March 15, 2021

Office of the Inspector General
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Complaint Category: *Crime, gross misconduct, or conflicts of interest involving HHS employees, grantees or contractors.*

Primary Person of Interest: Jeffrey E. Shuren, M.D., J.D., *Director, Centers for Devices and Radiological Health, Food and Drug Administration*

Inspector General Grimm:

In February 2020, the *Food and Drug Administration (FDA)*, under the signature of Dr. Jeffrey Shuren, released to the public a report entitled, "*Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and Cancer".* This report was subsequently cited by the *Federal Communications Commission (FCC)* as their exclusive scientific rationale to forego updating 25 years old safety standards for wireless devices and infrastructure that were based on technologies that no longer exist.

On January 25th, 2021, before a three Judge panel of the *United States Court of Appeals for the District of Columbia Circuit*, these same issues regarding the adequacy of current safety guidelines were presented in oral argument, with the Court pressing the *FCC* to justify its reliance on the *FDA* report. The discourse in that proceeding included a frank indication by one Appellate Judge that his present view on the facts would lead him to rule against the agencies in this regard. Based on their questioning and narrative during the oral argument, there was apparent concurrence by the other two Appellate Judges on many of these points. In a response letter to the Court, dated January 26th, 2021, the *FCC*, in a narrative best described as obfuscation, repeated the position that their primary resource to inform their decision-making on the matter were the *FDA* and the opinion of Dr. Shuren.

The scientific inadequacy of, and key research exclusions from, the *FDA* cancer report, were suspicious. When considered alongside the full body of relevant science that points in the direction of increased risk, and communications with members of *Congress* in response to their inquiries about the safety of wireless technology relying on the *FDA* report, there was an unusually high degree of congruity, including catch phrases and messages, among wireless industry 'talking points' and both *FDA* and *FCC* website statements denying wireless technology dangers. Further, actions taken by these government agencies pursuant to the *FDA* report raised 'red-flags' that compelled us to investigate further as to the reasons for these dangerous lapses in judgement and responsibility by two government authorities charged with protecting the public health and safety.

As we investigated, more alarming information emerged.

For example, on November 1, 2018, Dr. Shuren released a confusing public statement disagreeing with the findings of a multi-million-dollar *National Toxicology Program* study, commissioned by Dr. Shuren's own *FDA*, which concluded "clear evidence of carcinogenicity" from cell phone exposure. The statement by Dr. Shuren carried the wireless industry position that, despite the study results, cell phones were safe. Several months later, on April 24, 2019, in a communication with the *FCC*, Dr. Shuren advised unequivocally that cell phones have the 'all clear' as far as safety, even though the review cited above that was commissioned within his *FDA* as the basis for decisions on the cancer-causing potential of cell phones, was not completed until 9 months later, in February 2020.

Our investigative findings, highlights of which are appended hereto, compelled us to reach out to you, the *Inspector General,* as it has revealed that the documents herein, and other prior communications and public releases, exhibit a pattern of apparent *collusion* and possible *conspiracy* among the *FCC*, the *FDA* and the many trade association and corporate appendages of the wireless industry.

It further shows that this behavior has been spearheaded by Dr. Shuren, who we learned is replete with both personal and professional conflicts of interest. For example, Dr. Shuren's family benefits from a billion-dollar telecom practice in the Arnold & Porter law firm where his wife is a partner. Most alarming was this quote from the law firm's website: *"We played a lead role in every transaction undertaken by AT&T (formerly SBC) since the passage of the 1996 Telecommunications Act…"* Further, decisions by Dr. Shuren's department with regard to diagnostic imaging can be construed to limit his ability to consider the dangers of wireless technology independently, as recognition of cell phone dangers that would compel alterations to prior *FDA* positions would also be disruptive to health care delivery.

The sum total is that these apparent *collusive* and possibly *conspiratorial* actions serve to mislead the American public about the safety of a technology which now reaches virtually every man, woman and child in the country.

We write as concerned citizens, and in the public interest, to request that the *Inspector General* conduct a thorough investigation, of not only the evidence of the patterns that we have identified in the public record, but to dig deeper into relevant non-public government files, many of which we understand have not been able to be secured despite several FOIA petitions that we have become aware of.

It is critically important that wrongdoing which has potentially put a large portion of the U.S. population in grave danger be identified, redressed, and prevented from future occurrence, with those responsible for these breaches properly held to account.

Sincerely yours,

Kevin Mottus
California Brain Tumor Association (CALIBTA.org)
kevinCABTA@hotmail.com

APPENDICES

To assist in this important and time-sensitive work, we have appended the following documentation, gathered through our investigation.

Appendix 1: Report: "*Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and Cancer"*

Appendix 2: Transcript of Oral Argument, *Environmental Health Trust, et al., v. Federal Communications Commission, Nos.20-1025 and 20-1138*

Appendix 3: Response letter from Ashley Boizelle, Deputy General Counsel, Federal Communications Commission to Mark J. Langer, Clerk of the United States Court of Appeals for the District of Columbia Circuit

Appendix 4: Evidence of extensive congruity among wireless industry 'talking points' conveyed in package inserts and websites, and official positions of the *FDA* and the *FCC* with respect to wireless technology safety.

Appendix 5: FDA statement from Dr. Shuren on justifying the "difference of opinion" between the *FDA* and the *National Toxicology Program* on a $25M study ordered to be conducted by the FDA

Appendix 6: Key scientific studies and reports excluded from the *FDA* report.

Appendix 7: Letters to Congress from *FDA* and *FCC* officials justifying their 'no-action' positions regarding wireless technology standards and risks.

Appendix 8: Factual determinations regarding ignored personal conflicts of interest in Dr. Shuren's executive functions, including illegal dealings with his wife's law firm.

Appendix 9: Professional credential inadequacies of Dr. Shuren as pertains to wireless technology risks and risk management.

Appendix 10: History of decisions driven by Dr. Shuren showing deference to medical device companies regarding patient safety under his jurisdiction as Director of the Center for Devices and Radiological Health.

Appendix 11: *Amicus curiae* briefs submitted by the FCC to support the positions of wireless industry defendants in unresolved personal injury litigation.

Appendix 12: Civil litigation complaints brought against wireless industry defendants to which the *FDA* and *FCC* positions are proffered as evidence of no wrongdoing.

Appendix 13: Public media and investigative journalism challenging the veracity and competence of the FCC and the FDA in managing dangers of wireless technology.

Appendix 14: Citizen petitions for removal of Jeffrey Shuren

Appendix 15: Congressional Testimony Addressing Dr. Shuren's Professional Behavior

This Complaint Has Been Copied to the Following:

Mr. Eric May, Chief of Staff, Office of Congresswoman Carolyn B. Maloney, Chairwoman of House Committee on Oversight and Reform

Ms. Julie Tagen, Chief of Staff, Office of Congressman Jamie Raskin, Chairman of Subcommittee on Civil Rights and Civil Liberties of House Committee on Oversight and Reform

Mr. Mark Schauerte, Chief of Staff, Office of Congressman Raja Krishnamoorthi, Chairman of Subcommittee on Economic and Consumer Policy of House Committee on Oversight and Reform

Mr. Geo Saba, Chief of Staff, Office of Congressman Ro Khanna, Chairman of Subcommittee on Environment of House Committee on Oversight and Reform

Ms. Jamie Smith, Chief of Staff, Office of Congressman Gerald Connolly, Chairman of Subcommittee on Government Operations of House Committee on Oversight and Reform

Mr. Kevin Ryan, Chief of Staff, Office of Congressman Stephen Lynch, Chairman of the Subcommittee on National Security in the House Committee on Oversight and Reform

Mr. Joshua Rogin, Chief of Staff, Office of Congressman Theodore E. Deutch, Chairman of House Committee on Ethics

Mr. Tim Cummings, Chief of Staff, Office of Congresswoman Jackie Walorski, Ranking Member of House Committee on Ethics.

Mr. Tom Rust, Chief Counsel and Staff Director, House Committee on Ethics

Ms. Liz Albertine, Chief of Staff, Office of Congresswoman Rosa DeLauro, Chairwoman of House Committee on Appropriations

Mr. Juan Hinojosa, Chief of Staff, Office of Congressman Mike Quigley, Chairman of Subcommittee on Financial Services-General Government of House Committee on Appropriations

Mr. Michael Reed, Chief of Staff, Office of Congressman Sanford Bishop Jr., Chairman of Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies of House Committee on Appropriations

Mr. Hunter Ridgway, Chief of Staff, Office of Congressman Matt Cartwright, Chairman of Subcommittee on Commerce, Justice, Science, and Related Agencies of House Committee on Appropriations

Mr. Jesse Connolly, Chief of Staff, Office of Congresswoman Chellie Pingree, Chairwoman of Subcommittee on Interior, Environment, and Related Agencies of House Committee on Appropriations

Mr. John Dowd, Chief of Staff, Office of Senator Patrick Leahy, Chairman of Senate Committee on Appropriations

Mr. Ken Reidy, Chief of Staff, Office of Senator Tammy Baldwin, Chairwoman of Subcommittee on Agriculture, Rural Development, Food and Drug Administration of Senate Committee on Appropriations

Mr. Chad Kreikemeier, Chief of Staff, Office of Senator Jeanne Shaheen, Chairwoman of Subcommittee on Commerce, Justice, Science, and Related Agencies of Senate Committee on Appropriations

Mr. Mike Zamore, Chief of Staff, Office of Senator Jeff Merkley, Chairman of Subcommittee on Interior, Environment, and Related Agencies of Senate Committee on Appropriations

Ms. Mindi Linquist, Chief of Staff, Office of Senator Patty Murray, Chairwoman of Subcommittee on Labor, Health and Human Services, Education, and Related Agencies of Senate Committee on Appropriations

Mr. Neil Campbell, Chief of Staff, Office of Senator Jack Reed, Chairman of Subcommittee on Legislative Branch of Senate Committee on Appropriations

Mr. Pat Souders, Chief of Staff, Office of Senator Dick Durbin, Chairman of Senate Committee on Judiciary

Mr. Aaron Cumming, Chief of Staff, Office of Senator Chuck Grassley, Ranking Member of Senate Committee on Judiciary

Ms. Elizabeth Peluso, Chief of Staff, Office of Senator Amy Klobuchar, Chairwoman of Subcommittee on Competition Policy, Antitrust, and Consumer Rights of Senate Committee on Judiciary

Ms. Allyson Bell, Chief of Staff, Office of Senator Mike Lee, Ranking Member of Subcommittee on Competition Policy, Antitrust, and Consumer Rights of Senate Committee on Judiciary

Mr. Joel Kelsey, Chief of Staff, Office of Senator Richard Blumenthal, Chairman of Subcommittee on The Constitution of Senate Committee on Judiciary

Mr. Steve Chartan, Chief of Staff, Office of Senator Ted Cruz, Ranking Member of Subcommittee on The Constitution of Senate Committee on Judiciary

Mr. Matt Klapper, Chief of Staff, Office of Senator Cory Booker, Chairman of Subcommittee on Criminal Justice and Counterterrorism of Senate Committee on Judiciary

Mr. Doug Coutts, Chief of Staff, Office of Senator Tom Cotton, Ranking Member of Subcommittee on Criminal Justice and Counterterrorism of Senate Committee on Judiciary

Mr. Sam Goodstein, Chief of Staff, Office of Senator Sheldon Whitehouse, Chairman of Subcommittee on Federal Courts, Oversight, Agency Action, and Federal Rights of Senate Committee on Judiciary

Mr. David Stokes, Chief of Staff, Office of Senator John Kennedy, Ranking Member of Subcommittee on Federal Courts, Oversight, Agency Action, and Federal Rights of Senate Committee on Judiciary

Mr. David Grannis, Chief of Staff, Office of Senator Dianne Feinstein, Chairwoman of Subcommittee on Human Rights and the Law of Senate Committee on Judiciary

Mr. Kyle Plotkin, Chief of Staff, Office of Senator Joshua D. Hawley, Ranking Member of Subcommittee on Human Rights and the Law of Senate Committee on Judiciary

Mr. Jonathan Stahler, Chief of Staff, Office of Senator Christopher Coons, Chairman of Subcommittee on Privacy, Technology, and the Law of Senate Committee on Judiciary, Chairman of Senate Committee on Ethics

Ms. Michelle Altman, Chief of Staff, Office of Senator James Lankford, Vice Chairman of Senate Committee on Ethics

Mr. Raymond Sass, Chief of Staff, Office of Senator Ben Sasse, Ranking Member of Subcommittee on Privacy, Technology, and the Law of Senate Committee on Judiciary

Ms. Emily Spain, Chief of Staff, Office of Senator Tom Carper, Chairman of the Senate Committee on Environment and Public Works

Mr. Joe Knowles, Chief of Staff, Office of Congressman Brian Fitzpatrick, Chairman of the Congressional Citizen Legislature Caucus

Ms. Susan Wheeler, Chief of Staff, Office of Senator Mike Crapo, Ranking Member Senate Committee on Finance

Ms. Deborah Sue Mayer, Chief Counsel and Staff Director, Senate Committee on Ethics

Ms. Angela Canterbury, Director, Strategic Communications and Advocacy, International Foundation for Electoral Systems' (IFES)

Appendix 1:

Report: "*Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and Cancer"*

Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and Cancer
https://www.fda.gov/media/135043/download

Appendix 2:

Transcript of Oral Argument, *Environmental Health Trust, et al., v. Federal Communications Commission, Nos.20-1025 and 20-1138*

Link to Hearing for EHT et al v. FCC:
https://www.cadc.uscourts.gov/recordings/recordings2020.nsf/016504286D7B16B385258668006BF6FC/$file/20-1025.mp3

Key Documents for EHT et al v. FCC:
https://ehtrust.org/5g-wireless-harms-lawsuit-against-the-fcc-eht-et-al-v-fcc/

Unofficial Transcript of EHT et al v. FCC
https://ehtrust.org/wp-content/uploads/EHT-et-al.-v-FCC-1.pdf

Appendix 3:

Response letter from Ashley Boizelle, Deputy General Counsel, Federal Communications Commission to Mark J. Langer, Clerk of the United States Court of Appeals for the District of Columbia Circuit

RE: *Environmental Health Trust, et al. v. Federal Communications Commission*, Nos. 20-1025 and 20-1138 (oral argument held January 25, 2021)
https://ehtrust.org/wp-content/uploads/20-1025-FCC-response-to-Court-from-oral-argument.pdf

> "This letter responds to Judge Henderson's request, made at oral argument yesterday, that the FCC submit information regarding the establishment, membership, and current status of (1) the Food and Drug Administration's Technical Electronic Product Radiation Safety Standards Committee (Committee) and (2) the Radiofrequency Interagency Work Group (Work Group)."

Appendix 4:

Evidence of extensive congruity among wireless industry 'talking points' conveyed in package inserts and websites, and official positions of the *FDA* and the *FCC* with respect to wireless technology safety.

At Senate Commerce Hearing, Blumenthal Raises Concerns on 5G Wireless Technology's Potential Health Risks – February 6, 2019
https://www.blumenthal.senate.gov/newsroom/press/release/at-senate-commerce-hearing-blumenthal-raises-concerns-on-5g-wireless-technologys-potential-health-risks

> "***Blumenthal criticizes the FCC & FDA for inadequate answers on outstanding public health questions***
> ***Wireless carriers concede they are not aware of any independent scientific studies on safety of 5G technologies…***
> Blumenthal blasted the Federal Communications Commission (FCC) and the Food and Drug Administration (FDA)—government agencies jointly-responsible for ensuring that cellphone technologies are safe to use—for failing to conduct any research into the safety of 5G technology, and instead, engaging in bureaucratic finger-pointing and deferring to industry…"

Video Senator Blumenthal Raises Concerns on 5G Wireless Technology Health Risks at Senate Hearing:
https://www.youtube.com/watch?v=ekNC0J3xx1w&feature=emb_logo

CTIA Claims:
Experts – Wireless Health Facts
https://www.wirelesshealthfacts.com/experts/

Media – Wireless Health Facts
https://www.wirelesshealthfacts.com/media/

FAQ – Wireless Health Facts
https://www.wirelesshealthfacts.com/faq/

FCC Claims:
Radio Frequency Safety | Federal Communications Commission
https://www.fcc.gov/general/radio-frequency-safety-0

RF Safety FAQ | Federal Communications Commission
https://www.fcc.gov/engineering-technology/electromagnetic-compatibility-division/radio-frequency-safety/faq/rf-safety

RF Safety Highlighted Releases | Federal Communications Commission
https://www.fcc.gov/engineering-technology/electromagnetic-compatibility-division/radio-frequency-safety/general/rf

Wireless Devices and Health Concerns | Federal Communications Commission

https://www.fcc.gov/consumers/guides/wireless-devices-and-health-concerns

FCC Policy on Human Exposure | Federal Communications Commission
https://www.fcc.gov/general/fcc-policy-human-exposure

FDA Claims:
Cell Phones | FDA
https://www.fda.gov/radiation-emitting-products/home-business-and-entertainment-products/cell-phones

Children and Teens and Cell Phones | FDA
https://www.fda.gov/radiation-emitting-products/cell-phones/children-and-teens-and-cell-phones

Do Cell Phones Pose a Health Hazard? | FDA
https://www.fda.gov/radiation-emitting-products/cell-phones/do-cell-phones-pose-health-hazard

Hearing Aids and Cell Phones | FDA
https://www.fda.gov/radiation-emitting-products/cell-phones/hearing-aids-and-cell-phones

Potential Cell Phone Interference with Pacemakers and Other Medical Devices | FDA
https://www.fda.gov/radiation-emitting-products/cell-phones/potential-cell-phone-interference-pacemakers-and-other-medical-devices

Radio Frequency Radiation and Cell Phones | FDA
https://www.fda.gov/radiation-emitting-products/cell-phones/radio-frequency-radiation-and-cell-phones

Reducing Radio Frequency Exposure from Cell Phones | FDA
https://www.fda.gov/radiation-emitting-products/cell-phones/reducing-radio-frequency-exposure-cell-phones

Scientific Evidence for Cell Phone Safety | FDA
https://www.fda.gov/radiation-emitting-products/cell-phones/scientific-evidence-cell-phone-safety

AT&T Claims:
Terms of Service - Legal Policy Center - AT&T
https://www.att.com/legal/terms.InformationonWirelessTelephonesandHealth.html

T-Mobile Claims:
Radio Frequency Safety | Health & Safety/RF Emissions
https://www.t-mobile.com/responsibility/consumer-info/safety/radio-frequency-safety

Verizon Claims:
Consumer Information About Radio Frequency Emissions
https://www.verizon.com/support/radio-emissions/

Appendix 5:

FDA statement from Dr. Shuren on justifying the "difference of opinion" between the *FDA* and the *National Toxicology Program* on a $25M study ordered to be conducted by the FDA

November 1, 2018 – Dr. Shuren's Press Release denying the findings of the $25 million NIH, National Institute of Environmental Health Sciences, National Toxicology Program Cell Phone Study: https://www.fda.gov/news-events/press-announcements/statement-jeffrey-shuren-md-jd-director-fdas-center-devices-and-radiological-health-national

In Contrast To:

November 1, 2018 - The NIH, NIEHS, **NTP Cell Phone study findings**: https://ntp.niehs.nih.gov/results/areas/cellphones/index.html

- **"Clear evidence of tumors in the hearts of male rats.** The tumors were malignant schwannomas.
- **Some evidence of tumors in the brains of male rats.** The tumors were malignant gliomas.
- **Some evidence of tumors in the adrenal glands of male rats.** The tumors were benign, malignant, or complex combined pheochromocytoma…

NTP scientists found that RFR exposure was associated with an increase in DNA damage."

May 19, 1999 - Submitted to NTP - Nominations from FDA's Center from Device and Radiological Health Radio Frequency Radiation Emissions of Wireless Communication Devices (CDRH) - https://ehtrust.org/wp-content/uploads/FDA-Nomination-for-Cell-Phone-NTP-Study-.pdf

> "A significant research effort, involving large well-planned animal experiments is needed to provide the basis to assess the risk to **human health** of wireless communications devices."

August 5, 2020 - Amicus Brief for EH Trust et al. v. FCC by Linda Birnbaum PhD, Former Director at the NIEHS during the NTP Cell Phone study - https://ehtrust.org/wp-content/uploads/20-1025-Amicus-Brief-Joe-Sandri.pdf

> "Overall, the NTP findings demonstrate the potential for **RFR to cause cancer in humans**. The independent peer review of the entire proceedings carried out by toxicologists, pathologists and statisticians independent of the NTP staff conducted March 26-28, 2018, concluded that there was "clear evidence of cancer," with respect to

the schwannomas of the heart in male rats, and "some evidence of cancer" with respect to the gliomas in the male rats. In addition, that review also documented DNA damage in multiple organs along with preneoplastic lesions in cardiac and brain tissue. The DNA findings were later published by NTP scientists in another peer-reviewed publication with the conclusion: exposure to RFR is associated with an increase in DNA damage."

Ronald Melnick PhD, is an independent consultant and was a senior toxicologist and director of special programs in the Environmental Toxicology Program at the National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health. Melnick led the design of the National Toxicology Program Carcinogenesis Studies of Cell Phone Radiofrequency Radiation in Rodents.

November 13, 2018 - Ronald Melnick, PhD OpEd Published in the "The Hill"
https://thehill.com/opinion/healthcare/416515-theres-a-clear-cell-phone-cancer-link-but-fda-is-downplaying-it

> "The FDA needs to fulfill the intent of their nomination to the NTP and conduct a quantitative risk assessment so that the FCC can develop health-protective exposure standards. For example, what is the level of exposure associated with cancer risk of one per thousand or one per million people?"

January 2019 - Ronald Melnick, PhD Published in Science Direct: *Commentary on the utility of the National Toxicology Program study on cell phone radiofrequency radiation data for assessing human health risks despite unfounded criticisms aimed at minimizing the findings of adverse health effects*
https://www.sciencedirect.com/science/article/abs/pii/S0013935118304973
Dropbox Link: https://www.dropbox.com/s/nqzowjpfyvsn4fu/Melnick%20Study.pdf?dl=0

> "The animal data are relevant and useful for assessment of human health risks."

March 15, 2021 - Expert Report by Former U.S. Government Official Concludes High Probability Radio Frequency Radiation Causes Brain Tumors
https://www.saferemr.com/2021/03/expert-report-by-former-us-government.html

> "Christopher J. Portier, Ph.D., former director of the National Center for Environmental Health at the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR), and a scientific advisor for the World Health Organization (WHO), recently completed an expert report on brain tumor risk from exposure to radio frequency (RF) radiation used in cellphone technology.
>
> After completing a comprehensive review of the scientific literature, Dr. Portier concluded:
>
> > 'In my opinion, RF exposure probably causes gliomas and neuromas and, given the human, animal and experimental evidence, I assert that, to a reasonable degree

> of scientific certainty, the probability that RF exposure causes gliomas and neuromas is high.'"

April 24, 2019 - Dr. Shuren sends a letter to the FCC regarding FCC ET Docket No's 03-137, 13-84 and 19-226 reassessment and changes to FCC Radiofrequency Exposure Limits and Policies. https://ecfsapi.fcc.gov/file/10815418118189/13-84.pdf

> "…As a part of our ongoing monitoring activities, we have reviewed the results and conclusions of the recently published rodent study from the National Toxicology Program in the context of all available scientific information, including epidemiological studies, and concluded that no changes to the current standards are warranted at this time. As we have stated publicly, NTP's experimental findings should not be applied to human cell phone usage, that the available scientific evidence to date does not support adverse health effects in humans due to exposures at or under the current limits…"

August 8, 2019 - In a Press Release, FCC Chairman Ajit Pai states:
https://docs.fcc.gov/public/attachments/DOC-358968A1.pdf

> "As Jeffrey Shuren, Director of the Food and Drug Administration's Center for Devices and Radiological Health, wrote to the FCC, '[t]he available scientific evidence to date does not support adverse health effects in humans due to exposures at or under the current limits...' and '[n]o changes to the current standards are warranted at this time.'"

December 4, 2019 - FCC terminates ET Docket No. 03-137, ET Docket No. 13-84 and resolve ET Docket No. 19-226 that were to decide whether to reassess Radiofrequency Human Exposure Limits and Policies:
https://docs.fcc.gov/public/attachments/FCC-19-126A1.pdf

> "First, we resolve a Notice of Inquiry that sought public input on, among other issues, whether the Commission should amend its existing RF emission exposure limits. After reviewing the extensive record submitted in response to that inquiry, we find no appropriate basis for and thus decline to propose amendments to our existing limits at this time. We take to heart the findings of the Food & Drug Administration (FDA), an expert agency regarding the health impacts of consumer products, that "[t]he weight of scientific evidence has not linked cell phones with any health problems."

Appendix 6:

Key scientific studies and reports excluded from the *FDA* report.

The following are studies excluded from the FDA *Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and Cancer report, February 2020*, that was presented to the public and the FCC as a comprehensive assessment of cell phone safety. It was criticized for both not being a complete risk assessment because it only looked at cancer, and for failing to consider other critical outcomes such as biological effects, genetic effects, reproductive effects, immune system effects and neurological effects which the science points to.

The report was also criticized because it did not take into consideration other wireless devices, cumulative exposures, and effects on vulnerable populations as well as other factors. See below a critical review of the report written by Victor Leech, Radiation Health Physicist, Oceania Radiofrequency Scientific Association (orsaa.org).**Victor Leach of ORSAA: Critical Review of the FDA 2020 Report** https://ecfsapi.fcc.gov/file/10916520207299/Victor Leach of ORSAA Critical review of the FDA 2020 Report_BRHP.pdf

Arbitrarily, Dr. Shuren chose to focus on the scientific evidence between 2008 to 2018 for no apparent scientific reason, even though our safety limit regulations date back to 1996. The following provides highlights of some of the other relevant studies completed before 2008 and those focusing on other effects.

Dr. Shuren's assessment included a limited number of studies that appear to be carefully chosen. I encourage investigators to look at the public comments uploaded to the FCC website FCC website Docket 13-84 and Docket 19-226 where thousands of studies, relevant government reports, and news articles related to wireless effects are posted along with hundreds of formal testimonies from Americans across the country unnecessarily suffering from wireless radiation health effects.

Docket 13-84:
https://www.fcc.gov/ecfs/search/filings?sort=date_disseminated,DESC&proceedings_name=13-84
Docket 19-226:
https://www.fcc.gov/ecfs/search/filings?proceedings_name=19-226&sort=date_disseminated,DESC

Further, court case EHT et al v. FCC, which specifically focuses on the scientific evidence, not considered by the FCC in reviewing their safety limits. The FCC decided to close the dockets, which were to reassess the wireless safety limits due to Dr. Shuren's input. https://ehtrust.org/5g-wireless-harms-lawsuit-against-the-fcc-eht-et-al-v-fcc/

Studies

Powerwatch – An Independent Academic Forum of Scientists, Engineers and Medical Researchers focused on Electromagnetic Field Effects – 95 page list of 1,600 studies showing effects from various wireless sources 1979-2018 http://bit.ly/PowerWatch1670

SaferEMR.com - Joel M. Moskowitz, Ph.D., Director, Center for Family and Community Health, School of Public Health, University of California, Berkeley - Key Cell Phone Radiation Research Studies
https://www.saferemr.com/2016/08/key-cell-phone-radiation-research.html

Scientific Evidence of Harm from Cell Phone Radiation: Two Years of Research
https://www.saferemr.com/2018/08/cellphonestudies2years.html

Henry Lai Ph.D, Professor Emeritus, Department of Bioengineering, University of Washington, Research Summaries:
https://bioinitiative.org/research-summaries/

"These are invaluable sets of abstracts (data-based to be searchable) covering the RFR scientific literature, as well as collections of scientific abstracts on oxidative effects (from both RFR and ELF), and a set specific to Electrohypersensitivity. New comet assay abstracts for RFR and ELF are added in 2017.

1. RFR Research Summary (1990-2017)
2. ELF-EMF_Static Field Free Radical (Oxidatve Damage) Abstracts (2020)
3. RFR Free Radical (Oxidative Damage) Abstracts (2020)
4. Table 1 RFR Comet Assay Studies (2020)
5. Genetic Effects of Non-Ionizing EMF Abstracts (2020)
6. Table 2 Static Field_ELF-EMF Comet Assay Studies (2020)
7. RFR Neurological Effects Abstracts (2020)
8. Electrohypersensitivity Abstracts (2017)
9. ELF-EMF/Static Field Neurological Effects Abstracts (2019)
10. Free Radical Studies – Percent Comparison, 2020
11. Comet Assay Studies – Percent Comparison, 2020
12. Genetics Percent Graphic Sept 1, 2020
13. Neurological Effects Studies Percent Comparison 2020"

EPA: Index Of Publications On Biological Effects Of Electromagnetic Radiation (0-100 GHz)

NIH, NIEHS, National Toxicology Program Cell Phone Study
https://www.niehs.nih.gov/health/topics/agents/cellphones/index.cfm

US Naval Medical Research Institute: BIBLIOGRAPHY OF REPORTED BIOLOGICAL PHENOMENA ('EFFECTS') AND CLINICAL MANIFESTATIONS ATTRIBUTED TO MICROWAVE AND RADIO-FREQUENCY RADIATION
Click HERE for Navy Report 1 (122 symptoms identified 2300 studies cited)
Click HERE for Naval Report 2 (3700 studies identified showing effects)

Blue Cross Blue Shield
https://www.bcbs.com/press-releases/blue-cross-blue-shield-association-study-finds-millennials-are-less-healthy

https://www.bcbs.com/the-health-of-america/reports/the-health-of-millennials

Expert Report by Former U.S. Government Official Concludes High Probability Radio Frequency Radiation Causes Brain Tumors

Christopher J. Portier, Ph.D., former director of the National Center for Environmental Health at the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR), and a scientific advisor for the World Health Organization (WHO), recently completed an expert report on brain tumor risk from exposure to radio frequency (RF) radiation used in cellphone technology.

https://www.saferemr.com/2021/03/expert-report-by-former-us-government.html

Appendix 7

Letters to Congress from *FDA* and *FCC* officials justifying their 'no-action' positions regarding wireless technology standards and risks

Letter from Congresswoman Eshoo and Senator Merkley to Dr. Shuren requesting a summary of the research and methodologies used by the FDA to conclude that cell phones are safe - July 18, 2019
https://mdsafetech.files.wordpress.com/2019/10/eshoo-merkley-letter-to-fda-re-rf-emissions-copy.pdf

Response letter from Dr. Shuren to Congresswoman Eshoo and Senator Merkley - Sept 9, 2019
https://mdsafetech.files.wordpress.com/2020/03/fda-shuren-letter-to-eshoo-re-cell-phone-rf-safety-sept-9-2019-.pdf

Letter from Senator Blumenthal and Congresswoman Eshoo to FCC Chairman Pai with questions regarding the health and safety of workers near cellular antennas due to exposure of radiofrequency (RF) radiation over the FCC exposure limit – August 15, 2017
https://docs.fcc.gov/public/attachments/DOC-347543A2.pdf

Response from FCC Chairman Pai to Senator Blumenthal and Congresswoman Eshoo – October 15, 2017
https://docs.fcc.gov/public/attachments/DOC-347543A1.pdf

Letter from Senator Blumenthal and Congresswoman Eshoo to FCC Commissioner Carr posing questions regarding Commissioner Carr's recent remarks on safety of 5G technology – December 3, 2018
http://electromagnetichealth.org/wp-content/uploads/2018/12/IMG_20181203_0002.pdf

Response of Commissioner Carr to Senator Blumenthal and Congresswoman Eshoo – December 17, 2018
https://www.blumenthal.senate.gov/imo/media/doc/2018.12.17%20FCC%20Carr%20to%20Blumenthal%20and%20Eshoo%20re%20RF%20Safety.pdf

Letter from Congressman DeFazio to FCC Chairman Pai and Acting Commissioner Sharpless to inquire about the status of the Federal Government research into the potential health effects of radiofrequency radiation and related issues – April 15, 2019
https://docs.fcc.gov/public/attachments/DOC-357620A2.pdf

Response from FCC Chairman Pai to Congressman DeFazio – April 30, 2019
https://docs.fcc.gov/public/attachments/DOC-357620A1.pdf

Letter from Congressman Defazio to FCC Chairman Pai asking for a response that provides answers to his specific questions posed by his previous letter – May 29, 2019
https://docs.fcc.gov/public/attachments/DOC-359365A2.pdf

Response from FCC Chairman Pai to Congressman DeFazio – August 21, 2019
https://docs.fcc.gov/public/attachments/DOC-359365A1.pdf

Letter from Congressman DeFazio and Congressman Suozzi to FCC Chairman Pai questioning the FCC's decision to maintain the 23-year-old radiofrequency (RF) radiation exposure limits- September 13, 2019
https://docs.fcc.gov/public/attachments/DOC-362706A1.pdf

Response letter from FCC Chairman Pai to Congressman Defazio and Congressman Suozzi – February 21, 2020
https://docs.fcc.gov/public/attachments/DOC-362706A2.pdf

Letter from Congressman Suozzi to FCC Chaiman Pai to express the concern of constituents and local officials regarding possible detrimental health effects of radiofrequency radiation emitted by 5G – April 16, 2019
https://docs.fcc.gov/public/attachments/DOC-357620A5.pdf

Response of FCC Chairman Pai to Congressman Suozzi – April 30, 2019
https://docs.fcc.gov/public/attachments/DOC-357620A4.pdf

Letter from Congressman Lipinsky to FCC Chairman Pai to request information about research studies used by the FCC in the agency's decision-making regarding radiofrequency (RF) exposure safety standards– November 19, 2019
https://docs.fcc.gov/public/attachments/DOC-362706A3.pdf

Response of FCC Chairman Pai to Congressman Lipinsky – February 21, 2020
https://docs.fcc.gov/public/attachments/DOC-362706A4.pdf

Letter from Congressman Kim to FCC Commissioner Pai regarding the FCC's Accelerating Wireless Broadband Deployment by Removing Barriers to Infrastructure Investment order– March 28, 2019
https://docs.fcc.gov/public/attachments/DOC-357620A6.pdf

Response from FCC Chairman Pai to Congressman Kim – April 30, 2019
https://docs.fcc.gov/public/attachments/DOC-357620A3.pdf

Chairman Pai's Letters to Congress
https://www.fcc.gov/chairman-letters-congress

Appendix 8:

Factual determinations regarding ignored personal conflicts of interest in Dr. Shuren's executive functions, including illegal dealings with his wife's law firm.

The legal practice of Jeffrey Shuren's wife Alison Shuren seems to constitute a conflict of interest as defined by FDA's department policy, the Office of Government Ethics policy (5 C.F.R. § 2635.502), Guidance and Criminal Code (18 U.S.C.§ 207, 18 U.S.C. § 208) as listed below. As part of his position as Director, Center for Device and Radiological Health, Dr. Shuren is required to give advice and guidance regarding the health and safety of cell phones as per their website: "the FDA shares regulatory responsibilities for cell phones with the Federal Communications Commission (FCC)." The conflict of interest arises because Allison Shuren is a Partner in the law firm of Arnold and Porter who as advertised has a booming telecom practice. The firm has managed more than $200 billion in transactions for AT&T – a client whose business interests would be impacted if Dr. Shuren were to report the risks of cell phone use and warn the public of possible adverse effects from cell phones. Arnold and Porter has a long relationship with the wireless industry, exemplified by the fact that the firm was co-founded by former Chairman of the FCC, Paul Porter.

Transactions, Mergers & Acquisitions, Bankruptcy
https://www.arnoldporter.com/en/services/capabilities/practices/telecommunications-internet-and-media/transactionsmergers--acquisitionsbankruptcy

> **"We played a lead role in every transaction undertaken by AT&T (formerly SBC) since the passage of the 1996 Telecommunications Act. In these large projects, we prepared the FCC regulatory approval papers, which included the major Public Interest Statements and myriad other pleadings needed to gain FCC approval for the mergers. In this regard, we advised the client on framing the regulatory issues, developed supporting arguments, and prepared responses and rebuttals to the many opposing parties. We worked with teams of other lawyers and economists to help gain DOJ and state approvals as well. Globally, in the Cingular/AT&T Wireless, SBC/AT&T, and AT&T/BellSouth transactions, we secured all the necessary regulatory and competition approvals and prepared all the requisite governmental notifications coordinating the work of local counsel in various countries as appropriate. We were responsible for obtaining local approvals for cable television franchise transfers that were involved in the Ameritech and BellSouth mergers. We also assisted with due diligence across the many areas of our experience."**

https://www.arnoldporter.com/en/services/capabilities/practices/telecommunications-internet-and-media/transactionsmergers--acquisitionsbankruptcy
*Note - This link use to go to the information below. See this additional link for previous source information:
https://www.dropbox.com/sh/ti5mpnjq5ovd56c/AADRRpMky2L5p2uQ3m3p4l47a?dl=0

“SBC Communications (1996 – 1997)
Our attorneys represented SBC in its acquisition of Pacific Telesis Group (the Regional Bell Operating Company serving California and Nevada). This transaction was the first RBOC merger following the Telecommunications Act of 1996 and began the consolidation that has transformed the telecommunications industry over the past decade. This merger also was the first of the series that had led to the new AT&T Inc.

SBC Communications (1998 – 1998)
Our attorneys represented SBC in its acquisition of Southern New England Telecommunications Corporation (the telephone company serving most of Connecticut). We obtained prompt approval from the Federal Communications Commission and clearance from the Department of Justice under the Hart-Scott-Rodino statute.

SBC Communications (1998 – 1999)
Our attorneys represented SBC in Ameritech Corporation (the Regional Bell Operating Company serving Illinois, Indiana, Michigan, Ohio, and Wisconsin). In this landmark transaction, SBC substantially expanded its wireline and wireless service areas. After hotly contested proceedings, we obtained approval from the Federal Communications Commission and clearance from the Department of Justice under the Hart-Scott-Rodino statute.

AT&T Inc.
Our attorneys represent AT&T Inc. on spectrum transactions including the divestiture of BellSouth's 2.5 GHz assets to Clearwire.

AT&T Inc.
Our attorneys have counseled AT&T and other clients on the FCC's spectrum leasing rules. In addition, we have negotiated spectrum leases and management agreements to enable parties to use spectrum licensed to other parties consistent with the FCC's rules on unauthorized transfers of control.

SBC Communications (2000 – 2000)
Our attorneys represented SBC in the joint venture of SBC's wireless business with BellSouth Corporation's wireless business to form Cingular Wireless LLC (now AT&T Mobility LLC). This transaction transformed SBC and BellSouth's wireless business from largely regional coverage to a combined carrier with near-nationwide coverage. As a result, Cingular has been able to offer nationwide calling plans and was positions to be one of the few largest wireless companies in the country.

Cingular Wireless (2000 – 2003)
Our attorneys helped Cingular Wireless LLC (now AT&T Mobility LLC) to structure its joint venture with Salmon PCS LLC to qualify as a "designated entity" for bidding on

PCS licenses in FCC Auction #35. Auction #35 was the first auction of PCS spectrum since the Commission amended its designated entity rules to adopt the "controlling interest" standard to determine which applicants qualify as designated entities eligible for bidding credits and other auction preferences.

Cingular Wireless (2004 – 2004)
Our attorneys represented SBC Communications and Cingular Wireless in obtaining telecommunications and approval in the US for Cingular's $41-billion acquisition of AT&T Wireless Services, Inc., the largest all-cash deal in US history. The engagement included the transfer of control, spectrum, and competition reviews in multiple countries. As a result of this transaction, Cingular became the largest US wireless carrier.

SBC Communications (2005 – 2005)
On a landmark transaction heralding a new era for the telecommunications industry, SBC Communications Inc. completed its US$16-billion acquisition of AT&T Corp. on November 18, 2005, forming the new AT&T Inc. Our attorneys assisted SBC in this landmark transaction, as the firm has in all of SBC's previous major mergers, including its acquisitions of Pacific Telesis, Ameritech, and SNET; the combination of SBC's and BellSouth's wireless businesses to form Cingular Wireless; and Cingular's US$41-billion acquisition of AT&T Wireless.

AT&T Inc. (2006 – 2006)
Our attorneys represented AT&T (formerly SBC) in its $89-billion acquisition of BellSouth Corporation (the Regional Bell Operating Company serving Alabama, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, and Tennessee). This transaction unified the ownership of Cingular Wireless and heralded new advances in the integration of wireless and wireless communications services. Our attorneys helped AT&T obtain approval from the Federal Communications Commission and the Department of Justice, as well as approvals or clearances from competition and regulatory authorities in a number of countries. The firm also handled the national security and government contracts issues associated with the acquisition.

AT&T Inc. (2007 – 2009)
Our attorneys represented AT&T Inc. before the Department of Justice in obtaining antitrust clearance for its acquisition of Dobson Communications Corp., a US regional wireless telecommunications provider. We negotiated limited divestitures with the DOJ that allowed the transaction to close promptly.

AT&T Inc. (2008 – 2009)
Our attorneys represented AT&T Inc. before the Department of Justice in obtaining antitrust clearance for its acquisition of Centennial Communications, a US regional wireless and wireline telecommunications provider.

AT&T Inc. (2013 – 2013)
Our attorneys represented AT&T on the regulatory and antitrust review of AT&T's US $780 million acquisition of Atlantic Tele-Network, Inc.'s US retail wireless operations (known as Allied Wireless), including licenses, network assets, retail stores, and approximately 585,000 subscribers. Atlantic Tele-Network, Inc.'s network covers approximately 4.6 million people in rural areas across six states.

AT&T Inc. (2008 – 2009)
Our attorneys represented AT&T Inc. before the Department of Justice in obtaining antitrust clearance for its acquisition of Centennial Communications, a US regional wireless and wireline telecommunications provider.

AT&T Inc. (2015)
Our attorneys represented AT&T in its US$48.5 billion merger with DIRECTV. The firm acted as lead Federal Communications Commission counsel on competition and regulatory issues and participated actively in the US Department of Justice antitrust review process. Our Washington and London offices also handled the Latin American regulatory and competition approvals for AT&T.

Numerex Corp (2017)
Our attorneys advised Numerex Corp., a publicly traded provider of enterprise solutions enabling the Internet of Things, in its stock-for-stock merger with Sierra Wireless, Inc., a Canadian company and leading provider of fully integrated device-to-cloud solutions for the IoT."

$85 billion Merger between AT&T and Time Warner:
https://www.compasslexecon.com/cases/compass-lexecon-clients-att-and-time-warner-prevail-in-historic-merger-case/

Telecommunications, Internet & Media
https://www.arnoldporter.com/en/services/capabilities/practices/telecommunications-internet-and-media

"Business and Technical Savvy: Our in-depth understanding of our clients' business imperatives and technology enables us to develop and execute on practical legal strategies and tactics.

Enduring Client Relationships: We have advised AT&T and its predecessor SBC Communications for more than 25 years, successfully guiding the organizations through regulatory approvals for dozens of business-transformative transactions.

Well Connected With the Government: Our team includes attorneys who have held senior positions dealing with communications policy in government agencies such as the DOJ, CIA, NSA, and FTC.

Key Read: "Team Telecom" Revamp: New Executive Branch Process for Reviewing Foreign Participation in US Telecom Sector

Experience Highlights

AT&T, as regulatory counsel, in matters related to FCC conditions on its acquisition of DIRECTV in 2015, including the preparation of semi-annual compliance reports to the FCC.

Private equity firm in monitoring and advising on the federal regulatory issues related to Ligado Networks' spectrum license to use L-band spectrum to build a terrestrial wireless network.

L3 Technologies Inc., as FCC regulatory counsel, in its merger with Harris Corporation.

AT&T, as antitrust and regulatory counsel, in leading the effort to obtain US Department of Justice clearance for the $85 billion AT&T-Time Warner merger: successful defense of the Department of Justice's lawsuit to block the transaction; and the coordination of work with local antitrust and regulatory counsel to secure approvals in nearly 30 other countries, including the negotiation of conditional approvals in Brazil, Chile and Mexico. KCETLink Media Group, as lead FCC counsel, in a merger between KCETLink Media Group and PBS SoCal, the two primary PBS stations in the central and southern California markets.

AT&T, as antitrust and regulatory counsel, in leading the effort to obtain US Department of Justice clearance and Federal Communications Commission approval for the sale of its Puerto Rico and US Virgin Island assets to Liberty Latin America.

Leading cloud communications services provider in advising on telecommunications regulations.

Ad hoc group of term lenders to iHeartMedia Inc. in the restructuring of approximately $20 billion of debt issued by iHeartMedia and its affiliates.

Ad hoc group of first lien lenders to Cumulus Media Inc. in the restructuring of the radio, media and special event company.

Technology company in advising on 5G wireless standard matters.”

Wireless
https://www.arnoldporter.com/en/services/capabilities/industries/technology-media-telecommunications/telecommunications/wireless-satellite-spectrum-services

> "Our Telecommunications, Internet & Media team helps clients both drive and take advantage of the dramatic and continuing changes in the way wireless spectrum is used and regulated. We represent clients before the FCC, other government agencies, Congress, and the courts; offer counseling and strategic advice; and assist with both routine and complex transactions. For example, we have counseled clients on participation in FCC spectrum auctions; advised on compliance with FCC rules governing wireless services; developed the structure for a joint venture to qualify as a designated entity for bidding purposes; and represented clients on spectrum transactions, including transfers, leases, and management agreements. Whether our clients are seeking to reshape the laws and regulations in this area, to comply efficiently with those already on the books, or to find spectrum for a new service, our experience and skills enable us to complete simple projects efficiently and to devise creative solutions to more complex problems.
>
> We have represented wireless licensees since the Commission first allocated spectrum for cellular service, and our ranks include a former Chief of the FCC's Common Carrier Bureau, responsible for licensing and regulation of commercial wireless providers, and a former Chief of the Communications and Finance Section and a former Deputy Assistant Attorney General of the Antitrust Division, which is responsible for the Department of Justice's review of all wireless transactions and industry conduct."

Telecommunications
https://www.arnoldporter.com/en/services/capabilities/industries/technology-media-telecommunications/telecommunications

> "Arnold & Porter's Telecommunications, Internet & Media team practices where law, technology and the marketplace are unsettled. Since the firm's founding by Paul Porter, a former Federal Communications Commission chairman, our team has provided strategic counsel and found creative ways to help our clients achieve their goals. In addition to guiding companies through some of the largest mergers in the industry, our attorneys advise both terrestrial wireless and satellite carriers in novel spectrum transactions, **counsel clients on obtaining favorable regulatory treatment for new technologies**, provide regulatory advice to lenders and investors, and advise media clients on First Amendment and regulatory issues. We bring the benefits of a seasoned telecommunications team with the coordinated resources of a global firm."

According to FDA website, FDA shares responsibility for regulating cell phones

FDA Website

https://www.fda.gov/radiation-emitting-products/home-business-and-entertainment-products/cell-phones

"**Cell Phones**
The FDA shares regulatory responsibilities for cell phones with the Federal Communications Commission (FCC). 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 radiofrequency energy by cell phones and similar wireless products.
- Collecting, analyzing, and making available scientific information on the nature and extent of the hazards and control of electronic product radiation.
  -For example, the FDA provides information for the public about the radio frequency energy emitted by cell phones."

FCC Website
https://www.fcc.gov/consumers/guides/wireless-devices-and-health-concerns

"Wireless Devices and Health Concerns
Many federal agencies have considered the important issue of determining safe levels of exposure to radiofrequency (RF) energy….

For example, the FDA has issued guidelines for safe RF emission levels from microwave ovens, has reviewed scientific literature of relevance to RF exposure (see fda.gov/media/135043/download), and continues to monitor exposure issues related to the use of certain RF devices such as cell phones**."**

According to our research, there is an apparent conflict of interest because Jeffrey Shuren benefits from the fruits of Allison Shuren's legal practice that involves the FDA and the wireless industry.

18 U.S.C. § 208 - U.S. Code - Unannotated Title 18.
Crimes and Criminal Procedure § 208. Acts affecting a personal financial interest
https://codes.findlaw.com/us/title-18-crimes-and-criminal-procedure/18-usc-sect-208.html

"(a) Except as permitted by subsection (b) hereof, whoever, being an officer or employee of the executive branch of the United States Government, or of any independent agency of the United States, …participates personally and substantially as a Government officer or employee, through decision, approval, disapproval, recommendation, the rendering of advice, investigation, or otherwise, in a … request for a ruling or other determination, … in which, to his knowledge, he, his spouse, minor child, general partner, organization in

which he is serving as officer, director, trustee, general partner or employee, or any person or organization with whom he is negotiating or has any arrangement concerning prospective employment, has a financial interest—"

Office of Government Ethics 84 x 3 -- 03/19/84
Letter to an Employee dated March 19, 1984
https://www2.oge.gov/web/oge.nsf/All%20Documents/6FE48053B4617D9D85257E96005FBBF6/$FILE/591edf99ba58486ca90b123dd6eca9412.pdf?open

"18 U.S.C. § 207(g) prohibits a partner of a Federal employee from acting as an agent or attorney for anyone other than the Government on any official matter in which the employee has personally and substantially participated or which is the subject of his or her official responsibility."

United States Office of Government Ethics - Memorandum
To: Designated Agency Ethics Officials
From: Stephen D. Potts, Director
Subject: Recusal Obligation and Screening Arrangements - April 26, 1999
https://www2.oge.gov/web/oge.nsf/All Documents/040610F38BD3682485257E96005FBD62/$FILE/do-99-018.pdf?open

"RECUSAL
Under 18 U.S.C. § 208, an employee is prohibited from participating personally and substantially in any particular matter that would have a direct and predictable effect upon an employee's own financial interest or upon the financial interests of other persons or organizations specifically designated in the statute. Adherence to the statute is accomplished by not participating in the particular matter.

Under 5 C.F.R. § 2635.502, an employee is required to consider whether the employee's impartiality would reasonably be questioned if the employee were to participate in a particular matter involving specific parties where persons with certain personal or business relationships with the employee are involved. If the employee determines that a reasonable person would question the employee's impartiality, or if the agency determines that there is an appearance concern, then the employee should not participate in the matter unless he or she has informed the agency designee of the appearance question and received authorization from the agency. Otherwise an employee "shall not participate" in the matter as provided under 5 C.F.R. § 2635.502(e). Adherence to the regulation is accomplished by not participating in the particular matter involving specific parties…

Employees who reduce to writing an intent to recuse and list specific interests that will trigger recusal should understand the continuing need to update that document whenever relevant changes occur such as a change in the conflicting interest, a change in duties or

work assignments, a promotion or other change in position. Changes such as acquisition of a new asset or changes relating to a spouse's employment may also affect a recusal. For example, if a spouse has clients who have matters that may come before the employee and those clients are identified in a written recusal document, that list should be regularly updated. In some situations, changes may be so significant that a commitment to recuse is no longer a viable remedy. For example, a corporation in which an employee owns stock may increase its activity with the Government to such an extent as to require frequent abstention from matters critical to the performance of the employee's duties. Some other remedial action may then be necessary to deal with the potential conflict…

I must not participate in any particular matter involving specific parties where I or the agency designee have concluded that the financial interest of a member of my household, or the role of a person with whom I have a covered relationship, is likely to raise a question in the mind of a reasonable person about my impartiality**."**

FDA Advisory Committees: Financial Conflicts of Interest Overview
https://www.fda.gov/media/87421/download

"Financial interests include anything currently held that can financially impact the SGE (Special Government Employee) or the interests of others with whom the SGE has a certain relationship, including the SGE's spouse, minor children, business partners, employer, and organizations in which the individual serves as officer, director, or trustee.
– Examples include:
• Stocks;
• Bonds;
• Interests through ownership, partnership, LLC; • Consulting arrangements;
• Grants or contracts; and
• Employment."

In another case, where the wife of an officer of the court worked at Arnold and Porter, the judge recused himself from the matter. We expect Dr. Shuren to recuse himself from all matters regarding the health and safety of cell phones and other wireless devices.

US: Meet the judge in antitrust case against AT&T-Time Warner
https://www.competitionpolicyinternational.com/us-meet-the-judge-in-antitrust-case-against-att-time-warner/

"The case had been assigned to Judge Christopher Cooper, an Obama-appointee, but was switched to Leon's courtroom less than two hours later. The court did not provide a

reason for the reassignment, however, Cooper's wife works at the law firm Arnold & Porter, which is lead counsel for AT&T on antitrust issues, posing a potential conflict."

Why I'm challenging the FCC about antiquated safety standards for wireless devices
https://www.washingtontimes.com/news/2021/feb/23/why-im-challenging-the-fcc-about-antiquated-safe

In sum, Dr. Shuren has been criticized for not properly assessing the risks of cell phones and other wireless devices, not warning the public of possible effects, and not initiating traditional steps of risk management which are the responsibility of the FDA since "The FDA shares regulatory responsibilities for cell phones with the Federal Communications Commission (FCC)." In addition, Dr. Shuren seems to have extended himself to minimize and explain away the risks, resulting in industry friendly decisions by the FCC regarding wireless health and safety and encouraging the public not to take precautions.

At the very least, Dr. Shuren should recuse himself from all input and decision making regarding cell phone and other wireless devices health and safety because of his multiple conflicts of interest. Of particular concern is his wife being a partner at the Arnold & Porter law firm, which enjoys a long-standing, substantial, relationship with AT&T. It is also clear that his press release regarding the National Toxicology Program Cell Phone study, his statement regarding the adequacy of the wireless safety guidelines sent to the FCC regarding FCC Docket 13-84 & 19-226, and his Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and Cancer should be formally retracted and the public dually notified.

Evidence of serious consequences of personal injury to unsuspecting private citizens continues to grow as evidenced by the recognition by the World Health Organization that these types of environmental exposures are troublesome. To wit, the WHO'S International Classification of Diseases has recognized that there are related medical conditions, and the WHO'S International Agency for Research on Cancer has designated cell phones as possible carcinogens. Dr. Shuren has exhibited a pattern of continual disregard for the entire body of scientific evidence of biological and health effects from wireless device exposure. He and the office directed by him have not engaged legally mandated public health protection steps and, because of these continued lapses, it is clear that he either chose to not do his job over his 11-year tenure, or is incapable of doing it. In either case, he has put the American public in potential grave danger.

For these lapses, at minimum he should be investigated and perhaps held accountable for the injuries his actions may have caused members of the public. In our investigation, we identified hundreds of personal claims submitted to the FCC in Docket 13-84 & 19-226 from Americans across the country. There are also dozens of plaintiffs in the $1.9 billion Murray vs. Motorola cell phone brain tumor litigation, which has been moving through DC Superior Court.

Note: Your office can find more information regarding Americans suffering from illness due to wireless emissions by searching additional terms and diagnosis that have been used such as microwave sickness, radiation sickness, electrosensitivity (ES), Electrohypersensitivity (EHS), Electromagnetic Sensitivity, Electromagnetic Radiation Hypersensitivity, and EMF Intolerance Syndrome

Testimonies of Sickness Due to Wireless FCC 13-84:
https://www.dropbox.com/sh/4pgcqbbnk9rdsks/AADxgDlWlkdLaeusjJqzG4zpa?dl=0
Testimonies of Sickness Due to Wireless FCC 19-226:
https://www.dropbox.com/sh/ckxun07vm2lnljp/AAB0Fglb0zAQbC4TfCzgzWcPa?dl=0

Appendix 9:

Professional credential inadequacies of Dr. Shuren as pertains to wireless technology risks and risk management

Dr. Jeffrey Shuren lacks the expertise in cell phone technology and risk management to make the statements he has regarding wireless radiation safety. See his biography information below from a variety of sources:

Source: Committee on Homeland Security and Governmental Affairs
https://www.hsgac.senate.gov/imo/media/doc/Bio%20and%20Remarks%20of%20Jeffrey%20Shuren%20FDA.pdf

> "Jeffrey Shuren, M.D., J.D., Director of the Center for Devices and Radiological Health at the U.S. Food and Drug Administration
>
> Dr. Jeffrey Shuren is currently the Director, Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA). Prior to becoming Director, Dr. Shuren served as Acting Director for the Center for Devices and Radiological Health. Previous to that, he held various policy and planning positions within FDA from 1998 to 2009, including Acting Deputy Commissioner for Policy, Planning, and Budget; Associate Commissioner for Policy and Planning; and Special Counsel to the Principal Deputy Commissioner. Dr. Shuren is board certified in Neurology and served as an Assistant Professor of Neurology at the University of Cincinnati. In 1998, he joined FDA as a Medical Officer in the Office of Policy. In 2000, he served as a detailee on the Senate HELP Committee. In 2001, he became the Director of the Division of Items and Devices in the Coverage and Analysis Group at the Centers for Medicare and Medicaid Services and then returned to FDA as the Assistant Commissioner for Policy in 2003, and assumed his current position in September 2009. Dr. Shuren received both BS and MD degrees from Northwestern University under its Honors Program in Medical Education and JD from the University of Michigan Law School.
>
> Dr. Shuren oversees the Office of the Center Director (OCD) which provides scientific, policy and managerial leadership and direction to the seven offices comprising the CDRH. OCD provides advice and consultation on policy matters about medical device and radiological health issues to the Commissioner and other FDA officials, Congress, the Department of Health and Human Services, the Public Health Service, other government agencies, the scientific and academic communities, and representatives of regulated industry. It communicates agency initiatives and guidance to consumers and industry in support of the public health. Other activities supported by OCD are the CDRH Ombudsman who investigates outside complaints and resolves disputes, and the Medical Device Fellowship Program."

Source: FDA Website
https://www.fda.gov/about-fda/fda-organization/jeffrey-shuren

"Dr. Jeffrey E. Shuren MD, JD
DIRECTOR - CDRH OFFICES: OFFICE OF THE CENTER DIRECTOR

Jeffrey E. Shuren became the director of the Center for Devices and Radiological Health at the Food and Drug Administration (FDA) in January 2010. He previously served as Acting Center Director, beginning in September 2009. The center is responsible for assuring the safety, effectiveness, and quality of medical devices; assuring the safety of radiation-emitting products (such as cell phones and microwave ovens); and fostering device innovation.

'Our center experts and programs help get safe and effective technology to patients and health care professionals on a daily basis,' says Dr. Shuren. 'Rapid technological advances enable us to approve such innovations as a diagnostic test for the H1N1 influenza virus, an expandable prosthetic rib for children with abnormal growth conditions, and a test that can help detect ovarian cancer.'

Dr. Shuren received his B.S. and M.D. degrees from Northwestern University under its Honors Program in Medical Education. He completed his medical internship at Beth Israel Hospital in Boston, his neurology residency at Tufts New England Medical Center, and a fellowship in behavioral neurology and neuropsychology at the University of Florida. He received his J.D. from the University of Michigan.

Dr. Shuren has held various policy and planning positions within FDA from 1998 to 2009, including acting deputy commissioner for policy, planning, and budget; associate commissioner for policy and planning; special counsel to the principal deputy commissioner; assistant commissioner for policy; and medical officer in the Office of Policy.

Dr. Shuren has served in a leadership role at FDA or on behalf of the agency on numerous initiatives, including

- reauthorization of the Medical Device User Fee Act, which dramatically shortens review times for device applications
- creation of the Sentinel Initiative, which works toward a national electronic system for monitoring medical product safety
- development of FDA's Pandemic Influenza Preparedness Strategic Plan
- development of FDA's Counterfeit Drug Task Force Report
- development of the Interagency Food Safety Working Report to the President
- implementation of FDA provisions of the Medicare Prescription Drug Improvement and Modernization Act
- development and implementation of the Interagency Import Safety Working Group's Report to the President: Action Plan for Import Safety

From 1999 to 2000, Dr. Shuren served as a detailee on Senator Edward Kennedy's staff on the Senate Health, Education, Labor, and Pensions Committee. From 1998 to 2003, he also was a staff volunteer in the National Institutes of Health's Cognitive Neuroscience Section where he supervised and designed clinical studies on human reasoning.

As director of the Division of Items and Devices, Coverage and Analysis Group at the Centers for Medicare and Medicaid Services, Dr. Shuren oversaw the development of Medicare national coverage determinations for drugs, biologics, and non-implantable devices."

Source: House Committee on Energy and Commerce
https://docs.house.gov/meetings/IF/IF14/20151117/104127/HMTG-114-IF14-TTF-ShurenJ-20151117.pdf

"Bio for Dr. Jeffrey Shuren, MD, JD

Jeff is a neurologist and attorney, currently serving as the Director of the FDA's Center for Devices and Radiological Health. He's been at CDRH since the Fall of 2009. Prior to that he held several policy positions in the agency, including acting Deputy Commissioner for Policy, Planning, and Budget, special counsel to the Principal Deputy Commissioner, and Associate Commissioner for Policy and Planning. Jeff has served as a division director in the Center for Medicare and Medicaid Services' Coverage and Analysis Group, a staff fellow in the National Institutes of Health's Cognitive Neuroscience Section, was on detail to Senator Ted Kennedy, and an Assistant Professor in the University of Cincinnati's Department of Neurology."

Source: Wikipedia
https://en.wikipedia.org/wiki/Jeffrey_Shuren

"Education

- B.S. in Medical Education, Northwestern University
- M.D. in Medical Education, Northwestern University
- Residency: Neurology, Tufts University School of Medicine
- Fellowship: University of Florida College of Medicine, Behavioral Neurology and Clinical Neuropsychology
- J.D., University of Michigan[1]"

Appendix 10:

History of decisions driven by Dr. Shuren showing deference to medical device companies regarding patient safety under his jurisdiction as Director of the Center for Devices and Radiological Health.

Our investigation shows the following:

It appears Dr. Shuren has been investigated by the FBI, the GAO, the International Consortium of Investigative Journalists, and plaintiff lawyers seeking compensation for injuries and deaths allegedly associated with his actions, including a lack of transparency with respect to notifications to medical doctors and the public.

There appears to be a conflict of interest with he and his family benefitting from his wife Allison Shuren's lucrative practice at Arnold and Porter where she is a partner. She is Co-Chair of the FDA/Healthcare Practice Group at the firm. There is definitely chatter among the medical and legal communities and community at large with respect to the conflict that we have identified in our investigation.

Most recently, Dr. Shuren has led efforts to greatly accelerate the approval process for certain classes of medical devices which has resulted in dangerous misclassification of devices and exemptions from testing that have led experts and former FDA officials to believe that public safety is not being adequately protected.

Under the creative concept programs supported by Dr. Shuren (MDIC/NEST) the burden of responsibility is shifted from both the FDA and the industry to this nebulous entity, which has no enforcement authority, and thus patients are not protected. The boards commingle federal regulators and subject industries creating a system of self-policing.

Included herein is documentation that we uncovered in our investigation regarding these conflicts:

F.B.I. Investigates Whether Harm From Surgical Power Tool Was Ignored
https://www.nytimes.com/2015/05/28/business/fbi-investigates-whether-harm-from-surgical-power-tool-was-ignored.html?_r=0

> "The Federal Bureau of Investigation has begun looking into whether medical device makers, doctors and hospitals broke the law by failing to report problems linked to a power tool used during gynecologic surgery....

In November, the Food and Drug Administration said that morcellators should no longer be used in 'the vast majority' of women. But **the agency did not take the devices off the market or ban their use."**

80,000 Deaths. 2 Million Injuries. It's Time for a Reckoning on Medical Devices.
https://www.nytimes.com/2019/05/04/opinion/sunday/medical-devices.html

"Patients suffer as the F.D.A. fails to adequately screen or monitor products…

In the past decade, seven companies have spent a collective **$8 billion to resolve more than 100,000 patient claims** — making litigation over vaginal mesh (or pelvic mesh, as it is sometimes called) one of the largest mass tort cases in United States history. As those lawsuits have made clear, most of these medical devices were approved for market with nearly no clinical data…

In the past decade, nearly two million injuries and more than 80,000 deaths have been linked to faulty medical devices, many approved with little to no clinical testing, according to **a global investigation by the International Consortium of Investigative Journalists**…

Companies need only to convince regulators that their products are similar to ones that are already approved, even if the other products are decades old or were subsequently pulled from the market. Eight years ago the **Institute of Medicine advised the F.D.A. to abolish at least one of these loopholes, what's known as the 510(k) pathway**. It's past time for the agency to heed that advice, and to ensure that no medical device intended for permanent residence inside a human body is used on patients without first being rigorously tested."

Hidden FDA Reports Detail Harm Caused By Scores Of Medical Devices
https://khn.org/news/hidden-fda-database-medical-device-injuries-malfunctions/

"The Food and Drug Administration has let medical device companies file reports of injuries and malfunctions **outside a widely scrutinized public database**, which leave doctors and medical sleuths in the dark…

The FDA has also **opened additional — and equally obscure — pathways** for device makers to report thousands of injuries brought to light by lawsuits or even deaths that **appear in private registries that medical societies use to track patients**. Those exemptions apply to risky and controversial products, including pelvic mesh and devices implanted in the heart.

FDA spokeswoman Deborah Kotz confirmed that **the "registry exemption" was created without any public notice or regulations**. **"Any device manufacturer can request an exemption from its reporting requirements,**" she said in an email.

Agency records provided to KHN show that more than **480,000 injuries or malfunctions were reported through the alternative summary reporting program in 2017 alone…**

The FDA is basically giving away its authority over device manufacturers," said Tomes, who now runs Device Events, a website that makes FDA device data user-friendly. "If they've given that up**, they've handed over their ability to oversee the safety and effectiveness of these devices**."

Millions of Reports on Medical Device Malfunctions and Injuries Discovered in Hidden FDA Database
https://drugsafetynews.com/2020/03/13/millions-of-reports-on-medical-device-malfunctions-and-injuries-discovered-in-hidden-fda-database/

"…the FDA introduced reporting exemptions permitting companies to compile their reports—hundreds at a time—into benign-looking **'alternative summaries.' The FDA would then file this document in a separate archive.**

…Adverse Events Stack Up At FDA; 2016 Warning Letter Data Show Troubles With MDRs, Complaints" called out evidence of underreporting of adverse events through Medical Device Reports (MDRs). The article reported that, at the time, more than 440,000 reports were submitted to the FDA via its Alternative Summary Reporting Program…"

When Jewett asked the FDA press office to simply update this number, they told her more than **one million Alternative Summary reports now existed**. This information encouraged Jewett to press forward with requests for specific data—which she eventually got, piece by piece, year by year.

From this data, Jewett penned a series of articles for *Kaiser Health News*, in which she revealed several alarming trends, including the following collections of reports:

- 500,000 breast-implant-related malfunctions or injuries
- 66,000 malfunctions connected to surgical staplers
- 50,000 events resulting from an implantable heart defibrillator"

Medical Device Failures Brought To Light Now Bolster Lawsuits And Research
https://khn.org/news/medical-device-failures-brought-to-light-now-bolster-lawsuits-and-research/

> "KHN's investigation prompted then-FDA commissioner Scott Gottlieb to pledge in a tweet to open the hidden data to the public. The agency **released all 5.7 million records** in June."

Breast implants tied to rare cancer to remain on US market
https://www.fox61.com/article/news/nation-world/breast-implants-tied-to-rare-cancer-to-remain-on-us-market/507-52e1beff-f3ec-4793-9f58-94e15331e99b

> "Ahead of a March meeting, the FDA revealed for the first time that it had received more than **350,000 reports related to breast implants over the last decade**. That was roughly seven times the number of reports visible in the agency's publicly searchable database, according to Madris Tomes, a former FDA staffer who founded a company to analyze medical device reports."

FDA's Shuren on Tightening Future FDA Review of High-Risk Devices
https://www.meshmedicaldevicenewsdesk.com/articles/fdas-shuren-tightening-future-fda-review-high-risk-devices

> "We know from **150,000 defective product lawsuits** filed over transvaginal mesh in the U.S. alone, that the agency failed in its mission to assure the safety of high-risk medical devices it cleared for market."

Women Sue Over Device to Stop Urine Leaks
https://www.nytimes.com/2009/05/05/health/05tape.html

> "Asked **why the agency would clear a product based on a recalled predecessor**, they replied, 'Any legally marketed device can serve as a predicate for a premarket submission.'"

F.D.A. Seeks to Tighten Regulation of All-Metal Hip Implants
https://www.nytimes.com/2013/01/17/business/fda-to-tighten-regulation-of-all-metal-hip-implants.html?_r=0"

> "But in the case of all-metal hips, the final classification never happened. Over the years, the F.D.A. started procedures to classify the implants but never completed them. Implant companies also lobbied the agency to classify all-metal hips as moderate-risk products rather than high-risk ones.
>
> The result was that device makers like Johnson & Johnson and Zimmer Holdings were able to start selling a new generation of all-metal hips a decade ago without running clinical tests…
>
> About 20 types of older medical devices still await reclassification.

In recent weeks, the first of thousands of patient lawsuits involving the most troubled all-metal device, an implant once sold by the DePuy division of Johnson & Johnson, have started to come to trial."

Dangerous medical implants and devices
Most medical implants have never been tested for safety
https://www.consumerreports.org/cro/magazine/2012/04/cr-investigates-dangerous-medical-devices/index.htm

"In 2011, a panel from the prestigious **Institute of Medicine said the FDA should overhaul its device regulatory system because it fails to ensure patient safety before and after products go on the market**…

The FDA believes "the program has served American patients well," says Jeffrey Shuren, M.D., director of the agency's Center for Devices and Radiological Health. 'As a responsible guardian of public health, the FDA believes it's a challenge to eliminate a program without having a better alternative.'

But an investigation by Consumer Reports, which included interviews with doctors and patients and an analysis of medical research and a device-safety database maintained by the FDA, shows the following areas of concern:

- **Medical devices often aren't tested before they come on the market**. "What they're doing is conducting clinical trials on the American public," says Dan Walter, a political consultant from Maryland. His wife was left with heart and cognitive damage from a specialty catheter, cleared without testing, that malfunctioned during a procedure to treat an abnormal heartbeat.
- **There's no systematic way for the government, researchers, or patients to spot or learn about problems with devices**. "A coffeemaker or toaster oven has a unique serial number so if a problem is found, the company can contact you to warn you. Your artificial hip or heart valve doesn't," Zuckerman says. "Your doctor is supposed to notify you of a problem but may not be able to if he has retired or passed away."
- **Without major changes in the system, there's not much that patients can do to protect themselves.**"

Allison Shuren – Conflict of Interest

CONFLICTS OF INTEREST
https://www.freedommag.org/magazine/201610-the-shocking-truth/cover-story/conflicts-of-interest.html

> "How ECT manufacturers and the FDA have been able to thumb their noses at one of the nation's most respected agencies is a story riddled with conflicts of interest that can surprise even the most dogged investigator.
>
> In January 2010, almost exactly a year after the GAO asked for proof of the safety and effectiveness of medical devices on the market, Jeffrey E. Shuren, an official who had held various policy and planning positions at the FDA, became director of the agency's Center for Devices and Radiological Health (CDRH). It just so happened that Shuren's wife, Allison Shuren, was—and still is—a partner at the Washington, D.C. office of the law firm Arnold & Porter, where she co-chairs the firm's FDA/healthcare practice group."

Arnold & Porter – Biography Arnold & Porter
Allison Shuren
https://www.arnoldporter.com/en/people/s/shuren-allison-w

> "Her clients include **large international manufacturers of medical devices**, pharmaceuticals, biologics, emerging companies with early stage concepts, hospitals and integrated health networks, ambulatory surgery centers, diagnostic testing facilities, clinical laboratories, dialysis centers, physicians, physician practice management companies, and **developers of mobile and digital health technology…** represents clients in government investigations and qui tam actions involving False Claims Act, Anti-Kickback Statute, Stark Law, and health care fraud allegations. She regularly interacts with the US Department of Health and Human Services Office of Inspector General, the US Department of Justice, and the Centers for Medicare and Medicaid Services."

Alison Shuren is Co-Chair of the Life Sciences Division at Arnold & Porter
Arnold & Porter – Role of Allison Shuren's Department
https://www.arnoldporter.com/en/services/capabilities/industries/life-sciences

> "Strategic Litigation Counsel: Viewed as "master strategists," our litigators have a well-established track record resolving large-scale, **high-stakes pharmaceutical and medical device disputes...**
>
> Major pharmaceutical and medical device companies in responding to critical regulatory matters, **including approval strategies**, inspections, investigations, FDA Advisory Committee meetings, dispute resolution proceedings, and litigation."

The Most Challenging Compliance Arena in Health Care: Pharmaceutical and Medical Device Manufacturing
https://www.arnoldporter.com/~/media/files/perspectives/publications/2017/08/the-most-challenging-compliance-arena-in-health-care.pdf

> "Compliance Professionals Can Take Steps to Better Prepare Themselves and Their Companies to Deal with Allegations of Wrongdoing
> **By Kirk Ogrosky / Allison W. Shuren "**

Biography Ophthalmology Innovation Summit
Allison Shuren, Partner Arnold & Porter –
https://ois.net/allison-shuren/

> "Her clients include **large international manufacturers of medical devices**, pharmaceuticals, and biologics; emerging companies with early-stage concepts; hospitals and integrated health networks; ambulatory surgery centers, diagnostic testing facilities; dialysis providers; physicians; physician practice management companies; **and developers of mobile and digital health technology**."

ARNOLD & PORTER>THE LEGAL 500 RANKINGS
https://www.legal500.com/firms/50060-arnold-porter/56211-palo-alto-usa/

> "The team is jointly led by FDA specialists Daniel Kracov and Allison Shuren…"

Linked In profile
Allison Shuren
https://www.linkedin.com/in/allison-shuren-aa271311?trk=people-guest_people_search-card

> **"Partner - Co-Chair FDA/Healthcare Practice Group Arnold & Porter Kaye Scholer"**

Chambers and Partners - Arnold & Porter
Allison W Shuren
https://chambers.com/lawyer/allison-w-shuren-usa-5:328489

> "She advises pharmaceutical, **medical device**, and biotechnology companies, **mobile health and health technology companies**, private equity groups, physician practice management companies and physician practices, ambulatory surgery centers, **diagnostic imaging centers**, clinical laboratories, and health care professional societies"

Shuren's Accelerated Approval of Devices

At FDA, a new goal, then a push for speedy device reviews
https://apnews.com/article/9f8ea03a4d324d1ba5585680d280804b

"And yet the next year, Shuren and his team adopted an approach that surprised even some of his closest colleagues: The FDA would strive to be **"first in the world"** to approve devices it considered important to public health.

The agency's shift mirrored the talking points of the $400 billion medical device industry — a lobbying behemoth on Capitol Hill — and ushered in a series of changes that critics say have allowed manufacturers to seek regulatory approval for high-risk devices using smaller, shorter, less rigorous studies that provide less certainty of safety and effectiveness.

Under Shuren, annual new device approvals have more than tripled, while warnings letters to device manufacturers about product safety and quality issues have **fallen roughly 80 percent, an Associated Press investigation found**.

The assortment of medical devices now on the market **includes spinal rods that can leave metal shards in children** and a nerve-zapping obesity implant that may not work for many patients.

The cheaper and faster medical device approvals began despite **multiple, high-profile safety problems** involving pelvic mesh, hip replacements and other implants…

Still, some current and former FDA officials are worried about the ambition to be first on approvals. They include Dr. Peter Lurie, who calls the agency's new direction "**an invitation to a race to the bottom for scientific standards"** seemingly prompted by industry pressure. **Lurie held senior posts at FDA from 2009 to 2017 and now heads the nonprofit Center for Science in the Public Interest…**

The philosophy of **"acceptable uncertainty"** is sometimes the price of making life-saving devices quickly available, according to the FDA. At the same time, it acknowledges its main system for tracking problems is riddled with "incomplete, inaccurate, untimely, unverified or biased data."

'So instead, you have devices of unknown benefit on the **market that still harm patients,' said Dr. Rita Redberg, a prominent medical researcher and cardiologist at the University of California San Francisco**. 'I do feel that the FDA sees their role as making industry happy and not as much protecting the public health"…

To win FDA approval, for example, most new prescription drugs undergo two large, rigorous clinical studies proving they benefit patients. But most new medical devices enter the market with no clinical trial testing.

Historically, more than 95 percent of FDA-reviewed devices on the market went through a streamlined process in which they need only show that they are **'substantially equivalent'** to a product already on the market…

The result, though, is that some medical products barely resemble the decades-old 'predicates' they reference in applying for FDA clearance. And **even when old devices have been linked to injuries or death, future products are allowed to reference them for approval** because the FDA lacks explicit legal authority to swiftly intervene…

One of the rationales FDA cites for accepting uncertainty in new device safety and effectiveness is **"patient preference,"** which holds that the agency should consider patient opinions in its approval decisions.

Former FDA regulators say Shuren has repurposed that idea to justify putting even more devices on the market.

Jeff tells wonderful stories in terms of 'We're doing this to make sure patients have this greatly improved technology,'" Foreman said. "But there's another side to it, too.

In recent years, **patient preference information** has been used to push approvals through the FDA's pathway for high-risk devices, even in a case where the manufacturer **failed to meet its own study goal.**"

Injured Device Patients Blitz CDRH's Shuren
http://fida-advocate.blogspot.com/2015/10/injured-device-patients-blitz-cdrhs.html

"This bifurcated effort was quickly joined by a third injured-patient campaign that co-opted Noorchashm's email template to the extent of demanding Shuren's resignation and the revocation of PMAs for LASIK-approved lasers.

As the forces were joining, the email campaign folded in a new element: Shuren's wife, Allison, was discovered to be a partner at **the heavily FDA-oriented law firm of Arnold & Porter, and she had medical device companies as clients**. Shuren was, therefore, "literally in bed with industry…"

Since the 2008 U.S. Supreme Court decision in Riegel v. Medtronic, **devices like Essure and the LASIK lasers that have PMAs have been preempted from state court product liability claims.** According to the Noorchashm-Reed template letter to Shuren, CDRH's "inability to properly consider the adverse consequences of nickel allergies and hypersensitivity in some [Essure] patients, as well as the evidence of fraud and data tampering at the time of this device's approval, renders this PMA status invalid. **These failures have very literally harmed thousands of young and otherwise healthy American women since 2002**."

Despite Protests, FDA Hangs Tough on LASIK
https://www.lasiknewswire.com/2015/09/despite-protests-fda-hangs-tough-on-lasik/

"….investigative report in the September issue of Consumers Digest and advising him that two more ex-FDA officials are now speaking out against LASIK: Former CDER ophthalmic division deputy director **Everett Beers, quoted in Consumers Digest as supporting Waxler's assertion that LASIK should not have been approved, and former medical device compliance director Larry Pilot, quoted in the same article as saying, 'When it comes to LASIK, it isn't that the agency has dropped the ball, it's that they never even moved it….'**

In 2008 your agency said you would reevaluate the safety of LASIK. It's been seven and one-half years, and nothing has changed except for the growing number of injured LASIK patients."

Dr. Shuren's Pattern of Effectively Deregulating for the Benefit of Industry

Medical Device Innovation Consortium (MDIC)
History
https://mdic.org/about/history/

"Building research collaborations in regulatory science.
The FDA's Center for Devices and Radiological Health (CDRH) and Medical Alley Association, formerly known as LifeScience Alley, Inc., a Minnesota trade association, executed a Memorandum of Understanding in December 2011 to work together to establish research collaborations in regulatory science.

Medical Alley Association filed Articles of Incorporation with the State of Minnesota in August 2012 to create an independent entity focused on advancing medical device regulatory science at an industry level."

Medical Device Innovation Consortium (MDIC)
Title: Project Manager
https://mdic.org/wp-content/uploads/2020/10/NESTcc-Project-Manager-Research.pdf

The Medical Device Innovation Consortium (MDIC) is the first-ever 501(c)3 public-private partnership created with the sole objective of advancing medical device regulatory science for patient benefit. As a membership based organization, MDIC brings together representatives of **the Food and Drug Administration (FDA)**, National Institutes of Health (NIH), Centers for Medicare & Medicaid Services (CMS), **industry,** non-profits, and patient organizations to improve the processes for development, assessment, and review of new medical technologies. **Our work is unique and complementary to trade associations such as the Advanced Medical Technology Association (AdvaMed) and the Medical Device Manufacturers Association**

(MDMA). Members of MDIC share a vision of providing U.S. patients with timely access to high-quality, safe and effective medical devices.
In September 2016, the FDA awarded a grant for the National Evaluation System for health Technology (NEST) Coordinating Center (NESTcc) to MDIC. The mission of NESTcc is the creation of structures for responsible sharing and efficient analysis of real-world evidence to inform and empower patients, accelerate medical device innovation, and improve health care outcomes. Stakeholders across the medical device ecosystem stand to benefit from improved use of real-world evidence (RWE) generated in the routine course of care.

Medical Device Innovation Consortium (MDIC)
Mission & Purpose
https://mdic.org/about/mission-purpose/

"Faster, safer, and more cost-effective innovation for patient benefit.
The Medical Device Innovation Consortium (MDIC) is the first-ever public-private partnership created with the sole objective of advancing medical device regulatory science for patient benefit. Formed in late 2012, MDIC brings together representatives of the FDA, NIH, CMS, industry, non-profits, and patient organizations to improve the processes for development, assessment, and review of new medical technologies. **Our work is unique and complementary to trade associations such as AdvaMed and MDMA.**"

Medical Device Innovation Consortium (MDIC)
Leadership
https://mdic.org/about/leadership/

"MDIC's Board of Directors consists of world-class representatives from the medical device industry, government, and patient groups who work together to advance the mission of the consortium.

- **Andrew Cleeland**, CEO | **Fogarty Institute for Innovation**
- **Steve Ferguson**, Chairman of the Board | **Cook Group Incorporated**
- **Rick Geoffrion**, President and CEO | **Cyrano Therapeutics, Inc.**
- **Pamela Goldberg**, MBA President and CEO | MDIC
- **Chip Hance**, CEO | **Regatta Medical**
- **Jijo James,** MD, MPH, Chief Medical Officer, Medical Devices | **Johnson & Johnson**
- **Tamara Syrek Jensen**, JD Director, Coverage and Analysis Group (CAG) | Centers for Medicare & Medicaid Services (CMS)
- **Gary Johnson** Vice President, Regulatory Affairs, Clinical Research and Health Economics & Reimbursement | **Abbott**
- **Krishna Kandarpa, MD, PhD**, Director, Research Sciences and Strategic Directions | NIBIB, NIH

- **Samrat ("Sam") S. Khichi, JD, MBA**, Executive Vice President and General Counsel | **BD**
- **Richard E. Kuntz, MD, MSc,** Senior Vice President, Chief Medical and Scientific Officer | **Medtronic, Inc.**
- **Michael R. Minogue**, President, CEO, and Chairman | **ABIOMED**
- **Shacey Petrovic,** Director, President and Chief Executive Officer | **Insulet**
- **Jody Powell,** Vice President, Global Regulatory Affairs and Quality Assurance | **Stryker**
- **Peter Saltonstall**, President and CEO | National Organization for Rare Disorders (NORD)
- **Randall Schiestl,** Vice President, Global Technology | **Boston Scientific Corporation**
- **Jeffrey Shuren, MD, JD, Director, Center for Devices and Radiological Health (CDRH) | Food and Drug Administration (FDA)**
- **Jean R. Slutsky, PA, MSPH,** Chief Engagement and Dissemination Officer; Program Director | PCORI
- **Nadim Yared**, President and CEO | CVRx
- **Wes Cetnarowski, MD, SVP** Scientific Affairs & Chief Medical Officer | **B. Braun USA Medical**
- **Esther Krofah, MPP,** Executive Director | Faster Cures, a Center of the Milken Institute"

NEST Coordinating Center – An Initiative of MDIC
https://nestcc.org/about/about-us/

> "NESTcc serves a dual role in the medical device ecosystem:
> As a coordinating center offering services to organizations seeking to sponsor medical device/technology research based on high-quality real-world data (RWD).
> As a collaborative community comprised of **representatives from across the medical device ecosystem**, including **FDA**, working together to coalesce teams of diverse stakeholders around common needs and initiatives."

NEST Coordinating Center – An Initiative of MDIC
Governance
https://nestcc.org/about/governance/

> "NESTcc's organizational structure consists of a multi-stakeholder Governing Committee, which is a Committee established by the MDIC Board of Directors, and an Executive Director supported by program staff.
> Working Groups composed of experts representing diverse perspectives may be established by the Governing Committee on an ad hoc basis."

Appendix 11:

Amicus curiae briefs submitted by the FCC to support the positions of wireless industry defendants in unresolved personal injury litigation.

CTIA – THE WIRELESS ASSOCIATION, Plaintiff, v. THE CITY OF BERKELEY, CALIFORNIA, et al., Defendants. Case No.: 3:15-cv-2529-EMC; STATEMENT OF INTEREST OF THE UNITED STATES
https://www.docketbird.com/court-documents/Cohen-et-al-v-Apple-Inc-et-al/STATEMENT-OF-RECENT-DECISION-pursuant-to-Civil-Local-Rule-7-3-d-in-Support-of-Apple-s-Motion-for-Summary-Judgment-filed-by-Apple-Inc/cand-3:2019-cv-05322-00119

***Cohen v. Apple, Inc.*, No. C 19-05322 WHA (N.D. Cal.) ; April 13, 2020**
https://docs.fcc.gov/public/attachments/DOC-363717A1.pdf

Appendix 12:

Civil litigation complaints brought against wireless industry defendants to which the *FDA* and *FCC* positions are proffered as evidence of no wrongdoing.

NO IMPLIED EFFECT: THE "SAFE" FCC CELL PHONE RADIATION STANDARD AND TORT IMMUNITY BY IMPLIED CONFLICT PREEMPTION
https://www.dropbox.com/s/56zo7xbgee855um/Section%20704%20-%20Federal%20Preemption%20-%20Legal%20%20Analysis.pdf?dl=0

> "So long as Dr. Newman's cell phone complied with the Federal Communication Commission's ("FCC") standard for a "safe" level of radiation, he would have been barred from claiming that the cell phone caused or contributed to his injury. However, it is far from clear that the FCC standard is actually safe."

Case 2001 CA 008479 B; Patricia Murray, Individual and as Aministrator With Will Annexed for the Estate of Michael Murray, Deceased, Paintiffs, v. Motorola, Inc., et al., Defendants; Judge A. Franklin Burgess Jr.
https://www.dropbox.com/s/cc4oxd9i0l2ug1w/Murray.pdf?dl=0

Case 2002 CA 001368 A; Baldassare S. Agro and Deborah A. Agro Plaintiffs v. Motorola, Inc., et al. Defendant; Judge A. Franklin Burgess Jr.
Jr.https://www.dropbox.com/s/n8dugwqpc92l076/Agro_FirstAmendedComplaint.pdf?dl=0

Case 4:15-cv-0116-TSH Document 130 Filed 09/29/17; G, a 12-year-old minor suing by a fictitious name for privacy reasons, MOTHER, and FATHER, suing under fictitious names to protect the identity and privacy of G, their minor child,
Plaintiffs v. THE FAY SCHOOL, INC. (by and through its Board of Trustees) and ROBERT J. GUSTAVSON, JR. Defendants.
https://www.dropbox.com/s/gsci1hre2wqybgv/Faye%20School%20Case.pdf?dl=0

Case 2002 CA 001372 A; David C. Keller and Marsha L. Keller, Plaintiffs v. Nokia, Inc., et a., Defendants; Judge A. Franklin Burgess Jr.
https://www.dropbox.com/s/q9yhw791k743cb7/KellerSecondAmendedComplaint.pdf?dl=0

Case NO. CIV.CCB-00-2609.; Christopher NEWMAN, et al. v. MOTOROLA, INC., et al. United States District Court, D. Maryland. September 30, 2002.
https://www.dropbox.com/s/cc4oxd9i0l2ug1w/Murray.pdf?dl=0

Case 2002 CA 001370 A; Richard Schwamb and Eret Schwamb, Plaintiffs, v. Qualcomm Incorporated., et al., Defendants; Judge A. Franklin Burgess Jr.
https://www.dropbox.com/s/tluzvp2spvqmq8l/SchwambFirstAmendedComplaint.pdf?dl=0

Appendix 13

Public media and investigative journalism challenging the veracity and competence of the FCC and the FDA in managing dangers of wireless technology

FCC Supports Mobile Industry In RF Emissions Suit
https://www.law360.com/california/articles/1286019
Dropbox Link: https://www.dropbox.com/scl/fi/mskcx9chx7tn8xpq96lr6/Law-360-FCC-Supports-Mobile-Industry-In-RF-Emissions-Suit.docx?dl=0&rlkey=esb9d7kmks7sqos47odp533ex

DC Circ. Picks Apart FCC Over 5G Wireless Safety Review
https://www.law360.com/appellate/articles/1347648
Dropbox Link: https://www.dropbox.com/scl/fi/d22qlzjaqxplm8hhxdp20/Law-360-DC-Circ.-Picks-Apart-FCC-Over-5G-Wireless-Safety-Review.docx?dl=0&rlkey=hnkpg9jvapic83wi3hpz09ynz

CORRECTION: Alsup Laments Apple's Reading Of FCC Cellphone Rule
https://www.law360.com/articles/1241627
Dropbox Link to article: https://www.dropbox.com/scl/fi/wsorxlbwuobrq6qsqhnzk/law-360-Alsup-Laments-Dumb-FCC-In-IPhone-Radiation-Suit.docx?dl=0&rlkey=exc3j659lrti7fejchbz5stj1

Ajit Pai is making lots of enemies on the road to 5G
In moving to free up Wi-Fi and bolster superfast service, Pai has alienated some industries, congressional committees and Trump Cabinet leaders.
https://www.politico.com/news/2020/07/08/ajit-pai-enemies-5g-351803

How Big Wireless Made Us Think That Cell Phones Are Safe: A Special Investigation
The disinformation campaign—and massive radiation increase—behind the 5G rollout.
https://www.thenation.com/article/archive/how-big-wireless-made-us-think-that-cell-phones-are-safe-a-special-investigation/

We tested popular cellphones for radiofrequency radiation. Now the FCC is investigating.
https://www.chicagotribune.com/investigations/ct-cell-phone-radiation-testing-20190821-72qgu4nzlfda5kyuhteiieh4da-story.html

Appendix 14:

Citizen Petitions for Removal of Jeffrey Shuren

Hundreds Petition Congress to Fire CDRH's Shuren
https://www.lasiknewswire.com/2016/04/hundreds-petition-congress-to-fire-cdrhs-shuren/

> "An Internet petition to Congress authored by LASIK injured patient/activist and former CDRH advisory committee consumer representative Paula Cofer has drawn more than 270 signatures from across the country in its first 24 hours, demanding the removal of CDRH director Jeffrey Shuren from office. Last October, Cofer and some of the current signatories were involved in a 1,500-message email blitz of Shuren's government in-box calling on him to resign."

Petition to Remove CDRH Director Jeffrey Shuren from FDA
https://www.thepetitionsite.com/375/735/542/remove-cdrh-director-jeffrey-shuren-from-fda/

> "Under the current leadership of Jeffrey Shuren, M.D., the FDA's Center for Devices and Radiological Health (CDRH) -- the arm of the agency that oversees medical devices -- has become mission-corrupted, placing industry interests over public health.
>
> Failures of the CDRH have harmed countless people and led to many preventable deaths.
>
> CDRH is "captured" by industry. Division managers at the CDRH have close working relationships with representatives of medical device manufacturers.
> Fraud and data tampering occurs regularly in FDA clinical trials of medical devices. The CDRH's oversight of device trials is weak and ineffective, leading to approval or clearance of unsafe devices."

Internet petition wants Congress to oust CDRH head Shuren
https://www.massdevice.com/internet-petition-wants-congress-oust-cdrh-head-shuren/

> "The petitioners state that patient advocacy groups and whistle-blowers who reach out to the CDRH to raise a red flag on medical device issues are shut out and ignored, and that MedWatch reports of device-related injuries "fall into a black hole at the agency."

Exclusive: Essure victims plan hunger strike in front of FDA during Pope's visit
https://www.catholicnewsagency.com/news/exclusive-essure-victims-plan-hunger-strike-in-front-of-fda-during-popes-visit-43120

> "(This) isn't just about Essure anymore. This is about anyone that's fallen a victim or been hurt by a faulty FDA process, bad laws and lack of oversight," Desa-Lynch said. "The FDA has to much blood on its hands to continued to be ignored."

Injured Patients' Attack on CDRH Chief Moves to Capitol Hill
https://www.mddionline.com/regulatory-quality/injured-patients-attack-cdrh-chief-moves-capitol-hill

> "Patients injured by medical devices have stepped up their attack on CDRH director Jeffrey Shuren, appealing to Congress to fire him."

Stop Poisoning Us with Dental Amalgam Mercury Fillings!
https://www.change.org/p/dr-jeffrey-shuren-director-of-the-fda-s-center-for-devices-stop-poisoning-us-with-dental-amalgam-mercury-fillings

Ban Electroshock (ECT) Device Being Used on Children, the Elderly and Vulnerable Patients – 122,225 Supporters
https://www.change.org/p/ban-electroshock-ect-device-being-used-on-children-the-elderly-and-vulnerable-patients

> "The Food and Drug Administration (FDA) has allowed the electroshock therapy (ECT) device to remain on the market without requiring clinical studies proving safety and efficacy, and is considering the American Psychiatric Association's written proposal to expand ECT's use on the general public, including on children."

FDA: Ban Torture of People with Disabilities and #StopTheShock – 307,466 Supporters
https://www.change.org/p/fda-ban-torture-of-people-with-disabilities-and-stoptheshock?source_location=topic_page

> "In 2014 the FDA held hearings about these devices. In April 2016 it drafted regulations to ban contingent shock -- but it has not implemented them. It is time for FDA to release the regulations."

Tell the FDA we need a hearing on breast implant illness, complications, and BIA-ALCL – 23,844 Supporters
https://www.change.org/p/center-for-devices-tell-the-fda-we-need-a-hearing-on-breast-implant-illness-complications-and-bia-alcl-breast-implant-associated-anaplastic-large-cell-lymphoma

> "Breast implants are causing illness and harm to thousands of women. The FDA needs to hear from those of us that are sick and disabled. Our symptoms are the same as were described three decades ago despite innovations in implant manufacturing. Studies have been terminated. Women have been dropped from studies. Ladies are facing disability and struggling financially to remove their breast implants."

FDA: Warn women about health risks from breast implants – 80,256 Supporters
https://www.change.org/p/fda-warn-women-about-health-risks-from-breast-implants

> "The U.S. Food & Drug Administration has known since 2011 that textured breast implants can cause a potentially fatal man-made lymphoma: Breast Implant Associated ALCL (BIA-ALCL).
> Thousands of mastectomy patients, like myself, had Allergan textured implants placed inside them with no warning about BIA-ALCL."

FDA & CDC - Develop a medical code for sick women suffering from breast implants.
https://www.change.org/p/fda-cdc-develop-a-medical-code-for-sick-women-suffering-from-breast-implants

> "Breast implants have been making women sick for over 50 years.
> Please help us request action to develop an ICD medical diagnostic code for breast implant illness, which will help women who are suffering from health complications caused by breast implants. Breast implants cause autoimmune diseases and cancers, including scleroderma, joint pain, muscle pain, debilitating chronic fatigue, postexertional malaise, low-grade fever, skin rashes, memory loss, multiple sclerosis-like symptoms, night sweats, headaches, chronic diarrhea, recurrent infections, melanoma, and BIA-ALCL, a cancer of the immune system."

Pro & Con Quotes: Is Cell Phone Radiation Safe?
https://cellphones.procon.org/is-cell-phone-radiation-safe-pro-con-quotes/#quote-134

Justice for Victims of Morcellation NOW
https://www.change.org/t/hysterectomy-en-us

Hundreds of formal testimonials from people harmed by wireless technology emissions submitted to the FCC for Docket 13-84 and Docket 19-226:

Testimonies of Microwave Sickness from FCC Docket 13-84:
https://www.dropbox.com/sh/4pgcqbbnk9rdsks/AADxgDlWlkdLaeusjJqzG4zpa?dl=0
Testimonies of Microwave Sickness from FCC Docket 19-226:
https://www.dropbox.com/sh/ckxun07vm2lnljp/AAB0Fglb0zAQbC4TfCzgzWcPa?dl=0

Appendix 15:

Congressional Testimony Addressing Dr. Shuren's Professional Behavior

HEARING before the COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM; HOUSE OF REPRESENTATIVES: *LIMITLESS SURVEILLANCE AT THE FDA: PROTECTING THE RIGHTS OF FEDERAL WHISTLEBLOWERS*, February 26, 2014

https://www.govinfo.gov/content/pkg/CHRG-113hhrg87176/html/CHRG-113hhrg87176.htm

SENATOR CHARLES E. GRASSLEY

"…who authorized the targeted operation. Worse than that, it was misleading in its denials about intentionally intercepting communications with Congress…

These whistleblowers thought the FDA was caving to pressure from the companies that were applying for FDA approval. I don't know whether they were right. But they have a legal right to express those concerns.

After expressing their safety concerns, two whistleblowers were fired, two more were forced to leave FDA, and five of them were subjected to an intense spying campaign…"

ANGELA CANTERBURY

"The FDA spied on whistleblowers, which set off a firestorm that led us to this hearing today. But the public story of whistleblowers began in 2008, when FDA physicians and scientists warned Congress, and shortly thereafter the President, that the process for approving medical devices was broken, allowing potentially ineffective and unsafe products to be marketed. And as Senator Grassley noted, there has long been problems with bureaucrats at the FDA respecting the scientific process…

To be frank, we question why FDA should be in the surveillance business in the first place. The FDA's mission is to ensure our food and drugs and devices are safe.

Any suspicion of unlawful disclosures of information or criminal misconduct should be investigated by law enforcement. Federal agencies cannot be allowed to police themselves. That is why we have IGs, the OSC, the FBI, and Congress…

Rather than protect whistleblowers from unwarranted FDA surveillance, its interim policy protects the FDA from whistleblowers…How can the FDA ensure the public's health and safety if the scientists and physicians are too afraid to come over when deadly mistakes are made?

And far too many mistakes are made. Inadequately tested metal-on-metal hip replacements cause crippling disability. Defective cardiac defibrillators, unclean syringes containing deadly bacteria, old-fashioned pediatric feeding tubes cause fatalities because they lack the well-known, inexpensive safeguard. And these are just the medical devices that the FDA allowed on the market, not to mention the food and drug approval disasters.

And if the FDA isn't doing its job and lives are at risk, we have to ask why. The FDA whistleblowers warned us that corners were being cut and scientists were being overruled by the bureaucrats…

…we must not forget what brought us here today, which is the FDA whistleblowers. They were concerned about the device approval process they believed might put lives at risk.

FDA officials should not be held accountable for approving--they should be held accountable for approving ineffective and unsafe products, and flawed devices must be taken off the market. There must be more transparency and less deference to the demands for confidentiality by drug and device companies. Seriously, I wonder how much time and taxpayer dollars is spent protecting so-called confidential commercial information.

Finally, please do all you can to ensure that FDA managers are held accountable for any violations of the rights of the scientists and physicians who sought to make medical devices more safe and more effective…"