Citizen Petition

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Electronic submission

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

The undersigned, Jianqing Wu, submits this amended petition pursuant to 21 C.F.R. § 10.30 and 21 U.S.C. § 355, 21 U.S. § 564(g)(2), 21 U.S. § 379dd of the Federal Food, Drug, and Cosmetic Act and 42 U.S. § 262(a)(2) of the Public Health Service Act and any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs, to request the Commissioner of Food and Drugs to suspend all outstanding mRNA vaccine use authorizations, re-evaluate vaccines' effectiveness and safety, and revoke their use authorizations as soon as possible, and make a plan to systematically overhaul its approval framework.

I. ACTIONS REQUESTED

1. Investigate medical science information laundering by monopolistic medical publishers and how they have suppressed new discoveries that would have thrown out the reductionist research and treatment model, knowingly produce flawed and fraudulent knowledge for their revenue in the name of science, pursuant to the implied power under 21 U.S. § 355(b)-(c), 42 U.S. § 262(a)(2), 21 U.S. §564(g)(2), 21 U.S. § 379dd, and 21 C.F.R. §§ 1.21;

2. Evaluate a true life model and reject the reductionist research and treatment model, and evaluate safety and effectiveness of the mRNA vaccines, pursuant to 21 U.S. § 355(b)-(c), 42 U.S. § 262(a)(2), 21 U.S. § 564(g)(2), and 21 U.S. § 379dd;

3. Suspend all outstanding mRNA vaccine use authorizations and revoke same, pursuant to 21 U.S. § 564(g)(2). All dangers and potential risks are present in all mRNA

vaccines and all flaws in the research model, data analysis, and conclusions have impacted the approval of all mRNA vaccines;

4. Urge FDA to initiate investigation with DOJ, FTC, FCC, etc. to understand the extent of criminal violations by information launders, particularly, antitrust violation, wire fraud violation, and wastes of massive federal research funds attributable to the conduct of monopolistic medical publishers. The authority is implied by FDA statutory mission to protect public health.

5. Request FDA to overhaul its approval framework: rejecting the drugs-for-health hypothesis, adopting a holistic analysis approach, avoiding trade art and junk science, restructuring advisory committee structure and member compositions, pursuant to implied power provided in 21 U.S. § 379dd. Since this will take time, FDA does not need to address this request within 180 days, I will follow up by filing my continuous petitions.

6. The outcome of this petition will affect the health and lives of the U.S. population and potentially billions of people globally. However, federal government, state governments, foundations, etc. generally do not provide funding for researches for finding vaccines risks. Due to such funding biases and suppression of vital researches, Petitioner has to rely on observations, “misinformation”, and “underground” data (per the characterization of information-launders) in this petition. FDA should bear responsibility to validate the accuracy of information from such sources. However, even if FDA rejects all “misinformation’ and “underground” data, this petition still invalidates research conclusions that FDA has relied upon in granting mRNA vaccines use authorizations.

7. Petitioner started peerless researches as early as the start of the COVID-19 pandemic, but do not get any support from any peers, any funding agencies, and any media. Moreover, this petition is based on a different life model which is backed up by an extremely large amount of factual findings by independent researchers. In the eyes of people who have gotten used to the reductionist “science”, the petition may appear to contain inaccuracies, inconsistent data, non-conventional expressions, etc. Those problems cannot be addressed until readers fully understand the new life model. If Petitioner spends years to address those problems, all damages to the U.S. population and humankind will be quickly realized. Petitioner therefore has a need to file this petition without any peer comment and review. The extraordinary circumstance justifies this decision. I hope that public readers of this petition will provide constructive feedback during the review period. Therefore, Petitioner requests FDA to grant a permission to file one to more updated petitions to clarify all difficulties that may inherently arise from evaluating two different science frameworks.

II. STATEMENT OF GROUNDS

Factual Grounds

A. Introduction

In 1941, FDA approved DES for human use without considering data on its long-term safety and resulted in a big health crisis that has not been over yet. In 1976, FDA approved Swine Flu vaccine quickly and caused 24% of the population to receive dangerous Swine Flu vaccines, which was found to damage the nerve system. From 2020 to now, FDA approved multiple RNA vaccines without considering long-term safety study, pharmacodynamic and pharmacokinetic data, and even without doing any serious analysis of potential dangers to humans. As a U.S. citizen, I have explored flaws in medicine on and off since 2001, and in the last five years, I have found ways to prove key flaws in the foundation of medicine. In the last two years, I tried to have my findings published, but monopolistic medical publishers and large media systematically suppressed my findings to protect their revenue. From my further study, I discovered that monopolistic medial publishers and monopolistic media have jointly laundered medical science information for decades. Their practices were known several decades before, but societies, government agents, public entities, and private citizens have accepted laundered science as best science. As a result, medical literature is filled with junk science, trade articles, wrong disease theories, information on dangerous drugs, aggressive treatments, and revenue-making medical practices, etc. When the life model, core research model, and risk evaluation method are all wrong, nearly all accepted medical knowledge on treatments of chronic diseases are wrong or grossly inaccurate. Due to the business model used in science publishing, science merit of any research is measured by the amount of revenue it would generate for sponsors and publishers. Under the laundered medical knowledge, anything that does not generate revenue is “junk science”; and drugs and vaccines are the best medicines because they can generate the largest amounts of revenue.

Over the years, FDA routinely relies on laundered science to make its decisions that can affect health and life of millions of Americans to potentially billions of people in the world. By relying on laundered science, FDA approved mRNA vaccines. In this petition, I will prove the foundation of medicine is deeply flawed and summarily prove that all key evidence that FDA had relied on, including, risk model or risk factor, treatment effectiveness rate, and hazard ratio (e.g., adjusted rate ratio) are irrelevant to any persons, and capable of being massively inflated by manipulating small probabilities and concealing real dangers. The inflated benefits-to-risk ratio of the vaccines are magnitudes higher than their real values. After adjusting the benefits-to-risk ratio against all identified flaws and data manipulations over small probabilities, I must find that vaccines (as well as any drug approved in the past) impose unreasonable dangers with little real benefits, and short-term benefits observed in a small number of recipients are far lower than the noted dangers and expected risks that will realize in their life times. I thus urge FDA to suspend all mRNA vaccines use authorizations, reevaluate all mRNA vaccines under a new life model and new analytic framework, revoke all use authorizations, and

preferentially make a first ban on their uses on human population. I will incorporate my detailed analysis posted on both Researchgate.net and Open Science Foundation Server (www.osf.io) as additional factual support [325].

The subject matter in this petition covers half of medicine. It is impossible to fully describe what would require a database to hold. Thus, I will only state key points here. FDA can refer to my long article for more details [325].

B. Medicine Developed on Flawed Foundation

Based on thousands of studied I actually reviewed, I proposed a new life model as follows: Each multiple-cellular life being like human is an extremely complex distinctive system controlled by distinctive genome and a large number of personal, environmental, and emotional variables, the optimum performance of which can be achieved only by maintaining balances among a large number of metabolic and disease processes in the life time. Life is maintained by the vascular system which is susceptible to current impacts of life activities, diseases and a large number of other factors. Life can be altered by altering any of the factors in place of other factors. Any of a large number of factors can add current burdens to the vascular system leading to death or reduce burdens on the system to avoid death. Burdens caused by cancer or other diseases could be offset in part or in whole by reducing burdens of other sources. The working order of the life system is maintained by the immune system which is run and influenced by environmental factors, cellular substances/nutrition, emotion/thinking, anger, memory, life activities, life stress, hormones, climate, etc. Good health can be achieved by optimizing some of those factors in place of others. In one aspect, life is like a rechargeable battery which has both energy reserves and vital functional reserves: the person can add more life to the reserves or reduce some of his life from the reserves on a daily basis. In another aspect, life is influenced by cellular memory and CNS memory that affect biochemical and cellular processes and body's structure profile. Hundreds of additional properties could be derived from this life model. The findings of half a century of researches provide irrefutable support to this life model.

The proposed new life model invalidates the reductionist medical research and treatment model which focuses on a single factor in a static manner often by comparing disease outcomes in a binary scale between two groups. The reductionist model was wrong in all core presumptions. The discoveries of a large number of health influence factors on health [8-9, 13] refuted the reductionist treatment model. The discovery of the stress role on personal health [14-24] implies that diseases cannot be cured by focusing on the body part only. The findings of cellular damages and the findings of a large number of harmful drugs/chemicals [29-54] refute the Independent Action Model [56]. The tightly integrated nature of biological or metabolic pathways in human metabolic pathways networks implies that intervention by a synthetic drug cannot correct a diseased pathway without disrupting other pathways in the metabolic network [9, 57, 58]. Based

on thousands of post-1980 studies, the binary disease categorization method [9] introduces too many and too big errors.

Those factual findings imply that nearly everything about researches and treatments in medicine is deeply flawed. The findings explain why medicine has been failed to find cures [59-67]. The failure is most clearly reflected in cancer research: Drug performance is very poor based on randomly selected reviews for cancer drugs and treatments [68-86]. Drug performance is inflated by all model flaws [9], and their real benefits-to-risks ratios are magnitudes lower [1]. Most early disease theories are very poor or largely wrong [51, 92-97]. Most latent side effects can be observed after long delays: 4 years to several decades for non-naturally occurring cancer [98], at least 10 years for pesticides [99], and about three decades for DES [49-50]. The long latent periods are implied by the cellular damage mechanisms, the massive redundant vital organ functional capacities in healthy humans and a large number of interference factors. The true performance of drugs like chemo drugs is much worse based on long-term studies [63, 100-101].

FDA should find that everything from the reductionist, experiment-based research model, disease classification method, most mathematical models, use of statistical models, the use of the binary scale, major disease theories, mechanism-based drug discovery model, outcome-based research approach, symptom-based diagnostic approach, standardized medical research model, symptom-based causation method, etc. are wrong or very poor as long as they are concerned with personal health and chronic diseases [9]. Health is far more complex than any physical system. The complexity of the human body can be attributed to three distinctive parameters: personal genome [25], personal environment [101-104] and personal emotional state [14-24, 314], each of which requires that each disease must be addressed in a specific way [9]. Each human is made of a unique genetic blueprint which precludes use of the population approach. If the population approach were used to repair cars and planes, it would cripple all cars and planes. It is a fact requiring no proof. Those discoveries imply that medicine cannot find cures for chronic diseases [9] but must endanger all patient lives. Actual harms are concealed by massive vital functional reserves, insufficient time for damage realization in clinical trials, masking effects of a large number of super strong persons, and interference effects of a large number of lifestyle and other factors.

The biggest flaw of clinical trials are attempts to transfer disease risks from a small number of distinctive individuals to the population, extend short-term benefits from some individuals to the population, dramatically conceal acute drug injuries, and completely “write off” all latent side effects. Due to all of those problems, the benefits-to-risk ratios of mRNA vaccines are inflated by several MAGNITUDES. FDA approval is mainly based on one piece of meaningless evidence or effectiveness rate or rate ratio and thus is invalid as a matter of law.

C. Flawed Medicine Has been Hijacked to Advance Trade Revenue but Never Cures

In the long history, medicines always mean natural products [9]. After humans gained the ability to synthesize chemicals, synthesized chemicals were used as anesthetic agents, antibiotics, and painkillers. None of those uses have the effect of curing chronic diseases. However, a hypothesis silently entered into medicine without scrutinizing all inherent problems of synthetic chemicals. No attempt has been made to vet potential dangers of synthetic chemicals [9]. There was never a systematic theory or justification for their use.

New drugs must be approved by FDA before they can be sold in the U.S. [107-108]. Since drug merits must be determined by some kinds of research, drug industry must seek to establish and maintain a research framework that favors drug discoveries and approvals. Since there is no plausible theory to show that synthetic drugs can cure chronic diseases [1, 9], drug industry does not need to find drugs that can actually cure diseases; the drug industry must have found that human bodies have massive vital functional capacities for tolerating drug side effects in expected use conditions [10-14] and take advantage of this property in promoting drugs as medicines. What matters is that a drug can produce nominal short-term benefits but does not cause imminent danger. This can be achieved only by using the flawed research models or clinical trials.

The drug industry controls the medical industry by controlling commercial medical publishers [109-116], financing researches [117-128], supporting medical practices [129-130], and “educating” consumers [132-133]. By manipulating various things [134-137], the drug industry can always get the results they want [124, 130]. They sponsor researches, award scholarships to medical students, award fellowships to medical researchers, provide financial assistance to scholars covering traveling expense, conference registration fees, etc. Researches sponsored by drug companies are expected to promote drugs. It is generally understood that if research findings are negative, they would lose future funding. Drug industry also influences doctors by providing free drug samples, sponsoring clinical researches, paying publication fees, paying for speaker fees, etc [129-131, 193]. Drug industry also influences consumers by massive TV and Radio campaigns directed to both patients and doctors [133]. From 1997 through 2016, the drug industry spent $17.7 to $29.9 billion each year for targeting consumers and doctors.

Drug industry has no duty to humankind [134]. After drug business exists for more than a century, drug vendors must have learned how to get required data and conclusions by paying medical journals. They published articles in fake journals [110-115] and do various things to achieve favorable results [119, 122, 134]. It is clear that clinical trials have the magic role of concealing latent side effects. The drug industry has inherent interest in keeping the deeply flawed reductionist research and treatment models that favor drug discoveries and commercialization. Leading medical publishers have a

strong interest in maintaining existing revenues from the drug industry and creating entrance barriers to secure their monopoly revenue [109]. Thus, the drug industry and the medical journals have a common interest in keeping alive the research and treatment models that favor drug discoveries and commercialization. The more articles the medical publishers publish, the more revenues they get from the drug industry. They have formed a de factor revenue-sharing partnership.

The partnership between the drug industry and the publishing industry become even more important after 1980. Massive post-1980 research findings [46, 69-82, 138-146] started showing failure of drugs. Thus, the drug-for-health hypothesis is constantly under challenge and the need to use alternative health measures arose. Disruptive discoveries provide irrefutable evidence to throw out the reductionist research and treatment models [9]. Acceptance of those discoveries could disrupt drug industry's revenues and thus the medical publishers' revenues. The drug industry must cling onto flawed research models that can inflate drug benefits and write off drug side effects, and the publishers must do their part to suppress discoveries that could pronounce the end of drug-for-health era. Moreover, since the medical publishers share medical trade revenue, they must know that putting more people on more drugs can generate more profits than curing their diseases and they have the same incentive to keep alive the drug-for-health medicine. They slowly found themselves in "unethical but profitable business", and must do everything necessary to protect their revenue. They slowly developed peer review [150], impact factors [173-175] and overwhelming editorial requirements, and successfully sold them to societies, and created irrelevant article standards for deceiving people and societies.

Peer review is the most powerful monopolistic instrumentality because it requires long time to build a huge reviewers pool like those used by Nature, Lancet, and NEJM; and this factor alone could preclude new publishers, open access journals, and open science foundations from effectively completing with them. Impact factor is the second powerful factor for preventing new publishers from entering publishing business. It is like gaining a future power by counting their monopoly power. The medical publishers adopted a large number of technicalities to inflate the perception of article "quality". In fact, all of those measures were intended to preclude competition, turn more people into their revenue feeds, and create more diseases expanding their revenue. Based on the nature of their conducts, the medical journals "have devolved into information laundering operations for the pharmaceutical industry" [147]. However, their impacts are far more than what a traditional information launders could achieve. They promote junk science, suppress truth, preclude competition, and expand patient population. By using their marketing power, the drug industry and the medical publishers influence legislative process, medical practices, and popular belief, and thus ruined population health wisdom and thus preclude reform. They have inflicted worst damages to patients, public health, species, and the planet.

D. Medical Knowledge Laundered for Maximizing Trade Revenues and Entrenching Monopoly Positions in Violation of Anti Trust Law.

Due to extremely complex factual patterns and long development history, I can only describe those issues briefly. Some details can be found in my article, more details will be forthcoming, and yet more details can be found by anyone interested in doing research in this subject. The full details would require a database to hold.

The science publishers [328] have become a $26 billion industry with 70% scientific articles published by journals owned by five major publishers. Its profit margins have increased from around 10 percents to nearly 40%, higher than Amazon's and Apple's. The biggest medical publishers include Elsevier, Springer Nature, the American Medical Association, the Massachusetts Medical Society, the American Association for the Advancement of Science, Wolters Kluwer, John Wiley & Sons, Informa, and Thieme Publishing. Other publishers such as Hearst Health, athenahealth, and IBM Watson Health have some influence in medical publishing. While medical publishers control medicine field by oligopoly as a whole, they actually have monopoly impacts in most specific medical fields by collusion or concerted actions. Most of them join the monopoly compact by sharing many of the following features: (1) developing and following a large number of anti competitive devices to protect their monopoly positions in their specialized fields, specific market, specific customers, or certain diseases, etc. to stabilize their trade revenue; (2) promoting and maintaining junk science such as reductionist treatment model, clinical trials, statistical models, flawed disease theories, drug-for-health hypothesis, and whatever that can help them to generate revenues; (3) using ill-intended meaningless peer review which gives the peers in controlling research fields to suppress innovations and discoveries by non-controlling researchers; (4) collectively misleading the public and societies that they promote "science" and "innovations" whereas in reality all their business decisions must be made to keep the flawed models alive; (5) extracting government fund and public funds by exaggerating "research quality" to achieve very high profit margins (the governments pay for researches, pay salaries for peer reviewers, and subsidize public libraries for purchase of their journals); (6) using anti-competitive devices in the name of promoting "research quality" to secure their subscription revenues and audience; (7) promoting drug-for-health, a hypothesis that has never worked for chronic diseases; (8) collectively ruining public wisdom by disseminating junk science as "science" and swapping between truth and falsity and thus precluding, suppressing and killing disruptive discoveries so that they can eliminate true science which could necessitate medical reform; (9) precluding competition of new types of publishers such as open access publishers and open science foundations that support innovations and pioneer discoveries; and (10) selling junk science, flawed and misleading knowledge to people and societies and resulting in public health crisis, societal inability to address environment, ecosystem and climate, and accelerated extinction of species and the human evolutionary crisis.

They all have same incentives to promote drugs which help them to generate the most revenue. The medical publishers work like middlemen securing subscription fees from universities and public libraries by using anti competitive means. After they have perfected this sophisticated business model, they can extract fund from governments and public sources, and perpetuate their monopoly positions by precluding new publishers from competing with them. They promote drug-for-health researches by tailoring their article specifications to drugs discoveries and get large amounts of fund by obtaining government trust. When they become bigger and bigger, they are capable of deliver more damages to people, societies and the planet. While none of the medical publishers has absolute monopoly control in the entire field of medicine, they have monopoly roles in specific area of medicine, specific sections of market, specific diseases, or specific type of journals. Their anti competitive violations may include both per se violations or violations under rule of reason. The damages are sustained by patients, researchers, government, all people, species and the planet.

Over decades, the drug industry, monopolistic medical publishers, social media, search engines, and popular media have found their common interest in increasing the largest patients basis and securing their common monopolistic positions. They have formed a long chain of monopolistic controlling points over medical information. Monopolistic medical journals developed ill-intended peer review, use of impact factors, and overwhelming editorial policies in the name of improving research quality. They have successfully suppressed truth, and thus truth cannot be found. Laundered information helps them to escape from the reach of wire fraud statute. They can sell flawed and deceptive knowledge to promote dangerous drugs, reckless treatments, dangerous medical information, all in the name of science. Information launders can successfully escape from the reach of all state fraud laws because “truth” is what they have chosen or say and publish. The worst danger is from persons that have the power to create “truth”.

Effects of their conduct are precluding new discoveries, suppressing innovations, and setting up roadblock preventing medical reform. By killing true science, they were able to keep junk science in the medial literature and destroy the health of the population and turn them into life-time revenue feeds. Thus each will get more share of medical trade revenue. By using anti-competitive devices, they can prevent innovative publishing models such as open source journals, non-profits publish model and open science foundation from competing with them. By using those anti competitive devices, they preclude new scientists from conducting researches that are vital to rescue humans and species. The information launders consistently use flawed and fraudulent language to justify the use of monopolistic devices. If an article proves that clinical trials are wrong, every journal controlled by them would reject it without review. This has been built in their editorial policies and article specifications and reflected in their subjects,

formats of articles they have published. All problems can be seen from the articles they have published.

When junk science is laundered as only valid science, junk science has gained new identity with the force to compel people to accept dangerous drugs and toxic chemicals that keep coming out of the production pipeline. Flawed science is published, maintained and promoted by the monopolistic medical publishers and then being disseminated as living medical knowledge by monopolistic media to ruin public health wisdom. Articles and knowledge disseminated for money have poisoned people's minds with an effect of blocking every path to reforming. Half a century delay in starting a civilization-rescuing mission is the worst damages by information launders in the human history. The information laundering enterprise will continue its destructive mission: doing everything to suppress anything that challenges junk science, keeping death spells (incurable diseases) for humankind, and inducing the population or patients to commit chronic suicides. Due to their roles, dangerous drugs and products come out one after another, tormenting people and societies like each of those past personal injuries catastrophes, and human species will be buried in the toxic chemicals that are dumping at the rate of 220 billion tons a year, promoted by flawed and fraudulent safety information.

Monopolistic businesses have inherent incentives to protect their monopolistic positions by using unfair, deceptive, and unproductive means. However, there is one big difference between classic monopoly business and information launders in medicine. The monopoly motivation in medicine is extreme in kind because real cures for diseases do not support medical revenue, but maximum revenues can be achieved only by selling useless, disease-creating and dangerous drugs. Thus, financial interest of the drug industry and societies' interest in finding cures are diametrically in conflict. Their conflict is like getting revenue by crewing up patients OR curing patients with little or no revenue. In such a bizarre situation, this monopolistic information laundering enterprise must develop the maximum destructive force to ruin pubic health and kill human species. It is plainly obvious: putting the whole population in terminal diseases will produce the maximum revenue. That is how humans, as a species, have lost half a century to address environment, ecosystem and climate problems, and have suffered unprecedented damages.

Information laundering has self-protection effects, a reform-precluding effects, innovation suppressing effects, etc. When all of those evils are used by overwhelming number of monopoly entities, they exert terminal impacts on public health, human species, all other species, and the planet. Uncontrolled production of dangerous drugs and toxic chemicals is responsible for prevalence of chronic diseases, deterioration of public health, poor ability to control pandemics, prevalent cancer instances and deaths, destruction of ecosystem, irreversible climate changes, accelerated species extinction, formation of the toxic planet, and accelerated process of human extinction. We find ourselves in the world without cures but with every rescue path being blocked by information launders.

If corrections are made to offset all errors introduced by (1) intention to destroy other species (species-targeting killing practice), (2) the independent action model, (3) the buffering effects of organ functional reserves (the cellular damages model), (4) damage-delaying effects, and (5) interference factors of life factors, the real stress of all toxic substances including drugs, chemicals, and toxic substances on life would be **millions to billions** times of the predicted impacts by the reductionist approach. However, due to diversity of life and differences between different individuals, there is no reductionist index which is good for all species and all humans. Any yardstick must be based on a target life and specific individual being. The numeric value of the total stress of all toxic substances depends on the model to be used. While there is no good model, it is clear that medicine has made a disastrous and game-ending mistake that has an effect of putting humans and other species on the brink of extinction.

Junk medicine has influenced all aspects of the medical industry like a malignant cancer. The cancer has found its way into all federal laws and regulations. It forces all federal agencies to take similar actions in the same way. Every aspect of flawed medicine is recognized, favored, promoted, or even legally enforced as the only valid medicine by all federal agencies including NIH, CDC, FDA, DOD, U.S. army, U.S. Navy, EPA, etc. There is absolutely no fix which can come from the research field. Even if one agency wants to fix, there is no point to start with, and any intended change must have severe tension with other agencies. All parts of society are interconnected like a steel ball without any access point and junk science is integrated in all part of the ball. When medicine is about to destroy human species, none of them could do anything directly. The only possible remedy is to stop information laundering to slowly restore true science. All federal agencies have done what they are supposed to support information laundering operation, but none of them has done what they should to stop it. After the medical literature has been filled with junk science, this slow path cannot give human species a realistic hope. When the risk assessment model is completely wrong under the laundered junk science, people and societies cannot see the biggest peril that has developed for more than half a century and there are no predictable remedies….

E. Medical Knowledge Laundered in Violation of U.S. Wire Fraud Statute

In their routinely business activities and communications, the medical journals falsely state or imply that everything they do is to improve research quality while in reality everything they do is to achieve maximum revenues and protect their monopoly positions at the costs of public health and human survival. Since information laundering is conducted over the internet, they clearly violate the U.S. wire fraud statute [176]. The required elements for this violation are: (1) there is a scheme (e.g., the whole publishing model including peer review, impact factor and all editorial requirements); (2) to defraud (anyone), or by means of false or fraudulent pretenses, representations (e.g. “science” articles and promote research quality, etc.); (3) transmits or causes to be transmitted by means of wire, radio, or television communication in interstate or foreign commerce any writings (e.g., research articles, editorial articles, commercial messages, etc.), signs,

signals, pictures, or sounds; and (4) for obtaining money or property (e.g., reprint money from the drug industry and triple funding from federal government and other public sources). Under the common law fraud doctrine, victims must be ones who have received misrepresentation. However, the wire fraud statute does not have this requirement. The medical journals and participants actually get money from the federal government and patients through drug companies. The only central question is whether their articles are advancing science or keep junk science for money.

Facts in support of their conduct of committing wire fraud have existed for a long time. Since truth has been suppressed, societies cannot see the falsity of laundered science. Another key issue is their motivation. They make their publication decisions to achieve revenue, but they have misled the world that they are promoting science. If their decisions are made for revenue, it is perfectly legitimate if they openly told the world about this fact. However, they do not. In all editorial policies, their marketing slogans, and editorial articles, they hold out as science publishers whose mission is to disseminate medical science for promoting public health. Their lottery-like peer review is clearly used to perpetuate their monopolistic position and maintain junk medicine which can keep patients as their revenue feeds, but they tell the world that they use peer review etc. to improve research quality. What they have improved is the quality of junk science in suppressing innovation and blocking medical reform. They use impact factors to compound their monopolistic influence, and mislead the world that impact factor can measure article quality. Their marketing has been done so well that even NIH, CDC, and FDA have been misled to rely on their laundered "science." All federal and state agencies accept or condone their practices. Despite the contrary claims, their publication model is the absolute protection of junk science, an absolute killer of innovations, absolute stonewalls against medical reform, the destroyer of public health wisdom, and the root culprits for killing patients and destroying the planet.

By fraudulent marketing together with information laundering, they sell their articles as the best science to practicing doctors, patients and societies for their detrimental reliance.

F. Flaws in FDA Analysis of Vaccine Performance Data

Concerning the approval, FDA states: "Our scientific and medical experts conducted an incredibly thorough and thoughtful evaluation of this vaccine. We evaluated scientific data and information included in hundreds of thousands of pages, conducted our own analyses of Comirnaty's safety and effectiveness, and performed a detailed assessment of the manufacturing processes….[2]" "Specifically, in the FDA's review for approval, the agency analyzed effectiveness data from approximately 20,000 vaccine and 20,000 placebo recipients ages 16 and older who did not have evidence of the COVID-19 virus infection within a week of receiving the second dose. The safety of Comirnaty was evaluated in approximately 22,000 people who received the vaccine and

22,000 people who received a placebo 16 years of age and older. Based on results from the clinical trial, the vaccine was 91% effective in preventing COVID-19 disease [2]."

1. FDA failed to see flaws in population medicine and clinical trials.

FDA's decision was mainly based on Applicant's clinical trial outcome. I have posed two articles to refute the validity of clinical trials. My first article showed that statistical analysis cannot produce right results for hypothetical model data under the same assumptions used in research. Statistical method has been used to address a problem that cannot be cured by any method. The second articles published on September 2020, while the article has been suppressed by medical journals, they are available as preprint articles and can be found by anyone worldwide. FDA made no comment on those findings.

Based on thousands of post-1980 studies, all key presumptions in medicine are invalid [9]. This is enough to invalidate most conclusions from studies relying on those key presumptions or require re-interpretation of acquired data. Medicine was established on deeply flawed foundation due to lack of understanding of life in the past. The use of clinical trials is based on the simplest system like goods weight and volume. The impacts of those studies and my findings are wiping out nearly all existing research models, nearly all disease theories and most medical practicing methods as far as they concern human health and chronic diseases. Anti-viral properties and personal ability to withstand vaccine acute and latent injuries are clearly the kind of properties that are directly impacted by my discoveries. My findings do not automatically invalidate all clinical trials, but place very subtle limitations on their use and interpretation. The biggest limit is that data from clinical trials may not be extended to specific persons as a treatment guideline. The same study conclusion may be used for other purposes. Thus, Pfizer and Moderna could not prove that the effectiveness from a clinical trial can be extended to nearly all people except by accident. They must successfully invalidate my discoveries together with millions of post-1980 discoveries or accept my findings.

A large number of post-1980 studies have an effect of invalidating the FDA review framework. Medical knowledge on research models, disease theories, research evaluation methods, and medical practices have been promoted by the monopolistic medical publishers to advance their revenues. FDA failed to address any of those known problems, gave unwarranted credibility to applicant's self-serving evidence, failed to consider research articles unfavorable to the vaccines, and failed to exercise sound wisdom.

Comparative approach used in clinical trials was based on intuition almost three centuries ago [106], but it is wrong [8-9]. This wrong approach was formed because past researchers believed all humans are nearly identical. Now, any of millions of studies prove each person is unique and all people are different [8-9, 102-103]. The flaw is like studying cars such as Honda, Toyoda, Ford and Lincoln by using a comparative

method. It was much later to find that each person's human genome is distinctive, like the unique blueprint of a car model. In an attempt to address observed inconsistencies and outcome discrepancies, it was previously attempted to use statistical model as a solution [106] and thus compounded with more errors and flaws [8-9]. Based on statistical theory, the mean of a population is an unbiased representation of the population. This law does NOT imply that each person's health properties can be represented by the population means, and nor (never) that a population mean can be imposed on to any individual member. Statistical theory does not care about whether such a mean exists or not in reality and does not mean that personal values can be replaced by the means.

For clinical trials, the summation of individual measurements violates the forbidden rule [9]: all health properties are process attributes that strictly tied to each person, and have no meaning when they are viewed outside the person. Such process numbers from different persons have different scales and different significance. They are added up like adding apple, orange, watermelon and sesame to reach the total sum which is naturally meaningless. Saving an old and vulnerable person from dying is magnitudes more difficult than saving a twenty years old healthy person, but a population mean is computed without addressing such scale differences. The benefit of a drug must be sufficiently strong to overcome the buffering effects of the vital organs. Unfortunately, strong drug effects are not what could cure chronic diseases because they must disrupt other related and coupled biological pathways in cells. All chronic diseases are caused by small amounts of departures in process attributes. Therefore, drugs can control only symptoms, an indisputable fact that has been confirmed by over thousands of studies. Those critical facts determine that health cannot be directly evaluated by any experimental method except for rough approximations. Moreover, each person is unique in the organ buffering capacity, all health properties, and exposure to all interference factors, and thus responds to any drug in a distinctive way.

The validity of means must be determined by the physical system or the human body (but not mathematics). As I have showed in my original article, statistical distribution does not exist for nearly all health properties. This is a game-ending flaw. Thus, any mean is a meaningless number. This can be shown by a very simple hypothetical model. The risk from dying from mRNA vaccine is distinctive in all people. Assuming that a young person's risk of death is near 0, and the death risk of an old person with limited organ functional reserve is 1. For his two-person population, we get death rate of 0.5. This number is a statistical mean of this population. It is only true mathematically, but it cannot be used in the physical system. None of them has the risk of 0.5. The young person can survive the vaccine, but the old person dies. The risk in each person is a system's property that cannot be transferred from one person to another. In addition, death of young persons and death of old persons are different things. Their death rates mainly depend on their organ functional capacities. If their functional capacities are rated on the same scale, they may differ by 100 times. The two numbers also have

different significance. Thus 1 death of old person plus one death of a young person equal to 2 is meaningless. Most drug researches may find a few to 20% reduction in risk, but such a number is achieved by adding and averaging personal numbers which might differ by several times to nearly a hundred times. Such an averaged number cannot be applied to anyone.

A population consists of healthy persons, young persons, old persons, males and females, and chronically ill persons, and thus all the persons have distinctive risks of deaths. The computed mean has absolutely no bearing to any persons. As I have done extensive analysis in my original article, the root problem lies in the fact that the statistical mean is a completely wrong parameter. It is well known that many properties such as temperature, pressure, system attributes, etc. are intensive properties, their values are confined to their own systems. Thus, the values from different systems cannot be added up. In mathematics, one can add any set of numbers to get a sum. In the physical world, for two quantities to be additive, they must use the same unit, are rated in the same scale, and have same significance (perhaps a lot more other limitations). Volume, weight, and length can be extended. Among health properties, nearly all properties are not extensive. Temperature, blood pressure, matter concentration, enzymatic activities, and even structural strength cannot be added up. The structural failure points in different persons must be distinctively different. Even same numeric value in the same person can mean different things. The 10 mm Hg increase in blood pressure in the range well below the structural failure point is immaterial. The same amount pressure increase will become more and more lethal up to the failure point. Reduction in enzymatic activity controlling a critical path well below the threshold death is completely immaterial until when it is close to the critical point.

The meaning of temperature completely depends on physical systems: Each degree means same in mathematics; each degree is roughly same in many physical systems; each degree means different energy levels in some particle systems; each degree in different ranges in the core temperature of a human have different impacts. 37 °C is the optimum; 33 °C may kill the person; 40 °C may raise immune capacity to the maximum; and a temperature above 43 °C may destroy CNS. The average 37 °C of two lethal core temperatures, 30 and 44 °C could not alter two death risks. Strangely enough, most problems are originated from the needs to cure diseases. Mathematicians are interested in predicting outcomes, and do not care about altering risks and deaths. However doctors are interested in saving patients, and thus have to interpret impacts of each temperature value or change and may have to use different measures for different core temperatures. It is clear that a large number of health properties cannot be modeled by simple mathematical models. A super majority (99%) of statistical analyses in medical articles concerning treatments are wrong or grossly inaccurate because they have used linear models and use of intensive properties outside the associated human body. Use of non-linear models or multiple functions for a single person are beyond human current ability.

The additivity of properties actually depends on the purpose of research. If the death rate is used for estimating food supplies, house opportunities, social security usage, etc, they may become extensive. A strict rule is that the mean cannot be used to guide treatment of diseases. In medicine, a vast number of health properties are like system attributes that are tightly associated with specific persons because they are related to other biological processes in the body. A person with death risk of 1 may be caused by kidney disease and overall condition. This number cannot be imposed on persons who do not have this disease and condition. When such numbers are extracted out of the person, they have no meaning. Also, the heart output of a 300 lbs male and that of a 90 lbs female cannot be added up to get a mean for both. Imposing the mean on both of them would kill both of them. Due to great differences among individuals, infection risk numbers cannot be added up on the same scale as guidance for treatments. With limited exceptions, risk conclusions from clinical trials and best treatments based on clinical trials are simply wrong except that treatments are strong effects for short term use. This explains why medicine fails to find cures for chronic diseases in centuries.

Effectiveness value from clinical trials is deeply flawed also under the multiple factors disease cause model. Since health and disease outcome is actually controlled by multiple factors, health or disease cannot be characterized by looking at just one factor (e.g., the vaccine). Measuring health property by focusing on a single factor must be wrong. This is because the optimum health or disease outcome is defined by a set of best values for all relevant factors or variables. In other words, the performance of a drug depends on all lifestyle factors, diets, exercise, and overall health. Many of those variables can take different values among individual persons. So, the actual performance of a vaccine on a person must be poor simply because one or more factors or variables hold wrong values. For example, if a person happens to have an infection, vaccination at this close time window would kill the person. However, a much worst problem is that all people may hold different values temporarily, and their outcomes must be different among them. They may have different values in food intake, hydration level, physical stress, thinking activities, emotional stress, and even good-or-bad dream. Thus, some persons may take values to produce outcomes closer to their optimum performance, and others may happen to be in the worst states. It is also possible that a particular value of a specific factor is good for some persons, neutral for others, and bad for yet others. This implies that using multiple factors in a controlled trial is impossible and investigating one single factor like vaccines is also improper. The effect of one factor cannot be freely extended to any of others due to its tight associations with other related factors. However, lost health due to one factor could be compensated by gained health by other factors in some aspects (even though the effect is not transferred, compensation is due to sharing of vital functional reserves). This becomes an important way to extend personal life with challenging diseases when some factors cannot be altered.

The extreme complexity of the human body requires a completely different way to address chronic diseases….

2. FDA failed to see that the research model "writes off" injuries and deaths and latent side effects

FDA vaccine safety conclusion for booster shots is based on clinical trials, where 12,000 participants were followed for safety outcomes for four to six months after the second dose. The conclusion from such a trial is deeply wrong based on every past failed drug or personal injury instance. I have conducted an analysis based on holistic model to predict dozen of side effects. Senef et al. also predicted a dozen potential risks based on biological and cellular mechanisms [237].

The safety of vaccines was exaggerated on the people who have massive vital functional capacities. The trial shows all of those vaccinated persons survived. This does not mean the vaccine had not caused acute injury or latent side effects which will show up after long time delays [1]. Before the organ functional reserves were understood, it was natural to assume that drug injury symptoms can be used as an accurate measure of drugs side effects. A large number of studies found that damages at cellular levels can be widespread. The redundant organ functions work like a HUGE buffer, which conceals weak side effects that do not cause death. Due to the buffering effects, drug A ruing 50% vital functional capacity, drug B ruining 25% of vital functional capacity, and drug C raising 5% vital functional capacity would appear similar. FDA never knows how the vaccine has diminished recipients' vital functional reserves. Among all recipients, they may lose different amounts of the organ functional capacities from nearly zero to any reasonable values. If the vaccine diminishes only 10% vital functional capacities, it will not show up among all people who have more than 10% surplus functions. The person may lose 10 to 20 years of life spans.

Most latent side effects would take at least 4 years up to 70 years to materialize. This can be due to slow-accumulative effects of reduced vital functional capacities or accumulative damaging effects of toxic components. Organ functional reserves are not the only factor contributing to the long delay. Persistent toxic substance strikes cells with time by random chances and damages are accumulated in the entire life of the host person. This means a short trial will not enable a researcher to see the full adverse impacts. Long delays can be caused by durable cellular changes which might be maintained by cellular memory and CNS system memory. One known fact is that toxic substance can alter gene expression pattern in cells and their adverse impacts continue with time even after the toxic substance is eliminated [26]. An one-time instance (such as trauma) can totally change a person's health, presumably by altering CNS memory and thus its regulation over the body. If an alteration is a further reduction in a limiting biological resource or a limiting vital function, the effect is disastrous. I urge FDA to conduct some simulations to show how a 0.01 to 0.1% decrease in a vital functional capacity can cause big adverse impacts in a person's lifetime. Measurement of health

properties can be further interfered by a large number of factors in personal lifestyle, daily activities, emotional condition, environment, etc. The existing knowledge from a large number of studies explain that most acute injuries cannot be determined by observing symptoms in a short trial. Thus, clinical trials, particularly with less than a year, can conceal nearly most acute side effects and completely write off all latent side effects. Conclusions on vaccine benefit-to-risk ratio from clinical trials is meaningless except they can screen out imminent danger.

All non-distinctive symptoms are “written off” as not having been caused by vaccines. Even though mRNA is predicted to cause an unlimited number of non-distinctive side effects, medicine recognizes only a few distinctive symptoms. Due to this flaw, even deaths happen in the vicinity of vaccination are incorrectly attributed to other causes. The vaccines can kill those who have lower vital functional capacities, are allergic to the vaccines, or people where vaccine-induced cytokine storm happens to superimpose over infection-induced cytokine storm or life stress, but most deaths are written off by attributing deaths to other causes. After a super majority of deaths have been written off, death risk attributable to vaccines is further reduced by improper averaging effect of a large number of healthy recipients who always survive. This averaging is done against the forbidden rule that death rate cannot be transferred from the at-risk people to no-risk people. Clinical trials actually attempt to use the large number of healthy people to underestimate the danger to the smaller number of vulnerable people; the symptoms-based method can conveniently write off most acute injuries and latent injuries that are not sufficiently eat off all vital functional reserves; and lifestyle and activities can further interfere with delayed side effects and latent side effects. The final risk of vaccines is massively reduced. Such findings from clinical trials cannot be used as treatment guidance but creates a misleading impression of safety.

The clinical trials can advance medical trade revenue: Clinical trials can spread disease risk from vulnerable persons to the whole population, extend benefits from a small number of distinctive people to the whole population, and conceal most acute injuries and all latent injuries [1]. For the COVID-19 disease, clinical trials expand the risk from the small number of at-risk people by 10 to 100 times to cover the whole population. The method effectively conceals side effects potentially by hundreds to thousands times due to massive organ functional reserves and use of symptoms for tracking side effects. Effectiveness number like 95% misleads by exaggerating the treatment’s benefits by extending short-term benefits from a small number of at-risk persons to all people in the population. By refusing to explore alternative methods, they also create a misleading impression that nothing else can have the same benefits. This is why the medical publishers [232] keep clinical trials as the best research method to secure their trade revenues [233].

3. FDA failed to evaluate all predictable and potential risks

FDA did not mention three root problems of mRNA vaccine dangers: the coating property variations, variations in hydrodynamic property in each human body, and huge differences between different persons [1]. Another important factor is that mRNA is small particles can have great penetrating power. Based on known mRNA migration properties [316-319], I must find that mRNA particles can enter any types of cells [1]. Without considering those root problems, FDA could not see clear risks. FDA has not done analysis of both acute vaccine injuries and latent side effects at cellular levels but still uses observed symptoms to determine damages which would appear several years to several decades after vaccination.

Here I will discuss only several key dangers which are on the way to realize. I will show that all dangers can be traced to three inherent problems that cannot be solved [1]. It is mistakenly assumed that a particles delivery system can be designed so that mRNA molecules can be delivered to nearby lymph nodes. It is hoped that mRNA molecules do not get into blood and the cells of vital organs in meaningful amounts. I must find that the coatings for all mRNA molecules vary, the hydrodynamic properties in any localities are different from those at any other localities, and a large number of factors affect the survival lifetime of the coatings or their protection times or their traveling distances [1]. An mRNA vaccine that works the best on some persons cannot work well on others. They must have no benefits or endanger many recipients.

Damage the CNS, the brain and nerves [1]. I predicted that mRNA vaccines can enter the blood brain barrier cells and thus disrupt the normal protein synthesis for carrier proteins based on several relevant studies [238-241]. When the barrier cells cannot maintain protein change over balance, it impairs the barrier integrity. mRNA molecules have some of the barrier cells destroyed and allow survival mRNA molecules to enter into brain neurons. There, each mRNA may produce many copies of spike protein and thus invite the immune system to attack the affected neurons or cause brain inflammation. The T cells can get into and out of the brain and have affected neurons destroyed. Even if some affected neurons survive, chances are that the synapse connections are impaired by disrupting highly regulated mRNA synthesis. The vaccines can systematically damage the CNS system, the spinal cord, and terminal nerves. The vulnerability of the nerve system is reflected in vaccines roles in causing autism, sensory loss, visual impairments, lost balance, impaired memory, diminished intellectual capacities, etc. In addition, high blood pressure caused by vaccine cytokine or inflammation may cause damages to local brain tissues purely by chances. (FDA should review recently published case reports on mRNA vaccines' impacts on CNS.)

Deaths due to raised blood pressure and damaged heart. After vaccine is administrated, some of particles can quickly get into the heart by blood return. The amount of particles getting into the heart would depend on how close the needle is placed to some moderately large veins. If some mRNA particles find their ways into the heart, they cause acute heart inflammation although whether the person can feel depends on degree of impacts and heart functional reserve. The person may be unable to feel

symptoms. The particles may cause significant inflammation in heart muscles and loss of heart pumping power. At the same time, the cytokine storm will increase all overall blood flow resistance. The vaccine can be more dangerous by suddenly raising blood pressure. Viral infection is a progressive process but vaccination instantly introduces a massive number of particles [1, 320]. The human does not have time to make adaptive response. The mRNA must disrupt normal protein synthesis. Protein synthesis is vitally important to maintain heart function, and protein synthesis in the heart must be maintained even when protein synthesis in other parts is disrupted by starving and fasting [243-244]. I predict that mRNA can disrupt the protein synthesis and impair the heart's ability to repair damages. Thus, raised vascular pressure, diminished heart muscle power and disruptive abnormal protein synthesis work as a triple combination to rapidly degrade the heart working condition. This explains why the symptoms of vaccination in some persons can last very long. The disrupted brain functions may also impair the brain's signals for controlling the heart.

Damage vital organs and diminish vital organ functional reserves. mRNA molecules are able to get into blood and to land on any types of cells in vital organs including heart lungs, liver, spleen, nerve cells, etc. They injure each organ in double actions. They hijack the protein production machinery to produce spike protein. The spike protein produced by mRNA in affected cells will invite immune system to attack the cells. However, normal protein synthesis is highly regulated in brain and heart [1] or critically important in vital organ cell regeneration in lungs, kidneys, and liver [245-253]. Damages are felted first in the weakest organs. Damages in all vital organs must ultimately result in degraded performance of the vascular system. The mRNA must disrupt normal protein synthesis in affected cells and all cells globally due to sudden depressed concentration of essential amino acids for protein synthesis. I predict that when the mRNA suddenly hijacks protein synthesis machinery in a significant number of cells in various parts of the body, it must disrupt the heart function even if mRNA particles have not entered into the heart. However, the heart muscle may inflame if a significant number of mRNA particles have entered into muscle cells. Vaccines must cause immunological damages based on observed cell death in COVID-19 patients (no need to find a specific mechanism). The damages in vital organ cells thus reduce organ cell numbers, their mass and vital functional capacities. In addition, it is very likely that disrupted protein synthesis cannot be restored fully and changes may affect the person by long term effects. With time passing, this side effect increases risks of death for all causes and thus shortened recipients life spans. Whether the person survives depends on whether his vital organ functional capacity is more than what the body requires in any time. In the pandemic season, the total required vital functional capacity is the sum of minimum functional capacities required for maintaining basic functions, the burden from infection, the burden from acute vaccine reaction, and burden of personal activities. Among those three, the burden from vaccine adverse reactions is the largest. Thus, vaccines must be reviewed as the primary, secondary or contributory cause of deaths. Even after a death

happens long after vaccine is administrated, it is possible the death is caused by reduced vital functional capacities.

Disrupt the immune system balance. By examining several limits of immune system such as B cell population changes from general infections, excessive activation of the immune system or excessive long active duration is predicted to be harmful to health as a whole [1]. One reason is that all immune process attributes tell only a partial story. For a similar immune response intensity, the person's ability to survive depends on the vascular system to maintain blood circulation and blood vessel structure for withstanding local blood pressure. Moreover, whether a person suffers stroke, heart attack, and thrombosis would depend on the structures of organs and structure of blood vessels. Repeated activation of the immune system by vaccination must keep high B cells and T cell concentration and cause systematic inflammation in vital organs and tissue cells. Second and booster shots pose the highest endanger to recipients because such shots are equivalent to introducing massive antigens after a person's immune system has been activated. In this situation, the person does not have a sufficient time to adapt the sudden burden on heart, kidneys, lungs and all vital organs. In addition, the Pfizer vaccine can reprogram the immune system. Contrary to general prediction, the mRNA vaccines weaken the innate immunity against the SARS-CoV-2 virus and make recipients more vulnerable to the virus. The UK data show dramatically increased death risks among those who have received two shots.

Two personal injury catastrophes, stress effects and DES injury, provide a strong hint that excessive activation of the immune system is most probably bad. Stress hormone release in a way consistent with the pattern and intensity set in evolution is good, but release of excessive amount of stress hormone at too high frequency can cause all kinds of diseases including cancers. Similarly, female sex hormone is highly dynamic in a person's normal life cycle, but alternation by DES (as well as many other drugs) turns out to be a nightmare. I predict that the immune system is not for unrestrained abuses. It has bounds and limitations set in evolution.

mRNA vaccines promote selection of virulent virus. Since mRNA vaccines are imperfect vaccines, they are selection pressures for viral evolution [253-254]. The virus would try to mutate to evade the immune system's attack. When the virus mutates in a large number of asymptomatic vaccinated persons, it can increase the risk of cross-infecting among themselves. If this prediction were wrong, the entire researches in collective infection theories done in the last century would be wrong. I am confident this prediction will come true. It was found that Pfizer mRNA can weaken vaccinated persons' resistance to the virus [255].

The mRNA vaccines increase cancer risks. They will accelerate cancer growth speed if the vaccines have impaired brain structures and functions. The observed massive signs of their impacts on the CNS are the strong basis for making this prediction.

mRNA vaccines are more dangerous to fetuses [1]**.** Neurons are connected by synapses during fetus development. Signal firing and transmission in the brain depend on synapses connections. The development of synapse connections depends on highly regulated protein synthesis (e.g., synaptic vesicle, snare complex, V-APTase, etc.). It is believed that >67% (about 13227) of all human proteins (n>=19670) are detected in neuronal cells and 2533 of these genes show an elevated expression in any neuronal cells compared to other cell type groups [238-239b]. Spike protein production triggered by mRNA vaccines must disrupt normal protein synthesis. If mRNA vaccines are administrated on pregnant women, spike-protein production disrupts normal protein synthesis in the fetus and has neurons killed, resulting in abnormal brain structure, which has fewer neurons, fewer connections and impaired signal firing capacity. The mRNA babies will have diminished memory and intellectual capacities.

Analysis by Seneff et al. The authors predicted health risks for mRNA vaccines by using conventional approach [237]. One of the risks is polyethylene glycol- or PEG-induced anaphylaxis and cardiovascular collapse which happens upon a second and booster shot. Other risks they predicted include pathogenic priming, multisystem inflammatory disease, autoimmunity, idiopathic thrombocytopenic purpur (platelet destruction), immune thrombocytopenia (ITP), activation of latent Herpes Zoster, spike protein toxicity, prion diseases and neurodegeneration, vaccine shedding (vaccinated people causing disease in unvaccinated people in close proximity), permanent incorporation of spike protein gene into human DNA (the sperm would be free to take up RNA-embedded liposomes from the vaccine and convert them to DNA), etc. While two studies used completely different approaches, both points to severe damages to the nerve system, the heart and the immune system. Both predictions strengthen each other. For example, I predicted that the brain may be damaged by having neurons killed or synaptic connections impaired, while they predicted the spike protein may cause prison-like disease. While I predicted that a certain number of mRNA particles must enter the main circulation, they found that mRNA can be carried by immune cells or via the lymphatic system to reach spleen or any parts. I found that most vaccine-caused deaths are written off, they also found this risk. In addition, some side effects are caused by ingredients used in the vaccines, they should be additional to all risks I have predicted. They also predicted that the spike protein sequence may be incorporated into the DNA chain in human sperm cells and thus will become a part of human genome in future human being. I think far more side effects will appear with time. The total number of site effects of DES and Roundup is very large even though they have no predicable problems at the time of use [1].

4. FDA failed to consider how acute vaccine injuries kill recipients

FDA analysis of acute injuries is based on classical method: examining symptoms. However, this method has been proved to be wrong in all personal injuries in the last century [1]. Medicine must have assumed that after the symptoms is gone, no harm is done. However, in reality, such symptoms will reduce organ vital functional capacity

[1]. Flu vaccine can have lifetime side effects [263]. If the acute injury is strong enough to show symptoms, it may reduce the organ functional capacity permanently. If adverse effect is weak, it may cause no symptom. If the acute injures are severe, the vaccine may cause widespread damages to organs and tissues temporarily. After the symptoms are resolved, the body may recover most of the lost functions but not all [1]. The amount of lost functional capacity depends on severity of symptoms. If the vaccine has destroyed the blood brain barrier and kills some neurons, the person might experience CNS problems and have diminished vital organ functional capacities. The change may be as little as a few percents. This change will exhibit as latent side effects. FDA did not appraise how those strong adverse response will ruin the vital organs and how the injuries will affect future health.

5. FDA used an obsolete and wrong approach in evaluating latent side effects.

Concerning side effects, FDA states:

> "FDA's review of the available safety data from 37,586 of the participants 16 years of age and older, who were followed for a median of two months after receiving the second dose, did not identify specific safety concerns that would preclude issuance of an EUA."

This statement can be rejected on dozens of grounds. To be short, by using its logic, FDA would approve any drug and any vaccine as long as it will not kill its recipients immediately. Ignoring a large number of flaws in researches, its safety conclusion must be based on the hypothesis that when people have recovered, no harm has been done. This hypothesis is wrong as it is consistently refuted by studies of drug and chemical injuries [1]. One study found that vaccination for H influenza type b in childhood can increase the risk of developing diabetes in adults [263] and may damage CNS with obvious signs [264]. However, the risk model is wrong. The vaccines must damage all people by similar cellular mechanisms, but only the injuries will show up against all masking effects only on a small number of persons or one the impacted persons whose impacted vital functional reserve has run out. A claim like several times rise in risk implies much severer and widespread damages among all persons. mRNA vaccines can cause Bell's palsy [265]. Vaccine benefits for influenza are small [266]. Those studies show that vaccine injuries may be hidden and lasting. Moreover, nearly all drug-induced personal injuries do not cause pain, discomfort or serious illness in the early times [1].

Perhaps, FDA might have hoped that newly discovered side effects can be addressed later. While FDA requires drug sponsors to conduct post-marketing surveillance, this measure cannot prevent vaccinated persons from being injured. FDA also failed to see how vaccine-induced inflammation might cause death by burdening the vascular system. Under its current evaluation method, nearly all vaccines induced deaths would be attributed to other causes. FDA cannot ignore the fact that a severe inflammation can dramatically raise blood pressure and may cause stroke, heart attack

and thrombosis whenever a local blood pressure exceeds what the blood vessels at the weakest point can withstand. FDA must know that there is no conceivable method to undo realized personal injuries. Even after the first waves of personal injuries are detected, it may take additional several decades to a century [1] to see personal injury cases to wind down. I must predict that FDA's gamble will be a disaster.

Latent side effects may take long times to materialize because they will be detectable only after damages are severe enough to eat off the surplus vital functional capacities [1]. From the statement, FDA did not consider the vaccine's effects on vital functional reserves, redundant biological resources, time-dependent effects, organ/tissue structure, and the interference factors. FDA did not consider how disturbance of 0.01 to 1% in a main health process attribute can cause a severe chronic disease after a sufficiently long time has passed [8-9, 58]. FDA did not explore how all uncontrollable lifestyle factors affect side effects. It is too easy to attribute all delayed vaccine-induced deaths to accidents, heart diseases, stroke, existing chronic diseases, natural causes, etc and then claim vaccines caused personal injuries only in one in a million. It took thousands of years for humans to recognize lead toxicity [1]. The approach to predicting risks by symptoms is refuted by large number of post-1980 studies on drug/chemicals' cellular damages [1]. FDA cannot ignore those findings and their implications and then continue to use the wrong method to repeat failure. When medicine trade has used overwhelming known devices to keep this flawed approach alive, FDA must find a way to bypass its control.

6. FDA failed to consider safe and effective alternatives

The vaccine applicants claim that there is no alternative measure for treating and preventing the COVID-19 disease. However, the death rates between highest nations and lowest nations can differ by more than 10 times [232]. By examining national incidence and death rates within the U.S. data [232], one could have found that seasonable temperature changes are responsible for at least ten times of differences [233-235]. By comparing the differences in incidence rate and death rate, lifestyle factors are responsible for more than 100 folds differences between different nations. Those data implies that the pandemic is easy to contain without using any vaccines (See my long analysis on small probability effects). No good faith argument can be made that societies have explored all safe alternatives. Infection and death rates in U.S. is more than 100 times of those in many nations [232]. Mask is very effective measure against infection [236]. Vitamin D and Zinc were found to improve antiviral capability and reduce disease severity [306, 322-323]. Both applicants are predetermined to develop vaccines for profits.

G. Key Evidence, 95% Effective Rate, Is Meaningless, but Misleading

Looking at the data in Table 6 in the FDA memorandum [3, 5], the claimed the vaccine effectiveness was 95%. The study found that for participants without evidence of SARS-CoV-2 infection prior to 7 days after second injection, the effective rate was

95.0%. There were 8 COVID-19 cases in the vaccinated group of 18,198 persons and there were 162 COVID-19 infection cases in the control group of 18,325 persons (see its Table 6). I will show that 95% is an index number acquired in violation of fundamental law, does not tell how vaccine performs relative to other measures, does not tell anything about acute personal injuries and latent side effects, and cannot be applied to any person.

Before flaws can be exposed, it is necessary to discuss disease risk factors. Infection/death frequencies can tell how likely a disease can attack people. A high frequency means more likely people will be infected or die. When a person has certain poor health condition known as a risk factor, the chance for them to get the disease is higher. If the normal persons get infection at 5% while those with kidney diseases get the infection at 20%, the hazard rate ratio is 4. Hazard ratio or (adjusted) rate ratios are used to measure events such as infection, hospitalization, serious events, or death. A high ratio means the risk factor has more adverse impacts. A study found following adjusted rate ratios: severe obesity (4.4), chronic kidney disease (4.0), diabetes (3.2), obesity (2.9), hypertension (2.8), and asthma (1.4), after adjusting for age, sex, and race/ethnicity [273]. Another study found that in-hospital mortality for 50-64, 65-74, 75-84, and ≥ 85 years (3.11, 5.77, 7.67, and 10.98 using 18-39 years as the control), male sex (1.30); immunosuppression (1.39); renal disease (1.33); chronic lung disease (1.31); cardiovascular disease (1.28); neurologic disorders (1.25); and diabetes (1.19) [274]. Those are only exemplar risk factors. People's infection and death risks depend on their risk factors. A person may have one, two, several and even a large number of risk factors (including many that have not been studied in medicine or have not been recognized as risk factors officially). Some persons may have very high hazard ratio.

The risk model makes an assumption that infection, hospitalization and death are quantities that can be added and transferred from any person to others. However, each of those events such as hospitalization means a different thing for different persons. Adding up those numbers violates a forbidden rule against addition across different persons. The death of Jack at age of 100 and death of John Young at 20 are completely two different things as far treatments are concerned (they may be treated as same for other purposes like bus tickets, hotel reservation, etc). Moreover, frequency representing hazard has introduced averaging effect (even though no averaging operation is actually done). In reality, such frequency cannot be used as risk probability for any person and the ratio has no meaning to each specific person. Each death happened to persons with reasons. It is now known that a large number of other factors (like expanded "risk factors") also affect the immune system and whole person health. Death does not happen to the young, health, and responsible persons without reasons except by accident. The rate ratios for diabetes (3.2), obesity (2.9), hypertension (2.8), etc. cannot be used to accurately predict personal risks even for people with those risk conditions because any of the expanded risk factors differs.

The linear model used in risk assessment is very poor. Death happens when vital functional capacities cannot meet required minimum functional capacities plus all burdens from all diseases and life activities. Many variables can be manipulated to alter outcomes. I have shown that any of health properties has different meanings in different ranges. When a person is far away from death, depressing his vital functional capacities will not cause death. If the person is near the threshold of death, any mistake, additional burden or additional health problem may cause death. For example, if a person can withstand systemic blood pressure up to 250 mm Hg, the contribution of 50 to 100 mm Hg by life factors is not harmful until his blood pressure has reached nearly 240 mm Hg. Even at that pressure, if he learns to use proper measures to avoid further rising, he may void vascular failure. Adding additional 15 mm Hg by doing a wrong thing may cause heart failure or stroke. Those with a risk factor may have a high chance to experience adverse event or death but this prediction can be defeated by altering a large number of life factors. Only if are personal death risks analyzed with current life factors, avoidance skills, personal behaviors, etc, can we predict who get infected, who might get serious infection, and who might die. The risk factor value tells only a ballpark relative risk, but cannot be used to predict outcome for any specific person in specific circumstance.

Death risk such as 2% death rate and 2,000/million infection derived from population is only an abstract value for measuring the disease agent, the overall health condition of all people in the population, the distribution of people with different health conditions, weather conditions, environment, time of year, etc. The value changes with time, weather, culture, personal belief, personal skills, and personal behaviors. It is simply irrelevant to any of the people. It is like an averaged fuel injection rate for all car models and makes in the U.S., we can get such an abstract index number but cannot apply it to any specific car at all. Imposing the population mean to any car would ruin the car. All population-based numbers cannot be applied to any person such as John Doe or Jack Doe. In reality, super healthy persons get no infection or a mild infection, those with poor health get severer infection, those who have learned prevention skills may avoid infection, those with suppressed immune system or diminished vital functional reserves may be infected, severely disabled or die. With the massive studies in medical literature, FDA should expand the risk factors to include hundreds to thousands of factors that have not officially recognized in treatment of diseases. For example, certain individuals may have special microbiota which produces immune suppressants. Some individuals might lack vitamin D, but others might be under poisoning of vitamin D. None of the expanded list of risk factors can be addressed by mRNA vaccines. The risk deduced from a population cannot be applied to even any of the persons in the clinical trials, and vaccines cannot have the magic for fixing all of the expanded risk issues.

Ignoring all other problems in risk and risk factors, the effectiveness is based on a small number principle: Even if no vaccine had been given to the vaccinated group, only about 162 persons could get the infection. Assuming that 2% of them would die,

the total number of deaths would be about 3. So, the benefits are very small. Based on the Pfizer study, the infection risk for the vaccinated group is 8/18,198=0.04%, and the risk for un-vaccinated group is estimated to be 162/18325=0.88%. For the sake of argument, I assume that those people were identical (this is a wrong assumption). The effectiveness is estimated to be (0.0088-0.0004)/0.0088=95.4%.

The effectiveness 95% is based on a small frequency or a small probability, and thus the actual benefits can be very small, assuming the benefits were deliverable. If infection rate is a large number, then reduction would have a practical meaning. Second, when effectiveness is expressed as ratio, it produces a number that is misleadingly large like 95%. In reality, the un-vaccinated group just has only 162 cases. The low infection rate for the control group indicates that the disease is not bad.

The data imply that only less than one in every 100 persons would get infection. In reality, who get infected is not decided by random probability but by their health, avoidance skills, lifestyle factors, and personal daily activities (e.g., expanded risk factors). The vaccines can dramatically reduce infection risk for a small portion of at-risk persons (based on the data). If the vaccine is the only anti-pandemic measure, it can prevent about 1% the people from getting infection. Thus, the effectiveness rate is relevant to this small portion of persons. The risk of severe infection and death are not irrelevant to a super majority of people (at least say 80% of the people). Even if some of them do get an infection, their diseases are so mild that they could not feel. If all disease risks are transferable, the same 95% could be achieved by permuting patients. If the 3 original patients were prevented by staying at home and any of other 3 patients are infection by exposure, the trial would have gotten the same 95% effectiveness. Similarly, the 168 infections could be relocated to other persons by changing their personal behaviors in a large number of different ways. Such a number represents a great reduction of information and is irrelevant to the super majority of people including healthy and young people, healthy middle-aged people, healthy and old responsible persons.

The number NEVER means that the vaccine can reduce infection risk by 95% for each person. Despite misleading impression, the number, 95%, does not prove that vaccine is the best measure because it cannot disprove each of hundreds other life and preventive factors such as right lifestyle, avoidance skills, daily activities, management of body temperature, balanced diet, certain handy exercises, etc. By using the same flawed logic (the same population method), any of a large number of factors would be used to have similar or better benefits. Temperature has more than 10 folds effects on national incidence rate [1]. When temperature is changed from winter to the summer, it would have a similar effectiveness rate (10-1)/10=90%. Wearing masks would have a similar effectiveness of 90% even though I do not have data. Deep breathing exercise, meditation, and right exercise at right times may have similar effectiveness ratio if they were studied. Those well studied risk factors can affect people by combination. Similarly, those life-related expanded risk factors can be beneficially used in combination, they can easily exceed the vaccine's short-term effectiveness. Based on infection rate

between different nations, 99% reduction is possible without using vaccines. However, much large benefits can be found by using personalized approach: by addressing the small probability. Among each 100 persons, we identify those with various risks by using lifestyle, avoidance skill, alter daily activity, skillful use of exercise, etc, if we succeed in preventing one person in the 100, the measures beat the vaccine. If five sets of measures are used to alter outcomes for 5 persons in the 100 persons, the measures can completely beat vaccines. Each set of measures may employ many factors such as diets, exercise, emotional management, etc. It is entirely realistic based on the fact that this disease has little impact on most healthy persons. Life skills for avoiding exposure and lifestyle factors [1, 232] are not studied due to lack of financial interest. Based on studies in cancer and chronic diseases, emotion management, exercise, diets, etc. can deliver long-term survival benefits that can easily beat drugs. Reviews by Segerstrom and Miller, Booth et al., and Comie et al. [24, 179, 184] provide yardsticks of long-term beneficial effects.

One biggest problem is that this small vaccine benefits on a small number of people are achieved by endangering the whole population. To get this short-term benefit for a very small number of persons, the entire population must be vaccinated. The 95% does not tell what kind of dangers the vaccine may bring to the population. In the Pfizer trial, the vaccine was administered to all 18,198 persons but their long-term adverse effects are unknown. **The claimed short-term benefits on 162 persons must be weighted against their risks on all 18,198 persons in their life times.** If the vaccine actually prevented 3 deaths, the costs are on 18,195 persons. The whole population must bear the risks of causing brain damage, heart damages, mRNA babies, potentially altered human genome, potential prion disease, diminished intellectual capacity, and millions of unidentified and unidentifiable damages. In contrast, good lifestyle, improved health, learned avoidance skills, sensible daily activities, etc. can have both short-term and long-term beneficial impacts without endangering selves and others. The second difference is that vaccine benefits are short-living and will be quickly defeated by mutation of the virus, while avoidance skills, improved health and protective measures can have long-term or even lifetime benefits, and can work well on all people against all kinds of infectious diseases. Yet, another difference is that vaccine-induced benefits can be defeated by many other factors that impair the immune system, while the lifestyle measures are improving the immune system. It is fair to say that vaccines can keep vulnerable persons forever vulnerable while lifestyle measures can turn those vulnerable persons into those who can better resist the virus.

Since NIH, FDA, CDC, foundations, etc. provide zero funding to any strategic researches on vaccine's dangers, I can run only two clinical trials by imagination here. In the first one, I will identify ALL at-risk persons (without including healthy persons) and have them vaccinated by three shots per FDA approved use instructions. What I can "see" is an outcome like mass deaths! All of those with very little vascular reserves would be killed instantly without reaching the second shots; many of those with major

organ diseases would be killed on the second shots, and some of remaining persons would die on the third shots; and all of those surviving will die earlier than their expected lifespans. This trial cannot detect future deaths: if a vaccine causes young men to lose a few years to twenty or more years life spans, the vaccine would have a similar effect of causing death to a 85-year old man by cutting off 5 years of his remaining lifespan. If fragile people are infected and also vaccinated at nearly same time, the chances of death are virtually certain (but medicine always attributes causes of death to infection or other causes). The vaccine must have short-term protection to a very small number of persons purely by luck, but this benefit will not show up in this trial outcome. The outcome of this imaginary trial will reveal the true dangers of mRNA vaccines because the trial lacks safety-buffering people who can massively dilute the adverse effects of the vaccines on the vulnerable. Clinical trials have an effect of using the survival outcomes of >80% healthy persons to conceal the adverse outcomes of 5% persons and hide the adverse effects on those healthy people by refusing to recognize their earlier deaths in the future. Medical industry does not do such a trail because it will not turn the whole population into its revenue feeds and instantly prove vaccines' disasters.

Now, I conduct a second imaginary trial for the same vulnerable persons by altering their lifestyle, daily activities, behaviors, etc. Most people's survival ability can be altered by addressing those well-studied risk factors, many of which can be addressed by changing lifestyle and improving life skills. Inferring from magnitudes of known risk factors, I would find that a 10-folder reduction is possible for those with multiple risk factors. However, an expanded list of factors can be used in a beneficial way. Improve diets for those with poor dietary habits, do excises for those who are inactive in their daily life, learn to use protective skills for those who are normally lacking, and mitigate stress for those exposed to high stress, learn basic skills to manage body temperature, etc. For those highly vulnerable persons, multiple measures may be used in combination. Based on small probabilities, each measure may alter the outcome of 1% of persons. If those measures are applied by tailoring each of them to personal conditions, they must have superior benefits. Such measures and their well-matched combinations could alter outcomes for up to 10-20% persons and thus prevent them from dying from the pandemic. My prediction is very realistic because those factors are responsible for more than 100 times differences in infection rate and death rate, as implied in the incidence and death data for different nations.

Four big flaws of the population model are transferring disease risks from a small number of persons to the population, inflating incidental treatment benefits and extending the inflated benefits to the population, writing off most acute side effects, and concealing latent side effects. Each of those transfers is in violation of the forbidden rule that all health properties cannot exist out of each person's body. Population approach is maintained as science because it can turn the whole population as revenue feeds for the medicine trade. However, it is grossly unfair to those (about 80% or 14,568 or more) healthy people in the Pfizer trial) because the risks of deaths of COVID-19 are **com-**

pletely irrelevant to them. The claimed treatment benefits are based on short-terms benefits on a small number of persons, and transferred to them. The benefits predicted by the flawed effectiveness can NEVER be realized.

Confidence Interval (90.3, 97.6) used in Table 6 is also flawed and meaningless [8-9]. It is based on frequency achieved by adding non-extensive property. The same value range (90.3, 97.6) could be achieved for all similar data sets like the one shown in Table 6. If the data were acquired from another disease or even an automobile accident reduction study, it would have the same CI values. The CI values actually depend on drawing probability but do not reflect the effects of all influence factors while each factor would have similar effects of vaccines. The CI is misleading because it has absolutely no relevance to any real person. The effectiveness rate 95% is an index for the whole trial, and the CI would indicate how likely the rate, which is useless, could fall within the CI range if the same research is repeated. In reality, the infection risk is not applicable to those healthy persons; nor is the reduction in infection risk, and nor is the CI. The effectiveness value and CI values will differ if a similar trial is done in a different time of year, using different people, against a different variant, after change of health wisdom, etc. The CI creates a misleading impression that is often misunderstood by laypersons. All lifestyle factors, personal activities and other diseases are bundled into the error or standard error. If we study the effects of wearing mask, body temperature management, exercise, avoidance skills, etc., each could produce a similar number like 90%. Each of them would have a similar effect like the vaccine, this implies that none of those factors could be regarded as errors. The statistical model is wrong. The population research model essentially is tailored to drugs with an effect of precluding the multiple factors life model.

None of the infection and death risks is a stable and durable property [68]. All population-based risk numbers can be altered by any of a large number of factors. It is possible that the vaccinated group may be worse off in a long run due to slowly delivered damages to vital organs. It is possible that the infection risk and disease severity rise more rapidly than those for the control group. Death risk may be different if the virus has been mutated, people's preventive skills have been improved, and weather condition is improved. The number can be changed by all people preventive efforts. If person 1 tries to avoid infection, person 2 tries to avoid infection…, and person N tries to avoid infection, more of them will survive and fewer will die, resulting in a lower disease risk.

Curing and treating diseases is similar to repairing machines in some aspects. Repairing cars/planes is NEVER a probability problem, and nor is curing diseases. Given the massive vital functional differences, death risk highly depends on their current organ functional capacities or general health, avoidance skills and other factors. An old person can mitigate infection risk by improving general health and avoid exposure; a super healthy person can get infected and even die from temporarily healthy problem and a bad exposure. A triple combination like extreme fatigue, exposure to severe low temperature, and exposure to a huge number of viral particles may kill anyone [1]. True

drawing probability in typical probability trials cannot be altered, but the effects of all expanded risk factors in a human can be altered during the trial process, predictably.

It has been widely believed that clinical trials can provide useful data because the results are based on comparison between a treatment and control group. The proponent of the population model would argue that clinical trial data in Table 6 clearly shows that the treatment group has only 8 infection cases and the unvaccinated group has 162 infection cases while both groups have similar persons. The benefit is only a small probability of short-term benefits without predicting long-term harm. Comparison is valid only if a treatment has a very strong effect, all people can be treated as identical units, those frequency data becomes useful estimates. In this situation, personal differences can be dropped out, and each death can have one numeric value and frequency data is valid. When the treatment is very strong relative to personal differences, the objection to intensive property can be overcome. Gun's killing power is not tightly associated with personal condition and the stop power from a population study could be valid. In contrast, those vaccines are weak, slow-delivering with long term impacts in both benefits and risks, population study lacks a comparative basis so that comparison is like comparing apple with watermelons.

The comparative method is capable of finding vaccine short-term benefits under the trial conditions. Such results cannot be extended to long-term benefits. Since comparison can only be done for short duration for practical reasons, clinical trials cannot assess the adverse impacts that are realized in long terms. Thus, it is the best method for concealing drug side effects. Those vaccine trials last only several months to less than a year. Moreover, while trials are said to be under control, there is no way to explore multiple factors and there is no way for predicting long-term effects. If the temperature goes down in the winter, low temperature can cripple the immune function of the lungs. If all two groups (e.g., vaccinated and unvaccinated) are under very cold weather, the rate of infections will increase. However, the low temperature may disable the immune function and thus nullify the vaccine short-term benefits. The infection rates change with different slopes in the two groups. If the virus has generated a new variant, the mutation has more adverse impacts on the vaccinated group. Thus, activated partial immunity against the virus may be lost substantially, and adverse effects of vaccines work against the vaccinated persons in the long run. In sum, comparison favors drug short-term benefits and conceal drug long-term side effects.

Flawed clinical trials have an effect of forcing the population to accept painful, dangerous, and reckless vaccine. This practice is expected to hurt healthy persons unnecessarily. However, the imperfect vaccines cannot protect those vulnerable persons, neither. If they die, vaccines are most likely important causal factors, but research models will attribute causes of deaths to other diseases, natural causes, infections, etc. Finally, the vaccine could not help to eradicate the virus but all new evidence and prior prediction show that they will make the pandemic worse. This is the reason to ban all

imperfect vaccines including mRNA vaccines because they must make our future more uncertain.

The number 95% is misleading, with no predictive utility for specific persons, does not tell all vaccine risks. It precludes the population from exploring better and safer alternatives. The predetermined use of the vaccines with a predetermined mind of precluding all other preventive measures most probably result in a pandemic outcome that is magnitudes worse than what could be brought by a holistic approach.

H. FDA Failed to Count Most Vaccine Injuries and Vaccine-induced Deaths

By relying on flawed research and treatment models, FDA failed to see all kinds of deaths that are caused by the vaccines. Now, FDA must consider and reject the binary-quantitative risk model.

Medicine uses binary disease definition which does not reflect reality in most health issues except the death/alive issue. Each person's life is controlled by vital functional reserves. Both vaccines-induced inflammation, infection-induced inflammation and other injures can temporarily and permanently reduce such vital functional reserves while life activity may demand more vital functional capacities. Death occurs when the vital organs are unable to perform the basic functions for survival. Based on true quantitative model, damages at the cellular level by vaccines are absolute, but medicine counts as death only the damages that have caused death and ignore all quantitative damages that have not caused death yet. A healthy person may have functional capacities at 100%, and vaccines may temporarily or permanently depress them to 30% without causing death. Most quantitative damages will not exhibit as symptoms until the damages have impaired certain aspects of biological and cellular functions. This binary disease model has a magic effect of writing off all permanent personal injuries that do not cause imminent deaths. What the binary model enables the researchers to capture are only damages that can use up all of the massive vital functional capacities or the damages that are enough to consume the remaining functional capacities of elderly persons. The model captures only exceptional injuries but miss all the rest. The epidemiological model then turns around to use the death frequency (now, an artificially created quantitative value) as a disease risk or death risk. Ironically, both the binary disease model and population-deduced death frequency are wrong. The double wrongs do not make them right as predicted in mathematics, but make them worse. As I have shown, a deduced quantitative value like death risk is quantitative value downgraded by buffering effects of those healthy persons, and has no meaning to anyone including those who are the subjects in the clinical trial. Life is like a charged battery; the vaccine can drain some of surviving power and can drain the battery to total death only in those worst circumstances. Based on a quantitative model, vaccine injury frequency must be 100%. Young people are like batteries with massive charged energy and surplus current capacities, and can survive from endless abuses like forced vaccinations. Like batteries, they will expire sooner.

The current method of counting vaccine deaths are wrong:

(1) **Deaths close to the vaccination time.** Vaccines must be the primary factor of death of vaccinated persons as long as death happens in a time window close to the vaccination date. Acute vaccine damages, vaccine-induced inflammation and vaccine-induced latent damages affect both vital functional capacities and the body vascular resistance. Inflammation raises blood flow resistance in all affected tissues. The total vascular resistance depends on the resistance of all of tissues and organs that are connected in serial and parallel combination. Thus, an increase in local flow resistance in any and all tissues and organs must contribute to a rise in systemic blood pressure. Based on observed cytokine storm magnitudes, the vaccine's impact is very large particularly in the early times while most COVID-19 infections are mild due to relatively slow progression [320]. Death happens whenever the total burdens from all sources (including the basic function) have exceeded what the weakest vital organ can bear. Even personal activities and other infections can jointly burden all vital organs such as liver, kidneys and lungs [1]. Most deaths lack distinctive symptom of vaccine injuries. Both symptom-based side-effect evaluation method and the use of distinctive signs to determine side effects have the magic effect of writing off deaths caused by vaccines. Most deaths caused by ultimate vascular failure in a time window close to vaccination injection time have been incorrectly attributed to COVID-19 infection, chronic diseases, and natural causes. In a hypothetical example, a death from heart failure two weeks after the vaccination of mRNA must be caused by the vaccine in part even though there is no sign of "vaccine injury".

(2) **Delayed deaths.** All delayed deaths caused by insufficient vital functional capacities have been incorrectly attributed to other causes as a result of using distinctive symptoms for cause of death. In such cases, vaccine-induced organ inflammation is actually the primary, secondary, or contributory causal factor of deaths that have happened in reasonable time windows after vaccination. Acute vaccine injuries may be felt within certain days of vaccine shots, but its adverse impacts can continue affecting the person for much longer times. One main reason is that mRNA vaccine might result in cell loss in brain and all vital organs and mRNA vaccines may impair normal protein synthesis, resulting in reduced vital organ reserves.

(3) **Future deaths.** The recipient lifespans may be shortened by disturbed immune systems, disrupted protein synthesis, systemic damages to the vascular system, latent damages in the brain and vital organs, etc and their combination. All of such deaths are written off. By using the new model, the number of deaths attributable to vaccines must be magnitudes higher. If mRNA vaccine in a person causes little symptoms but causes the person to lose about 10% liver functional capacities (based on the maximum as 100%), he feels perfectly good. If this person ultimately dies from complications triggered by insufficient liver function, the vaccine side effect may cause the person to lose about 20 years lifespan. He may die at 50 rather than at 70 if he had not accepted the vaccine. In another hypothetical case, a vaccinated person dies 80 days

after vaccination. Even though no “direct” evidence of vaccine side effects can be established, it is possible that the vaccine has caused the immune system to kill a portion of brain cells and thus diminishes its regulatory capacity for the body, causing the person to die earlier. Lack of evidence does not mean it has no damage at the cellular level. A large number of case reports have shown mRNA vaccines tend to cause old diseases (CNS) to relapse, provide firm evidence that life is controlled by the weakest vital organs.

(4) **Deaths without any clue.** Premature deaths may be caused by weakened structure of body organs, bone, and blood vessels but are written off in medicine. This is a point medicine has not considered yet. Personal capability to survive from a disease and accident also depends on those structural features, particularly, vital organ mass, bone mass, and the blood vessels’ physical strength. It may take a long time to alter those structural features. They can be weakened or damaged by strong cytokine storm, over active immune response, extended duration of immune response, and altered mRNA protein synthesis. Protein synthesis in the brain and heart are highly regulated and is not what humans should intervene by foreign matters. Medicine fails to see those risks because medicine cannot appreciate the quantitative model. Under the quantitative model, over active immune system might kill more host cells that the body can replenish, resulting in structural damages. Over active immune system and disrupted protein synthesis may collectively weaken the blood vessel structure. When failure point (expressed in systemic peak pressure) in a person’s vascular system is reduced from 300 mm Hg to 200 mm Hg, the person may die at more situations. Similarly, protein synthesis pattern may be altered by varying degrees. Damaged bone structure may result in a diminished capacity of generating white blood cells. When the body needs more immune cells, bone marrows could not generate them to meet short term demand. Those problems can be addressed only by using a holistic balance approach, the validity of which has been found in the roles of sex hormones and stress hormones. Evolution might have set a sophisticated balance in stress hormone, sex hormone and use of the immune system. Even though stress hormone is intended specifically for reacting to stressful events, but nature still places subtle limits which cannot be freely ignored. It is very possible that use of adoptive immune response is intended as the last resorts. The role of human body structure can be justified by examining car’s lifespans and airplanes’ airworthiness, which must also depend on body structure and parts’ physical strengths, rather than just operational process attributes. This argument is very new, but I hope FDA can see this point: the population cannot be better off by boosting the immune systems at every six months with severe adverse responses.

For those reasons, both death data and incident data for mRNA vaccines must be rejected.

I. Deep Analysis of Effectiveness Data Concerning Second and Booster Shots

FDA has approved booster shots based on findings from clinical trials. I will show why such a study is deeply flawed due to use of a wrong life model, wrong research model, and wrong analysis method.

One recent article is published in NEJM to support booster shots [324]. In this study, a total of 843,208 participants met the eligibility criteria, of whom 758,118 (90%) received the booster during the 54-day study period. Death due to Covid-19 occurred in 65 participants in the booster group (0.16 per 100,000 persons per day) and in 137 participants in the nonbooster group (83,989) (2.98 per 100,000 persons per day or 2 deaths in 1,000 in the entire period). The adjusted hazard ratio for death due to Covid-19 in the booster group, as compared with the nonbooster group, was 0.10 (95% confidence interval, 0.07 to 0.14; P<0.001). It is thus concluded that participants who received a booster at least 5 months after a second dose of BNT162b2 had 90% lower mortality due to Covid-19 than participants who did not receive a booster. I will show this analysis is deeply flawed and the conclusion is completely wrong and misleading.

This 90% reduction in death rate is based on small probability (assuming infection and death WERE suitable properties for probability analysis). The total number of deaths is 2.98 per 100,000 persons per day for the non-booster group and 0.16 per 100,000 per day for the booster group. The total number of deaths is 65+137=202 (expressed as frequency, 0.0086% v. 0.16%). In both groups, death odds are very small probabilities. The overall death rate for the entire 54 days is 65/757,614=0.000086 for the booster group and 137/83,898=0.0016 equivalent to 1.6 deaths per 1,000 for the nonbooster group.

First, assuming that hazard ratio is 0.10 with 95% chance being 0.07 to 0.14 is valid, there is still a small chance that the appearance of this ratio was due to drawing odds (based on misused statistical theory). The validity of the conclusion is based on the notion that events with small probability cannot happen. Thus, the authors accept this proposition that small properties can be ignored. However, the primary data (both death rate) are all quantity of very small probability (0.0001 to 0.0007). If FDA accepts the proposition that small probability will no happen, then we do not need to mind the small probability of deaths. The study accepts the small probability principle in its analysis, but refuse to accept it in all observed data. I make this hair-splitting argument because I will show that data with small probabilities are unreliable in medicine, can be manipulated easily, and cannot prove its relative benefits against overwhelming lifestyle factors.

Second, the small probability will have no meaning if we consider multiple factor life model. In classical probability models, each observational value (equivalent to each death or infection in this cited study) is fixed or cannot be changed. However, the death number can be easily altered by using any of other factors. In other words, outcome does not depend on random probability, but on a large number of other alterable factors that can be changed. Based on the national incidence and death data, temperature

change from cold winter to a warm summer would have a similar risk reduction (10 folds or 90% reduction). I believe that doing any of a few correct preventive things could have similar effects. The common practice of forcing shoppers standing under cold rain, snow, and chilly wind must have bigger adverse impacts. Avoidable knowledge alone can make similar beneficial impacts than vaccines.

Third, the alleged benefits are saving 1.6 or 2 persons in 1,000 persons. To get the benefits, all of other 998 must accept the dangerous mRNA vaccine. The cost to their health and lifespans cannot be accurately determined without decades delay. The vaccines may shorten lives of those 998 persons, or impact their life quality in material ways. No long-term data is available to preclude. My predictions, the predictions by Senef et al, and all current signs are negative.

Fourth, booster shots are a flawed concept. Assuming the first shot is justified, the second shot is like injecting massive antigen particles into a person, whose immune has been activated for the antigen. Kinetically, it is extremely dangerous: natural infection gets viral numbers by slow replication in a time window at least 24 hours to 2 weeks. However, billions of vaccine molecules are injected into the body in seconds and produce the peak of adverse reaction in hours. People feel pain and discomfort within an hour. Some observed deaths took place within hours. In a natural infection, human body has times to make an adaptive response but booster shots do not give such a chance. If something is wrong, there is no remedy. I predicted that second shots can cause more deaths, but those deaths were excluded from the study. The risk of deaths for the second shots is expected to be high during winter COVID-19 outbreak.

Fifth, the death rate in the study is most probably biased. Since second shots can have huge stress to the vascular system of recipients as 50%-70% recipients reported some severe symptoms. Since deaths caused by first and second shots automatically disqualify the dead from the trial, excluding them could be the biggest but “legitimate” bias. Death happens to those like batteries with limited energy reserves and limited capacity redundancy. Two things must be true: those feeling very bad reactions in the first and second shots will not take the booster shots, and those who feel well with the second shots will take the booster shots. Those taking the booster shots are like strong batteries, who can have better health condition to survive from COVID-19 infection.

Finally, the conclusion, “Participants who received a booster at least 5 months after a second dose of BNT162b2 had 90% lower mortality due to COVID-19 than participants who did not receive a booster.” is false and misleading. This number 90% is a pooled abstract index having no meaning to all people. All health properties including death is an intensive property, which has no meaning outside the person. Death risk for one person can never be applied to another person. The mean for a population has no meaning to people. Its values depend on the treatment and a large number of other variables. If we view all persons as rechargeable batteries, those with little energy or low current capacity will not survive from short-circuit strikes. All persons, teens, young

men, old persons and persons with different chronic diseases have distinctive risks of death. While booster shots are not recommended for young persons at this point, people told stories how they have gotten boosters shots. The long 5-month delay in getting the booster shots is a big mitigating factor. Whether a person dies from vaccine or infection also depends on avoidance kills, personal care, life stress, environment, and post-infection mitigating measures.

Considering small probability of less than 1%, any one of those biases would change outcome: adding deaths caused by the first shots and particularly the second shots, adding deaths which are excluded due to the combination of COVID-19 infection and booster shots, and adding deaths that will be caused by vaccine's latent side effects. Thus, a big part of the claimed short-term benefits is the artifact of eliminating those highly vulnerable persons and failure to recognize future deaths caused by vaccines in very long times. The biased effects cannot be corrected by comparison: those refusing to take boosters shots are most probably have higher risks while those taking booster shots are better and strong persons. Those who have successfully passed second and booster shots safely must have sufficiently large vital functional reserves to do well in the event of later infection. While those who felt severe adverse reactions will not receive booster shots. Those receiving booster shots have better health for survival and have presently activated immune system plus high antibody concentration to deliver short-term benefits. In contrast, those with only second shots have lower functional reserves and also less active immune system due to lapses. This does not mean that all of them can get the short-term benefits of booster shots. Some of them might have died from booster shots if their vaccination time window is in overlay with COVID-19 infection.

A recent study, Morbidity and Mortality Weekly Report [326] found that those mRNA vaccines are safe. This study assessed the mortality not associated with COVID-19 (non–COVID-19 mortality) after COVID-19 vaccination in a general population setting. The cohort study was conducted during December 2020–July 2021 among approximately 11 million persons enrolled in seven Vaccine Safety Datalink (VSD) sites. The study found that the vaccines are safe. I refute the conclusion. First, the person-years concept is deeply flawed. It would have the same effect of using healthy persons to buffer adverse effects on those showing adverse effects. For example, deaths for one dose group is 1,157 (0.42) and for two doses is 5,143 (0.35) for Pfizer-BioNTech and deaths for one dose group is 1,202 (0.37) and two doses group is 4,434 (0.34) for Moderna vaccine while the control is 6,660 (1.11). The death rate reduction per 100 person-years is only about 0.69-0.74 or adjusted Rate Ratio is 0.31-0.41. For the 12-17 age group, death rates are not changed, but death rates for old people 65-74, 75-84, and >85 in the control group are much higher. The higher death rates for the control cannot be caused by lack of vaccine only, but most probably due to their poor health and vulnerability of some unvaccinated persons. It is hard to imagine that immune activation by spike protein can mitigate all other causes of death. In the designs, all deaths from

COVID-19 infection were excluded. Thus, those persons dying from COVID-19 in the first and second shots groups are eliminated by definition. In addition, the study lasted only seven months, the duration is just good to see short-term benefits but is not enough to see long-term side effects. Personal characteristics used in the study are not those directly relevant to disease outcomes. Those who take the second doses must be ones who could tolerate the first dose well or otherwise in a better shape. I imagine that, to keep the benefits against COVID-19, they must keep being vaccinated. My prediction is each subject will end with a final death. Another study [327] should be rejected for conducting cross-personal transferring, tweaking small probabilities, committing conscious/unconscious biases, taking advantage of short-term-effects of activated immune systems, inability to detect long-term side effects, inability to control lifestyle factors, and taking advantage of buffering effects of massive vital organ reserves. Those factors have different effects on the control and vaccinated groups in a subtle way. All studies can be rejected for same reasons (even though much bigger problems would be found by digging into original data in each study).

Vaccines inflict unnecessary harm to a super majority of recipients. While vaccines may have incidental short-term benefits in a small number of persons, they are not worthwhile measure because many other measures would have similar short-term benefits plus long-term benefits: They could survive by avoiding do a few unwise things, and doing a few helpful things. In reality, each person could reduce risk of death to the minimum by using well matched other measures. Vitamin D and Zinc may work for some individuals, exercise is the best for those physically inactive; avoidance may be the key for those with immune problems; reducing stress is more important for those who are exposed to high-level stress. Each of those measures can easily beat small probabilities. The study's conclusion misleads the population into believing that vaccines can help them to avoid death. The 90% risk reduction is a product of flawed research model, manipulation of small probabilities, great exaggeration of short-term incidental benefits that may be realized under certain conditions, and use of forbidden mathematical operations.

J. Evidence Reveals Dangers of mRNA Booster Shots

Various sources of data point to the vaccine's role in damaging the vascular system. Israel observational data [256], Gundry data [257], Lab founder data [258] and common sense form a concordant factual evidence that mRNA vaccines do damage the heart. All latter acquired data strongly support my prediction that some of mRNA vaccines can quickly reach the heart if the needle happens to be close to some major veins and thus some intact mRNA vaccines can be quickly pushed into the heart muscle cells where they start producing spike protein and turn each affected cell into the destruction target of the immune system. Since most people have huge vital functional reserves, they will not feel the damage unless their impacts are sufficiently severe to JUMP OUT relative to functional reserves. Those findings also strongly support my prediction that

second and booster shots will pose grave risks to recipients who have low vital functional reserves.

The UK data (Table 5) [262-263] showed how vaccination affects the death of COVID-19 infection. It shows that most of the deaths are vaccinated persons. The numbers alone do not tell because most people were vaccinated. However, their true impacts can be estimated from hidden information. The first fact is that more COVID deaths are associated with those first shots that lapse between the shot and infection. Thus, one might suspect, as nearly all experts have held, their higher death rate was due to faded vaccine protection (this is the reason for administrating second and booster shots).

It is known that the antibody concentration in a vaccinated person will decline with time, and so will the number of B and T cells. It takes time to slowly diminish immune protection of vaccination against COVID-19 infection. Thus, a longer time delay would be associated with severe infection and higher risk of deaths. This view is most probably flawed because it fails to consider vaccine overwhelming side effects on the brain, the heart and other vital organs. If any of metabolic processes is altered by an mRNA vaccine, its adverse impacts on vital organs and the tissue structure is also realized with time. If neuron signal transmission efficiency is reduced by 5% due to impaired synapse connections, it would take many months to years to see changes in all affected organs and tissues. Thus, weakening of blood vessels, losing of organ mass, and diminishing of vital organs functional reserves cannot be detected without a time delay. If the net affects of vaccines are dominated by the adverse effects, death rate from COVID-19 infection will be high among those who have a longer time lapse from the first shot and COVID-19 infection. It is possible that both fading immune protection and impaired vital functions work together.

I must suspect that the popular view is most probably wrong. This can be seen from the dramatically increased death rate among those who have received second shots [261-262]. The total number of deaths among those with one short is 57+4=61, but the deaths among those with second shots are 1,790 for the >80 group. For this group people, true harms of mRNA vaccines show up because people at 80 higher have very little vital functional reserves. The total number of people with one short must be more than the number of people getting two shots. Also, some people with a first shot might have died or decided not to take a second shot, the number of total people with two shots can be only smaller. Those numbers can be used as estimates of the vaccine impacts. This observed 29 times increase in death rate cannot be explained by change in antibody concentration or lost immune memory. After the second shot, the antibody concentration in those persons would be higher and the immune system must be more active. The most probable cause is that the second shots harm the recipients by other mechanisms. When CNS is altered and some vital organs are damaged, their must diminish the whole person's health: diminishing organ functional reserve, organ mass, and the overall structure of blood vessels. Like cars and planes, their life spans depend

on not only just all process attributes, but also the engine's surplus power and the structure of the body. The vaccine, particularly the second shot, has an effect of ruining whole person health [1] by diminishing organ's functional capacity and body structure. The active level of the immune system is only one factor which works as a double edged sword: it can powerfully fight infection as a current effect, but can slowly weaken the body structure. Some of them might die simply because the body could not sustain peak blood pressure. It is even possibly that an overly active immune system with excessive B and T cells can change the overall health in the direction of reducing the number of organ cells and reducing cell quality in the long run. I believe that good health cannot be achieved by maintaining active immune system, but improving the hardware for running the immune system. We must rethink the wisdom that sickness can progressively ruin health and vaccine-induced adverse response is a severe illness. For people older than 80, vaccine's impairments to organs and body structure probably exert dominant effects over hypothetical benefits of the active immune responses.

Based on Table 6 [261], two vaccine shots did not reduce infection cases for all people from 30-79 as compared with those with only one shot. The incidence rates between vaccinated persons and un-vaccinated persons are respectively 1314 v 948, 2043 v. 929, 1442 v 689, 1061 v. 495, and 660 v. 420, respectively for 30-39, 40-49, 50-59, 60-69, and 70-79 age groups. Those data has been normalized to 100,000 persons for weeks 42 to 45 in 2021 so that it is a reasonable basis for making a rough comparison. I found that the two vaccine shots are responsible for observed increase in infection rate. The data in the same table show that second shots have small short-term benefits only for young people 18 or below. This can be explained by the fact that young people have very high functional reserves and robust body structure so that it would take a longer time to see the adverse impacts of the vaccine on vital organ functions. In young people, the benefits from increased immune sensitivity are more than the vaccine's adverse impacts on their vital organs and structure in the short observation times. My prediction is that if the observation made for a much longer time, young people will show a higher susceptibility to infection. The observed increase in the infection rate in UK is also consistent with the finding that Pfizer mRNA vaccine actually diminishes innate immunity [255].

Other UK death data in Table 6 [261] concerns small frequency of overnight inpatient admission, deaths within 28 days of COVID-19 infection, and deaths within 60 of COVID-19 infection, which cannot be reliably interpreted in light of overwhelming lifestyles, weather and environmental factors. Those data concerned adverse events or death rate of people in small time windows. Their frequencies are very low (0.000001 to 0.0016). Table 6 shows that vaccines can reduce death rates in the short-term follow-up period; however, no data tell differences between those with one shot and those with two shots for a long-term. For extremely small properties, unvaccinated persons may be associated with poor health, poor financial standing and biases against vaccines. The data shows vaccines' short-term benefits (in less than 1 year) in reducing infection

severity, but I can hypothesize that materialization of adverse effects takes much longer time. If an organ or brain's mRNA machinery is disrupted just by as little as 0.01% in its speed, the organ's cell quality, tissue mass of viable cells and/or vital functional reserves may decrease with time faster than the normal aging in the same person. If an affected organ is one with a limiting vital function, it must cause future health problems and earlier deaths. Immunological properties are only a part of the equation, and whether a person can survive would depend more on the overall organ structure and particularly limiting vital functional reserves at a latter time. The ability of the vascular system to maintain necessary blood circulation and blood vessel's structural strength to tolerate elevated blood pressure can be more important than all process attributes of the immune system in any instance of time. A similar point can be seen from airplane airworthiness. The plane's structure and physical strength of all vital parts must be important factors for airworthiness. The great dangers of repeated vaccination are also reflected in side effect reports [307]. This study [307] shows that second shots can dramatically increase frequency and severity of side effects; and severe systemic side effects were found in more than 50% persons, but can be as high as 70% for some side effects.

K. Differential Analysis of UK Observational Data and Israel Study

FDA should consider why UK observed death data on second shots and Israel study on booster shot differ. UK data indicates that second shots can cause death risks by almost 29 times over those with only one shots for the persons older than 80, but the Israel study found that booster shots can reduce risk of death.

The Israel study tracked only certain people who meet eligibility criteria while the UK data reflect all deaths. When dealing with small probability, altering one outcome per a hundred persons would make difference to "conclusion". The biggest source of biases are originated from the research purpose. In the Israel study, it is intended to study the third shots that were administrated with a sufficient long delay. In this study, all deaths caused by the first shots and second shots could not become the subjects of the study. Both shots remove those individuals who are highly vulnerable to the vaccines. Those who died, those who have experienced severe adverse reactions, those with bad health will not become subjects of the booster shot group. This may result in a pool of persons who can tolerate vaccine current adverse reactions and infection better, and take full advantage of the short-term benefits of the highly activated immune system. How this pool performs in the long term as against further vaccines, future variants, and other diseases are entirely uncertain. However, every prediction is bad or very bad.

In addition, many exclusions can also have an effect of unintended manipulation of small probabilities as in the Israel study [324]. 85,500 participants were excluded for having been infected by SARS-CoV-2 before the start of the study; 9534 have received only one dose of vaccine are excluded; 1777 had received a booster before August 6, 2021; 174,111 had received the second dose within 5 mo earlier; 1020 received the

booster and had a confirmed case of COVID-19 within 3 days before the effective-booster date (defined as 7 days after the booster was administered). Each of the exclusions seems very reasonable for the study purpose, but may have introduced biases to alter outcome due to their impacts on small probabilities.

The authors naturally assume that whenever there is SARS-CoV-2 infection, death is caused by infection but not the vaccine but should consider vaccine having similar effects of infection. The elimination of the earliest infection (85,500) remove those persons who are more vulnerable to the virus. This results in a better pool of persons who can tolerate repeated vaccination for short-term protection. Those 9534 who have received only one shot (excluded by definition) most probably feel bad and at least some of them could not survive over the second shots, also resulting in a healthy pool who can survive repeated vaccination. The second exclusion of 1777 who have received earlier booster shots. Their temporary immune protection might have been faded and their motivation to seek repeated vaccination may be due to their concern with their vulnerability or high risk of exposure to the virus. By excluding them, the study avoid those data with faded immune protection. The third exclusion of 1020 may remove some deaths which can be attributed to combination of booster shots and COVID-19 infection. In this case, the infection peek and the vaccine's adverse reaction peak was in overlap. Predictably, it would result in deaths at higher chances. The authors might think that booster shots could not protect patients due to being too later, but did not consider the hard-to-avoid reality that death can be caused by booster shots particularly when vaccine reaction is superimposed by virus infection and such deaths are necessitated by vaccination. It is possible that the study design resulted in a pool of relatively healthy heroes who can survive over first, second and booster shots with higher active immune systems to ward off infection in 54 days while the control group consists of people with different health conditions. When dealing with a small probability, each of the exclusions would make differences. If the vaccine adverse effect dominates in future true benefits-to-harm ratio, booster shots can be a big nightmare for those who have accepted. The death rate in Cox plot are from 0.005% to 0.070% and can be altered easily by any of known life factors, avoidance skills, behaviors, diets, well-used exercises, etc.

FDA should note that the biggest biases are from research design and the very questions to be answered. Whether booster shots can prevent infection is a wrong question because it must have short-term benefits for those who can get there. Correct questions are (1) how three unnecessary vaccine shots hurt those healthy persons in their life times, (2) how three shots would impact those 80 years or older, and (3) whether successive booster shots a viable measure for containing the pandemic. The answers to the first question must be very bad. The answer to the second question cannot be found by conducting a population study because the first two shots can eliminate the vulnerable persons, resulting in a pool of persons who can get short-term benefits. But all deaths must be counted as the cost to get this pool. To understand the impacts of immune abuse, the best proof can be found by conducting an animal booster shot

trial to see how many shots can kill animals. The third question can be found by adding up three costs: life time damages to all healthy persons, the deaths of those vulnerable persons by all three shots, and the appearance of more virulent viruses. Applicants' studies cannot answer any of those questions. FDA should note that "sponsorship of drug and device studies by the manufacturing company leads to more favorable efficacy results and conclusions than sponsorship by other sources [120-127]. Their analyses suggest the existence of an industry bias that cannot be explained by standard 'Risk of bias' assessments [124]. By paying 300,000 research fund, or annual salaries, or high consulting fees, or great stock dividend, etc, authors have dozes to hundreds of things to manipulate. They only need to alter outcomes for one to two persons per one hundred. This is very easy to achieve. FDA could find some details in a study involving Avandia [126-127] which killed tens of thousands of people.

Obviously, vaccines do not work like a static variable that can be studied by clinical trials. Even if a vaccine is good in some instances, it can be a killer due to its temporary burden on the vascular system. The hazard ratio was observed without considering the dynamics of adverse reactions. Data analysis involves extensive mathematical operations, while the regression analysis involving complex covariate analysis. It is possible that some benefits are neutralized by adverse effects within the group. If FDA accepts reality that each person is a distinctive being, none of other persons' outcomes, infection and death, have any bearing on a particular John Doe, teen or a chronically-ill person. Deaths of different persons mean different things, and so are infections among different persons. None of the persons even belong to the Cox regression curve in the personalized medicine. No car can ever be repaired by referring to problems in other cars except by accident. Human population exists only in the traditional demographic sense, statistical analysis is valid only for studying population size, structure, and movements of populations over space and time, etc. Strangely enough, study conclusions may be used for some purposes but cannot be used as treatment guidance.

The claim that booster shots can reduce mortality by 90% is wrong and misleading. While the recommended age for booster shots is 50, I have read stories that people get their third shots and even fourth shots. It cannot deliver real benefits for the 80% healthy persons who can survive well, it may provide short-term benefits for a very small number of people in small time windows but at the costs of ruining their long-term health, it most probably kills those with very low functional reserves or allergic to the vaccines. The research model writes off most deaths and inflates the small benefits by dividing a small rate by an extremely small number. The large reduction comes from a magic ratio like 0.007/0.0007=10. Benefits are largely false. It can never have 90% risk reduction. It must harm all people by 100%. The costs of the vaccine to benefited persons are shorted lifespans, degraded health, increased vulnerability to the virus. The vaccine cannot eradicate the pandemic, but increase chances to see more virulent variants. The death rate ratio does not reflect real deaths in reality. I thus urge FDA to reject such numbers.

On Feb 1, 2022, Pfizer is applying for mRNA use authorizations for children from 6 months to 5 years old. One of its justifications is 0.00%-0.02% death rate among all child COVID-19 cases. It will bring unnecessary risks to 99.98% (the non-death population) or the full children population (which is much larger than the infected children group) and inflict injuries for their life times.

Legal Grounds

21 U.S. §355(b)(1)(A) requires that "(i) Such persons shall submit to the Secretary as part of the application— (i) full reports of investigations which have been made to show whether such drug is safe for use and whether such drug is effective in use,... (vii) any assessments required under section 355c of this title; and" I have shown that safety and effectiveness is a fact that depends on the context of science. When the life model, research model, and risk evaluation models are all wrong, the safety and effectiveness findings are wrong or grossly inaccurate.

Flawed foundation presents a systematic difficulty in evaluating scientific evidence acquired by relying on the flawed research model. The limitation is mainly on formulation of treatments of chronic diseases or health. Even some population studies can provide the best estimate of disease agents, the reason for doing such studies is that no better model is available. In evaluating evidence, FDA should use an asymmetrical approach: studies relying on existing models can be used to refute the validity of treatments or other collateral issues. By tracing those flaws, FDA should see their predictable impacts and can interpret original data in a way different from what original authors might have. For example, lack of side effect may not be used to rule out side effects, but finding any signs of side effects even in an animal model cannot be dismissed. FDA should pay more attention to failed drug trials, drug poor performance, sponsor's biases, and even poorly-designed studies because they can serve as powerful or unique evidence for addressing a unique issue.

21 U.S. § 355c requires that, before the use authorization can be granted, that FDA determine safety and effectiveness of drugs or biological product under (a)(2)(A)(i), "to assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations;..." I have shown that the benefits-to-risks ratios of mRNA Vaccines have been inflated by wrong life model, wrong research method, wrong analysis method, and manipulation of small probabilities. The effectiveness rate computed from a ratio like (0.0088-0.0004)/0.0088=95.4% is absolutely meaningless and misleading. Based on the pattern of biases in sponsored researches and a large number of ways of manipulating small probabilities, FDA should summarily disregard sponsor's studies. Any of the biases such as research designs, questions to be answer, selection of comparison, plus all fatal flaws in the research models, influenced by massive sponsors' money, can easily alter trial outcomes by affecting a small portion of people like 0.01.

42 U.S. § 262(a)(2) (concerning Regulation of biological products) requires "(I) that the biological product that is the subject of the application is safe, pure, and potent; …" I have shown that effectiveness is computed from data reflecting small probability and adjusted rate ratio is computed from data involving small probability with massive design biases in addition to wrong life model, wrong research model, and wrong analysis method. In addition, based on small probability, any of a large number of lifestyle factor, activity, avoidance skills, special exercise would have similar beneficial impacts without long-term adverse effects.

21 U.S. § 564(g)(2) of the Federal Food, Drug, and Cosmetic Act provides Secretary authority to revise and revoke use authorization if "(C) other circumstances make such revision or revocation appropriate to protect the public health or safety." I have demonstrated that the foundation of medicine is flawed and all flaws are not subject to good-faith dispute. FDA did not see my findings as well as findings by others because information launders have actively suppressed such findings and have prevented anyone from exposing flawed foundation in medicine.

21 C.F.R. §§ 1.21, 7.40(b) provides "Labeling of a food, drug, device, cosmetic, or tobacco product shall be deemed to be misleading if it fails to reveal facts that are: (1) Material in light of other representations made or suggested by statement, word, design, device or any combination thereof…." The labels or inserts of mRNA vaccines fail to disclose that their approval was based on flawed, meaningless and misleading effectiveness like 95% and risk reduction like 90%. They mislead people into believing that the vaccine would benefits most people in most cases. In reality, all risks disclosed to the public are based on four big flaws. The true side effects are concealed by massive organ functional reserves (hiding at least 90%), use of symptom-based method (recognize only a few out of unlimited possibilities), time-delay impacts (missing 90% or more cellular damages), and interference effects of a large number of life factors. All of those biased effects work in combination and their research conclusions meaningless. By using flawed mathematical model, the vaccine risk is further reduced by averaging effects between those at-risk persons and those super strong persons, and further concealed by random positive and negative effects of other interference factors. Thus true side effects of vaccines are magnitudes larger than what have been told to the public. While size of errors cannot be expressed in one numeric value, to give FDA a yardstick based on current people health composition, the disclosed risk is off the mark by 1,000 to 1,000,000 times. After being corrected against those flaws, the true adverse effects of mRNA vaccines must be 100%. A statement like 3-5 times high risk is wrong to those vulnerable persons. Their adverse effects are certain but will not show up until the impacted vital functional reserves become a limiting factor for sustaining life.

In the past, FDA relied on data from clinical trials because clinical trials were mistakenly believed to be an unbiased and valid research method, and historically regarded as the gold standard. The statutory standards are intended to insure that the drugs can actually deliver real beneficial effects on intended users, but not merely to produce fake

or meaningless effectiveness and safety promises. Expressly mention of clinical trials or controlled studies in the statute is a manifested intent to use the highest standard but not as a limitation to preclude other better research methods. The conclusion of effectiveness and safety always depends on research models, data analysis, and relevant contextual knowledge. A large number of post-1980 studies have proved that clinical trials cannot provide valid comparison with a controlled group [8-9, 105]. Petitioner has proved that the effectiveness and safety cannot be directly measured reliably by using a controlled trial because there are no similar persons for comparison [9] and the statistical analysis is often misused because there is no statistical distribution [8]. Any problem in the research model, data analysis and contextual knowledge must be corrected before the effectiveness and safety conclusions can be trusted. The standard is not static, but must be improved continuously with the progress of scientific discoveries. FDA is obligated to find how those findings affect its drug approval. Its current legal standard does not preclude use of additional and better research methods and holistic risk analysis framework. The new medical discoveries require that drug applicants to address flaws in clinical trials and seek better methods with higher accuracy, but failed.

21 U.S. § 379dd (concerning Reagan-Udall foundation) provides: “The purpose of the Foundation is to advance the mission of the Food and Drug Administration to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate **innovation**, and **enhance** product safety.” The foundation has a statutory duty to “provide objective clinical and scientific information to the Food and Drug Administration and, upon request, to other Federal agencies to assist in agency determinations of how to ensure that regulatory policy accommodates scientific advances and meets the agency’s public health mission;” Congress has provided a path for incorporating latest scientific advances into FDA approval framework. When science has been laundered for private revenues for decades at the expense of ruining pubic health and destroying all lives, FDA must use its statutory power to bypass unlawful control by monopolistic medical publishers in violation of wire fraud statute. Concerning my request for regulatory overhaul, FDA does not need to address this request within 180 days due to the complexity of the issue, Petitioner will update by filing continuous citizen petition.

Since laundered medical information directly impairs FDA mission and can cause FDA to approve dangerous drugs and vaccines, FDA has an implied statutory authority to defend. Thus, I urge FDA to conduct its own investigation with other federal and state agencies and foreign governments on how monopolistic medical publishers and monopolistic media laundered medical information for their monopolistic revenues and what changes must be made to change the fate of mankind. FDA should fund studies to estimate the magnitudes of impacts of junk science on lives by simulation methods. Without addressing flaws in the foundation of medicine, every big problem in environment, ecosystem, climate and public health cannot be solved. Without fixing foundation of science, nothing can stop monopolistic businesses from rapidly dragging humankind into

the grave. I hope that FDA action will prompt federal agencies, foundations and private entities to start funding researches for exploring remedial measures that would mitigate, stop and reverse vaccine injuries.

III. ENVIRONMENT IMPACT

Petitioner claims categorical exclusion under 25.30, 25.31, 25.32, 25.33, or 25.34 of this chapter or an environmental assessment under 25.40 of this chapter.

IV. ECONOMIC IMPACT

Economic impact information will be submitted upon request of the commissioner.

V. CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully Submitted,

Jianqinq Wu\
Jianqing Wu, Ph.D.,J.D.

REFERENCES