. National Toxicology Program study found DNA damage as well as brain and heart tumors. Professionals in all sectors will benefit from updated education on EMFs.</td>
</tr>
<tr>
<td>There is nothing we can do, wi-fi is everywhere.</td>
<td>Leading non-industry funded EMF scientists from around the world have already sent a formal appeal to the World Health Organization and United Nations to address this “emerging public health crisis”. They succinctly outline specific measures to solve this problem, the first of which is to protect children and pregnant women. Until public policy catches up with science and biologically safe technology is brought to market:</td>
</tr>
<tr>
<td></td>
<td>- Use hard-wired connections with antennas turned off (cell, data, Bluetooth, wi-fi, hotspot) to access the internet safely and avoid legal exposure. Hard-wired is not only safer, it is faster, more reliable and more secure than wireless. Use Ethernet cables and adapters to hard-wire routers, laptops, tablets, etc. Clear sleeping areas of EMFs, and never give to or use an active device near a child.</td>
</tr>
<tr>
<td></td>
<td>- Choose cabled baby monitors, gaming devices, entertainment systems; turn off any wi-fi antennas.</td>
</tr>
<tr>
<td></td>
<td>- Use cabled landline phones, they are safer and more reliable, especially during power outages. Avoid DECT cordless phones, they have high EMF emissions. Cell phones can be forwarded to landlines.</td>
</tr>
<tr>
<td></td>
<td>- Keep analog utility meters, they do not emit the electromagnetic radiation that “smart” meters do.</td>
</tr>
<tr>
<td></td>
<td>- Work with public servants to keep wireless infrastructure away from where we live, work, learn, play. The U.S. Collaborative for High Performance Schools provides Low-EMF Best Practices to establish a hard-wired school environment and prohibit use of personal wi-fi devices in school, except during emergencies.</td>
</tr>
<tr>
<td></td>
<td>See WirelessEducation.org, a non-profit charity that distills the science and medical recommendations into easy-to-learn concepts in affordable 30-minute e-learning courses for families, schools, and workplaces.</td>
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May 24, 2023

[Submitted Electronically]

Division of Dockets Management
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**CITIZEN PETITION AND REQUEST FOR LEGAL COMPLIANCE**

**Legal Obligations of FDA Regarding Public Exposure to Non-Ionizing Radiation from Electronic Products**

Pursuant to 21 C.F.R. §§ 10.20, 10.30 (Citizen Petitions), Petitioner Americans for Responsible Technology and other petitioners Grassroots Environmental Education, Consumers for Safe Cell Phones, California Brain Tumor Association, Manhattan Neighbors for Safer Telecommunications, Michelle Lewis, Zen Honeycutt, Michele Hertz, and Laurie Brown hereby respectfully request that the Secretary of Health and Human Services (HHS) and the Commissioner of the Food and Drug Administration (FDA) fully execute, implement, fulfill and carry out their administrative obligations under 21 USC Federal Food, Drug and Cosmetic Act, Subchapter V, Part C Electronic Product Radiation Control, Section 360ii - Program of Control, regarding public exposure to non-ionizing radiation, a part of the electromagnetic spectrum. We further petition the FDA to produce and make public information detailing its activities and administrative actions that demonstrate full compliance with the specifications of the statute, especially as they relate to non-medical products and devices emitting this radiation.
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SECTION 1. STATEMENT OF GROUNDS

Petitioners are individuals and non-profit organizations representing individuals who are, or have been directly, negatively, and substantially affected by the failure of FDA to adhere to basic and fundamental principles and requirements of its organic statute (21 U.S.C., Subchapter V) and administrative law, or to engage in the on-going risk assessment required.\footnote{As the Secretary has customarily delegated authority over these matters to the Food and Drug Administration, in this document we will hereafter refer only to FDA except when quoting the law.} FDA’s repeated failure to fully comply with the plainly worded requirements in Subchapter V as it relates to electronic products and devices has resulted in a void of public information and exerted a serious and negative influence on medical practitioners and their patients, local, state, and federal officials, school administrators, parents, and other individuals, resulting in a clear and present danger to public health and a violation of public trust.

SECTION 2. ISSUES INVOLVED

In 1968, Congress passed Public Law 90-602, "An Act to Amend the Public Health Service Act to provide for the protection of the public health from radiation emissions from electronic products," also known as the Radiation Control for Health and Safety Act of 1968. In its Declaration of Purpose, Congress wrote, "The Congress hereby declares that the public health and safety must be protected from the dangers of electronic product radiation." The law was updated and codified into the current law in 1991,\footnote{The Radiation Control for Health and Safety Act, P.L. 90-62, Subpart 3 (enacting then 42 U.S.C. Sec. 354) provided that "The Congress hereby declares that the public health and safety must be protected from the dangers of electronic product radiation. Thus, it is the purpose of this subpart to provide for the establishment by the Secretary of an electronic product radiation control program which shall include the development and administration of performance standards to control the emission of electronic product radiation from electronic products and the undertaking by public and private organizations of research and investigation into the effects and control of such radiation emissions." The Section 354 purpose and policy statement was repealed in P.L. 101-629, the Safe Medical Devices Act of 1990, Sec. 19(a)(3), but the underlying understanding of risks remains given the still-effective duty to "protect the public health and safety from electronic product radiation" by requiring "activities to minimize the emissions of and the exposure of people to, unnecessary electronic product radiation." (§ 360ii(a)(2)).} with no significant change in its underlying purpose of minimizing the public's exposure to both ionizing and non-ionizing radiation.
Over the past two decades the ubiquity of personal wireless devices, the deployment of hundreds of thousands of new small cell wireless antennas, the installation of millions of wireless utility meters, the outfitting of school classrooms with wireless routers, tablets, and smart boards, and the surge of popularity of personal wireless wearables and the myriad of other wireless devices now in near-constant use by the public has created a level of exposure to radiation unfathomable to the drafters of the 1968 law. Their belief that exposure to non-ionizing radiation would constitute an on-going and significant risk to public health was prescient.

The issue we address in this Petition is that FDA has failed to execute the clear obligations imposed by Congress, placing the agency in violation of the law. The determination of risk regarding human exposure to non-ionizing radiation has already been made by Congress. Because of the risk involved, Congress instructed FDA to minimize that risk by actively participating in the development of publicly available materials designed to help the public reduce its exposures to radiation emanating from electronic products. Despite acknowledging its authority in this area and its responsibility for protecting the public from hazardous and unnecessary exposure to radiation from electronic products,3 Petitioners assert that these actions have not been, and continue not to be, properly taken by FDA, resulting in an escalating risk and significant harm to public health.

Administrative agencies such as FDA must adhere to their governing statutes and, like all agencies and individuals, obey the law. While the statute is equivocal as to whether the Commissioner has a mandatory duty to promulgate "standards" for human exposure, or whether a predicate finding is required,4 no such leeway exists regarding the other clear obligations of FDA to carry out the activities enumerated in the law. These include:

- [P]lanning, conducting, coordinating, and/or supporting research, development, training, and operational activities to minimize the emissions of, and the

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4 Compare 21 U.S.C. § 360ii(a)(1) ("shall" “develop and administer performance standards…”); § 360kk(a)(1) “shall by regulation prescribe performance standards for electronic products to control the emission of electronic product radiation from such products if he determines that such standards are necessary for the protection of the public health and safety.” (Emphasis added).
exposure of people to, unnecessary electronic product radiation [21 USC 360ii (a) (2)]

- [S]tudying and evaluating emissions of, and conditions of exposure to, electronic product radiation and intense magnetic fields [21 USC 360ii (a) (4)]

- [D]eveloping, testing and evaluating the effectiveness of procedures and techniques for minimizing exposure to electronic product radiation [21 USC 360ii (a) (5)].

These obligations are not dependent on an FDA determination of risk, or any arbitrary exposure level established by FDA or any other entity, and cannot be extinguished by other means. Congress understood that any reduction to a known health hazard will inevitably have a beneficial impact on public health. Petitioners note that FDA does have a Technical Electronic Product Radiation Safety Standards Committee, established in 1968. But as if to underscore its failure to recognize its responsibilities under the law or take them seriously, the Committee has not met since 2016, and FDA has allowed the committee's membership to dwindle to just five out of the required 15 members. This situation has only recently been addressed by FDA after the matter was brought to the attention of the Court in EHT v. FCC.

Moreover, because the purpose of the prescribed activities in Section 360ii is to protect public health and safety by having the FDA produce and make public materials to help members of the public reduce their exposure, activities that take place out of public view, such as private deliberations or discussions within FDA with no public record, public notice, or public participation, do not and will not satisfy the requirements of the statute.

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5 This advisory committee was established in accordance with Section 21 U.S.C. 360kk(f)(1) of the Radiation Control for Health and Safety Act. The committee is supposed to advise FDA regarding proposed performance standards for electronic products which emit radiation.

6 Envl. Health Tr. v. FCC, 9 F.4th 893, 904-906 (D.C. Cir. 2021) "EHT v. FCC"
SECTION 3. SPECIFIC ACTIONS REQUESTED

Petitioners hereby respectfully request that the Commissioner direct the Centers for Devices and Radiological Health (CDRH), or such other new or existing division as he may designate, to take the following three actions to bring FDA into full compliance with the law.

A. REQUESTED ACTION NO. 1

21 USC 360ii (a) (2) requires FDA to "plan, conduct, coordinate, and/or support research, development, training, and operational activities to minimize the emissions of and the exposure of people to, unnecessary electronic product radiation."

1. Planning, conducting, coordinating and/or supporting research

In its own "Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and Cancer" published in 2020, FDA fails to identify a single peer-reviewed study designed to help the public reduce its exposure in which FDA has been actively engaged regarding the planning, coordination, or support of the study. Instead, FDA claims it regularly "monitors" scientific studies performed by others, as if such passive activity satisfies the demands of the law. It does not.

The one study on non-ionizing radiation in which FDA actually played a role was the study conducted at FDA's request to determine whether or not non-thermal levels of radiation such as that from cell phones posed a cancer risk to humans. That study, which fails to meet the requirements of the law since it is not about reducing

7 https://www.fda.gov/media/135043/download

8 The review ignored hundreds of published, peer-reviewed independent scientific studies which demonstrated biological harm from exposure.


"The FDA's physicians, scientists, and engineers regularly analyze scientific studies and publications for evidence of health effects of exposure to radio frequency energy from cell phones."

exposures, was nominated by FDA to the National Institutes of Health in 1999.\textsuperscript{11} Preliminary results were released by the NIH's National Toxicology Program (NTP) in 2016, with an independent peer review panel releasing its own findings in 2018. The panel found that the study results showed "clear evidence" of an increased risk of cancer,\textsuperscript{12} the highest level of scientific confidence. FDA, however, immediately disputed the study's findings, claiming, among other things, that the results were not conclusive.

The NTP study could have been useful in meeting the law's requirements, if FDA had alerted the public that exposure to non-ionizing radiation could increase their own risk of cancer. Instead, CDRH's Director Dr. Jeffrey Shuren issued a statement\textsuperscript{13} in response to the independent panel's conclusion, asserting that the study's findings "\textit{should not be applied to human cell phone usage,}" when, in fact, determining whether or not there was a potential risk to humans was the whole purpose guiding the study's design.\textsuperscript{14} Dr. Shuren's statement, unsupported by any documentation, drew a sharp rebuke from the U.S. Court of Appeals for the District of Columbia Circuit in Washington, DC\textsuperscript{15} for its "conclusory" nature, when the Court stated:

\begin{quote}
"Such conclusory statements 'cannot substitute for a reasoned explanation,' for they provide 'neither assurance that the [FDA] considered the relevant factors nor [do they reveal] a discernable path to which the court may defer.' Am. Radio, 524 F.3d at 241. They instead represent a failure by the FDA to address the implication of Petitioners' studies: The factual premise — the non-existence of
\end{quote}

\textsuperscript{11} https://ntp.niehs.nih.gov/getinvolved/nominate/summary/nm-n99019.html

\textsuperscript{12} https://ntp.niehs.nih.gov/whatwestudy/topics/cellphones/index.html


\textsuperscript{14} The original 1999 FDA nomination of the subject for study defined its rationale as follows: "Little is known about the possible health effects of repeated long-term exposure to low levels of radio frequency radiation (RFR) of the types emitted by wireless communication devices, like cellular phones." See https://ntp.niehs.nih.gov/getinvolved/nominate/summary/nm-n99019.html

non-thermal biological effects — underlying the current radio-frequency guidelines may no longer be accurate.”

We note here that FDA seems to believe its responsibility for planning, supporting or conducting research on reducing exposures is limited to the radiation emitted by mobile phones. In its 2020 literature review, the agency goes to great lengths to explain how difficult it is to study the effect of non-ionizing radiation using animals because "the effects of whole-body exposure do not reflect the real-world situation of localized exposure to the ear and head from a handset as used by humans." Here, intentionally or not, FDA misses the point. Whole-body exposure is exactly what the public is currently experiencing, resulting from the ubiquity and aggregate exposures of wireless devices in public spaces as well as private homes. FDA’s negligence in failing to recognize and address this large and growing public exposure, and failing to advise the public about ways to reduce exposure, violates both the letter and spirit of this section of the law and puts public health at increased risk.

2. Planning, conducting, coordinating and supporting training and operational activities

The law requires FDA to engage in training and operational activities that result in minimizing the public’s "unnecessary" exposure to non-ionizing radiation. Given the wide array of potential exposures, this requirement might be satisfied by coordinating or conducting professional training of medical, educational, and commercial providers in techniques through which public exposure might be minimized. It could include participation at continuing medical education conferences. Due to the recent deployment of wireless technology in school settings, it should include evaluations of methods to reduce exposures of children in classrooms and coordination with the Department of Education to promulgate recommendations and best practices. At the very least, FDA should be requiring commercial providers to participate in the development of exposure reduction techniques, such as one-button wireless disconnects, which could then be promulgated by FDA, or FDA could develop its own exposure reduction techniques.

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None of these activities, or any others that might reasonably satisfy the requirements of the law are being undertaken by FDA. While FDA does include some cursory language on its website about how individuals may voluntarily limit their own exposure by taking simple steps such as reducing the amount of time spent on phones or using the speaker setting, it only does so in the context of actions it portrays as entirely unnecessary, and which only pertain to cell phones. FDA is doing nothing about singular or aggregate exposures from other electronic products or workplace environments where prolonged and sustained exposure is unavoidable. FDA’s innocuous, incidental and half-hearted advisories do not in any way constitute "support" for such measures or reasonable compliance with the law.

3. Conclusion: Requested Action No. 1

For the foregoing reasons, Petitioners respectfully request the Commissioner to direct CDRH or such other division of FDA as may be capable of carrying out the requirements of this section to take such actions as may be required to bring FDA into full compliance with § 360 ii (a) (2), including regularly producing and making public information detailing the agency’s actions that help consumers reduce their exposures and demonstrate compliance with the law. Such information should include details of specific actions taken by FDA including (1) research commissioned, organized, conducted and/or supported by FDA concerning methods or techniques for reducing exposures, (2) records of meetings, conferences or other events at which FDA solicited or presented scientific studies on exposure reduction, (3) publication of specific and dedicated web pages on FDA’s website regarding this research and its conclusions,

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17 FDA, through the Office of Medical Device and Radiological Health Operations (OMDRHO), a program office within the Office of Medical Products and Tobacco Operations (OMPTO), a part the Office of Regulatory Affairs (ORA), does conduct an annual conference and other activities designed to allow government agencies and medical professionals to share ideas and collaborate on methods to protect public health from some types of radiation exposure. However, the OMDRHO is focused exclusively on medical devices and radiological health products, and Congress did not limit the purview of FDA with regard to different types of radiation exposure. Accordingly, such efforts fail to extinguish the FDA’s obligation to address all types of radiation exposure, including those identified in this Petition.

18 See, inter alia, https://www.fda.gov/radiation-emitting-products/cell-phones/reducing-radio-frequency-exposure-cell-phones "There is no established health benefit from reducing an individual’s exposure from cell phones."
and (4) notices of the publication of FDA's research specifically addressing non-ionizing radiation exposure reduction.

B. REQUESTED ACTION NO. 2

21 USC 360ii (a) (4) requires FDA to study and evaluate emissions of, and conditions of exposure to, electronic products that emit non-ionizing radiation.

1. Studying Emissions of Electronic Products

The number of electronic products that emit radiation has grown by orders of magnitude since passage of the original Radiation Control for Health and Safety Act of 1968. These products now include not only mobile phones, but routers, smart utility meters, cordless phones, GPS devices, wireless computer keyboards, tablets, virtual reality headsets, baby monitors, wearables and the myriad other radiation-emitting devices to which millions of Americans are exposed every day.

Petitioners are unable to find any evidence that FDA has engaged or participated in any publicly available research regarding the emissions of such devices, maintained any record of citizen complaints or adverse effects of exposure, participated in or directed any monitoring activities, or required manufacturers to do so. Available technologies that can accurately measure levels of non-ionizing radiation, especially aggregate levels from multiple devices which characterize the majority of public exposures today, remain unutilized by FDA. Instead, FDA seems to be relying on other federal agencies to do the research. The Federal Communications Commission (FCC) does require manufacturers to submit test results showing their individual devices comply with the agency's thermal-only emission standards, but the FCC does not have, by its own admission, either the authority or capacity to study, evaluate and promulgate techniques for reducing the risk to public health. That is the duty and legal obligation of FDA.

Miriam-Webster defines the word "study" as "careful or extended consideration" and "careful examination of a phenomenon, development or question." and "application of the
mental faculties to the acquisition of knowledge.”19 Congress clearly intended FDA to devote time, attention, and resources to considering, examining and understanding ways in which people are exposed to non-ionizing radiation and how they might reduce that exposure, including all of the ways mentioned above. FDA has repeatedly failed to comply with these statutory requirements.

2. Studying and Evaluating Conditions of Exposure

The law also instructs FDA to engage in activities to study the conditions under which the public may be exposed to non-ionizing radiation, and to evaluate those exposures for the purpose of finding ways to reduce them. As the use of electronic products that emit non-ionizing radiation has grown exponentially, with virtually every man, woman and child now regularly exposed, often without their knowledge or consent, FDA is failing to monitor these exposures or evaluate the conditions under which they take place.

For example, the introduction of wireless technology into America’s classrooms, where the exposure from multiple devices is nearly constant and affects the whole body of a uniquely vulnerable population, would, by any reasonable interpretation of the law, constitute a "condition of exposure" which demands investigation and evaluation by FDA. Yet Petitioners can find no publicly available evidence that FDA has studied, measured, or evaluated such exposures. There are no public reports of any FDA inspections of schools to measure cumulative or aggregate exposure levels in busy classrooms, or the effects of exposure on students, teachers, and staff. FDA maintains no records from schools of reported adverse reactions, and FDA’s website contains no mention of any research the agency is supporting or conducting to evaluate the potential risk associated with exposures in schools, especially those experienced by very young children. FDA has issued no advisories or recommendations to schools, educational organizations, or teachers unions about reducing their exposures.

Another common radiation exposure for many people are the high bursts of radiation emitted by so-called "smart" utility meters. These bursts of radiation emanating from the meter

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19 https://www.merriam-webster.com/dictionary/study
have caused many individuals, including several of the Petitioners, to experience acute symptoms often associated with exposure to non-ionizing radiation which are alleviated when the source of radiation is removed. These symptoms include headaches, dizziness, nausea, insomnia, tinnitus, confusion, and other symptoms. The installation of a smart meter has also triggered heightened electromagnetic sensitivity among a small but growing community of individuals who find their lives completely disrupted by the condition, and who cannot easily escape. Petitioners can find no evidence that FDA has engaged in any analysis or evaluation of the emissions of wireless utility meters, conducted any research to understand how bursts of non-ionizing radiation may impact humans differently from constant low levels, established a mechanism by which consumers can report adverse health reactions to such devices, or determined why some individuals are more sensitive to bursts of non-ionizing radiation than others, and what they can do about it. Under the plain language of the law, FDA is legally obligated to act but is failing to act.

The world's largest insurance companies, which employ legions of experts to evaluate potential risks, have decided that exposure to non-ionizing radiation poses a potential health risk so high it must be excluded from their commercial liability policies. An evaluation of the available science by experts at Swiss Re advises investors, "Existing concerns regarding potential negative health effects from electromagnetic fields (EMF) are only likely to increase. An uptick in liability claims could be a potential long-term consequence." Lloyds of London warns its customers in its commercial liability policies that the company's insurance does not cover any claims "directly or indirectly arising out of, resulting from or contributed to by electromagnetic fields, electromagnetic radiation, electromagnetism, radio waves or noise."

Even the purveyors of wireless technologies acknowledge the risk involved and warn their investors in their SEC 10K filings that their future earnings may be adversely affected by liability claims due to exposures.\(^\text{21}\) FDA is silent, issuing no advisories or warnings to the public, in spite of the law's clear requirement that it do so.


\(^{21}\) For example, this statement from Verizon's 2018 filing with the SEC: "Our wireless business also faces personal injury and wrongful death lawsuits relating to alleged health effects of wireless phones or radio frequency transmitters. We may incur significant expenses in defending these lawsuits. In addition, we may be required to pay
3. Conclusion: Requested Action No. 2

For the foregoing reasons, Petitioners respectfully request the Commissioner to direct CDRH or such other division of FDA as may be capable of carrying out the requirements of this section to take such actions as may be required to bring FDA into full compliance with the law, and specifically to study and evaluate the conditions of the public's many sources of exposure to non-ionizing radiation, including the impact of peak exposures and chronic exposures of children occurring in schools, and to produce and make public regularly updated information detailing the agency's actions to help the public reduce its exposures. Such information should include details of specific actions taken by FDA including (1) the design, execution and/or results of independent research designed, performed or commissioned by FDA regarding various types of public exposures, especially involuntary exposures emanating from wireless utility meters, high levels of radiation in workplace environments, and exposures of children in school classrooms, (2) summaries of reports or tests performed by other agencies and independent experts with whom FDA has consulted about reducing exposures, and (3) publication of this information on dedicated web pages of the FDA website.

C. REQUESTED ACTION NO. 3

21 USC 360ii (a) (5) requires FDA to develop, test and evaluate the effectiveness of procedures and techniques for minimizing exposure to electronic product radiation.

1. Developing Procedures and Techniques for Minimizing Exposure

In writing the law, Congress clearly intended for FDA to actively engage in developing plans, procedures, strategies, and techniques for minimizing the exposure of the public to radiation of all kinds. Such procedures might include working with wireless device manufacturers to provide a one-button disconnect that would immediately disable all wireless antennas. New cars could be outfitted with a switch to turn off all unnecessary wireless

significant awards or settlements.”
https://www.sec.gov/Archives/edgar/data/732712/000073271219000012/a2018q410-k.htm
circuits. Routers could be manufactured with circuits to automatically turn off when not in use or at night when users are asleep.

Public buildings could provide radiation-free zones for citizens. Colleges and universities could be encouraged to set aside spaces where non-ionizing radiation is minimized. Hotels could be encouraged to provide "Wi-Fi-free" rooms for individuals who suffer from electromagnetic sensitivity. All wireless devices, including cell phones, could be required to include more prominent consumer warnings about the hazards of exposure. FDA could engage with companies that provide shielding materials to reduce the transmission of radiation through walls and windows, and those that create equipment to test and monitor for radiation levels.

FDA's responsibility for developing techniques for minimizing exposure to electronic product radiation is not optional. FDA has been given the authority and responsibility by Congress, but has failed to engage in any of these, or other similar activities that meet even the minimum requirements of the law.

2. Testing the Techniques and Procedures for Minimizing Exposure

FDA is required by law to test the procedures it has developed for minimizing the public's exposure to all types of radiation, but obviously there can be no testing of procedures if no procedures have been developed. If FDA doesn't at present have sufficient staff to meet this requirement, the agency should request appropriations from Congress to fund such activity. Human lives are at stake. It is not a matter of administrative or corporate convenience. FDA's responsibility and failure are clear.

3. Evaluating the Effectiveness of Procedures and Techniques

Here again, FDA is unable to meet the requirements of the law because of its failure to carry out any of the activities specified earlier in this section. It's not up to FDA to decide which parts of the law it wants to comply with and which to disregard. If Congress wishes to change the law, it can. Barring such a change, FDA has no legal choice but to carry out the stipulated activities.
4. Conclusion: Requested Action No. 3

For the foregoing reasons, Petitioners respectfully request the Commissioner to direct CDRH or such other division of FDA as may be capable of carrying out the requirements of this section to take such actions as may be required to bring FDA into full compliance with the law, and specifically to develop or cause to be developed techniques for minimizing the public's exposure to non-ionizing radiation from the full array and aggregate emissions of electronic products to which people are exposed, and produce and make public regularly updated information detailing the agency's actions that demonstrate compliance with the law. The information should include details of specific actions taken by the agency including (1) specific techniques developed by or for FDA which result in minimizing human exposure to non-ionizing radiation, (2) meetings or conferences organized or attended by FDA where minimizing human exposure to non-ionizing radiation was discussed, (3) outreach efforts by FDA to acquire data about reducing exposure to non-ionizing radiation from third parties, (4) activities to educate the medical profession about techniques for reducing exposures, and (5) interim or final reports of FDA's related research or other relevant materials.

SECTION 4. PUBLICLY AVAILABLE INFORMATION IS REQUIRED

A. ACCURATE INFORMATION SERVES THE PUBLIC INTEREST

The public concern over the risk from non-ionizing radiation emitted from electronic products has been deepened recently by studies questioning the adequacy of current federal safety guidelines to protect public health, and media reports suggesting that the federal government is not focused on protecting the health of the public but instead on protecting the wireless industry from scrutiny. The plain language of the statute suggests that Congress expects FDA to promulgate information to help the public reduce its risk, at least in part to help assure the public that there are ways to use electronic products safely.

Congress actually got it right in 1968. It foresaw that certain values, particularly protection of the public from the risks of radiation, are imperative and superior to manufacturer or shareholder interests. Production and promulgation of publicly available information detailing the efforts of FDA to fully engage in a rigorous program of investigation, research, monitoring, and testing of the myriad wireless electronic devices currently in use every day by consumers, and otherwise fulfilling the requirements of the law, would provide local, state and federal elected officials, medical practitioners, school administrators, parents and other members of the public with tools to help them reduce exposures to those electronic devices, as Congress intended.

B. INFORMATION WOULD AID OTHER BRANCHES OF GOVERNMENT

Federal agencies and other branches of the government, including the Federal Communications Commission, the Department of Commerce, Department of Transportation, Department of Labor, Occupational Safety and Health Administration, Centers for Disease Control, Department of Defense, Department of Education, Congressional Research Service and others which depend on scientific information from FDA to determine their own policies will benefit from knowing the results of efforts by FDA to evaluate and reduce the public's exposures to non-ionizing radiation in schools, factories, office buildings, electric vehicles, trains, airplanes and other environments.

Such information would also be consistent with FDA's legal obligation under § 360ii (6) which requires the Secretary of HHS to:

"[C]onsult and maintain liaison with the Secretary of Commerce, the Secretary of Defense, the Secretary of Labor, the Atomic Energy Commission, and other appropriate Federal departments and agencies on (A) techniques, equipment, and programs for testing and evaluating electronic product radiation, and (B) the development of performance standards pursuant to section 360kk of this title to control such radiation emissions."

Publication of the information on the FDA website, with notice and opportunities
for public comment will help fulfill the agency's mission to protect public health and build public confidence that the agency is acting in their best interests, not the interests of the wireless industry.

SECTION 5. FDA'S FAILURE TO OBEY THE LAW IS PUTTING PUBLIC HEALTH AT RISK

Petitioners assert that FDA has a duty to act in good faith to convey accurate and truthful information to the public, and that the continued failure of FDA to abide by the clear and unambiguous language of the statute, combined with its unequivocal public stance that biological risks of exposure to non-thermal levels of non-ionizing radiation simply do not exist, is resulting in significant and growing harm to public health. This is manifested in numerous instances of irreversible but completely avoidable illness, mental anguish and stress among tens or hundreds of thousands of Americans who, because of FDA's negligence, may fail to attribute their own health conditions to over-exposure to non-ionizing radiation or worse, may develop a life-threatening illness.

A. MEDICAL PRACTITIONERS ARE NOT RECEIVING FULL DISCLOSURE OF RELEVANT MEDICAL INFORMATION FROM FDA

Petitioners acknowledge that scientific debate exists regarding the various mechanisms by which acute or long-term exposure to non-ionizing radiation triggers biological changes, although many studies exist to strongly suggest possible culprits, including, most notably, oxidative stress. However, the lack of scientific consensus regarding the root cause and mechanism of biological changes is not proof that such changes are not occurring, or that the science is settled on the subject, or that the public should bear the burden of proof of harm, especially when Congress has already recognized that a significant risk exists.

FDA's failure to advise the public on ways to reduce exposure, combined with its public stance on the issue of non-ionizing radiation from wireless devices is misleading and confusing to physicians and clinicians who—when faced with patients exhibiting a variety of

symptoms often associated with non-ionizing chronic radiation exposure — discount the possibility of a link to such exposure because they have been led to believe that this exposure is not a clinically relevant concern. As a result, physicians are misdiagnosing these conditions, making medical decisions, and prescribing medications for patients, all based on the false belief that FDA is actively carrying out its obligations under the law and has developed its official policy and position that the health risks associated with exposure to non-thermal levels of non-ionizing radiation are de minimis.

The development of any official FDA policy is subject to the Administrative Procedure Act (APA) (5 U.S.C. Chapter 5), the Congressional Review Act, the Paperwork Reduction Act, the Regulatory Flexibility Act and various Executive Orders. Petitioners can find no substantial evidence that FDA has engaged in any of the necessary steps to develop an official policy regarding human exposure to non-ionizing radiation from electronic devices, or any documentation from FDA about the basis for its claim of safety or acknowledgement of the vigorous scientific debate over this issue.

Nevertheless, FDA has articulated a de facto policy, whether official or not. FDA’s failure to research, analyze and promote techniques for reducing exposures is steering medical professionals away from information that may help them diagnose and treat medical conditions, which may in turn be caused by unnecessary exposures. This is a serious breach of the agency’s most fundamental duty of care.

B. FDA IS FAILING TO ADVISE SCHOOL OFFICIALS ABOUT REDUCING EXPOSURES IN CLASSROOMS

Today’s school classrooms are filled with wireless technology. In elementary schools, most students are provided with their own personal wireless device for use in class, and the classroom itself is outfitted with wireless routers, smart boards, and projectors among other wireless educational products; in secondary schools, personal wireless computers are required. In addition, many students have their own personal cell phones, making school classrooms
potentially "hot" environments for non-ionizing radiation with dozens of devices operating simultaneously in a confined area.

The implementation of wireless technology in classrooms is taking place in a regulatory vacuum caused by FDA's failure to implement the measures prescribed by Congress to avoid just such a situation. No other federal agency has been empowered, indeed directed, to identify situations such as school classrooms in which large numbers of people - in this case, children - are being regularly exposed to non-ionizing radiation from wireless devices, and to undertake efforts to reduce that exposure. FDA alone currently has this oversight authority and responsibility.

In the absence of FDA action, school administrators, parents and teachers are going along with the wireless industry's relentless push to transform education into a digital service based on the assumption that FDA has fulfilled its legal obligation to develop, test, evaluate and promulgate procedures and techniques for minimizing exposures, and that schools are complying with those recommendations. That is not the case.

Teachers, many of whom are of child-bearing age, are being exposed throughout the day to the cumulative non-ionizing radiation emanating from all wireless devices in the classroom. Some studies have shown that exposure during pregnancy can disrupt normal brain development,\(^\text{25}\) nevertheless, the FDA is mute, neither alerting young teachers to the potential for harm from constant exposure nor carrying out the activities prescribed by law that could provide teachers and administrators with information to help them reduce exposures in classrooms.

Parents of children suffering from acute symptoms of over-exposure to non-ionizing radiation in schools are facing an impossible choice: watch their children continue to suffer, day after day, or pull them out of school and provide some form of home schooling, which for working families may be impossible. Their concerns about their children are often summarily

dismissed by uninformed school nurses or school administrators, who trust FDA’s unfounded claims that there are no non-thermal effects from exposure to non-ionizing radiation. School officials also cite claims by manufacturers that each of their devices meets FCC guidelines - guidelines which, in turn, rely completely on the endorsement of FDA. In the absence of any advisories or warnings from FDA, school administrators lack any information on which to base decisions about the deployment of wireless devices and products -- the very opposite of what Congress intended.

C. FDA IS FAILING TO ADVISE PARENTS ABOUT HOW TO REDUCE EXPOSURES FOR SMALL CHILDREN

Today’s consumer marketplace is flooded with wireless devices of all kinds, from smart diapers to the Smart Elderly Tracker. According to researchers, the average American household now has 16 internet-connected devices, many of them wireless. Parents of pre-teens are besieged to provide their children with smart phones, game consoles, drone controllers, and other wireless devices. Peer pressure to have access to messaging apps on electronic devices is intense. Researchers at Stanford University found that about 25% of children received phones by age 10, and 75% by age 12. Nearly all children had phones by age 15 years.27

Instead of providing any information about the large and robust body of developing science regarding potential biological harm from exposure or carrying out its own evaluations as required by law, the FDA’s website conveys a false and inaccurate sense of security and safety to anxious parents who may have concerns about the health and safety of their children. It boldly proclaims:

"Current scientific evidence does not show a danger to any users of cell phones from radio frequency [non-ionizing] energy, including children and teenagers."28

20 https://www.parksassociates.com/blog/article/04272022
This is a blatantly false statement. There is current scientific evidence showing a danger to users of cell phones. FDA may not like the results or choose not to assign the benefit of the doubt to studies showing harm, but the agency does not serve the interest of public health by ignoring or discounting important scientific studies – including its own study – that show an elevated risk of harm. Moreover, FDA has failed to engage in the legally required activities that would result in alerting the public to possible harm and advising them on ways to lower their risk of harm.

It is well established that children are not just little adults; their rapidly developing physiology, behavioral patterns and immature detoxification systems make them more prone to environmental insults than adults. Among other things, their thinner skulls allow for the deeper penetration of non-ionizing radiation into the brain. Despite solid scientific evidence of this phenomenon, FDA has not conducted or supported any publicly available research into the typical patterns of electronic product use by children and teenagers or developed any procedures to reduce their exposures, both of which are required by law.

Any inquisitive parent, visiting FDA’s website for information on the possible health risks of exposure to radiation from electronic devices would be misled and falsely comforted by the statements and pictures found there and assume that FDA’s statement is based on rigorous scientific inquiry and compliance with the law. They would be tragically wrong.

D. FDA IS FAILING TO ADVISE UTILITY CUSTOMERS ABOUT REDUCING EXPOSURES FROM SMART METERS

According to the U.S. Energy Information Administration, there are now more than 111 million Advanced Metering Infrastructure (AMI) or "smart" utility meters installed in the United States, and as of 2018, more than 80% of them had been installed on residential buildings.\footnote{https://www.eia.gov/tools/faqs/faq.php} These meters provide the utility with detailed information about the customer's use of electricity (similar types of meters are used for monitoring and reporting gas and water),

\footnote{https://www.eia.gov/tools/faqs/faq.php}
including the exact time of usage. Some meters also allow the utility to restrict or cut off the customer's service. AMI meters use pulsed non-ionizing radiation to transmit large amounts of data at various intervals throughout the day.

There is increasing evidence that pulsed, polarized radiation has a greater effect on human biology than non-pulsed signals. In 2011, personnel at the U.S. Army Medical Research Detachment of the Walter Reed Army Institute of Research and the Air Force Research Laboratory at Brooks Air Force Base conducted a review of the extensive scientific literature regarding the biological effects of pulsed radiation that had been developed by Russian scientists. The authors noted:

"Unfortunately, most of this research was published in Russian; these publications are scarcely available in the West and have not ever been reviewed in English. Even some key findings, which may affect the conceptual understanding of interaction mechanisms and approaches to [non-ionizing radiation] safety, seem to be not known in the West, and their replication in Western laboratories has never been attempted."  

Petitioners can find no evidence that FDA has evaluated these kinds of exposures, or worked with manufacturers to reduce exposures, even though more than 90% of residential households now have at least one pulsing electronic meter attached to their home which they can neither turn off nor move. The failure of FDA to investigate this widespread public exposure violates Congress' explicit instruction to study and evaluate the emissions of, and conditions of exposure to, electronic product radiation as well as its directive to develop, test and evaluate the effectiveness of procedures and techniques for minimizing exposure to such devices.

Petitioners note here that hundreds of individuals have previously submitted comments to FDA regarding serious health problems which developed shortly after the installation of a "smart" utility meter on their home or apartment. While correlation is not causation, hundreds of field reports of adverse health conditions would normally trigger an immediate response from

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FDA and an investigation of potential causes. In this case, there was no response, no investigation, and no compliance with the clear letter of the law. The burden has been placed entirely - and unfairly - on the consumer, as FDA continues to ignore its legal responsibility.

E. FDA IS FAILING TO ADVISE EMPLOYERS ABOUT HOW TO REDUCE WORKPLACE EXPOSURES

Today's modern workplaces, from factory floors to executive suites, are filled with wireless technology, connecting workers to their superiors and each other. Local area networks pervade virtually every business environment, connecting wireless computers, printers, scanners and myriad other wireless devices.

Wearable wireless devices, first popular as a trendy fashion accessory, are now taking their place as required equipment in a growing number of manufacturing, warehousing and distribution situations, with estimates of wearable devices now exceeding one billion worldwide. Workplace wearables are promoted as important elements to improve worker safety and comfort but can also be used to monitor employee behavior and precise locations during the workday. Some workplace environments are now using "smart helmets" that continuously monitor employees' location, physical symptoms or chemical exposures and wirelessly transmit data to central servers.

This type of near-constant, close proximity use of wireless technology is entirely unmonitored and unprecedented, and is taking place in a regulatory vacuum, with no pre-market safety testing, and subject only to long-outdated non-ionizing radiation exposure guidelines developed by engineers in the 1980s based on very limited studies of monkeys and rats.

FDA has again failed to evaluate these kinds of exposures, or promulgated any recommendations to employers or employees on how to they can reduce them. Employers, questioned about the relative safety of such exposures or faced with employees complaining of headaches, nausea, dizziness, tinnitus or other symptoms commonly associated with exposure to non-ionizing radiation, are relying completely on manufacturer's claims of compliance with FCC

standards, which themselves rely on the unsubstantiated and conclusory assertions by the FDA that there are no risks associated with exposure to non-thermal levels of non-ionizing radiation. This chain of reliance by employees, employers, manufacturers and the FCC is built entirely on the premise that FDA is, and has always been, in full compliance with the law. It is not.

SECTION 6. CONCLUSION

FDA's website boasts that the agency relies on "one of the world's most comprehensive and effective networks of public health and consumer protections" as it regulates food and food ingredients, ensures the safety and effectiveness of drugs and medical devices, and takes steps to make sure cosmetics, medical products and consumer products that emit radiation do no harm.

To accomplish its mission, the agency relies on the consumer protection laws enacted by Congress which give the agency this authority.

But the same laws that give the agency its authority to regulate also confer certain enumerated legal obligations on the agency to perform specified activities. In this instance, FDA has chosen to use the law when it wants to enforce its rules and regulations, but completely and blatantly ignore the law when it applies to its own conduct. The freedom to pick and choose which parts of the law it is obligated to obey was never granted to the FDA by Congress.

For the reasons above, Petitioners ask the Commissioner to grant this Petition and order such actions as may be required to bring the agency into full compliance with the law.

SECTION 7. ENVIRONMENTAL IMPACT

Petitioners claim a categorical exclusion under one or more provisions of 21 C.F.R. §§ 25.30-25.34.
SECTION 8. CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition and its attachments includes all information and views on which the petition relies.

Douglas A. Wood
Founder and National Director

SECTION 9. STATEMENTS OF PETITIONERS

All petitioners have granted permission for their statements to be made part of the public record.

Statement of Grassroots Environmental Education
Statement of Consumers for Safe Cell Phones
Statement of the California Brain Tumor Association
Statement of Manhattan Neighbors for Safer Telecommunications
Statement of Michelle Lewis
Statement of Zen Honeycutt
Statement of Michele Hertz
Statement of Laurie Brown
Statement of Grassroots Environmental Education

This document is submitted under penalty of perjury in support of the Citizens Petition filed by Americans for Responsible Technology regarding the failure of the FDA to abide by the clear and unambiguous requirements of the law regarding public exposure to radiofrequency (RF) radiation from all types of wireless devices.

Grassroots Environmental Education (Grassroots) is a science-based non-profit organization with a mission to inform the public about the links between common environmental exposures and human health, and to empower individuals to act as catalysts for change in their own communities.

Our work in the area of RF radiation and human health began in 2012, when we were introduced to the work of Dr. Hugh Taylor at Yale University and his team of researchers who had just published a study demonstrating that the offspring of mice exposed to radiation from a cell phone had abnormal brain development and behavioral characteristics. The study was the basis for our development, in partnership with Dr. Devra Davis of Environmental Health Trust, of the BabySafe Project (www.BabySafeProject.org). This project warns pregnant women not to keep their cell phones in a pocket over their developing babies or use their pregnant belly as a platform for their wireless laptop or tablet.

That project, and all of our ensuing work to inform the public about the potential risks of exposure to RF radiation was necessitated because of the failure of the FDA to carry out its most basic function: to make the public aware of potential health risks and provide information on reducing those risks.

It was only recently that we learned that this mandate to keep the public informed about the potential dangers associated with exposure to RF radiation is actually part of a 1968 law issued by Congress because of what Congress understood even back then to be a serious public health hazard. We were shocked to realize that all of our work to warn the public about exposure is work that the FDA was supposed to have been doing for more than half a century.

Grassroots has created websites, pamphlets, flyers and tip cards with accurate, science-based information about the potential harm from RF radiation exposure, and simple steps that can be taken to reduce that risk. We have attended conferences and trade shows, sent staff to testify at hearings and events across the country, engaged professional lobbyists to help carry our message to legislators in states from Connecticut to California. We have made hundreds of presentations to local groups throughout the Northeast, and handled phone and email inquiries
from thousands of individuals whose lives have been turned upside down by health problems associated with exposure to RF radiation.

We are particularly concerned about potentially elevated RF radiation exposures experienced by children in school classrooms utilizing wireless technology. We have developed and promoted an entire program (TechSafeSchools.org) to warn school administrators of the potential risk of chronic RF radiation exposure for students. The program is based in part on the legal concept of "Duty of Care" which all administrators have to ensure the safety of learning environments. This is exactly the same ethical and moral obligation that FDA has to the American people.

Our tireless work to try and protect people from RF radiation is not our job. This large expenditure of time, money, and resources was only made necessary because of FDA’s refusal to abide by the law, and its flagrant disregard for the safety and health of the American people. We urge the FDA to re-think its cavalier attitude toward this growing public health threat and fully engage in the activities Congress has mandated.

Sincerely,

[Signature]

Patricia J. Wood
Executive Director
DECLARATION OF CYNTHIA FRANKLIN
ON BEHALF OF
CONSUMERS FOR SAFE CELL PHONES

April 23, 2023 - I, Cynthia Franklin, hereby state, under penalty of perjury, that the following information is true to my knowledge, information, and belief:

I am the President of Consumers for Safe Cell Phones (“CSCP”), a 501(c)(3) non-profit organization. As the group’s name suggests, CSCP educates consumers as to ways to reduce microwave radio frequency radiation (RFR) exposure from cell phones, tablets, WIFI routers and other wireless devices.

This statement is submitted in support of the Citizens Petition filed by Americans for Responsible Technology and other petitioners pursuant to FDA's failure to abide by the language of 21 USC 360ii.

CSCP has approximately 5,800 social media followers who regularly receive information and advice from CSCP. The group also communicates with the public through webinars and online informational articles. CSCP provides updated information to its followers on, among other matters, the science and research being conducted on RFR and potential biological impacts. In offering these services, CSCP does not have the resources to conduct its own scientific studies, but instead reviews information from publicly available sources, including the FDA.

Congress intended that the FDA, as the nation’s premiere public health agency, should be the source of such studies; but, the FDA has failed to follow the law, causing CSCP to expend significant time, effort and resources researching and disseminating other sources of reliable scientific information.

One issue CSCP is focused on is the federal regulatory RFR exposure compliance testing procedures for approving the marketing and sale of cell phones. Cell phone manufacturers are not required to test their products directly against the body even though it is well known that consumers regularly wear and use their cell phones in shirt and pants pockets and bras.

In 2012, the U.S. Government Accountability Office (GAO) published the report, GAO-12-771 “Telecommunications: Exposure and Testing Requirements for Mobile Phones
Should Be Reassessed” in which it was concluded that:

“By not formally reassessing its current limit, FCC cannot ensure it is using a limit that reflects the latest research on RF energy exposure. FCC has also not reassessed its testing requirements to ensure that they identify the maximum RF energy exposure a user could experience. Some consumers may use mobile phones against the body, which FCC does not currently test, and could result in RF energy exposure higher than the FCC limit.”

While the FCC may possess legal authority to set exposure standards for products it regulates, it is the FDA which has the authority, capacity, and legal responsibility to provide the scientific foundation for such standards. It is the FDA, not the FCC, which is supposed to “plan, conduct, coordinate, and support research, development, training, and operational activities to minimize the emissions of and the exposure of people to, unnecessary electronic product radiation.” It is the FDA, not the FCC, which is supposed to evaluate the kinds of exposures people are experiencing as they use electronic devices that emit RFR. And it is the responsibility of the FDA, not the FCC, to develop ways in which cell phones can be made safer.

Cell phone manufacturers are substantially underestimating actual RFR exposure levels when demonstrating compliance with the FCC’s RFR exposure limits. The 2012 GAO report states that federal testing procedures for wireless devices allow consumers to be exposed to RFR levels “higher than the FCC limit.”

The FDA claims on its website that it provides guidance to “federal agencies on techniques and programs for testing and evaluating electronic product radiation:”

“Under the law, the FDA is responsible for, among other things: Consulting with other federal agencies on techniques and programs for testing and evaluating electronic product radiation. For example, the FDA provides scientific input and expertise to the Federal Communications Commission (FCC). The FCC sets limits on the emissions of radio frequency energy by cell phones and similar wireless products.

This statement implies that FDA is in full compliance with the law and has carried out all of the activities required by the law. Yet there is no publicly available evidence that this is true. There are no FDA studies (other than its own incriminating study curiously disavowed by the agency), and no record of FDA conducting any other research or investigation to support its conclusion that the exposure being experienced every day by millions of Americans is safe.

On August 13, 2021, the DC Circuit Court of Appeals in its ruling in Environmental
Health Trust v The Federal Communications Commission (EHT v FCC) found:

"...the Commission's [December 4th, 2019] order arbitrary and capricious in its failure to respond to record evidence that exposure to RF radiation at levels below the Commission's current [thermal] limits may cause negative health effects unrelated to cancer. That failure undermines the Commission's conclusions regarding the adequacy of its testing procedures, particularly as they relate to children."

An even more alarming statement from the EHT v FCC ruling is that "the factual premise - the non-existence of non-thermal biological effects — underlying the current RF guidelines may no longer be accurate."

Thousands of studies — including FDA's own multi-million dollar RFR study documenting "clear evidence" of cancer from cell phone exposure¹ - have documented serious biological harm from exposure to levels of RFR far below those that could possibly be powerful enough to cause heating of tissue. This means that the current FCC testing guidelines, based solely upon protection from heating, are thousands, possibly even hundreds of thousands of times more lenient than limits that would be necessary to protect the public from non-thermal exposures.

As the Court found in EHT v FCC, the FCC’s 27 year old exposure limits are based upon an outdated assumption that the only harm from RFR is that of heating — and the implications of this regulatory failure are a major public health threat, "particularly as they relate for children."

It is unclear why the FDA believes that the current RFR limits, which were adopted 27 years ago, still protect us even though patterns of use and the newer, more biologically harmful pulsed RFR exposures have changed significantly since 1996, with the amount of radiation we are exposed to on a daily basis increasing substantially.

The FDA has left all of us in the dark on how and why it decided that current research on biological risks from “non thermal” levels of RFR exposure does not warrant a change in federal RFR standards or cellphone testing procedures. The FDA has ignored all the scientific research documenting biological harm at low exposure levels far below those “heating-only” exposure limits currently being used by FCC in their testing protocols.

With seemingly little concern for the health and safety of the public, the FDA presents

¹ [https://ntp.niehs.nih.gov/whatwestudy/topics/cellphones/index.html](https://ntp.niehs.nih.gov/whatwestudy/topics/cellphones/index.html)
confusing and conflicting advice on its website\textsuperscript{2} and in public statements, assuring everyone that cell phones are safe even if used directly against the body while receiving RFR levels in excess of the FCC's limits....\textit{even with unlimited use by children and pregnant women.}

This absolute regulatory failure by the FDA means that CSCP now has to divert resources toward efforts to counter the disinformation being disseminated by the FDA website, as well as from biased and unfounded opinion reports and misleading public statements issued by Jeffrey Shuren, director of FDA's Center for Devices and Radiological Health.

This means CSCP is not able to supplement the information that it provides to its followers with what should be the most comprehensive assessment of RFR scientific research to date by the FDA, the agency charged with protecting the public from RFR exposures.

\hspace{2in}

\textit{Cynthia Franklin}

Cynthia Franklin, President
Consumers for Safe Cell Phones
829 Briar Rd
Bellingham, WA 98225

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\textsuperscript{2} \url{https://www.fda.gov/radiation-emitting-products/cell-phones/scientific-evidence-cell-phone-safety}
Statement of the California Brain Tumor Association

My name is Ellen Marks. I am the founder of the California Brain Tumor Association (CBTA) and I am submitting this declaration in support of the Citizens Petition by Americans for Responsible Technology and other petitioners regarding FDA's failure to follow the law and develop a Program of Control to protect consumers who are unaware of the potential danger posed by cell phones and other wireless devices.

In May of 2008, my seemingly healthy 56 year-old husband Alan had a grand mal seizure and subsequent diagnosis of a brain tumor. He was in real estate development and sales and always held his cell phone to his right ear, exactly where the tumor developed. He used the cell phone virtually all day, every day, holding the device against his head as he talked, unaware that such behavior could result in the development of brain cancer. FDA's failure to study these kinds of exposures, evaluate their potential health risks, develop techniques for reducing exposures and alert the public to the potential danger was directly responsible for my husband's condition.

In September of 2008, I testified at a Congressional hearing on Cell Phones and Health. A representative from the FCC was also there, and when asked why they had not changed their outdated obsolete guidelines since 1996, he responded that Congress had not instructed them to do so. He also stated they have no scientific expertise in this area; they defer to other government agencies like the FDA. I later learned that because the FDA had failed to follow the law, it was unable to provide the FCC with any scientific foundation on which to base its guidelines.

In 2012 I went to Washington again and met with officials of the General Accounting Office (GAO) at their request. They had been asked by several legislators to investigate this issue. The GEO released its report a short while later, instructing the FCC to reassess their guidelines for human exposure to cell phones. The FCC eventually opened a formal Notice of Inquiry and received thousands of comments from experts and individuals harmed by their exposure to wireless radiation. The FCC ignored the comments in their entirety and in 2019 decided - arbitrarily and capriciously - to keep the outdated guidelines in place.

The FDA, the nation's premiere public health agency, and the one charged with the responsibility for developing a Program of Control, provided a letter to the FCC saying the agency thought the current guidelines were just fine. This flimsy and unsupported document earned the FDA a sharp rebuke from the federal court in EHT et al v. FCC. (2019), which called the letter "conclusory" and rejected it as an adequate basis for the FCC's decision.

The FDA's action, or inaction, impacted my husband and millions of others. My husband had his first craniotomy in June of 2008. He was fortunate, as his glioma was a grade 2. However, it affected his cognitive abilities and behavior greatly. As his neuropsychiatrist stated: "This tumor set off a nuclear bomb in your living room." This tumor, caused by exposure to his cell phone and a lack of science-based information from the FDA, robbed me of my real husband and our 3 children of their real father. In 2020 his tumor returned and this time the doctors informed us it is terminal. He recently underwent another craniotomy and is not doing well.
My husband had no other exposures to radiation or other risk factors which are likely to be the primary cause of his brain tumors. There is excellent science proving the link to cell phone radiation, yet the FDA is ignoring its legal responsibility to conduct research, evaluate the different kinds of exposures which people are receiving, and develop ways to minimize exposures to devices like cell phones. It is pretending it has done the research to support its conclusions, but like Hans Christian Andersen's fable about the Emperor's New Clothes, there is nothing there. The FDA hasn't done the work, but instead, continues to spread misleading and unsupported information that is putting the public at risk.

In 2019 Dr. Jeffrey Shuren, director of the Center for Devices and Radiological Health at the FDA, responding to questions posed by Representative Anna Eshoo concerning radiofrequency radiation and health, furnished an unsigned, so-called "scientific review" which was neither scientific nor peer reviewed. The report read as though it was written by the cell phone industry. This bogus document, filled with only industry funded studies, appeared to appease Rep. Eshoo and other members of Congress, and the inquiry died. What FDA failed to acknowledge is that they never performed the activities required by the law, and thus were misleading Congress about their role.

Because of FDA's failure to follow the law and provide science-based information to the public, I have spent many hours of my life working to help cities and states adopt cell phone laws that do what the FDA is supposed to do - require retailers to post advisories about the dangers of exposure at the point of sale. The public wants this, but the industry has used the courts to block any such laws. In Berkeley, CA the law prevailed all the way to the Supreme Court of the United States. At the last moment the FCC joined in the case, stating they already have FDA-approved guidelines in place and therefore Berkeley's law was pre-empted. The Court agreed with the FCC, and once again, our government agencies kept the truth from the public, under the guise of already having provided "science-based" information. The plain fact is, the FDA/FCC guidelines are obsolete. They do not protect human health and are a disgrace and disservice to the American people.

My husband's cancer from his cell phone has destroyed our lives. Another victim commented to me that "the only thing worse than dying from a brain tumor is living with one." I agree. It is a horrific disease which affects the entire family. I am not foolish enough to advocate against the use of cell phone use. This technology is here to stay. But we do need safer equipment (which I understand the telecom industry has already patented but not yet released), clear use instructions at the point of sale, and most importantly federal guidelines that truly protect human health. It's time for the FDA to follow the law and do its job.

Under penalty of perjury I submit this declaration.

/s/ Ellen Marks
Ellen Marks
Camilla R. G. Rees

Manhattan Neighbors for Safer Telecommunications
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April 18, 2023

Division of Dockets Management
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

This letter is in support of the Citizen Petition and Request for Legal Compliance with the Legal Obligations of the FDA Regarding Public Exposure to Non-Ionizing Radiation from Electronic Products submitted by Americans for Responsible Technology and other Petitioners.

My name is Camilla Rees. I was seriously injured by Radiofrequency Radiation (RF) exposures on several occasions dating back over 15 years. Initially, by using a cell phone against my head, then severely impacted by a neighbor's wireless router that was on the other side of a wall from my pillow for several months, as well as in two office environments. As a result, I have dedicated much of my time to educating about cell phone and wireless risks through Manhattan Neighbors for Safer Telecommunications, ElectromagneticHealth.org and through policy work via the National Institute for Science, Law and Public Policy in Washington, D.C. By strictly limiting RF exposures I function well today, but this required me to retreat from city life, take time off to restore my health, and to live in an area without commercial activity, to a great degree, relatively speaking, very isolated. The quality of my daily life and career potential have been significantly impacted.

Like millions of Americans, when I first started using a cell phone I assumed the FDA had thoroughly evaluated cell phones for safety. I assumed the same about other electronic devices and equipment emitting Radiofrequency Radiation, such as computers, wireless routers, tablets, smart meters, etc. When cell towers increasingly appeared in cities, on highways, and when antennas appeared in residential neighborhoods on utility poles, near 2nd floor bedroom windows, I assumed the same—that this technology would not have been allowed on the market were it known to be dangerous for human or environment health.

I never imagined that volumes of science showing risk from this radiation would be suppressed in this country, with politicians and regulators turning a blind eye to very serious risks, as happened decades ago with tobacco risks, but this is what I found. I trusted that when it came to public health a genuine commitment to integrity existed in the United States at the FDA.
• I assumed, incorrectly, that the FDA had reviewed the safety of radiation emitting telecommunications technologies, as it does new drugs or medical devices (including Radiofrequency Radiation-emitting medical devices).

• I was aghast to learn the FDA officially does not review the safety of radiation emitting telecommunications technologies before they are allowed on the market, while the FCC claims it relies on the safety expertise of the FDA and that it considers opinions of the FDA in setting its safety guidelines for Radiofrequency Radiation.

• I later learned thousands of scientific studies dating back 80+ years document risks from Radiofrequency Radiation, and that this large (and ever growing) body of research includes many detailed scientific reports about risks prepared by the U.S. government itself, such as by the Naval Medical Research Institute (1971), NASA (1972, 1981), Defense Intelligence Agency (1976), EPA (review draft 1990, suppressed), U.S. Air Force (1994), Department of the Army (1998, declassified 2006), the National Institute on Drug Abuse /NIH with the Department of Energy (2011), Department of Interior (2014) and the National Institute of Environmental Health Sciences/NIH National Toxicology Program (NTP) (2018).

If the FDA had been doing its job, thoroughly researching the risks of these technologies, and informed the FCC as to what would be acceptable exposure limits for cell phones and wireless technologies from a biological perspective, we would be living in a different world today.

All of us would not be blanketed in harmful radiation, indoors and out, impacting our immune systems, DNA, neurological function, cognitive function, and much, much more. Fiber optic cables to the premises would be the technology of choice to access the Internet, affording advanced, far faster and more energy efficient Internet communication without any of the health risks (As described in the 2018 policy paper, "Re-Inventing Wires: The Future of Landlines and Networks").

If the FDA had done its job, I would have been informed of the risks from cell phones and wireless devices and been able to make informed choices about exposures to these technologies. I would likely not have purchased a cell phone, or at least never used it against my head, or used it frequently, or for long durations.

If the FDA had done its job, over a hundred million radiating utility meters would not have been installed across our country, severely damaging peoples' health right in their own homes. State and local governments would not have been deceived about the radiation risks to residents from these meters, nor about the alleged benefits (that they would support expansion of renewable energy technologies), nor deceived about alleged customer benefits (97% of which have never materialized).

Stimulus funding using taxpayer dollars would not have been wasted on 'smart' meters, that harm people while only serving the economic benefits of the utilities, which are incentivized to spend on capital investments to collect guaranteed rates of return from ratepayers on capital spending.
If the FDA had done its job, the media the world over would have been able to warn the public about cellphone and wireless risks, instead of parroting the 'no risk' narrative.

Because of the misperception that a thorough FDA evaluation had informed the FCC's exposure guidelines for Radiofrequency Radiation, the media has largely turned a blind eye to the cellphone and wireless risks, for decades, while exposures have impaired peoples' quality of life, job performance, ability to learn in educational settings, and driven up illnesses of many, many kinds, with most people in the dark not connecting the dots between their health challenges and the cellphone and wireless exposures.

If the FDA had done its job, health practitioners and patients would have been informed about the potential for Radiofrequency Radiation to impact drug actions, suppressing or amplifying the effects, in the over 4 billion U.S. retail prescriptions filled (2021).

If the FDA had done its job, industry representatives and their consultants would not have been able to mislead about Radiofrequency Radiation risk, as in this case, in a Verizon's consultant's report to a Manhattan Co-Op Board of Directors I advised. This is what was erroneously claimed:

"Note that both the FCC and the Food and Drug Administration (FDA) have certified that continuous human exposure at RF levels up to and including the FCC MPE [Maximum Permitted] limit is considered to present no RF health risk. Moreover, the FCC MPE limit has been designed to provide appropriate protection for humans of either sex, all ages, all sizes, and under all conditions."

_Misleading about risks using the FDA's name is being done all across the country, leading local officials to make decisions that are dangerous for public health._

If the FDA had done its job, society would also not live with non-stop online communications to the degree it does today, and the health and mental health risks from online time and social media algorithms that damage brains, including children's brains, would never be occurring.

I refer you to the Harvard University report by Norm Alster at the Edmond J. Safra Center for Ethics, "How the Federal Communications Commission is Dominated by the Industries it Presumably Regulates" (2015). This report suggests the telecommunications industry is using the same playbook the tobacco industry did to downplay the risks of Radiofrequency Radiation, including:

- Obtuse refusal to examine the health evidence
- Hyper-aggressive legal action and bullying
- Stonewalling PR
- Undermining credibility of the scientists
- Cutting scientist funding
- Publishing contradictory science
- Trivializing highly credible dissenters
- Misleading about scientific consensus
- Light regulation
- Industry control of Congressional committees
- Revolving door between industry & regulator
- Enormous sums on direct lobbying & via associations
- Hard $ and soft $ contributions

Clearly, if the FDA had been doing its job, and had thoroughly evaluated the biological and health risks from the Radiofrequency Radiation emitted by cell phones and wireless equipment, most of the above would never have been able to occur, or would have been called out.

An important question the Harvard analysis probed, by way of a poll, was:

"Would consumers embrace cell phones and WiFi so enthusiastically if the wireless industry, enabled by FCC and 'Congressional errand boys', had not so consistently stonewalled on evidence and substituted legal intimidation for honest inquiry?"

This poll showed that if certain health claims about cell phone radiation were known to be true, the public's behavior would change. Informed citizens, the poll showed, would:

- Reduce wireless use
- Restore landlines
- Protect their children

It is high time for the FDA to come into integrity and conduct a thorough analysis of risks from Radiofrequency Radiation so that proper protection of human, animal and environmental health interests can take place.

- Protective, biologically-based exposure guidelines for RFR must be set.
- The pros and cons of different telecommunications technologies (fiber, wireless, cable, advanced copper, etc.) must be known so that the public, government officials and businesses can make fully informed choices;
- The FDA must conduct pre-market safety testing of wireless devices and wireless infrastructure prior to release of new equipment onto the market;
- The FDA must conduct short- and long-term post-market health monitoring of individuals living in dense wireless environments, and require towers be moved to protect public health, if necessary;
- The FDA and others must educate about health risks and how, through lifestyle changes, exposures might be reduced.
- The FDA must do everything possible to assure the American people that regulators' top priority is public health and safety and demonstrate it is not a captured agency.
Additional steps that can restore the trust that has been lost due to lack of clarity on responsibility between the FCC and FDA and failure of government to protect public health can be found in “33 Recommendations for the FCC, FDA and Congress”.

Respectfully submitted in support of the Citizen Petition and Request for Legal Compliance with the Legal Obligations of the FDA Regarding Public Exposure to Non-Ionizing Radiation from Electronic Products submitted by Americans for Responsible Technology and other Petitioners

Camilla R. G. Rees
Statement of Michelle Lewis

My name is Michelle Lewis. I am an attorney and a brain cancer survivor, and I am writing this statement in support of a Citizens Petition from Americans for Responsible Technology concerning the responsibility of the Department of Health and Human Services and its FDA division to comply with 21 USC Section 360 II.

Having worked in law for a quarter century, I continually used two cell phones to balance my work life with my private life as a wife and mother. On calls, when I felt a slight burning sensation in my right ear, I simply switched the phones to my left and continued on with my calls. I had no idea that there could be any problem with cell phones, and was completely unaware that many independent scientific studies had demonstrated the potential for cell phone radiation to cause biological harm, at levels below government safety standards.

After many years of holding a cell phone against my head, doctors discovered a tumor the size of a grapefruit on the right side of my brain. I was devastated. I had no family history of brain cancer, and no other risk factors.

When I subsequently learned that the FDA has, since 1968, had a statutory responsibility to conduct research on this type of radiation, to evaluate the kinds of exposures that Americans are experiencing, and to develop techniques for reducing exposures, I was shocked. I wish I had been aware of the possible risk so I could have avoided a traumatic surgery that could have resulted in paralysis. Had I known, a simple change (not holding the phone to my ear) in my behavior would have saved my family many sleepless nights and the healthcare system significant expense.

I implore the FDA to embrace its legal responsibility to fully assess and disclose hazardous levels of radiation that result from improper cell phone usage.

Since my diagnosis and surgery, I have met countless other people who had experiences similar to mine, rarely with such positive outcomes. I am aware of others who have died from their cancer, never knowing that the FDA was supposed to be protecting public health by informing citizens of the potential danger from cell phones and other wireless devices.

I will always be grateful for a wonderful surgeon and a positive medical outcome, but my family and I now live with a chance of recurrence – all which I believe could have been prevented if the FDA had studied the risks, and made public the scientific debate
regarding those risks. To ignore this legal and ethical responsibility and place citizens in harm's way is unconscionable.

/s/

Michelle Lewis
Statement of Zen Honeycutt

My name is Zen Honeycutt. I am the Founding Executive Director of the non-profit organization Moms Across America. I am submitting this statement in support of the Petition to the Food and Drug Administration (FDA) by Americans for Responsible Technology and other petitioners. My family has suffered prolonged emotional stress, and my son has experienced debilitating physical symptoms related to exposure to radio-frequency radiation in his school. The failure of the FDA to follow the clear instructions of Congress to conduct research, evaluate current exposures and develop techniques for reducing or eliminating exposures is inexcusable, and has had a direct, profound and life-altering negative impact on my son and our family.

After a move, and after COVID shutdowns, our son entered a new high school in Buncombe County, NC. Within a few months, he was coming home with nosebleeds, headaches, fatigue, sadness, and a lack of focus. His normally straight A’s in honors and AP classes dropped to D’s and F’s. At that time I had seen articles and news about teenagers being exposed to wireless routers (wireless access points, or WAPS) at school, linking the technology to depression and suicide, and I asked him where he was sitting in relation to the WAPS. He realized he was sitting directly below them in almost all of his classrooms, and when he moved away from them, he felt somewhat better. We brought him to a psychologist MD and he was diagnosed with depression and side effects from electromagnetic sensitivity.¹

Our son finished his Junior year at high school, feeling depressed and enduring headaches, but could not attend his entire senior year at the public school because they refused to accommodate him by hardwiring even one classroom for him. He stayed home and homeschooled himself online, isolated, which contributed to a socialization depression. He is now likely permanently damaged from the close proximity and prolonged exposure to high levels of wireless radiation from the school. He can feel when a cell phone is on next to him and gets headaches when we travel due to the ubiquitous use of WiFi and Bluetooth technology in society. He is unable to attend college and sleep in dormitories or enjoy a social life with his peers. This is a young man who had the intelligence and drive to attend a college such as MIT and make huge contributions to society in technology. He can no longer do so. His life has been forever altered.

Because the school looks to the FCC and its guidelines, which in turn depend on rigorous scientific analysis by the FDA, administrators continue to maintain that the exposure levels the children are experiencing are safe and they have no responsibility to make changes. They are unaware that FDA has shirked its legal responsibility and failed to do what was mandated by Congress. My son reported that he knew several children in each class that were depressed and

¹ Note: According to Allan Brennan, award-winning WiFi installer, a WAP should never be placed directly in a classroom. Instead, they should be placed in the hallways, shielded and the power reduced by 99%. At these low levels, up to 1500 devices per school can be efficiently serviced. He states that the reason why service providers recommend one WAP per classroom is not for functionality but for the monthly service fees. The more devices they sell the more profit they make, regardless of the prolonged, close proximity exposure to our children.
reported headaches and nosebleeds as well, they just didn't know or want to believe it was the exposure to the WAPS that was causing the effects. At least one of those students that he knows of committed suicide that year.

Because the FDA has failed to follow the law, the FCC is refusing to acknowledge that prolonged exposure to wireless technology, in the forms of WAPs incorrectly placed in the classrooms (instead of in the hallways), and children across the nation are being harmed. This is unacceptable. Our children, our future workforce, and our leadership are being compromised. Therefore the future of our country is being compromised. The FDA must publicly admit its failure and advise the FCC to put out guidelines that account for the safety of the children.

Respectfully submitted,

/s/
Zen Honeycutt
STATMENT OF MICHIELE L. HERTZ

My name is Michele L. Hertz. I am 64, an artist, wife, mother and the President of the New York Safe Utility Meter Association (NYSUMA). I am submitting this statement in support of the Citizens Petition being filed by Americans for Responsible Technology and other Petitioners.

The facts I present below demonstrate that I have suffered an injury traceable to the radiofrequency (RF) radiation emissions from digital utility meters,¹ a situation created by the failure by the U.S. Food and Drug Administration (FDA) to fulfill its legal duty to oversee such emissions by non-medical RF radiation emitting devices.

Since 2010, I have researched and documented the health and fire problems associated with digital utility meters. I have filed comments, sent letters, emails and phoned New York State and Federal government agencies, including the FDA, the Federal Communications Commission (FCC) and the U.S. Department of Energy (DOE), regarding the injuries that I (and others) have suffered due to the pulsed transmitted and conducted electrical and RF radiation from digital utility meters, sometimes known as "smart meters".

Before I was injured by the RF radiation emissions from digital utility meters, my family and I led a normal life. My husband and I both worked. We took many family trips with our sons. We were happy in our community. At home we used Wi-Fi and both my husband and I used cell phones.

The biggest mistake I have ever made was to allow utility workers to install "smart" AMR utility meters on my properties. With no available information from the FDA, I had no idea that a utility meter could be a health hazard. I relied on utility employees who told me that digital meters were safe. I infer they were only repeating what they were told by their superiors.

In 2008, I began to experience heart palpitations and insomnia. Then came agitation, memory loss, inability to concentrate on my work and hormone disruption. Then came the nightmares and waking with frightening heart palpitations, pains in my head, buzzing in my ears and headaches. I developed constant diarrhea that lasted for months. I lost 25 pounds. Then I developed Grave's disease, a health condition that can be caused by exposure to radiation. During this time, there were nights I would wake up thinking there was an earthquake, but it was my own body quaking and shaking. Other members of my family also began having health problems too, however my health was the most affected.

Because the FDA has failed to follow the mandate of Congress to develop a Program of Control, there was very little available information on what was happening to me. After a great deal of research and speaking with experts in electricity, I learned that my health problems – which started after the installation of digital utility meters – were unequivocally caused by

¹ Digital Utility Meters include AMI, PLC, AMR, ERT, non-transmitting digital, Smart, etc. meters. Digital utility meters contain electronic components including antenna, switch-mode power supply, batteries, clocks and more. Analog utility meters are purely electro mechanical utility meters that contain no electronic components at all.
those meters. Finally, in 2010, I convinced the utilities to remove the offending meters and replace them with analog meters, and the worst of my health problems diminished substantially.

At this point I understood that there was something wrong with the new meters. I watched as other people in Hastings got sick and died. The meters were obviously dangerous. I tried to alert the utilities, elected officials, and state and federal government agencies, including the FCC, FDA, DOE, etc., thinking that the meters might be recalled. The evasive, irresponsible, dismissive, discourteous and lame responses I received from all of the above stunned me.

While I felt better after I convinced the utilities to remove the digital meters and replace them with analog meters, I continue, to this day, to experience RF sickness when I am exposed to some electronic and wireless devices and infrastructure.

In 2011, I had to relocate for periods of time from my home in Hastings, family, community and the art studio where I had worked for 15 years to a rural area in upstate, New York. I simply could no longer tolerate a congested RF environment flooded with radiation from numerous sources including cell towers, digital electric, water and gas utility meters and Wi-Fi routers.

In 2013, I got together with neighbors and commissioned an RF study of transmitting digital utility meters in our Hastings neighborhood, once we learned that digital meters were approved but never tested for health dangers by any government bodies. We hired an industry RF engineer, who discovered and documented that not only were the meters transmitting RF spikes constantly every 30 seconds, they were also causing RF to conduct onto home electrical wiring.\(^2\)

This conducted and transmitted RF and electrical radiation remains, to this day, an unprecedented whole-body radiation exposure that surrounds us in buildings and the environment. Utility companies continue to claim, with no proof or factual basis, that digital meters are safe and only transmit once a day or for a few seconds a day. The FDA, with legal responsibility for evaluating these kinds of emissions, has failed to do its job.

FCC testing failed to detect health risks caused by the meters, but the FCC is not a health protection agency. It was and remains the FDA that is a health agency and which should have required testing for digital meters before they were unleashed on an unknowing public. Had the FDA tested the meters, as it was obligated to do, they would not have been approved. Injuries would have been avoided and lives would have been saved.

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\(^2\) The engineer explains in his report that the FCC tested and approved electronic meters based on FCC Part 15 testing - not a test for health and safety but only to detect interference. The test was set up for wireless devices that employ power cords. This test was improper for digital utility meters because these meters do not employ power cords. Instead of developing testing for digital utility meters, the FCC-accredited lab workers altered the wireless meter by fastening a power cord to it. They altered the meter to fit a test modality that was not designed for utility meters. This laboratory setup, in isolated conditions, failed to include utility-side wiring, consumers' circuit breaker panels, consumers' electrical circuitry and real-life electrical events like voltage surges.
Based on the FCC's defective and inadequate testing and approval process, and in the absence of any effort by the FDA to evaluate the potential effect of exposures from these meters on people, state regulators across the US approved digital utility meters and then only tested the new meters for accuracy. Together this colossal system failure and negligence has resulted in suffering and loss of life and property.

We had spent over two decades carefully restoring our historic 1910 home in Hastings, getting involved in community and school affairs. Finally, in 2019, after 22 years, my husband and I left Hastings for good and moved to a quieter RF area where we now reside.

I felt well for one year. Then in 2020 "smart" digital meters were installed on other homes in my neighborhood along with the wireless equipment necessary for their operation, and two huge 4/5G cell towers were built within 1.5 miles of our home. More recently, fiber optic equipment has gone up in our neighborhood. For me, having an analog utility meter is lifesaving but with all of the other equipment that has been deployed once again I am suffering. I am waking up at night alarmed with heart palpitations and am often unable to fall asleep again. I am again concerned that I am going to have a heart attack. Again, I am facing dangerous disruptions in my life and injuries due to the fact that there is no oversight for the safety of any of this technology.

While the FCC, with no health expertise or authority, clings to its dangerously outdated RF guidelines and the FDA completely ignores its own obligations regarding RF radiation, people, like me, get sick. Through the years I have tried to help as many RF injured people as I can, but I can never really help because the impact of these devices is not in my control. This predicament is the result of incompetence, avoidance and, ultimately, the abdication by state and federal government agencies of their legal duties, including the FDA.

Respectfully submitted,

Michele L. Hertz
Statement of Laurie Brown

My name is Laurie Brown. I am submitting this declaration in support of the petition by Americans for Responsible Technology and other petitioners regarding FDA's failure to follow the law concerning the public's exposure to pulsating wireless devices emitting biologically disruptive radiation. The failure of FDA to provide truthful and complete information to the public has had a significant detrimental effect on my life and the lives of countless other Americans.

Despite the proliferation of wireless antennas, wireless devices, and the installation of cell towers and access points for Wi-Fi and wireless connectivity, the FDA is failing to ensure the public's safety as required by the law. The current safety guidelines promulgated by the FCC, which are allegedly based on information from the FDA, are outdated and are only thermal based. The FDA needs to conduct the necessary studies, evaluate the kinds of exposures that are happening in the real world, acknowledge, and address the biological harm caused by the increasing and limitless saturation of wireless radiation in our environment. The public deserves to know the truth and to be protected from increasing exposures that cause biological harm, symptoms, and diseases, preventing individuals from working, attending school, and living a healthy and fulfilling life.

I taught middle school for the Los Angeles Unified School District (LAUSD) for approximately 26 years. I rarely was ill and accumulated approximately 800 hours of sick time during my career, the equivalent of nearly 7-8 months of work. I enjoyed a normal, healthy life and never had to concern myself with routers, Wi-Fi or electro-magnetic radiation. Unfortunately, my career, health, and life as I knew it changed in April 2015, when my school “upgraded” our Wi-Fi system and added 190 access points, two in every classroom, and brought in wireless devices, increasing the total wireless radiation on campus. My District did little to protect me from the peaks or spikes of radiation emitted from all the wireless devices on campus.

Our system was activated in April 2015. After a few hours on campus, I would begin to feel ill and experience symptoms such as headaches, heart palpitations, skin burning, earaches, nausea, foggy headedness, inability to concentrate, and many other debilitating symptoms—all symptoms of microwave sickness. I was becoming electro sensitive and was diagnosed with Chronic Inflammatory Response Syndrome caused by exposure to RF radiation. After a few consecutive days of work and increased exposure on campus, I started using my illness days. Some other staff members experienced physical and debilitating symptoms from the increased radiofrequencies on campus, too.

My principal contacted LAUSD’s Office of Environmental Health and Safety (OEHS) and wrote to the Inspector General of LAUSD sharing his concern as well as staff members’ concerns. The District’s OEHS initially waited approximately 6 weeks, until Common Core Testing was over, when fewer students would be operating devices and on campus with cell phones, to measure the RF frequencies in specific classrooms. On June 22, 2015, during the
summer break, my principal wrote to LAUSD's Inspector General stating, "After the system was turned on, several employees complained of illness (headaches, light headedness, etc.)."

After the installation of the new commercial Wi-Fi system at my school and becoming ill from my exposure to EMF/EMR, I learned LAUSD had been warned by doctors and scientists, prior to installation, that the commercial grade Wi-Fi being considered was untested and potentially dangerous in school environments.

Meanwhile, the FDA is silent. It is not conducting studies, as the law requires. It is not evaluating workplace exposures like mine. And it is certainly not engaging in efforts to reduce or minimize those exposures, which is also required by the law.

When doctors prescribe medications, they do so with specific instructions to minimize side effects and over-dosing. The same safety precautions and concerns apply to overdosing on wireless radiation. More is not better and controls and guidelines are necessary. The FCC's old guidelines and school districts' RF protocols are not actually based on science, and are insufficient to protect children and the public. The FDA must address this immediate public health crisis. Protocols and protective measures must be developed and applied in real time, before it is too late.

Today, I no longer teach, something that was not only a career, but a great passion in my life. I loved teaching, found it stimulating, rewarding, and incredibly fulfilling. Because I enjoyed it so much, I intended to work for a lot longer, until a ripe old age, but I found it difficult to return to work without being reasonably accommodated. Unfortunately, I am unable to fill all my free time with meaningful activities and work due to the proliferation and installation of wireless antennas and devices everywhere. Therefore, I limit my time and exposure to RF radiation. Fortunately, my friends are willing to turn off their cell phones when they are out with me and in my home. My husband and I removed our Wi-Fi and cordless phones, turned off our wireless emitting devices, and use hardwired connections. I have a cell phone, but do not turn it on often and my husband mostly keeps his off around me. I know longer have the same freedom or luxury to enjoy limitless time out, travel, staying in a hotel, visiting family, and grocery shopping as I once did.

Living with Chronic Inflammatory Response Syndrome caused by EMFs (microwave sickness) is challenging and limiting. My quality of life has been severely reduced and none of it occurred by my choice: it was the direct result of FDA's failure to abide by the clear and unambiguous mandate from Congress. My health, lifestyle, quality of life, and freedom to come and go as I please have been drastically and negatively affected. In addition, my income and retirement have been significantly reduced. I am very fortunate to have a supportive and loving husband and family. Still, though, my condition and losses have impacted us.

As the nation's premiere public health agency, the FDA needs to be actively monitoring public exposure to wireless radiation. No longer should law-abiding, tax-paying citizens be
expected to sit by idly while our world is increasingly filled with dangerous radiation. Although it may be an inconvenient truth, more is dangerous and is very unhealthy. Too many people are already sick and more people will become seriously ill if we stand by and do nothing to address our chronic and limitless exposure to wireless radiation. I do not want others to suffer the same fate as me.

/s/Laurie Brown

Laurie Brown
4221 Noble Ave
Sherman Oaks, CA 91403
International EMF Scientist Appeal calls for greater health protection

In May 2015, 190 scientists submitted the International EMF Scientist Appeal addressed to the top leaders at the United Nations, the World Health Organization, and the UN Environment Program. The Appeal urgently calls for greater health protection in the midst of what has become an historic, global phenomenon -- the rapid expansion and proliferation of wireless communications and electrical technologies. The possible impact of deployment of these technologies on human health has not yet been thoroughly studied. As of September 1, 2018, 244 scientists have signed the Appeal.

These scientists have published over 2,000 research papers on electromagnetic fields (EMF) on biology or health. Their concern is based on the vast number of studies that reported biological and adverse health effects of non-ionizing EMF far below the current exposure guidelines set by the FCC and other international EMF-exposure guideline setting organizations. Their concerns mainly include radiofrequency radiation (RFR) emitting devices, such as cellular and cordless phones, cell towers, Wi-Fi, radio and TV broadcast antennas, smart meters, and baby monitors, as well as extremely-low frequency electromagnetic fields (ELF EMF) emitted by electric devices and infrastructures used in the delivery of electricity.

The scientific basis for their collective concern is “numerous recent scientific publications have shown that EMF affects living organisms at levels well below most international and national guidelines. Effects include increased cancer risk, cellular stress, increase in harmful free radicals, genetic damages, structural and functional changes of the reproductive system, learning and memory deficits, neurological disorders, and negative impacts on general well-being in humans.”

These scientists make the following recommendations: protection of children and pregnant women; strengthened guidelines and regulatory standards; development of safer technology; utilities maintain adequate power quality and ensure proper electrical wiring; public health information and harm reduction strategies; medical education and training, establishment of independent, sustained government research programs; media disclosure of EMF expert’s financial ties to industry; and designation of white zones (radiation-free areas).

The Advisors to the Appeal recommend that 5th Generation Wireless (i.e. 5G) should be investigated before it is deployed.

Ronald Melnick, Ph.D., Senior Toxicologist (retired) and former leader of the NTP’s health effects studies of cell phone radio frequency radiation, National Toxicology Program, National Institute of Environmental Health Sciences, USA, and an advisor to the Appeal, states:

"I find it appalling that mobile phone emission standards do not adjust for children when it is well established that the absorption of radiofrequency radiation by the brain is greater in children than in adults, the developing brain is highly susceptible to tissue damaging agents, and the use of wireless devices is being actively marketed to children. At a minimum, regulatory agencies need to make strong recommendations for consumers to take precautionary measures and avoid close contact with their mobile phones."

For the complete Appeal, go to https://emfscientist.org/. For more information, contact: Joel Moskowitz, Ph.D., (jmm@berkeley.edu) or Elizabeth Kelley, MA, (info@emfscientist.org).
Selected quotations from scientists who signed the International EMF Scientist Appeal

(Alphabetical, by country)

Note: Some of the signatories to this appeal are listed below as individuals, giving their professional affiliations, but this does not necessarily mean that this represents the views of their employers or the professional organizations they are affiliated with.

Don Maisch, Australia

“We are now entering the era of the ‘Internet of Things (IoT)’ where all our appliances will be Wi-Fi enabled, endlessly communicating with each other and us through so-called smart devices. This “brave new world” dictates that human exposure to radiofrequency radiation must greatly increase in order to accommodate the technology. This is a planned world being created by technocrats totally ignorant of the reality of our biology, an ignorance fostered by the existing thermal-effects only standards/guidelines. Now, more than ever, we need new, biologically relevant standards to meet the challenge of the future.”

Don Maisch, Ph.D., Australia.
Tel: +61 3 62430195   Email: dmaisch@emfacts.com

Mary Redmayne, Australia

“There is much high-quality research showing bio-physiological effects from permitted electromagnetic exposures; these findings are not nullified by research which fails to find effects. To claim that the ‘weight of evidence’ does not support these effects (even if it were true) is misleading. To infer that this means no precautions are needed is illogical and non-scientific.”

“It would help parents and policy makers if consensus among advisory organisations and scientists could be reached acknowledging that assurance of safety of chronic low-dose radiofrequency exposure cannot be guaranteed and is related to ill-health in some people. Therefore, minimising exposure, especially children’s, is sensible. This should be treated like other daily health precautions and warnings such as those about diet.”

Prof. Mary Redmayne, Ph.D., Department of Epidemiology & Preventive Medicine, Monash University, Australia
Email: mary.redmayne@gmail.com
Marie-Claire Cammaerts, Belgium

"Man-made electromagnetic fields impact all living organisms, acting first on the unit membrane. We must reduce our dependence on 'wireless' technologies, reduce the numbers of masts (i.e., cell towers), of Wi-Fi apparatus, of cordless phones and so on, and clearly indicate, in public spaces, the intensity of the ambient electromagnetic field."

Prof. Marie-Claire Cammaerts, Ph.D., Free University of Brussels, Faculty of Science, Belgium.
Email: mtricot@ulb.ac.be

Alvaro Augusto de Salles, Brazil

"Non-ionizing radiation (NIR) absorption by the population increased many times in the last few decades. The health effects of this will show a dramatic impact in the near future. Therefore effective precautionary procedures should urgently be adopted aiming to reduce NIR exposure and to reduce its health risks, in line with the IARC 2002 and 2011 recommendations that NIR is a possible human carcinogen."

Alvaro Augusto de Salles, Ph.D., Professor, Federal University of Rio Grande do Sul – UFRGS, Porto Alegre, RS, Brazil.
Email: aasalles@ufrgs.br

Magda Havas, Canada

"One of the most serious environmental pollutants affecting the health of human populations and resulting in chronic illness is electromag. A combination of low frequency electromagnetic fields, poor power quality, ground current and especially radio frequency and microwave radiation is making people sick. We have enough peer-reviewed scientific studies documenting the adverse effects, which include cancers, reproductive problems and symptoms of electrohypersensitivity, for governing bodies to promote practices, devices and legislation that reduce our exposure to these frequencies.

Putting Wi-Fi in schools; allowing cordless phones that radiate constantly to be manufactured; placing wireless baby monitors near an infant; using a wireless tablet, smart phone or computer while pregnant; holding a cell phone next to the head and keeping a cell phone in a bra or hip pocket or under a pillow; placing cell phone antennas near homes, schools and on hospitals; metering electricity, water and gas with wireless smart meters and designing smart appliances for the home will be viewed by future generations as dumb technology generated by greed for a population that is largely ignorant of the consequences. We need to protect the health and wellbeing of future generations, because without them there is no future! If we don’t do it ... who will?"

Magda Havas, Ph.D., Environmental and Resource Studies, Centre for Health Studies, Trent University, Canada
Email: DrMagdaHavas@gmail.com
**Paul Héroux, Canada**

"Electromagnetic fields from power and telecommunications systems, as they are present in our everyday environment, have biological and human health impacts that have not been officially acknowledged. The effects of these fields have simply not been taken seriously enough."

*Paul Héroux, Ph.D., Department of Epidemiology, Biostatistics and Occupational Health, McGill University Medicine, Montreal Canada, Tel. (514) 398-6888 Cell (514) 222-2197 InVitroPlus Laboratory, Department of Surgery Royal Victoria Hospital Tel. (514) 934-1934 ext 35270 Email: paul.heroux@mcgill.ca http://www.invitroplus.mcgill.ca/

**Wenjun Sun, China**

“我们的研究表明，强度低于 ICNIRP 暴露限值的电磁场依然可以产生生物效应。因此，在作用机制阐明之前，对无处不在并日益增强的环境电磁场暴露限值的制订应该慎重。”

“Our studies show that exposure to electromagnetic fields with intensity lower than the ICNIRP exposure guidelines can produce biological effects. Thus, on a precautionary basis, before we understand the detailed mechanisms, we should adopt protective standards that limit the ubiquitous and increasing electromagnetic fields in occupational and public environments.”

*Dr. Wenjun Sun, Director of Institute of Environmental Medicine, Bioelectromagnetics Key Laboratory, Zhejiang University School of Medicine, Hangzhou, China. Tel: +86-571-88208166, Email: sunwj@zju.edu.cn

**Dariusz Leszczynski, Finland**

“Evidence of health hazard is here since IARC 2011. It surely was enough time to introduce new safety standards and Precautionary Principle.”

*Dariusz Leszczynski, Ph.D., Adjunct Professor of Biochemistry, University of Helsinki, Finland; Member of the IARC Working Group that classified cell phone radiation as possible carcinogen. Email: blogbrhp@gmail.com. Blog: http://betweenrockandhardplace.wordpress.com/

**Dominique Belpomme, France**

“Les effets nocifs des champs électromagnétiques, quelle que soit leur fréquence, sont maintenant scientifiquement établis. Les femmes enceintes (le fœtus) et les enfants et adolescents sont particulièrement vulnérables. L’OMS a reconnu les effets possiblement cancérogènes des champs électromagnétiques; cette action doit être prolongée par la reconnaissance de l’électrohypersensibilité comme affection à part entière entrant dans le cadre nosologique de l’intolérance environnementale..."
idiopathique qu’elle a individualisé. C’est ce que propose le colloque international organisé le 18 mai à l’Académie Royale de Médecine de Belgique.”

“The harmful effects of electromagnetic fields, regardless of their frequencies, are now scientifically settled. Pregnant women (the fetus) and children and adolescents are particularly vulnerable. WHO has recognized the possibly carcinogenic effects of electromagnetic fields; its policy program should now recognize electrohypersensitivity as a disorder entering the nosologic framework of Idiopathic Environmental Intolerance. This is what the International Congress held on the 18th of May, 2015 at the Royal Belgian Academy of Medicine proposes.”

Dominique Belpomme, M.D., MPH, Professor in Oncology, Paris V Descartes University, European Cancer & Environment Research Institute, Executive Director.
Tel: 0033(0)1 45 78 53 53, E-mail: contact.belpomme@gmail.com

Lebrecht von Klitzing, Germany

“Our research finds that periodic, pulsed electromagnetic fields used for wireless communication reduce vegetative bioregulation activity. Continued exposure to WiFi in Germany has deleterious effects on the cardiovascular system. We must reduce the spread and utilization of these systems.”

Lebrecht von Klitzing, Ph.D. Medical Physicist, Institute of Environmental Physics,
DE 36466 Wiesenthal, Germany
Medizinphysiker (DGMP),
Medizinphysik - Umweltphysik, DE-36466 Wiesenthal, Schwimmbadweg 21
Tel: 036964 863446 + 831203, Email: vonklitzing@umweltphysik.com, www.umweltphysik.com

Lukas Margaritis, Greece

“Σχεδόν όλα τα σύγχρονα προϊόντα υψηλής τεχνολογίας της καθημερινής μας ζωής χρησιμοποιούν ασύρματη τεχνολογία. Παράλληλα, αυτή την πληθώρα εφαρμογών δεν έχουν γίνει σοβαρές και αντικειμενικές προσπάθειες από τον Παγκόσμιο Οργανισμό Υγείας να δει τις πιθανές επιπτώσεις στην υγεία, ειδικά σε καθημερινούς χρήστες, σε παιδιά και εγκύους. Η έρευνα μας οδηγεί στο συμπέρασμα ότι πρέπει να εφαρμοστεί η Αρχή της Πρόληψης και να μειωθούν τα «όρια ασφαλείας» με δεδομένη την πολυπλοκότητα των ακτινοβολιών αυτών (με διαμόρφωση και παλμούς) σε αντίθεση με όλες τις άλλες ακτινοβολίες στη γη.”

ΛΟΥΚΑΣ Χ. ΜΑΡΓΑΡΙΤΗΣ
Όμισθος Καθηγητής Κυτταρικής Βιολογίας και Ραδιοβιολογίας
Συντονιστής ερευνητικού προγράμματος ακτινοβολιών ΘΑΛΗΣ
Τμήμα Βιολογίας Κυττάρου και Βιοφυσικής, Τμήμα Βιολογίας,
ΕΘΝΙΚΟ & ΚΑΠΟΔΙΣΤΡΙΑΚΟ ΠΑΝΕΠΙΣΤΗΜΙΟ ΑΘΗΝΩΝ
Tel: +30-2107274542, +30-6972051345

“Wireless technology has driven most new high-tech products and has been a key factor in everyday domestic and commercial life. Still no serious efforts have been made by authorities to look seriously
without bias at the health effects especially for **heavy users, children, and pregnant women**. Our research points out the necessity for precautionary measures and new safety limits given the complexity of the signals (with modulation and pulses) unlike any other radiation on earth.”

**Luca H. Margaritis**  
Professor emeritus of Cell Biology and Radiobiology  
Coordinator, Radiation Research Program THALIS  
Dept of Cell Biology and Biophysics, Faculty of Biology  
NATIONAL AND KAPODISTRIAN UNIVERSITY OF ATHENS, Greece  
Tel: +30-2107274542, +30-6972051345 Email: lmargar@biol.uoa.gr

**Kavindra Kumar Kesari, India**

“The debate about the effect of electromagnetic fields (EMFs) on human health is a growing concern of the 21st century. On the basis of scientific evidence, there is no question that EMF emissions from devices like cell phones, cellular antennas, and microwave ovens, have a causative effect on the brain and reproductive organs. But no action has been taken despite our awareness of the harmful impact of electro-pollution due to political interference. It is therefore imperative that the implications of electro-pollution must be fully explored by government bodies after consulting with concerned experts, and safety criteria be re-examined.”

Dr. Kavindra Kesari, MBA, Ph.D., Resident scientist, School of Environmental Science, University of Eastern Finland, Kuopio Finland; Assistant Professor, Professor, Jaipur National University, India  
E-mail: kavindra_biotech@yahoo.co.in, kavindra.kesari@uef.fi

**SMJ Mortazavi, Iran**

“Limiting the exposure to electromagnetic fields is indeed among the basic steps to ensure a better life for mankind!”

SMJ Mortazavi, Ph.D., Professor of Medical Physics  
Ionizing and Non-ionizing Radiation Protection Research Center (INIRPC), Dean, Medical Physics & Medical Engineering Department, Dean, Shiraz University of Medical Sciences, Iran  
E-mail: mmortazavi@sums.ac.ir  
Tel: +98-711-2349332 Fax1: +98-711-2349332 Fax2: +98-711-2289113  
http://home.sums.ac.ir/~mmortazavi; http://crrs.sums.ac.ir

**Yury Grigoryev, Russian Federation**

“It is immoral that the regulatory standards for electromagnetic fields (EMF) used in cellular communication are inadequate and pose a serious health risk. The amount of harm from radio frequency EMF exposure to the brain is inestimable. **Children** are at higher risk than professional workers.”
Alonso Balmori, Spain

“Los árboles y los animales nos están mostrando cosas que las personas no estamos comprendiendo. Sabemos con certeza que las radiaciones electromagnéticas producidas por el hombre están debilitando lentamente la salud de los seres vivos: animales, plantas y hombres. Es urgente una toma de conciencia de la sociedad en su conjunto para afrontar este grave problema ambiental y sanitario.”

“Trees and animals are showing important signs that mankind does not comprehend. We know with certainty that anthropogenic electromagnetic radiation is slowly eroding the health of living organisms: animals, plants and people. It is urgent that society as a whole address this serious environmental and health problem.”

Alonso Balmori, Biologist. Independent researcher on wildlife and EMF, Spain
Alfonso Balmori, Biólogo. Investigador Independiente sobre los efectos de las radiaciones electromagnéticas en los seres vivos, España; Email: obalmorimartinez@gmail.com

Claudio Gomez-Perretta, Spain

“Technological applications using non-ionizing radiation are advancing rapidly, increasing at every step the gap with the assessment of their possible side effects. The REFLEX project and other scientific reports like the BioInitiative Report have unfortunately been ignored by authorities worldwide. Perhaps the coming generations will curse these leaders for their ineffectiveness at the right moment.”

Claudio Gomez-Perretta, M.D., Ph.D. Researcher, University La Fe of Valencia, Spain
Email: gomez_cla@gva.es

Yoon-Won Kim, South Korea (Republic of Korea)

"International exposure guidelines for electromagnetic fields (EMF) must be revisited due to the existence of their adverse effects on our bodies, particularly on the male reproductive system. It is time to re-establish the safety level of EMF for the general public to reduce our exposure to protect us from EMF."

Dr. Yoon-Won Kim, MD. PhD. Professor, Hallym University and member of the Bioelectromagnetics Society, Korea.
Tel: +82-33-248-2663, Email: ywkim@hallym.ac.kr
Lennart Hardell, Sweden

“Based upon epidemiological studies there is consistent evidence of increased risk for brain tumors (glioma and acoustic neuroma) associated with use of wireless phones. Urgent revision of current guidelines for exposure to radiofrequency emissions is needed.”

Lennart Hardell, MD, PhD, Department of Oncology, University Hospital, Orebro, Sweden
Email: Lennart.hardell@regionorbrolan.se

Daniel Favre, Switzerland

“Active mobile phone handsets have a dramatic impact on the behavior of honeybees by inducing the worker piping signal, triggering the swarming process, the sign of a disturbed bee colony. Signals from mobile phones and masts (i.e., cell towers) could also be contributing to the decline of honeybees around the world. I am calling on the international scientific community for more research in this field and for protection of this crucial pollinator.”

Dr. phil. nat. Daniel Favre, Biologist and apiary adviser, Switzerland (www.ephiscience.net).
Email: daniel_favre@yahoo.com

Suleyman Dasdag, Turkey

“Sağlıklı ve mutlu bir dünya için daha az ve kontrollü radyasyon.”

“We need shorter and more controlled radiation exposure for a happy and healthy world.”

Prof. Dr. Suleyman Dasdag, PhD., Dept. of Biophysics, Medical School of Dicle University, Turkey
Email: sdasdag@gmail.com

Nesrin Seyhan, Turkey

“Radyofrekans alanlara maruziyet sınırlarının hiç biri hamile anne karnındaki bebek, ve yaşlıları dikkate alarak hazırlanmamıştır. Genel Halkın Radyofrekans maruziyet sınırlar bu alanlara daha hassas olan hamile, anne karnındaki bebek, çocuk ve yaşlılar gözönüne alınarak aşağık çekilmelidir.”

“None of the radiofrequency radiation exposure guidelines take pregnant women, fetuses, and the elderly into consideration! RF exposure limits for the general public should be lowered to protect all those more vulnerable to electromagnetic fields.”

Prof. Dr. Nesrin Seyhan, Founding Chair, Biophysics Dept.; Founding Director, GNRK Center Medical Faculty of Gazi University, Ankara, Turkey. (Presently not available for media inquiries)
Martin Blank, USA

"International exposure guidelines for electromagnetic fields must be strengthened to reflect the reality of their impact on our bodies, especially on our DNA. The time to deal with the harmful biological and health effects is long overdue. We must reduce exposure by establishing more protective guidelines."

Martin Blank, Ph.D., Special Lecturer, Columbia University, New York USA
Email: mbphd32@gmail.com

Elizabeth Kelley, USA

"Solutions must be found that place the highest priority on protecting people and the planet over the powerful economic forces driving new technologies without thought for biology. We can have both innovation and public safety if there is political will. This transcends national boundaries. The UN, the World Health Organization, and the UN Environmental Programme are the best organizations on earth to make these recommendations."

Elizabeth Kelley, MA, is the Director of EMFScientist.org, and formerly was Managing Secretariat for the International Commission on Electromagnetic Safety (icems.eu), Italy
Email: info@EMFScientist.org

Albert Manville, USA

"While we like our electronic gadgets, the worldwide demand for these technologies of convenience only grows, as do the gargantuan profits that come from selling the devices and their services. While human health and safety continue to be dismissed by many, growing scientific evidence is showing a dark side to cell phone, WiFi, smart meter and point-to-point technologies. Migratory birds – incredibly important to the global economy and for the ecological services they provide – now appear to be negatively affected by non-ionizing radiation. This alarm sounds a call to action acknowledging that electromagnetic radiation is indeed a problem that needs to be addressed."

Dr. Albert Manville, Adjunct Professor, Johns Hopkins University; Senior Wildlife Biologist, U.S. Fish & Wildlife Service (FWS), Emeritus/Retired; and Wildlife Consultant, WHCS LLC, USA
Email: albertsandy@verizon.net, whcels006@verizon.net

Joel Moskowitz, USA

"U.S. regulatory standards and international guidelines only control for short-term heating of tissue. The standards do not protect us from the low-intensity, chronic exposures to electromagnetic fields (EMF) that are common today. The scientists who signed the Appeal request that the UN and member nations protect the global human population, animals and plants from EMF exposures."
There has been strong support from the international scientific community for the Appeal, even among those who believe that scientists should not take public policy positions. Some have taken personal risks to sign the Appeal because this is a public health issue that affects everyone now, as well as future generations.

The scientists who have signed the Appeal have published more than 2,000 peer-reviewed research papers on electromagnetic fields.”

Joel Moskowitz, Ph.D., Director, Center for Family and Community Health, School of Public Health, University of California, Berkeley, USA
Tel: 1-510-643-7314. Email: jmm@berkeley.edu. Electromagnetic Radiation Safety website: saferemr.com
June 15, 2023

Virginia Department of Health
9960 Mayland drive
Richmond VA

Re: Quarterly Meeting

To: Board Members of VDH

The following paragraph has been copied from the VDH website:

The Virginia Department of Health (VDH) is dedicated to protecting and promoting the health of Virginians. The VDH is made up of a statewide Central Office in Richmond and 35 local health districts. These entities work together to promote healthy lifestyle choices that can combat chronic disease, educate the public about emergency preparedness and threats to their health, and track disease outbreaks in Virginia.

However, I feel that for the past three years VDH has fallen short in their duties. I quote from "Cause Unknown" The epidemic of Sudden Deaths in 2021 and 2022 by Edward Dowd, Copyright 2022. Published by Skyhorse Publishing.

On Page 1 of the Foreword which is written by Robert F. Kennedy Jr., Dowd is quoted: “From February 2021 to March 2022, millennials experienced he equivalent of a Vietnam war with more than 60,000 excess deaths. The Vietnam war took 12 years to kill the same number of healthy young people we have seen die in 12 months.”

Also from the same book in the Afterword page 121:

"Imagine that thousands of healthy young Americans died suddenly, unexpectedly, mysteriously and then kept dying at an alarming and escalating rate. (Once upon a time) that would trigger an urgent CDC inquiry to determine the cause of the deaths. Imagine attentive and curious public health officials discover the deceased had all repeatedly ingested a new and little understood drug. Next, the officials determine to certainty that the drug these kids took has a clear mechanism of action for causing inflammation of the heart and other cardiac injuries in some people. They learn that public health officials in other countries have seen the same thing and stopped recommending this same drug to young people. Next, some of the most senior and revered scientific advisors to the U.S. Government publicly recommend the drug be stopped for young people. Finally thousands of doctors around the world sign petitions and write op-eds opposing the drug. Nothing changed."

There are 1000 scientific papers on COVID vaccine injury. Surely the VA Health Department is aware of this because it is part of their job. But nothing has been done except the continuing government narrative of “get the shot” Anthony Fauci, aka Dr. Mengele, is now facing criminal charges along with his co-conspirators. In addition, the family of a deceased college student who died from myocarditis as a result of the Covid shot has filed suit against the Biden administration and the Department of Defense. Operation “Warp Speed” was managed by the military and the shot produced by military contractors. I am hoping that VDH cares about the damage that is being perpetrated and will do their job as public health officials and stop these shots that are causing the death of young people, children, and the rest of us in between. Otherwise, I do not know how you sleep at night.

Carol Campbell Sargeant RN BSN MPH
Henrico County, VA
VAMFA speech 150623 for VA Board of Health Meeting
Lori D. Leonard

Over the past three years, we have known family members and friends who have “died suddenly”. People have “turbo cancers”, athletes and pilots are dying, and young people having life-threatening heart pathologies.

Stop normalizing the abnormal. Stop gaslighting truth tellers. Let’s call this for what it is: murder. And it needs to stop. NOW.

Pfizer’s documents admit that their mRNA injections do NOT prevent infection. (Kingston) Why are they still being given, and promoted in Virginia?

The jabs were patented by DoD and DARPA as bioweapons (Kingston, Martin, Malone, others), to kill as many people as quickly as possible worldwide. This is not subject to debate. WHO, WEF, UN, DoD, patents. Big Pharma, UNC Chapel Hill and others are all on record about this. Why do Virginia health care officials stand by, watching this complete destruction of society, and pretend like everything is okay?

Pfizer knew that their injections caused infertility, miscarriages, and even killed nursing babies. (Wolf) How can anyone still encourage everyone to get these jabs?

Doctors and hospitals are paid massive sums of money to use the covid cocktail which is KNOWN to kill patients. This needs to be open public knowledge.

The world’s children are being subjected to sacrifice, murder, and experimentation. Did you know that aborted children’s body parts have been used for years in manufacturing injections?

All bioweapon injections must be removed from Virginia immediately. Giving them amounts to crimes against humanity. Why do we still have doctors, nurses, and the media pushing us to get our next jab? How many more people will die or become permanently disabled before the Virginia health system acts on our behalf and stops this tyrannical genocide?
My name is Ann Parker, I’m a Mother, Grandmother and School Board Member with grave concerns of EMF Radiation levels everywhere in Virginia.

Over 200 Scientist have been Appealing to the UN and WHO with Urgent Pleas for Greater Health Protection from EMF Radiation since 2015. Their main concerns are RadioFrequency Radiation levels from cell and cordless phones, cell towers, wifi, radio/tv antennas, smart meters and baby monitors.

Numerous Scientific Studies prove Radiation levels Not flagged as harmful by current international guidelines, do in fact cause harms such as cancers, neurological disorders, changes in the reproductive system and worse.

These Scientists find dangerous radiation effects in all living organisms, and have identified children and pregnant women at highest risk of injury.

Ronald Melnick, PhD with the National Toxicology Program said “the absorption of radiation is greater in children” and “the developing brain is highly susceptible to tissue damage”.

We implore all of you to further educate yourselves on these dangers, and we ask the Dept of Health to demand safer technology by reducing the acceptable Radiation thresholds in Virginia, require hard-wiring infrastructures in public buildings, high occupancy residential and commercial spaces and provide education for all Virginians regarding the risks of non-ionizing Electromagnetic and RadioFrequency Radiation.
The Virginia Department of Health has informed doctors to recommend the Covid-19 injection, to include babies at 6 months of age. The doctors I have spoken to did not know about the release of the Pfizer documents with the potential adverse events known by February 28, 2021.

They also didn’t know about the CDC’s V-Safe data. Of course, the CDC had to be sued twice to release these documents.

My guess is that the doctors don’t know that Moderna had to be sued for their data. Hopefully it will be released in July 2023.

Recent data from Israel showed that zero healthy individuals under the age of 50 died of COVID.

My daughter is vaccine injured. It started with her menstrual cycle getting farther and farther apart. We now know that she also has vascular and autoimmune issues. Two of my friend’s daughters stopped having their menstrual cycles. These girls were not given informed consent when the colleges were mandating the jab. There are 36,209 Menstrual disorders reported in VAERS. My daughter and my friends’ daughters were not reported to VAERS. Evidently doctors don’t want to report them to VAERS because they are afraid to lose their job or their license. In a systematic review of over 78K women over 52% had menstrual issues.

My niece recently had a beautiful healthy son. She is unvaccinated. Two of her friends just had miscarriages. They were vaccinated. They were also not reported to VAERS.

My uncle that died 2 days after the booster was also not reported to VAERS.

I met a mom the other night whose daughter started having seizures after the jab. She said that she knows of 5 children that started having seizures. They were also not reported to VAERS. What else is going to happen to children when they are given the Covid jab?

If you are telling doctors to recommend this jab, then you need to give the doctors the information so they can give their patients informed consent. In general, people trust their doctors. Will they still trust their doctors when they find out that they weren’t given informed consent?
The Virginia Department of Health has informed doctors to recommend the Covid-19 injection, to include babies at 6 months of age. [https://www.vdh.virginia.gov/clinicians/covid-19-updates-for-virginia/](https://www.vdh.virginia.gov/clinicians/covid-19-updates-for-virginia/) The doctors I have spoken to did not know about the release of the Pfizer documents with the potential adverse events known by February 28, 2021.

Do the doctors know that the FDA had to be sued for this information and wanted to withhold it for 75 years? [https://www.fda.gov/news-events/press-announcements/fda-mandate-release-pandemic-vaccine-data](https://www.fda.gov/news-events/press-announcements/fda-mandate-release-pandemic-vaccine-data)

To find this in the full document, go to [www.phmont.org](http://www.phmont.org), click on documents, type in the search bar 5.3.6 - for the adverse reactions go to pages 30 – 38. Please note that these are only the side effects known as of February 28, 2021.

They also didn’t know about the CDC’s V-Safe data. Of course the CDC had to be sued twice to release these documents. Out of 10 million v-safe users over 7.7% had a health event requiring medical attention and 25%, 1.2 million were unable to perform normal activities. [https://icandecide.org/article/v-safe/](https://icandecide.org/article/v-safe/)


Recent data from Israel showed that zero healthy individuals under the age of 50 died of COVID. [https://www.thepochnitimes.com/zero-young-healthy-individuals-died-of-covid-19-israeli-data-show_5293587.html?utm_source=partner&utm_campaign=TheChiefNerd&utm_medium=blog&utm_term=TheChiefNerd Scripts] “Zero healthy individuals under the age of 50 have died of COVID-19 in Israel, according to newly released data.”

My daughter is vaccine injured. It started with her menstrual cycle getting farther and farther apart. We now know that she also has vascular and autoimmune issues. Two of my friend’s daughters stopped having their menstrual cycles. These girls were not given informed consent when the colleges were mandating the jab. [https://www.ace.pvaers.com/covid-data/reproductive-health](https://www.ace.pvaers.com/covid-data/reproductive-health) There are 36,209 Menstrual disorders reported in VAERS. My daughter and my friends’ daughters were not reported to VAERS. Evidently doctors either don’t want to report them to VAERS or I was also told that they don’t want to lose their license. In a systematic review of over 78K women over 52% had menstrual issues.

Menstrual Cycles: Consider adding your story there. [https://mycyclesstory.com/](https://mycyclesstory.com/) This systematic review of over 78K women reveals results that over 52% of women reported menstrual abnormalities post jab. [https://doi.org/10.1016/j.vaccine.2022.07.001](https://doi.org/10.1016/j.vaccine.2022.07.001)

My niece recently had a beautiful healthy son. She is unvaccinated. Two of her friends just had miscarriages. They were vaccinated. They were also not reported to VAERS.

My husband’s uncle that died of a heart attack 2 days after the booster was also not reported to VAERS.

I met a mom the other night whose daughter started having seizures after the jab. She said that she knows of 5 children that started having seizures. They were also not reported to VAERS. What else is going to happen to children when they are given the Covid jab?

If you are telling doctors to recommend this jab, then you need to give the doctors the information so they can give their patients informed consent. In general, people trust their doctors. Will they still trust their doctors when they find out that they weren’t given informed consent?
36,209 Menstrual Disorders Reports - VAERS

- Miscarriage/Stillbirth 4,930
- Menstrual Disorders 36,209
- Vaginal/Uterine Haemorrhage (All Ages) 12,683
- Caesarean / Preterm Labour / Birth Difficulties / Premature Birth 1,410
- Fetal Defects / Fetal Cardiac Issues / Fetal Disorders 1,011
- Pregnancy Difficulties 885

https://www.vaers.com/covid-data/reproductive-health
36,209 Menstrual Disorders Reports - VAERS

- Miscarriage/Stillbirth 4,930
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- Pregnancy Difficulties 885

https://www.openvaers.com/covid-data/reproductive-health
Hello, my name is Jennifer,

It is my understanding that the Virginia Department of Health has informed doctors to recommend the Covid-19 injection, to include babies at 6 months of age. The doctors I have spoken to did not know about the Pfizer documents and the adverse events that were known by February 28, 2021. Do the doctors know that the FDA had to be sued for this information and wanted to withhold it for 75 years? Do they know about the CDC’s V-Safe data that shows that out of 10 million v-safe users over 7.7% had a health event requiring medical attention and 25%, 1.2 million were unable to perform normal activities? Do they know that the CDC had to be sued twice for this information?

Do the doctors know that Moderna also had to be sued for their data and that hopefully it will be released in July 2023? How are people getting informed consent if the doctors haven’t been given this information?

My daughter is vaccine injured. It started with her menstrual cycle getting farther and farther apart. We now know that she also has vascular and autoimmune issues. Two of my friend’s daughters stopped having their menstrual cycles. These girls were not given informed consent when the colleges were mandating the jab. In fact, I don’t know of anyone that was giving informed consent prior to getting the jab. A “systematic review of over 78K women reveals results that over 52% of women reported menstrual abnormalities post jab”. Will they be able to have children? I could easily write a paper about my family and friends that are vaccine injured to include menstrual issues, blood clots, shingles, neurological issues, heart attacks and death 2 days after the booster. I spoke with a mom the other night and her daughter started having seizures after the jab. She knows of 5 children that started having seizures. If these aren’t caused by the jab, then there are an awful lot of coincidences.

If you are telling doctors to recommend this jab, then you need to give the doctors the information so they can give their patients informed consent. In general, people trust their doctors. Will they still trust their doctors when they find out that they weren’t given informed consent?
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If you are telling doctors to recommend this jab, then you need to give the doctors the information so they can give their patients informed consent. In general, people trust their doctors. Will they still trust their doctors when they find out that they weren’t given informed consent?
Hello, my name is Jennifer,

It is my understanding that the Virginia Department of Health has informed doctors to recommend the Covid-19 injection, to include babies at 6 months of age. [https://www.vdh.virginia.gov/clinicians/covid-19-updates-for-virginia/](https://www.vdh.virginia.gov/clinicians/covid-19-updates-for-virginia/) The doctors I have spoken to did not know about the Pfizer documents and the adverse events that were known by February 28, 2021.

To find this in the full document, go to [www.phmpt.org](http://www.phmpt.org) click on documents, type in the search bar 5.3.6 - for the adverse reactions go to pages 30 – 38. Please note that these are only the side effects known as of February 28, 2021.

Do the doctors know that the FDA had to be sued for this information and wanted to withhold it for 75 years? [https://www.fdanews.com/articles/206113-federal-judge-tells-fda-it-must-make-public-55000-pages-a-month-of-pfizer-vaccine-data](https://www.fdanews.com/articles/206113-federal-judge-tells-fda-it-must-make-public-55000-pages-a-month-of-pfizer-vaccine-data)

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Do the doctors know that Moderna also had to be sued for their data and that hopefully it will be released in July 2023? [https://icandecide.org/press-release/breaking-icans-attorneys-score-another-major-win-against-fda-with-pfizer-and-moderna-covid-19-vaccine-documents/](https://icandecide.org/press-release/breaking-icans-attorneys-score-another-major-win-against-fda-with-pfizer-and-moderna-covid-19-vaccine-documents/) How are people getting informed consent if the doctors haven’t been given this information?

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These girls were not given informed consent when the colleges were mandating the jab. In fact, I don’t know of anyone that was giving informed consent prior to getting the jab. Menstrual Cycles: Consider adding your story there. [https://mycyclesstory.com/](https://mycyclesstory.com/) This systematic review of over 78K women reveals results that over 52% of women reported menstrual abnormalities post jab. [https://doi.org/10.1016/j.vacme.2022.07.001](https://doi.org/10.1016/j.vacme.2022.07.001) I could easily write a paper about my family and friends that are vaccine injured to include menstrual issues, blood clots, shingles, neurological issues, heart attacks and death 2 days after the booster. If these aren’t caused by the jab, then there are an awful lot of coincidences. I do not believe that they could all be coincidences.

If you are telling doctors to recommend this jab, then you need to give the doctors the information so they can give their patients informed consent. In general, people trust their doctors. Will they still trust their doctors when they find out that they weren’t given informed consent?

Hello, my name is Jennifer, and I’m just a mom and a grandma. I would like to tell you about my observations over the past 3 years. Unfortunately, my observations are all too normal. So many people I have spoken to have had similar or worse experiences. I call them observances because they are written off as stress or just unfortunate.

Long story short, 3 of 4 of my kids were in college. One dropped out when the college went online. 2 were vaccinated. One came to me and told me that her menstrual cycles were getting farther and farther apart. I was in denial, but still doing my research listening to the silenced doctors and researching our history and the history of Africa and India where girls of childbearing age had been experimented on with vaccines and had become infertile or were having more and more miscarriages. I feel blessed that my eyes were opened and I could at least try to help my daughter. Two friends told me that their daughters had stopped having their menstrual cycle. I took the Pfizer documents and DMED data to 3 doctors and they said that they would put her on the pill. Fortunately, my research led me to 2 health professionals that knew what was going on and did the tests that led us to vascular issues or autoimmune issues that were also causing her to get sick every other week. I am thankful for the healthcare professionals that have cared for my daughter. How many girls are having this problem, or worse, and have been ignored? A systematic review of over 78K women reveals results that over 52% of women reported menstrual abnormalities post jab.

One of my best friends called me when her 20-year-old daughter was in the hospital with shingles (herpes zoster) then another in her twenties with shingles, then 2 more in their forties. They were all told that it was just stress.

I presented the Pfizer documents and DMED data to another friend. Her husband said that this may be why her thyroid issue had been so much worse. She had already told me about her father having mini strokes, a co-worker getting breast cancer, and another needing to see a neurologist.

Another friend’s husband started having tremors and shakes. Her mother had a mini stroke and had to have a clot removed from her neck.

My husband’s uncle passed away suddenly from a heart attack 2 days after the booster on his way to the hardware store to get materials for another one of his amazing backyard projects. He got the shots to protect his mom.

My cousin just had open heart surgery and his father (my uncle) just had a stroke.

It would take quite a while to tell you all my stories. Are these all coincidences? I don’t think so. I am more than thankful to all the doctors that are speaking up. I am thankful for them, and that God woke me up.
NOTES:

Menstrual Cycles: Consider adding your story there. https://mycyclestory.com/

This systematic review of over 78K women reveals results that over 52% of women reported menstrual abnormalities post jab.
https://doi.org/10.1016/j.vacun.2022.07.001
5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28 FEB-2021

Report Prepared by:

Worldwide Safety

Pfizer

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APPENDIX 1. LIST OF ADVERSE EVENTS OF SPECIAL INTEREST

1p36 deletion syndrome; 2-Hydroxyglutaric aciduria; 5-nucleotidase increased; Acoustic neuritis; Acquired C1 inhibitor deficiency; Acquired epidermolysis bullosa; Acquired epileptic aphasia; Acute cutaneous lupus erythematosus; Acute disseminated encephalomyelitis; Acute encephalitis with refractory, repetitive partial seizures; Acute febrile neutrophilic dermatosis; Acute fasciculitis; Acute haemorrhagic leukoencephalitis; Acute haemorrhagic oedema of infancy; Acute kidney injury; Acute macular outer retinopathy; Acute motor axonal neuropathy; Acute motor-sensory axonal neuropathy; Acute myocardial infarction; Acute respiratory distress syndrome; Acute respiratory failure; Addison's disease; Administration site thrombosis; Administration site vasculitis; Adrenal thrombosis; Adverse event following immunisation; Aegesis; Agranulocytosis; Air embolism; Alanine aminotransferase abnormal; Alanine aminotransferase increased; Alcoholic seizure; Allergic bronchopulmonary mycosis; Allergic oedema; Allimmune hepatitis; Alopecia areata; Alpers disease; Alveolar proteinosis; Ammonia abnormal; Ammonia increased; Amniotic cavity infection; Amygdalohippocampectomy; Amyloid arthropathy; Amyloidosis; Amyloidosis senile; Anaphylactic reaction; Anaphylactic shock; Anaphylactic transfusion reaction; Anaphylactoid reaction; Anaphylactoid shock; Anaphylactoid syndrome of pregnancy; Angioedema; Angiopathic neuropathy; Ankylosing spondylitis; Anosmia; Anti-acetylcholine receptor antibody positive; Anti-acetylcholine receptor antibody negative; Anti-aquaporin-4 antibody positive; Anti-basal ganglia antibody positive; Anti-cyclic citrullinated peptide antibody positive; Anti-epithelial antibody positive; Anti-erythrocyte antibody positive; Anti-exosome complex antibody positive; Anti-GAD antibody negative; Anti-GAD antibody positive; Anti-ganglioside antibody positive; Anti-IgG2 antibody positive; Anti-glomerular basement membrane antibody positive; Anti-glomerular basement membrane disease; Anti-glycyl-riNLA synthetase antibody positive; Anti-HLA antibody test positive; Anti-IA2 antibody positive; Anti-insulin antibody increased; Anti-insulin receptor antibody positive; Anti-insulin receptor antibody increased; Anti-interferon antibody positive; Anti-interferon antibody negative; Anti-islet cell antibody positive; Anti-islet cell antibody negative; Anti-mitochondrial antibody positive; Anti-muscle specific kinase antibody positive; Anti-myelin-associated glycoprotein antibodies positive; Anti-myelin-associated glycoprotein associated polysynaptopathy; Anti-myocardial antibody positive; Anti-neuronal antibody positive; Antineutrophil cytoplasmic antibody increased; Antineutrophil cytoplasmic antibody positive; Anti-neutrophil cytoplasmic antibody positive; Anti-NMDA antibody positive; Anti-nuclear antibody increased; Anti-nuclear antibody positive; Antiphospholipid antibodies positive; Antiphospholipid syndrome; Anti-platelet antibody positive; Anti-prothrombin antibody positive; Antiribosomal P antibody positive; Anti-RNA polymerase III antibody positive; Anti-saccharomyces cerevisiae antibody test positive; Anti-sperm antibody positive; Anti-5SRP antibody positive; Antisynthetase syndrome; Anti-thyroid antibody positive; Anti-transglutaminase antibody increased; Anti-VGCC antibody positive; Anti-VGKC antibody positive; Anti-vimentin antibody positive; Antiviral prophylaxis; Antiviral treatment; Anti-zinc transporter 8 antibody positive; Aortic embolus; Aortic thrombosis; Aortitis; Aphasia; Aplasia; Aplastic anaemia; Application site thrombosis; Application site vasculitis; Arrhythmia; Arterial bypass occlusion; Arterial bypass thrombosis; Arterial thrombosis; Arteriovenous fistula thrombosis; Arteriovenous graft site stenosis; Arteriovenous graft thrombosis; Arteritis; Arteritis.
coronary; Arthralgia; Arthritis; Arthritis enteropathic; Ascites; Aseptic cavernous sinus thrombosis; Aspartate aminotransferase abnormal; Aspartate aminotransferase increased; Aspartate-glutamate transporter deficiency; AST to platelet ratio index increased; AST/ALT ratio abnormal; Asthma; Asymptomatic COVID-19; Ataxia; Atheroembolism; Atopic seizures; Atlantothomboasis; Atlrophic thyroiditis; Atypical benign partial epilepsy; Atypical pneumonia; Aura; Autoantibody positive; Autoimmune anaemia; Autoimmune aplastic anaemia; Autoimmune arthritis; Autoimmune blistering disease; Autoimmune cholangitis; Autoimmune colitis; Autoimmune demyelinating disease; Autoimmune dermatitis; Autoimmune disorder; Autoimmune encephalopathy; Autoimmune endocrine disorder; Autoimmune enteropathy; Autoimmune eye disorder; Autoimmune haemolytic anaemia; Autoimmune heparin-induced thrombocytopenia; Autoimmune hepatitis; Autoimmune hyperlipidaemia; Autoimmune hypothyroidism; Autoimmune inner ear disease; Autoimmune lung disease; Autoimmune lymphoproliferative syndrome; Autoimmune myocarditis; Autoimmune myositis; Autoimmune nephritis; Autoimmune neuropathy; Autoimmune neutropenia; Autoimmune pancreatitis; Autoimmune pancytopenia; Autoimmune pericarditis; Autoimmune retinopathy; Autoimmune thyroid disorder; Autoimmune thyroiditis; Autoimmune uveitis; Autoinflammation with infantile enterocolitis; Autoinflammatory disease; Automatism epileptic; Autonomic nervous system imbalance; Autonomic seizure; Axial spondylarthropathy; Axillary vein thrombosis; Axonal and demyelinating polyneuropathy; Axonal neuropathy; Bacteriasepsis; Baltic myoclonic epilepsy; Bell sensation; Basedow's disease; Basilar artery thrombosis; Basophilopenia; B-cell aplasia; Behçet's syndrome; Benign chronic neutropenia; Benign familial neonatal convulsions; Benign familial pemphigus; Benign rolandic epilepsy; Beta-2 glycoprotein antibody positive; Bickerstaff's encephalitis; Bile output abnormal; Bile output decreased; Biliary ascites; Bilirubin conjugated abnormal; Bilirubin conjugated increased; Bilirubin urine present; Biopsy liver abnormal; Biotinidase deficiency; Birdshot chorioretinopathy; Blood alkaline phosphatase abnormal; Blood alkaline phosphatase increased; Blood bilirubin abnormal; Blood bilirubin increased; Blood bilirubin un conjugated increased; Blood cholesterol abnormal; Blood cholesterol decreased; Blood pressure decreased; Blood pressure diastolic decreased; Blood pressure systolic decreased; Blue toe syndrome; Brachiocephalic vein thrombosis; Brain stem embolism; Brain stem thrombosis; Broncholymphatic test abnormal; Bronchial edema; Bronchitis; Bronchitis mycoplasmal; Bronchitis viral; Bronchiopulmonary aspergillosis allergic; Bronchospasm; BuddChiari syndrome; Bulbar palsy; Butterfly rash; C1q nephropathy; Cesarean section; Calcium embolism; Capillitias; Caplan's syndrome; Cardiac amyloidosis; Cardiac arrest; Cardiac failure; Cardiac failure acute; Cardiac sarcoidosis; Cardiac ventricular thrombosis; Cardiogenic shock; Cardiolipin antibody positive; Cardiopulmonary failure; Cardio-respiratory arrest; Cardio-respiratory distress; Cardiovascular insufficiency; Carotid arterial embolism; Carotid artery thrombosis; Cataplexy; Catheter site thrombosis; Catheter site vasculitis; Cavernous sinus thrombosis; CDKL5 deficiency disorder; CEC syndrome; Cement embolism; Central nervous system lupus; Central nervous system vasculitis; Cerebellar artery thrombosis; Cerebellar embolism; Cerebral amyloid angiopathy; Cerebral arteritis; Cerebral artery embolism; Cerebral artery thrombosis; Cerebral gas embolism; Cerebral microembolism; Cerebral septic infarct; Cerebral thrombosis; Cerebral venous sinus thrombosis; Cerebral venous thrombosis; Cerebrospinal thrombotic
Cumulative Analysis of Post-authorization Adverse Event Reports

- Tamponade
- Cerebrovascular accident
- Change in seizure presentation
- Chest discomfort
- Child-Pugh-Turcotte score abnormal
- Child-Pugh-Turcotte score increased
- Chills
- Blaïns
- Choking
- Choking sensation
- Cholangitis
- Sclerosing
- Chronic autoimmune
- Glomerulonephritis
- Chronic cutaneous lupus erythematosus
- Chronic fatigue syndrome
- Chronic gastritis
- Chronic inflammatory demyelinating polyradiculoneuropathy
- Chronic lymphocytic inflammation with pontine perivascular enhancement responsive to steroids
- Chronic recurrent multifocal osteomyelitis
- Chronic respiratory failure
- Chronic spontaneous urticaria
- Circulatory collapse
- Circumoral oedema
- Circumoral swelling
- Clinically isolated syndrome
- Convulsive
- Cough
- Colitis
- Eosinophilic
- Colitis ulcerative
- Collagen vascular disease
- Complement factor abnormal
- Complement factor C1 decreased
- Complement factor C2 decreased
- Complement factor C3 decreased
- Complement factor C4 decreased
- Complement factor decreased
- Computerised tomogram liver abnormal
- Concentric sclerosis
- Congenital anomaly
- Congenital bilateral perisylvian syndrome
- Congenital herpes simplex infection
- Congenital myasthenic syndrome
- Congenital varicella infection
- Congestive hepatothropy
- Convulsion in childhood
- Convulsions local
- Convulsive threshold lowered
- Coombs positive haemolytic anaemia
- Coronary artery disease
- Coronary artery embolism
- Coronary artery thrombosis
- Coronary bypass thrombosis
- Coronavirus infection
- Coronavirus test
- Coronavirus test negative
- Coronavirus test positive
- Corpus callosum
- Cough
- Cough variant asthma
- COVID-19
- COVID-19 immunisation
- COVID-19 pneumonia
- COVID-19 prophylaxis
- COVID-19 treatment
- Cranial nerve disorder
- Cranial nerve palsies multiple
- Cranial nerve paralysis
- CREST syndrome
- Crohn's disease
- Cryoglobulinaemia
- Cryoglobulinemia
- CSF oligoclonal band present
- CSWS syndrome
- Cutaneous amyloidosis
- Cutaneous lupus erythematosus
- Cutaneous sarcoidosis
- Cutaneous vasculitis
- Cyanosis
- Cyclic neutropenia
- Cytisitis interstitialis
- Cytokine release syndrome
- Death
- Death neonatal
- Deep vein thrombosis
- Deep vein thrombosis postoperative
- Deficiency of bile secretion
- Deja vu
- Demyelinating polyneuropathy
- Demyelination
- Dermatitis
- Dermatitis bullous
- Dermatitis herpetiformis
- Dermatomyositis
- Device embolisation
- Device related thrombosis
- Diabetes mellitus
- Diabetic ketoacidosis
- Diabetic mastopathy
- Dialysis amyloidosis
- Dialysis membrane reaction
- Diastolic hypertension
- Diffuse vasculitis
- Digital pitting scar
- Disseminated intravascular coagulation
- Disseminated intravascular coagulation in newborn
- Disseminated neonatal herpes
- Disseminated varicella zoster virus infection
- Disseminated varicella zoster virus infection
- DNA antibody positive
- Double cortex syndrome
- Double stranded DNA antibody positive
- Dreamy state
- Dressler's syndrome
- Drop attacks
- Drug withdrawal convulsion
- Dyspnoea
- Early infantile epileptic encephalopathy with burst-suppression
- Eclampsia
- Eczema herpeticum
- Embolia cutis medicamentos
- Embolic cerebral infarction
- Embolic cerebral infarction
- Embolic pneumonia
- Embolic stroke
- Endocarditis
- Endocarditis infective
- Endocarditis infective arterital
- Endocarditis infective venous
- Encephalitis
- Encephalitis allergica
- Encephalitis autoimmune
- Encephalitis brain stem
- Encephalitis aicrophic
- Encephalitis periaxialis diffusa
- Encephalitis post immunisation
- Encephalomyelitis
- Encephalopathy
- Endocrine disorder
- Endocrine ophthalmopathy
- Endotracheal intubation
- Enteritis
- Enteritis leukopenic
- Enterobacter pneumonia
- Enterocolitis
- Enteropathic spondyilitis
- Fosinopinia
- Fosinophile
fasciitis; Eosinophilic granulomatosis with polyangiitis; Eosinophilic oesophagitis; Epidermolysis; Epilepsy; Epilepsy surgery; Epilepsy with myoclonic-atonic seizures; Epileptic aura; Epileptic psychosis; Erythema; Erythema induratum; Erythema multiforme; Erythema nodosum; Evans syndrome; Exanthema subitum; Expanded disability status scale score decreased; Expanded disability status scale score increased; Exposure to communicable disease; Exposure to SARS-CoV-2; Eye oedema; Eye pruritus; Eye swelling; Eyelid oedema; Face oedema; Facial paralysis; Facial paresis; Faciobrachial dystonic seizure; Fat embolism; Febrile convolution; Febrile infection-related epilepsy syndrome; Febrile neutropenia; Felty's syndrome; Femoral artery embolism; Fibrillary glomerulonephritis; Fibromyalgia; Flushing; Foaming at mouth; Focal cortical resection; Focal dyscognitive seizures; Focal distress syndrome; Focal placental thrombosis; Foetal hepaticus; Foreign body embolism; Frontal lobe epilepsy; Fulminant type 1 diabetes mellitus; Galactose elimination capacity test abnormal; Galactose elimination capacity test decreased; Gamma-glutamyltransferase abnormal; Gamma-glutamyltransferase increased; Gastritis herpes; Gastrointestinal amyloidosis; Gelastic seizure; Generalised onset non-motor seizure; Generalised tonic-clonic seizure; Genital herpes; Genital herpes zoster; Giant cell arteritis; Glomerulonephritis; Glomerulonephritis membranoproliferative; Glomerulonephritis membranous; Glomerulonephritis rapidly progressive; Glossopharyngeal nerve paralysis; Glucose transporter type 1 deficiency syndrome; Glutamate dehydrogenase increased; Glycocholic acid increased; GM2 gangliosidosis; Goodpasture's syndrome; Graft thrombosis; Granulocytopenia; Granulocytopenia neonatal; Granulomatosis with polyangiitis; Granulomatous dermatitis; Grey matter heterotopia; Guanase increased; Guillain-Barre syndrome; Haemolytic anaemia; Haemophagocytic lymphohistiocytosis; Haemorrhage; Haemorrhagic ascites; Haemorrhagic disorder; Haemorrhagic pneumonia; Haemorrhagic varicella syndrome; Haemorrhagic vasculitis; Hantavirus pulmonary infection; Hashimoto's encephalopathy; Hashitoxicosis; Hemimegalencephaly; Henoch-Schonlein purpura; Henoch-Schonlein purpura nephritis; Hepataplastin abnormal; Hepataplastin decreased; Heparin-induced thrombocytopenia; Hepatic amyloidosis; Hepatic artery embolism; Hepatic artery flow decreased; Hepatic artery thrombosis; Hepatic enzyme abnormal; Hepatic enzyme decreased; Hepatic enzyme increased; Hepatic fibrosis marker abnormal; Hepatic fibrosis marker increased; Hepatic function abnormal; Hepatic hydrothorax; Hepatic hypertrophy; Hepatic hyperperfusion; Hepatic lymphocytic infiltration; Hepatic mass; Hepatic pain; Hepatic sequestration; Hepatic vascular resistance increased; Hepatic vascular thrombosis; Hepatic vein embolism; Hepatic vein thrombosis; Hepatic venous pressure gradient abnormal; Hepatic venous pressure gradient increased; Hepatitis; Hepatobiliary scan abnormal; Hepatomegaly; Hepatosplenomegaly; Hereditary angioedema with C1 esterase inhibitor deficiency; Herpes dermatitis; Herpes gestationis; Herpes oesophagitis; Herpes ophthalmic; Herpes pharyngitis; Herpes simplex; Herpes simplex cervicitis; Herpes simplex colitis; Herpes simplex encephalitis; Herpes simplex gastritis; Herpes simplex meningitis; Herpes simplex meningoencephalitis; Herpes simplex necrotising retinopathy; Herpes simplex oesophagitis; Herpes simplex otitis externa; Herpes simplex pharyngitis; Herpes simplex pneumonia; Herpes simplex reactivation; Herpes simplex sepsis; Herpes simplex viraemia; Herpes simplex virus conjunctivitis neonatal; Herpes simplex virus visceral; Herpes
5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports

infection; Herpes zoster infection; Herpes zoster cutaneous disseminated; Herpes zoster infection neurological; Herpes zoster meningitis; Herpes zoster meningoencephalitis; Herpes zoster meningomyoclitis; Herpes zoster meningoradiculitis; Herpes zoster necrotising retinopathy; Herpes zoster oticus; Herpes zoster pharyngitis; Herpes zoster reactivation; Herpetic radiculopathy; Histone antibody positive; Hoigne's syndrome; Human herpesvirus 6 encephalitis; Human herpesvirus 6 infection; Human herpesvirus 5 infection; Human herpesvirus 8 infection; Hyperammonaemia; Hyperbilirubinaemia; Hypercholeolaemia; Hypergammaglobulinaemia; benign monoclonal; Hyperglycaemic seizure; Hypersensitivity; Hypersensitivity vasculitis; Hyperthyroidism; Hypertension; Hypoammonaemia; Hypocalcaemic seizure; Hypogammaglobulinaemia; Hypoglossal nerve paralysis; Hypoglossal nerve paresis; Hypoglycaemic seizure; Hyponatraemic seizure; Hypoosmolality; Hypersensitivity crisis; Hypothalamic syndrome; Hypothyroidism; Hypothyroidism; Idiopathic CD4 lymphocytopenia; Idiopathic generalised epilepsy; Idiopathic interstitial pneumonia; Idiopathic neutropenia; Idiopathic pulmonary fibrosis; IgA nephropathy; IgM nephropathy; IIIrd nerve paralysis; IIIrd nerve paresis; Iliac artery embolism; Immune thrombocytopenia; Immune-mediated adverse reaction; Immune-mediated cholangitis; Immune-mediated colitis; Immune-mediated colitis; Immune-mediated encephalitis; Immune-mediated encephalopathy; Immune-mediated eosinophilia; Immune-mediated glomerulitis; Immune-mediated gastritis; Immune-mediated hepatic disorder; Immune-mediated hepatitis; Immune-mediated hypothyroidism; Immune-mediated myocarditis; Immune-mediated myositis; Immune-mediated nephritis; Immune-mediated neuropathy; Immune-mediated pancreatitis; Immune-mediated pneumonitis; Immune-mediated renal disorder; Immune-mediated thyroiditis; Immune-mediated uveitis; Immunoglobulin G4 related disease; Immunoglobulins abnormal; Implant site thrombosis; Inclusion body myositis; Infantile genetic agranulocytosis; Infantile spasms; Infected vasculitis; Infective thrombosis; Inflammation; Inflammatory bowel disease; Infusion site thrombosis; Infusion site vasculitis; Injection site thrombosis; Injection site urticaria; Injection site vasculitis; Instillation site thrombosis; Intussusception; Intestinal granulomatous dermatitis; Interstitial lung disease; Intracardiac mass; Intracardiac thrombus; Intracranial pressure increased; Intracerebral thrombosis; Intrinsic factor antibody abnormal; Intrinsic factor antibody positive; IPF syndrome; Irregular breathing; IRVAN syndrome; IVth nerve paralysis; IVth nerve paresis; JC polyomavirus test positive; JC virus CSF test positive; Jevons syndrome; Jugular vein embolism; Jugular vein thrombosis; Juvenile idiopathic arthritis; Juvenile myoclonic epilepsy; Juvenile polyposis; Juvenile psoriatic arthritis; Juvenile spondyloarthritis; Kaposi sarcoma inflammatory cytokine syndrome; Kawasaki's disease; Kayser-Fleischer ring; Keratoderma blennorrhagica; Ketosis-prone diabetes mellitus; Kounis syndrome; Laffont's myoclonic epilepsy; Lamb's exencephaly; Laryngeal dyspnoea; Laryngeal oedema; Laryngeal rheumatoid arthritis; Laryngospasm; Laryngotracheal oedema; Latent autoimmune diabetes in adults; LE cells present; Lemierre syndrome; Lennox-Gastaut syndrome; Leucine aminopeptidase increased; Leukoencephalomyelitis; Leukoencephalopathy; Leukopenia; Leukopenia neonatal; Lewis-Sumner syndrome; Lhermitte's sign; Lie ber planipilaris; Lieben planus; Lieben scleerosus; Limbic encephalitis; Linear IgA disease; Lip oedema; Lip swelling; Liver function test abnormal; Liver function test decreased; Liver function test increased; Liver induration; Liver injury; Liver iron concentration abnormal; Liver iron concentration
increased; Liver opacity; Liver palpable; Liver sarcoidosis; Liver scan abnormal; Liver tenderness; Low birth weight baby; Lower respiratory tract infection; Lower respiratory tract infection; Lower respiratory tract infection viral; Lung abscess; Lupoid hepatic cirrhosis; Lupus cystitis; Lupus encephalitis; Lupus endocarditis; Lupus enteritis; Lupus hepatitis; Lupus myocardiits; Lupus myositis; Lupus nephritis; Lupus pancreatitis; Lupus pleurisy; Lupus pneumonitis; Lupus vasculitis; Lupus-like syndrome; Lymphocytic hypophysitis; Lymphocytopenia neonatal; Lymphopenia; MAGIC syndrome; Magnetic resonance imaging liver abnormal; Magnetic resonance proton density fat fraction measurement; Malignant sign; Manufacturing laboratory analytical testing issue; Manufacturing materials issue; Manufacturing production issue; Marburg's variant multiple sclerosis; Marchiafava-Bignami disease; Marine Lehnard syndrome; Mastocytic enterocolitis; Maternal exposure during pregnancy; Medical device site thrombosis; Medical device site vasculitis; MELAS syndrome; Meningitis; Meningitis aseptic; Meningitis herpetic; Meningoencephalitis simplex neonatal; Meningoencephalitis herpetic; Meningomyelitis; MERS-CoV test; MERS-CoV test negative; MERS-CoV test positive; Mesangioproliferative glomerulonephritis; Mesenteric artery embolism; Mesenteric artery thrombosis; Mesenteric vein thrombosis; Metapneumovirus infection; Metastatic cutaneous Crohn's disease; Metastatic pulmonary embolism; Microangiopathy; Microembolism; Microscopic polyangiitis; Middle East respiratory syndrome; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondrial encephalopathy; Mitochondria.
5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports

neuropathy; Optic perineuritis; Oral herpes; Oral lichen planus; Oropharyngeal oedema; Oropharyngeal spasm; Oropharyngeal swelling; Osmotic demyelination syndrome; Ovarian vein thrombosis; Overlap syndrome; Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection; Paget-Schroetter syndrome; Palindromic rheumatism; Palisaded neutrophilic granulomatous dermatitis; Palmoplantar keratoderma; Palpable purpura; Pancreatitis; Panencephalitis; Papillophlebitis; Paracancerous pneumonia; Paradoxical embolism; Parenchymal viral laryngotracheobronchitis; Paraneoplastic dermatomyositis; Paraneoplastic pemphigus; Paraneoplastic thrombosis; Parsis cranial nerve; Parietal cell antibody positive; Paroxysmal nocturnal haemoglobinuria; Partial seizures; Partial seizures with secondary generalisation; Patient isolation; Pelvic venous thrombosis; Pemphigoid; Pemphigus; Penile vein thrombosis; Pericarditis; Pericarditis lupus; Perihepatic discomfort; Periorbital oedema; Periorbital swelling; Peripheral artery thrombosis; Peripheral embolism; Peripheral ischaemia; Peripheral vein thrombus extension; Periportal oedema; Peritoneal fluid protein abnormal; Peritoneal fluid protein decreased; Peritoneal fluid protein increased; Peritonitis lupus; Pernicious anaemia; Petit mal epilepsy; Pharyngeal oedema; Pharyngeal swelling; Pityriasis lichenoides et varioliformis acuta; Placenta praevia; Pleuroparenchymal fibrolaesis; Pneumobilia; Pneumonia; Pneumonia adenoviral; Pneumonia cytomegaloviral; Pneumonia herpes viral; Pneumonia influenza; Pneumonia measles; Pneumonia mycoplasmal; Pneumonia necrotising; Pneumonia parainfluenza viral; Pneumonia respiratory syncytial viral; Pneumonia viral; POEMS syndrome; Polyarteritis nodosa; Polyarthritis; Polyenteritis; Polyglandular autoimmune syndrome type 1; Polyglandular autoimmune syndrome type II; Polyglandular autoimmune syndrome type III; Polyglandular disorder; Polymegaly; Polymyalgia rheumatica; Polymyxinosis; Polyneuropathy; Polyneuropathy idiopathic progressive; Portal pancytopenia; Portal vein embolism; Portal vein flow decreased; Portal vein pressure increased; Portal vein thrombosis; Portosplenomesenteric venous thrombosis; Post procedural hypotension; Post procedural pneumonia; Post procedural pulmonary embolism; Post stroke epilepsy; Post stroke seizure; Post thrombotic retinopathy; Post thrombotic syndrome; Post viral fatigue syndrome; Postictal headache; Postictal paralysis; Postictal psychosis; Postictal state; Postoperative respiratory distress; Postoperative respiratory failure; Postoperative thrombosis; Postpartum thrombosis; Postpartum venous thrombosis; Postpericardiectomy syndrome; Post-traumatic epilepsy; Postural orthostatic tachycardia syndrome; Preencephal artery thrombosis; Pre-eclampsia; Preictal state; Premature labour; Premature menopause; Primary amyloidosis; Primary biliary cholangitis; Primary progressive multiple sclerosis; Procedural shock; Proctitis herpes; Proctitis ulcerative; Product availability issue; Product distribution issue; Product supply issue; Progressive facial atrophy; Progressive multifocal leuкоencephalopathy; Progressive multiple sclerosis; Progressive relapsing multiple sclerosis; Prosthetic cardiac valve thrombosis; Pruritus; Pruritus allergic; Pseudovasculitis; Psoriasis; Psoriatic arthropathy; Pulmonary amyloidosis; Pulmonary artery thrombosis; Pulmonary embolism; Pulmonary fibrosis; Pulmonary haemorrhage; Pulmonary microemboli; Pulmonary oil microembolism; Pulmonary renal syndrome; Pulmonary sarcoïdosis; Pulmonary sepsis; Pulmonary thrombosis; Pulmonary tumour thrombotic microangiopathy; Pulmonary vasculitis; Pulmonary veno-occlusive disease; Pulmonary venous thrombosis; Pyoderma gangrenosum; Pyostomatitis vegetans; Pyrexia; Quarantine; Radiation leukopenia; Radiculitis
5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports

brachial; Radiologically isolated syndrome; Rash; Rash erythematous; Rash pruritic; Rasmussen encephalitis; Raynaud's phenomenon; Reactive capillary endothelial proliferation; Relapsing multiple sclerosis; Relapsing-remitting multiple sclerosis; Renal amyloidosis; Renal arteriitis; Renal artery thrombosis; Renal embolism; Renal failure; Renal vascular thrombosis; Renal vasculitis; Renal vein embolism; Renal vein thrombosis; Respiratory arrest; Respiratory disorder; Respiratory distress; Respiratory failure; Respiratory paralysis; Respiratory syncytial virus bronchiolitis; Respiratory syncytial virus bronchitis; Retinal artery embolism; Retinal artery occlusion; Retinal artery thrombosis; Retinal vascular thrombosis; Retinal vasculitis; Retinal vein occlusion; Retinal vein thrombosis; Retinol binding protein decreased; Retinopathy; Retrograde portal vein flow; Retroperitoneal fibrosis; Reversible airways obstruction; Reynold's syndrome; Rheumatic brain disease; Rheumatic disorder; Rheumatoid arthritis; Rheumatoid factor increased; Rheumatoid factor positive; Rheumatoid factor quantitative increased; Rheumatoid lung; Rheumatoid neutrophilic dermatosis; Rheumatoid nodule; Rheumatoid nodule removal; Rheumatoid sclerosis; Rheumatoid vasculitis; Saccadic eye movement; SAPHO syndrome; Sarcoïdosis; SARS-CoV-1 test SARS-CoV-1 test negative; SARS-CoV-2 test positive; SARS-CoV-2 antibody test; SARS-CoV-2 antibody test negative; SARS-CoV-2 antibody test positive; SARS-CoV-2 carrier; SARS-CoV-2 sepsis; SARS-CoV-2 test; SARS-CoV-2 test false negative; SARS-CoV-2 test false positive; SARS-CoV-2 test negative; SARS-CoV-2 test positive; SARS-CoV-2 viremia; Satoyoshi syndrome; Schizencephaly; Scleritis; Scleroderactyla; Scleroderma; Scleroderma-associated digital ulcer; Scleroderma renal crisis; Scleroderma-like reaction; Secondary amyloidosis; Secondary cerebellar degeneration; Secondary progressive multiple sclerosis; Segmental haemorrhaging vasculitis; Seizure; Seizure anoxic; Seizure cluster; Seizure like phenomena; Seizure prophylaxis; Sensation of foreign body; Septic embolus; Septic pulmonary embolism; Severe acute respiratory syndrome; Severe myoclonic epilepsy of infancy; Shock; Shock symptom; Shrunken lung syndrome; Shunt thrombosis; Silent thyroiditis; Simple partial seizures; Sjogren's syndrome; Skin swelling; SLE arthritis; Smooth muscle antibody positive; Sneezing; Spinal artery embolism; Spinal artery thrombosis; Splenic artery thrombosis; Splenic embolism; Splenic thrombosis; Splenic vein thrombosis; Spondylitis; Spondyloarthropathy; Spontaneous heparin-induced thrombocytopenia syndrome; Status epilepticus; Stevens-Johnson syndrome; Still leg syndrome; Still person syndrome; Still's disease; Stomal site thrombosis; Stomal site vasculitis; Stress cardiomyopathy; Stridor; Subacute cutaneous lupus erythematosus; Subacute endocarditis; Subacute inflammatory demyelinating polyneuropathy; Subcutaneous artery embolism; Subcutaneous artery thrombosis; Subcutaneous vein thrombosis; Subdural hematoma; Death in epilepsy; Superior sagittal sinus thrombosis; Susac's syndrome; Suspected COVID-19; Swelling; Swelling face; Swelling of eyelid; Swollen tongue; Sympathetic ophthalmia; Systemic lupus erythematosus; Systemic lupus erythematosus disease activity index abnormal; Systemic lupus erythematosus disease activity index decreased; Systemic lupus erythematosus disease activity index increased; Systemic lupus erythematosus rash; Systemic sclerosis; Systemic sclerosis pulmonary; Tachycardia; Tachypnoea; Takayasu's arteritis; Temporal lobe epilepsy; Terminal ileitis; Testicular autoimmunity; Throat tightness; Thromboangiitis obliterans; Thrombocytopenia; Thrombocytopenic purpura; Thrombophaebatitis; Thrombophlebitis migrans; Thrombophlebitis
neonatal;Thrombophlebitis septic;Thrombophlebitis superficial;Thromboplastin antibody positive;Thrombosis;Thrombosis corpora cavernosa;Thrombosis in device;Thrombosis mesenteric vessel;Thrombotic cerebral infarction;Thrombotic microangiopathy;Thrombotic stroke;Thrombotic thrombocytopenic purpura;Thyroid disorder;Thyroid stimulating immunoglobulin increased;Thyroiditis;Tongue amyloidosis;Tongue biting;Tongue oedema;Tonic clonic movements;Tonic convolution;Tonic posturing;Topeotomy;Total bile acids increased;Toxic epidermal necrolysis;Toxic leukoencephalopathy;Toxic oil syndrome;Tracheal obstruction;Tracheal oedema;Tracheobronchitis;Tracheobronchitis mycoplasmal;Tracheobronchitis viral;Transaminases abnormal;Transaminases increased;Transfusion-related alloimmune neutropenia;Transient epileptic amnesia;Transverse sinus thrombosis;Trigeminal nerve paresis;Trigeminal neuralgia;Trigeminal palsy;Truncus coeliacus thrombosis;Tuberous sclerosis complex;Tubulointerstitial nephritis and uveitis syndrome;Tumefactive multiple sclerosis;Tumour embolism;Tumour thrombosis;Type 1 diabetes mellitus;Type 1 hypersensitivity;Type III immune complex mediated reaction;Uthoff's phenomenon;Ulcereative keratitis;Ultrasound liver abnormal;Umbilical cord thrombosis;Uncinate fits;Undifferentiated connective tissue disease;Upper airway obstruction;Urine bilirubin increased;Urobilinogen urine decreased;Urobilinogen urine increased;Urticaria;Urticaria papular;Urticarial vasculitis;Uterine rupture;Uveitis;Vaccination site thrombosis;Vaccination site vasculitis;Vagus nerve paralysis;Varicella;Varicella keratitis;Varicella post vaccine;Varicella zoster gastritis;Varicella zoster oesophagitis;Varicella zoster pneumonia;Varicella zoster sepsis;Varicella zoster virus infection;Vasa praevia;Vascular graft thrombosis;Vascular pseudoneuromyism thrombosis;Vascular purpura;Vascular stent thrombosis;Vasculitic rash;Vasculitic ulcer;Vasculitis;Vasculitis gastrointestinal;Vasculitis necrotising;Vena cava embolism;Vena cava thrombosis;Venous intravasation;Venous recanalisation;Venous thrombosis;Venous thrombosis in pregnancy;Venous thrombosis limb;Venous thrombosis neonatal;Vertebral artery thrombosis;Vessel puncture site thrombosis;Visceral venous thrombosis;VIIIth nerve paralysis;VIIIth nerve paresis;Vitiligo;Vocal cord paralysis;Vocal cord paresis;Vogt-Koyanagi-Harada disease;Warm type haemolytic anaemia;Wheezing;White nipple sign;Xth nerve paralysis;X-ray hepatobiliary abnormal;Young's syndrome;Zika virus associated Guillain Barre syndrome.
<table>
<thead>
<tr>
<th>Disease Category</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
<th>2021 (partial year)</th>
<th>% increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diseases and Injuries (Ambulatory)</td>
<td>2,059,630</td>
<td>2,058,379</td>
<td>2,022,663</td>
<td>2,110,383</td>
<td>1,976,724</td>
<td>21,512,583</td>
<td>988.30%</td>
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<tr>
<td>Diseases and Injuries (Hospitalization)</td>
<td>43,786</td>
<td>43,338</td>
<td>42,024</td>
<td>43,493</td>
<td>40,052</td>
<td>54,776</td>
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<tr>
<td>Diseases of the Nervous System</td>
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<td>81,998</td>
<td>81,382</td>
<td>85,012</td>
<td>80,786</td>
<td>863,013</td>
<td>968.30%</td>
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<tr>
<td>Malignant Neuroendocrine Tumor</td>
<td>167</td>
<td>135</td>
<td>98</td>
<td>113</td>
<td>117</td>
<td>440</td>
<td>276.10%</td>
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<tr>
<td>Acute Myocardial Infarct</td>
<td>324</td>
<td>370</td>
<td>376</td>
<td>366</td>
<td>372</td>
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<td>343.50%</td>
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<tr>
<td>Acute Myocarditis</td>
<td>84</td>
<td>92</td>
<td>116</td>
<td>159</td>
<td>108</td>
<td>307</td>
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<tr>
<td>Acute Pericarditis</td>
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<td>538</td>
<td>522</td>
<td>531</td>
<td>499</td>
<td>850</td>
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<tr>
<td>Pulmonary Embolism</td>
<td>678</td>
<td>701</td>
<td>668</td>
<td>716</td>
<td>968</td>
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<td>Congenital Malformations</td>
<td>11,710</td>
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<td>10,456</td>
<td>11,081</td>
<td>10,153</td>
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<tr>
<td>Nontraumatic Subarachnoid Hemorrhage</td>
<td>219</td>
<td>139</td>
<td>134</td>
<td>170</td>
<td>196</td>
<td>640</td>
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<tr>
<td>Anxiety</td>
<td>37,011</td>
<td>36,667</td>
<td>36,145</td>
<td>37,762</td>
<td>37,870</td>
<td>931,791</td>
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<tr>
<td>Suicide</td>
<td>359</td>
<td>496</td>
<td>530</td>
<td>570</td>
<td>550</td>
<td>1,798</td>
<td>226.50%</td>
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<tr>
<td>Neoplasms for All Cancers</td>
<td>41,557</td>
<td>39,139</td>
<td>37,756</td>
<td>38,889</td>
<td>36,050</td>
<td>114,645</td>
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<tr>
<td>Cancer (Digestion)</td>
<td>660</td>
<td>654</td>
<td>633</td>
<td>602</td>
<td>704</td>
<td>4,060</td>
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<tr>
<td>Cancer (Breast)</td>
<td>934</td>
<td>810</td>
<td>766</td>
<td>792</td>
<td>766</td>
<td>4,357</td>
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<tr>
<td>Cancer (Testicular)</td>
<td>1,156</td>
<td>1,008</td>
<td>866</td>
<td>880</td>
<td>889</td>
<td>3,537</td>
<td>297.90%</td>
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<tr>
<td>Infertility (female)</td>
<td>2,261</td>
<td>2,262</td>
<td>2,243</td>
<td>2,340</td>
<td>2,262</td>
<td>11,748</td>
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<tr>
<td>Dismenorrrhea</td>
<td>3,104</td>
<td>3,403</td>
<td>3,481</td>
<td>3,943</td>
<td>3,900</td>
<td>12,539</td>
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<td>Ovarian Dysfunction</td>
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<td>936</td>
<td>908</td>
<td>945</td>
<td>1,022</td>
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<td>Infertility (male)</td>
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<td>2,287</td>
<td>2,037</td>
<td>2,152</td>
<td>1,990</td>
<td>8,365</td>
<td>320.40%</td>
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<td>Guillain-Bare Syndrome</td>
<td>66</td>
<td>79</td>
<td>71</td>
<td>85</td>
<td>65</td>
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<td>520.00%</td>
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<td>Condition</td>
<td>Count</td>
<td>Count</td>
<td>Count</td>
<td>Count</td>
<td>Count</td>
<td>Count</td>
<td>Percentage</td>
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<td>Acute Transverse Myelitis</td>
<td>46</td>
<td>57</td>
<td>48</td>
<td>35</td>
<td>34</td>
<td>202</td>
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<tr>
<td>Seizures</td>
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<td>148</td>
<td>130</td>
<td>150</td>
<td>123</td>
<td>489</td>
<td>297.60%</td>
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<tr>
<td>Narcolepsy Cataplexy</td>
<td>995</td>
<td>898</td>
<td>864</td>
<td>830</td>
<td>766</td>
<td>2,097</td>
<td>351.70%</td>
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<tr>
<td>Rhabdomyolysis</td>
<td>706</td>
<td>696</td>
<td>740</td>
<td>755</td>
<td>669</td>
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<tr>
<td>Multiple Sclerosis</td>
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<td>391</td>
<td>367</td>
<td>400</td>
<td>385</td>
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<td>614.30%</td>
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<tr>
<td>Migraine</td>
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<td>15,714</td>
<td>16,462</td>
<td>17,116</td>
<td>16,311</td>
<td>73,490</td>
<td>351.70%</td>
</tr>
<tr>
<td>Blood Disorders</td>
<td>11,533</td>
<td>11,122</td>
<td>10,851</td>
<td>11,773</td>
<td>11,429</td>
<td>34,486</td>
<td>204.10%</td>
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<tr>
<td>Hypertension</td>
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<td>2,323</td>
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<td>2,392</td>
<td>2,415</td>
<td>53,846</td>
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<tr>
<td>Cerebral Infarct</td>
<td>887</td>
<td>848</td>
<td>858</td>
<td>888</td>
<td>887</td>
<td>3,438</td>
<td>293.70%</td>
</tr>
</tbody>
</table>

Miscarriage - 2 of niece's friends

Heart attack - 2 of brother-in-law's coworkers
- Accountant's father (died)
- Family friend
- Husband's uncle - died

Infertility - several of niece's friends unable to conceive

Neonatal death (in Pfizer documents)
- Friend's niece - twin babies died

There are way too many coincidences!

Stop the Shots!!!