FDA Should Re-evaluate All mRNA Vaccines and Revoke Use Authorizations (4th Rev)

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Abstract

Drug industry, controlling medical publishers and large media promote flawed medicine for their revenues by systematically laundering medical knowledge. They promote the drugs-for-health hypothesis and flawed abstract disease mechanisms, and suppress disruptive discoveries thereby precluding reform of medicine. Due to all flaws, the side effects of a single drug are underestimated by thousands of times. By relying on laundered medical “knowledge”, FDA was never able to predict latent drug side effects for any drugs in its history, and has failed to see the need for fixing the foundation of medicine. In approving mRNA vaccines, FDA did not consider fatal flaws in clinical trials, the symptom-based research methods, and statistical models, and failed to consider all known mRNA risks, predictable acute personal injuries, and potential latent side effects. By blindly relying on flawed data from clinical trials, FDA made its decisions even faster than its approval of the disastrous DES. FDA even failed to consider mRNA special dangers to pregnant women, fetuses, babies and diseased people, and failed to see the clear dangers of booster shots. To stop repeating catastrophes, FDA must overhaul its approval framework including rejecting the drugs-for-health hypothesis and using a holistic risk analysis approach. Under the proposed framework, FDA can summarily ban all mRNA vaccines. Irrefutable evidence shows that monopolistic information launderers condoned by federal agencies have exerted terminal destructive impacts over all species and the planet by their concerted actions. The actual stress of all toxic substances on species is millions to billions of times of what laundered junk science

predicts. To rescue species, all federal agencies, all state governments, all private organizations, all foreign governments and all individuals must join force to dismantle this biggest monopolistic information laundering enterprise and systematically eliminate from the business framework all policies and practices responsible for greatly accelerated human extinction.

INTRODUCTION

DES was in 1938 and was used in 1939. In 1941, FDA approved DES, and it turned out later the drug can ruin at least three generations of women users. Last years, FDA quickly approved the mRNA vaccine for emergence use and has approved for non-emergence use based no real safety data. In my article [1], I extensively explored the known risks and unknown risks of mRNA vaccines. In that article, I found that all dangers come from the absolutely impossible to control the mRNA delivery to intended lymph nodes. This prediction is based on two distributions: the mRNA vaccine particles must have different thicknesses so that some particles can survive in blood and tissue for longer than others and this distribution is aggravated by obviously differing hydrodynamic conditions. The second problem is that each person's condition relevant to mRNA enzymatic hydrolysis is unique. The same mRNA vaccine made by using the same specification cannot work for all people. If it is the best from some people, it must be bad for others. Even if it is used on the same person, it is good in one set of use conditions but harmful under another set of use conditions. mRNA, like "a super virus", can penetrate into any types of cells and tissues, and disrupts the immune system, normal protein synthesis and causes systemic inflammation. It can damage blood brain barrier and has neurons damaged. The erratic mRNA particles can damage heart muscle cells, lung cells, kidney cells, and liver cells. Those actions are predicted to reduce vital functional reserves so that each of the affected vital organs has less functional capacities. In addition, mRNA induced spike protein will result in high T cell population, some of which must find their ways to the blood stream and cause incidental or secondary damages. In addition, the presence of spike protein in any affected tissue or in blood will cause systemic acute inflammation and cytokines will raise blood pressure. By damaging major vital organs, the vaccines cause recipients to reduce resistance to the virus. The Israel data show hundreds times higher death rate among young vaccine recipients while the recent UK data show that two vaccine shots increased death rate by 30 times. Those vaccines are on the way to create worst health catastrophe.

In this study, I deeply investigate how FDA approved those dangerous vaccines to be used on the population without addressing any of those predictable dangers, and what must be done to prevent FDA to approve DES, mRNA vaccines and more dangerous drugs in the future.

FLAWS IN MEDICINE CANNOT BE CORRECTED

A. Medicine Developed on Flawed Foundation.

Medicine was established on flawed foundation [8-9] as it uses population approach three centuries ago. As extensively discussed in my prior studies, a large number of post-1980 studies [10-56] have produced conclusive evidence that disease and health are controlled by multiple factors. Disease cannot be cured by focusing on one or few factors. Many researches provide irrefutable evidence to reject the reductionist model. Toxicity mechanism studies for drugs and chemicals [29-54] imply that symptom-based causation methods are wrong; the discoveries of vital organ surplus functional capacities [10-13] also imply gradual damages caused by toxic substances do not cause symptoms in most times, especially, in the early stage of damage. Based on all known drug damages, most of the withdrawn drugs [55] do not cause acute adverse reactions because it took years to recognize. While I only cited a few drugs/chemicals as examples, The findings of THOUSANDS of drug and chemical studies have an effect of proving that symptom-based side-effect research method is wrong.

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 pathways in human biological 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]. This can be easily seen from the traffic model. Based on thousands of post-1980 studies, the binary disease category 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].

The implication of the large number of post-1980 research findings is that all disease theories concerning chronic diseases and cancer are wrong or at least very poor. Personal health, which is a measure of life quality, is never something that can be evaluated by doing comparative experiments focusing on one factor at a time in a manner like weighing goods on a balance [1, 9]. The idea, which is based on common sense, turns out to be wrong in every aspect that I have studied. Based on factual findings from potentially millions of studies published in the last half century, I must reject 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, standard medical research model, symptom-based causation method, etc. 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 unique a 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. Those discoveries imply that medicine cannot find cures for chronic diseases [9] but endanger patient lives.

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

Long before the flaws in medical foundation were understood and challenged, a large number of problems in medical research were noted [105]. The development history of clinical trials reveals that the model was developed by adding various components in different times, as attempts to address inherent problems [106]. 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.

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 medicine. 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 for targeting consumers and doctors.

Drug industry has no duty to humankind [134]. After drug business exists for more than a century, it must have learned how to get required data and conclusions by manipulating 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 sales 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, drug industry and medical journals have a common interest in keeping alive the research and treatment models that favor drug discovery and commercialization. The more articles the medical publishers publish, the more revenues they get from the drug industry. They have formed a de facto revenue-sharing partnership.

The partnership between the drug industry and the publishing industry become extremely 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 the 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 in Nature, Lancet, and NEJM; and this factor alone could preclude new publishers, open access journals, and open science foundations from 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 “quality”. In fact, all 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.

C. Peer Review, Impact Factor, and Editorial Polices Are Placed to Kill Competitors, Torment Patents and Defraud Societies

The medical publishers have kept selling their articles for being peer reviewed. Most of them have adopted ill-intended peer review to reject articles for any reason. Peer review is known to cause a large number of problems [150-160] and consistently produce erratic, meaningless, and unjust results. Real purposes of using peer review are protecting trade interest, maintaining steady revenue, precluding competition, poisoning population wisdom and precluding reform.

1. Peer review kills competition and suppresses innovations

A constructive review is necessary to discern non-scholar articles and improve article quality. A peer reviewer cannot improve quality of a research which has been completed by researchers in years of trials and errors. The argument that peer review can improve research quality is factually untrue and theoretically impossible. It is found that peer review cannot produce consistent results [155] and cannot prevent scandalous articles [112]. Peer review was done for more than half a century, but failed to prevent massive problems in medicine. Medicine continues to refuse to acknowledge the limitations of the population model, flaws in clinical trials, and flaws in statistical models [8-9]. Peer review must have deterred researchers from writing articles for mitigating the im-

fact of Somatic Mutation Theory [92-93], correcting the effects of the Independent Action Model [56] in environment protection, exploring alternatives to the symptoms-based method for studying drug side effects [1], and limiting the use of flawed epidemiological model R0 [68]. Peer review, based on the rule of unanimous consent concept, must have prevented researchers from questioning the drugs-for-health hypothesis and from expunging junk science from the medical literature. Factual discoveries in support of multiple factors disease model started appearing as early as 1980, but peer review must have deterred anyone from bringing this model into the light of day. Peer review is the reason for medicine to repeat its failure in more than a century.

Peer reviewers are selected often by randomly drawing or at author suggestion. Two to three out of millions of potential reviewers are asked to determine research merit cannot be a serious measure but a marketing scam, giving that peer reviewers can have different opinions. Most existing medical theories can be in dispute for more than hundreds of years [1]. From a probability point of view, such a review is much worse than rolling a die and is closer to playing a lottery to see the luck of 2-3 over potentially millions. Peer review may be a good design for entertainment like a million dollars show, but is reckless way to decide the fate of researches that would affect human survival and the planet. No peer has the capacity to judge a discovery upon a brief review before the discovery has been actually tested in the world. Peer review can preferentially suppress research articles presented by individuals and small entities, but never research articles by the drug industry, which can easily select or even purchase journals and fund two reviewers to support their articles. Peer review is incapable of evaluating merit of any complex research, but created erratic results [151, 155]. It is a very unwise idea to get a verdict of two to three peers for an article that is reduced from years of research efforts and that may affect millions of people. Peers are unfit for reviewing “strikingly new work” [159-160, 165]. Medical literature reveals that the medicine could not resolve many disputes (e.g., in cancer theories, stress effects, lead toxicity, etc [1]) in hundreds to thousands years. Yet, the medical publishers have successfully sold to societies the idea that their peers can settle any dispute in a matter of hours. Now, society suffers the current plight because it has accepted or condoned such practices that should have been banned a century ago.

It is well known that peer review is the most powerful tool for killing innovations in medicine [159-160]. I will show that peer review can destroy innovative landscape in several ways. It eliminates innovation incentive by encouraging researchers to use accepted research model. Peer reviewers have created existing articles for new researchers to follow. By reading the published articles, researchers would find what research subjects can pass peer review. The researchers thus unconsciously fall in the trap: good and publishable articles must follow publishable subjects and written in acceptable article styles. New researchers and new authors must develop tolerance for junk science. One example is the model used to predict infectious diseases by R0 [68]. As I have shown, one must accept and promote if even if every assumption in the model

makes no sense [68]. The model sounds a good idea when all variables used in the model have not been studied. Inaccuracies in the variables are not about a 2%, 10% or 30% errors, but all assumptions are completely wrong [104]. Yet, peer reviewers must accept such a model year after year because it has been generally accepted. Peer review must disallow authors from criticizing anything that would affect the trade interest. If one criticizes any theory such as R0 in an article, the article most probably reviewed by peers who have written articles on the same theory. No one can criticize junk science and trade problems.

Peer review is the very reason to keep junk science forever; similar research is repeated in the same way, written in the same format, motivated to promote drugs, and ended up with similar failure. Peer review is exactly what enables the drug industry and the medical publishers to achieve the maximum revenues. After having been influenced by published articles, the mindset of new researchers will be downgraded to promote trade interest and enterprise interest. Researchers cannot advocate that chronic diseases must be addressed in a different way. If researchers find limitations in the research model, they must think if their disruptive view can pass peer review. Since peers are drawn from all potential peers, an acceptable research must be one that would please all peers except the sponsored researchers who can buy a journal and peers. The researchers must abandon any innovative idea in fears that their researches cannot be published. This is exactly what the drug industry and the medical publishers want to achieve: keeping the junk science forever. While peer reviewers cannot see disruptive discoveries, they can see whether a new research direction might hurt their reputations, their professional standing and competitiveness in grant seeking competition.

Peers are selected from researchers who may compete with the authors. Thus, authors, researchers, and peer reviewers are potentially competitors. Some people can be authors and peers in different times or in front of different journals. This idea of using peers may come from the jury system. Use of peers to decide civil and criminal cases have a sound rationale because peers used in litigation cannot be competitors of litigants. Jurors are selected from those who do not have any dealing with the parties cannot be competitors. Medical journals do not care about this kind of serious problems because it is none of their business. They can create all kinds of situations where author rights are infringed by reviewers, often resulting in severe damages to public interest. If researchers and authors would fabricate research data, they would dishonestly reject any articles if they serve as peer reviewers.

If peer review had been used to review patent applications, it would have wiped out nearly all inventions from the world. Ill-intended peer review serves to help medical journals to achieve triple illegal goals: precluding competition, protecting revenue stream by ruining public health and harming patients, and enlarging patient population

as their revenue feeds. Every claim to improve research quality is factually impossible. It is why all obsolete disease theories can live forever, and dangerous medical drugs can come out one after another from production pipelines.

Peer reviewer is also used as a device to deceive audience. To divert public attention to failure of drugs for curing diseases, the medical publishers use peer review to diffuse the attention of people and societies from true impacts on public health to peer review process. Instead paying attention to research discoveries and their impacts on patients, arguments are often revolved around peer review and its great merits. Whenever they made this argument, such argument also automatically belittle those non-peer reviewed articles as junk science. I saw often that when a controversial article was published, a critique did not address substantive issue, but only pointed out lack of peer review as the only attack. Peer review serves as the device of discrediting anything that might impair medical enterprise revenue.

When reviewer identities are disclosed, if something is wrong, it is possible to hold the reviewers accountable for bad faith decisions. To achieve the maximum lethal power to preclude disruptive researches, some medical journals use double-blind peer review method where both the author identity and reviewers are not disclosed. With this shield, peers can kill any disruptive discovery which would affect millions to billions of lives even without being disclosed. With such a protection, a peer reviewer can vote to reject any article if he does not like, cannot understand, or impair his reputation [145]. This kind of peer review is the most powerful device for protecting journal monopolistic position and medical trade interest. Maintaining high research quality is only a marketing slogan that has successfully deceived people and societies.

In addition to the ill-intended peer review, many medical publishers screen all articles by in-house reviewers [145] as the first step and suppress articles that might harm their revenue. When they reject articles, they claim rejected articles do not fit into their scopes. However, if price is right, they publish any articles, including set a fake journal [112]. An offer for buying a million dollars reprints cannot be rejected. By using in-house review, the medical publishers kill disruptive discoveries that could threaten their revenue streams and monopolistic positions.

Both editorial review and peer review can completely compromise whole field knowledge by their veto power. A large number of research articles do not support drug art but could provide powerful evidence to refute the drug-for-health hypothesis. As noted in an article, “In the case of clinical trials, withholding negative results from publication — publication bias — could have major consequences for the health of millions.”

[177]. Real problems are much worse. In reality, the overall success rates of drug researches from Phase I for all developmental candidates over 2011–2020 was 7.9% [178]. This implies that more than 90% drug candidates fail. The unpublished data implies that the drugs-for-health hypothesis is fundamentally flawed. By killing such studies for whatever reason, the medical journals keep medical researchers on a track of drug researches with no chance of success. Moreover, since each health problem is a multiple factor problem, no research attempt is completely useless. Even if a research is done in experiment with a wrong analysis, it may still contain some data pieces that show certain aspects of health issue. The very wrongness could be valuable finding for preventing repeating the same error. The failure of cancer drugs is the most powerful evidence for seeking new direction. To make changes in the research direction, the number of failures is important. One hundred of articles may be not enough, but millions of findings of past failures may become a compelling evidence for exploring new direction. It is possible that bad discoveries can be used in combination of other discoveries to address a critical problem. Thus, an old study on infection's role on cancer may still reflect one factor: toxic metabolic by-products of certain infection agents may be one causal factor for certain type of cancer or can impair the immune system. This piece of evidence may still be valid. By using peer review and editorial review, they keep obsolete and wrong disease theories, dangerous practices, the Voodoo spell, and the drug-for-health movement [132] going forever.

2. Use of impact factor to preclude competition and deceiving societies

The medical publishers developed impact factors [166-168] which can amplify the influence of money. This great invention can advance monopolistic influences. Now, we see a publication model which can publish more and more articles on drugs and turn drugs discoveries into the best science. "Science" value is artificially inflated by duplicating and repeating publication of the same researches [169-174]. Assuming one company republished the same article in several journals that cite each other, it will increase impact factors for all of those involved journals. Moreover, drug industry pays journalists for writing about drugs, drug discoveries, new promises for cures, and sponsored commercial articles in popular media, the same article naturally has high impacts for all kinds of predictable or unforeseen reasons. Impact factor has a compounding effect: the journals with more drug articles must have higher impact factors, and the high impact factors help them to attract more drug companies as future clients. It is like a circular electronic positive feedback driven by money. By promoting this kind of deceptive scheme, we see that a bizarre phenomena: a trade magazine may an impact factor of nearly 60 or more, but open assess journals for public interest might have less than one. However, impact factors does not tell whether the article is promoting public health, defraud patients and ruin the planet. Nearly all high impact journals advance drug industry interest at the costs of public health. The journals with monopoly power can increase their revenue-generating capacities by taking advantage of their achievements from prior monopolistic conduct and the fruit of information laundering. It is like the more

money, the better science; and strong monopoly power, the better science. If a medical publisher now designs this publishing scheme anew, it would invite worldwide condemnation. However, they achieved their current monopolistic standing by slowly gaining their monopoly power. The circumstances have diverted critical attention of people and societies to other things but not the illegal acts and severe consequences, and thus have escaped from antitrust scrutiny by federal enforcement agencies.

3. Use of editorial polices to preclude true science articles

To further deceive people and societies, medical publishers have created other devices such as formality standards, in-house formality review, article specifications, conflict declaration, etc. all in the name of promoting article quality. Other devices include requirements concerning article structure, length, citation number, table number, figure number, reference format, even subtitle length, evidence-based finding requirements, etc., each of which is tailored to articles for promoting drugs based on unrealistic and abstract drug mechanisms. They must know that an article challenging the foundation of medicine would need much larger space and an article concerning true health science cannot be limited to 4,000 to 6,000 words, but those journals provide no exception. The restrictions are to preclude challenges. One can present a new theory in 6,000 words. To throw a flawed theory out, the researcher cannot just rely on one piece of evidence, but must present tens to hundreds of pieces of evidence. To determine whether surgeries and chemo are good for patients [63], a thorough investigation would require much more space. Even their article structures have an effect of precluding true health science and suppressing articles that challenge the drug-for-health concept. They stress way of expressions, writing elegance, section formats, manner of presentation, etc. except the merit of curing diseases and effects on patients. Irrelevant requirements, unnecessary formality, and burdensome technicalities are all used to defraud audience, patients and societies. Medical journals have run their business for decades, and must know how to use barriers for preventing changes. As a result, each major problem in cancer treatments can be found only when they are reviewed together. Their ill-intended publication requirements could keep each dangerous treatment forever. One more thing they have done is to prevent popular media from bypassing their control. This has been achieved by the Ingelfinger Rule [182], which bars media from discussing articles that have not been published, clearly for monopoly purpose.

4. Information laundering violates U.S. wire fraud statute

In their routinely business activities and communication, 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 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 (any-

one), 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). Under 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.

Fact supports a finding that medical journals have committed wire fraud for a long time. The 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. They use the 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. 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 destroying the planet.

The medical journals have used peer review, impact factors, and other ill-intended technicalities to raise “scientific merit”, and by fraudulent marketing, they sell their articles as the best science to practicing doctors, patients and societies for their detrimental reliance. Their real purpose is entrenching themselves in their monopolistic positions. They could have avoided the violations by admitting that their articles promote drug revenue, junk science, and ruin public health wisdom.

D. Emergence of Monopolistic Information Laundering Enterprise

By years of concerted actions, drug companies, monopolistic medical publishers, and popular media have formed a gigantic information laundering enterprise. In this system, medical knowledge is disseminated in serial steps with clear biases in favor of promoting junk science and false revenue-generating information. The first layer of the biases was selection of research projects by drug sponsors. The drug sponsors promote drug-for-health concept by using paid medical publishers. The second layer of the biases is caused by trade medical journals: when their primary revenues come from the

drug business, they must do everything to promote drugs and have absolute incentives to suppress every discovery that could negatively affect their drug-related revenue. Those two industries have enough force to turn the medical science into junk medicine or trade journals. Leading trade journals such as Nature, NEJM, Science, JAMA, etc. have decisive control over living medical knowledge. The third layer of the biases is injected by popular media (e.g., TV, radio, websites, and other digital media) which are all owned by private entities. They distribute information for money, a big part of which come from the drug industry. Those trade journals must promote flawed medicine, drug-for-health concept, trade arts, toxic drugs, and whatever with highest revenue generating potential. Medical publishers and popular media share common financial interest [109]: each time when a trade medical publisher promotes a new drug concept, the concept will bring great revenue opportunities to the popular media. The fourth layer of the biases can be found in policies and practices of social media. They support the drug-for-health concept but bar any claim of treating and curing diseases. Their policies and practices have a net effect of destroying health culture and health wisdom. The fifth layer of the biases is found in monopolistic search engines. Junk sciences, trade art, scam protocols, trade articles, etc. cannot be discovered by consumers without search engines. Paid by drug vendors and other interest holders, search engines enable consumers and doctors to find information on trade articles, drugs benefits, drug theories, and drug sources, often by grabbing consumers attention by sponsored advertisements. Search engines also promote contents and services for medical practices, hospitals, medical information service companies, state and federal agencies, etc. Billions of dollars drive this system at multiple points to disseminate flawed and fraudulent medical information to people and societies. Since junk science and false information are also imposed on societies by legal means, many practicing doctors, experts, and organizations are involuntary participants. As a result, a piece of junk science or trade art may be presented to consumers millions to billions of times, but millions of contrary scientific discoveries are suppressed or ignored. This is why people cannot see the view that the cancer treatments are intended to extract the maximum revenues and maximum pains from cancer patients.

After decades of operation, the information laundering enterprise has (1) turned junk science into best science or painted flawed research and treatment models as “gold standard”; (2) turned trade magazines such as NEJM, JAMA, Nature, Lancet, Science, etc. into “scientific journals” to mislead people and societies; (3) turned trade motivated researches into “scientific” researches to conceal game-changing subjects selection biases; (4) misled societies to believe that a declaration of conflict of interest can eliminate monetary influences; (5) suppressed scientific discoveries that could hurt trade interest and enterprise revenue; (6) exaggerated the benefits of drugs and belittled the vital roles of lifestyles, personal daily activities and personal health wisdom; (7) used ill-intended peer review, impact factors, article formality, etc. to protect their revenues and monopoly positions; and (8) transferred personal health properties into the “population properties” and thus increase revenue feeds.

In order to achieve the maximum efficiency, they must raise the “scientific merit” of laundered information. By years of joint propaganda, they were able to eliminate the key distinction in revenue-seeking motivation between science and trade art. Each researcher has unlimited choices of research subjects, selecting a research subjects by funding or revenue completely eliminate scientific merit. By examining subjects of articles in NEJM, Nature, JAMA, Science, Lancet, etc, I found that a very high percentage of articles belong to trade articles. I estimate that more than 90% of articles concerning medical treatments are based on flawed models, junk science theories and rejected old theories, or otherwise motivated to promote drug revenue. When they cherry-pick one thing as a treatment over potentially millions of other better choices, they find “tallest dwarf” from a room full of dwarfs, but present it as the best treatment.

Information launders started developing theories to promote the drug-for-health business. By years of propaganda, they have successfully persuaded societies to accept the drug discovery paradigm: finding a drug to intervene a known metabolic pathway or a disease pathway as a way of treating a disease. However, all drug discovery theories are deeply flawed because (1) there is no real successful case in more than a century of tries, (2) all of drug theories cannot work, for crashing with well known metabolic pathway network in cells, and (3) none of drug discovery theories can stand over the multiple disease causes model. None of drug discovery theories can plausibly show how to correct one pathway without disrupting other metabolic pathways. The appearance of this drug developing paradigm was due to lack of understanding of life in the early time, but information launders now try to keep alive this unworkable drug paradigm by suppressing challenges and contrary discoveries.

E. Failure of Governments to Stop Monopolistic Information Laundering

Since flaws are found in the foundation of medicine, any reform or change would adversely affect a large number of persons with vested interest. It is anticipated that nobody can ever fix the flawed medicine without government intervention. Government can influence private behaviors by changing laws and regulations on drug approval, research funding programs, medicare laws, U.S. patent laws, tax laws, etc. In addition, antitrust law and wire fraud are powerful tool to stop information laundering.

Up to now, federal agencies have done nothing to ban information laundering despite overwhelming problems in medicine. Repeated failure in finding cures, aborted reforming attempts, and unmanageable medical spending are just obvious symptoms of this failed medical system. Federal agencies including NIH do not fund researches for public health and fail to examine obvious problems in the research landscape [185]. NIH has consistently supported researches by relying on deeply flawed research and treatment models [189-190] and using deeply flawed score-based grant evaluation process [188] to promote the “drug-for-health” health culture. All of those problems can be seen by searching NIH funded researches or examining the products of NIH-funded researches. NIH staff is dominated by medical professionals trained in medicine and NIH

heavily relies on the same kind of peers in reviewing grant applications. Due to influence of trade articles, NIH has long become a trade promoter rather than a strategic ashier for new health science. U.S. patent law also provide highest protection for toxic synthetic drugs but do not provide patent protection for products and processes coming from nature [189-190].

After influenced by information laundering for decades, junk science has become mainstream “science”. NIH could not see massive problems and fails to see the need to counteract medical enterprise interest. NIH keeps funding drug researches, drug mechanism researches, vaccine researches, narrow basic researches, etc [186, 187, 191] for the purposes of finding fast “treatments”. It keeps throwing funds to hot and popular researches like competing for hot researches, but has failed to fund research projects that are unpopular, disruptive and adverse to vested interest or that could expose fundamental flaws, establish a new health science, or lead to an alternative health service trade or industry. I have more than ten research projects for just mRNA vaccines [1], they would affect everyone’s health and lives, but my researches do not fit into any funding program due to use of restrictive criteria, unnecessary technicalities and specifications, or trade-protecting peer review.

NIH has not seen the scandalous nature and impacts of the publish-for-money model. NIH has not done anything to insure all failed drug trials are brought into light to refute the drug-for-health hypothesis. NIH must agree that systematic suppression of research model problems must have game-ending impacts on public health, species, and the planet. Yet, NIH has done nothing in its long history to fix the big cancer that control the direction of medicine. Being the victim of information launders, NIH can only follow the path carved out by information launders. NIH supports peer review, endorses the publication model, favor the use of impact factor and have never do anything to examine the monopoly intention of overwhelming editorial policies. NIH does not come up with a very simple solution: take article selection right away from information launders and hand it to its own review staff. By implication, NIH must support revenue-promoting criteria as article quality.

By failing to correct the flaws in the foundation of medicine, NIH cannot use its fund to fulfill its mission to improve public health. Most federal agencies use the same lottery-like peer review in running grant programs [187-188]. Fund-eligible researches must be of the same kind of failed researches, win support from any peer reviewers, and fit into an article style designed for a reductionist science model. When the whole medial enterprise is established on the flawed foundation, no bad conduct in conducting research can be more culpable and dangerous. The medical journals may suppress research articles [192], drug companies and doctors may engage in corruption [180], researchers may use fake data [181] or commit all forms of research fraud [193]. When both the foundation and awarding process are flawed, no research conduct can add more harm to people and society. A research fraud involving \$112.5 million [194-196] is not surprising. When a research change data, he or she most probably know the

change would make difference to outcomes. The impacts of such conduct are only on competing grant applicants, but not necessarily public health and the planet. If this fund had been awarded to other researches, it could have been resulted in more dangerous drugs.

National Library of Medicine accepts only articles that have been published by commercial publishers and articles that NIH has funded or under some agreements [197]. Its admission criteria for articles into the library database are not related to re-search motivation, actual subjects, or patient safety. The library excludes articles automatically by established criteria which can be traced to the journal ability to leap trade revenue and enterprise revenue. Essentially, it uses all flawed, burdensome, and fraud-favoring criteria to exclude open access journals that do not use ill-intended peer review. When the revenue-seeking ability of the journals is in conflict with the ability to cure diseases, its admission criteria favor the former and thus promote information-laundering operation. NLM policies actually favor drug-promoting articles from trade magazines, articles advancing junk science, and preclude articles that would be vitally important to public health and human existence. NLM would never care about my re-print articles that refute the foundation of medicine and explain why most of the \$40 billion federal research fund is wasted. When the operation of a federal agency is based on established policies and procedures without any exception in addressing issues that are dooming civilization, the agency cannot catch any opportunities for changing the fake of mankind. My articles directly affect the evaluation of vaccines and drugs, yet, NLM does not have a single living person to take a look and make a determination why it must be entered into its collection. NLM cannot think of a possibility that a discovery may affect the whole field of medicine and human survival, and but assume that all good researches can come from the monopolistic publishers supported by biased peer reviewers under the publish-for-money paradigm. So, I must find that the failure of medicine and approval of the dangerous mRNA vaccines can be attributed to performance of dysfunctional federal agencies.

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. 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. 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.

F. Information Laundering Destroys Population's Health Wisdom

The biggest effect of information laundering is impairment of population's health wisdom and people's thinking capacity. This problem is reflected in every aspect of medicine such as early diagnosis of cancer, use of drugs to achieve health and personal behaviors of people in the pandemic. Under the influence of laundered information, few people (except some doctors) can see problems that are very obvious to outsiders. Most people believe in the merit of early diagnosis and treatment of cancer. The only people who would object are doctors and researchers who have done researches in early diagnosis and over treatments of cancer [198-203]. All trade articles claim that cancer patients can have much better chance to achieve five-year survivals and thus powerfully "promote" this strategy. This claim is in fact true based on junk science.

Several lines of studies have refuted the claimed benefits of early diagnosis of most types of cancer. Most naturally occurring cancers have very long latent periods [63, 98-99] and could take 70 years to achieve a detectable tumor size. The total development time for most naturally occurring cancers is at least 10 years but often more than 20 years. It is also known that some cancers can stay in the same sizes for very long time [202] and dormant cancer is found in most people by the age of 85 [203-204]. Moreover, the growth speeds of most types of cancer can be dramatically altered by overwhelming factors including lifestyle [205], diets [206], emotional state [21-24], exercise [178-181], etc. Other factors influencing cancer growth speeds include chronic diseases [207], surgery [208], mechanical vibration [209], temperature [210], drugs [211-212], heavy metals [213-214], plastics [215], chemicals [216-217], bacteria [219-220], etc. Abnormal climate speed up carcinogens' spread [218] while tormenting temperature fluctuations can impair human daily immune capacity [27]. Fear of death among cancer patients is the biggest factor accelerating cancer growth [21-24, 221]. A large number of factors could be altered to slow down cancer growth rate while all medical treatments actually greatly speed up cancer growth speeds, and damage whole person health.

Simulations could be conducted to show early cancer diagnosis has worsened the cancer epidemic. The problem can be seen from a hypothetical example: a person has an early undetectable tumor, which could start threatening his life after 10 to 30 years, depending on his diet, exercise, emotional state, etc. An early diagnosis has an effect of labeling the person with an incurable disease and ruins his emotional state instantly. The high stress then dramatically speeds up his cancer growth speed [63], like a Voodoo spell [221]; with all toxic and dangerous treatments, the person might survive more than 5 years, which becomes "achievement" statistic of the medical trade. If the person is not diagnosed with the cancer, he could easily live for another 10-year productive life, and if he is lucky, the early tumor might self resolve, keep dormant until his

death, or undergo grow-and-shrink cycles in response to fluctuations in his overall health and emotional condition [27]. In this cited article, I reviewed many articles on cancer self resolution, which is beyond dispute. Early diagnosis thus deprives the patient of all potential slowing down or reversing opportunities. While early diagnosis can dramatically increase five-year survival rate, extended survival time cannot come from toxic chemo, cancer-inducing radiation and harmful diagnosis, and aggressive surgeries diminishing vital organs.

The increased survival time actually comes from the normally very long latent time of cancer. When a cancer is diagnosed early, some of the latent time was transferred to the survival time. Early diagnosis naturally creates a larger cancer population. By using early diagnosis, medicine turns cancer lifetime incidence rate from a very rare disease to 1/20 and finally into 0.4. With the massive toxic substance exposure, cancer will soon strike all human beings in each person lifetime with the first diagnosis ages going down to fifties, thirties, teens and newborns.... Based on irrefutable evidence, exposure to toxic substances [1], early diagnosis, and use of chemotherapeutic agents make the cancer epidemic worse. My question: is the cancer treatments are best? Medicine lacks incentive to root out the causes of cancer, but passionately promote extremely toxic drugs and increase the number of cancer patients as revenue feeds. It has no right to answer my question. When cancers are diagnosed in a very high frequency, a lot more people must die sooner from cancer. Most of them die after 5-year survivals. When medical trade and medical publishers are motivated by money, every treatment option is promoted for revenue, and its treatments cannot help patients except by accident.

The laundered information can ruin human mental state or thinking capability [83]. It is well known that cancer patients cannot weigh between 99% of big risks with potential 1% of benefits and may be willing to accept anything for hypothetical 1% chance of success. They are willing to receive toxic drugs just a few days before death [222-224]. Over treatment of cancer patients is the biggest problem. Patients could not see the dangers of over treatments, do not try hundreds of non-medical options, but cling onto drugs for a miracle which simply do not exist. Routine CT scanning and radiation treatments can increase the risks of getting cancers [225-226]. Cancer patients may demand CT scans to reach a level of exposure which could be enough to cause a new cancer. The high stress from ruined life and fears of death is the most severe factor. In addition, the increased sedentary lifestyle during cancer treatments also promotes cancer growth [179-181]. When all of those factors are considered together as a whole, anyone should see over treatments also shorten their lives. However, this practice turns potential cancer patients into revenue feeds and most probably dramatically increase the total number of cancer deaths.

Medicine is a trade for money but not a science for saving patients. Each disease or drug theory quickly brought new treatments to the world, but there is no way to end the wrong treatments after the theory was later rejected. Surgical removal and killing

cancer cells were once justified by the somatic mutation theory (AMT), but this theory is most probably wrong in a super majority of cases, based on a large body of later discovered evidence [92]. All of inference factors discussed indicate cancer is in the tissue environment or reaction media or memory. Moreover, cancer spreading takes place in the earliest stage [90] and thus cutting tumor with large margins could not stop the cancer from spreading. In addition, aggressive surgery cannot be justified by the massive background mutations in all humans, exercise benefits on cancer survival, lifestyle effects, and cancer self-resolution. Mutation is most probably not cancer cause at least in most cases [51, 93], but cells' adaptive response in a tumor environment for survival. There is no sound justification to remove tumors with large margins and killing all cancer cells as the primary purpose. All of cited evidence plus more I have not studied yet strongly implies that the old prior-1908 rule against surgery was correct. Medicine trade does not consider what would be better for cancer patients, lack incentive to explore the causes for cancer self resolution, and continue to promote gene tests and surgical operations together with all aggressive and harmful treatments as usual. Such cancer treatments thus deprive patients of the opportunities of using alternative measures, prevent cancer from self resolving, and inflict emotional pain like a Voodoo spell.

Cancer patients are the biggest victims of information laundering: the early- and over-diagnosis and over treatments shorten their lives and toxic drugs and aggressive treatments ruin their whole body health. The drug industry and the medical publishers do not disclose their financial gains from promoting their treatments and suppressing the indisputable fact that cancer is highly amendable to lifestyle, activities, exposure to toxic substance, emotional state, etc. They did not support any one to explore from self-resolution cases to find better approach. Information laundering results in a deeply flawed standard of care for cancer and thus imposes practicing doctors with a duty to prescribe harmful drugs and treatments [227-229]. The financial bias of practicing doctors could be enough to select unworkable drugs, but malpractice law forces them to choose the worst. That is why we see a strange phenomenon: 75% doctors would not prescribe chemo for themselves [198], but they must prescribe chemo to their patients. Even a super majority of doctors would not believe in laundered teaching. Influenced by laundered information, cancer patients are willing to accept drugs. Chemo therapy's contribution to five-year survival rate was about 2-2.3% [72], but exercise can extend survival time by very larger amount of time [179-184]. When population could not see information laundering, cancer patients cling onto toxic drugs, harmful diagnosis, and aggressive surgeries.

Laundered medical information has destroyed human willingness to consider new discoveries and scientific truth. Since my works are suppressed systematically, I tried to disseminate my mRNA vaccines risks by sending email to people. People have developed immunity against truth. After they have been bombarded with flawed and fraudulent knowledge thousands of times, they all believe they know science. Everything contrary to mainstream beliefs is treated as misinformation. A super majority of

recipients could not read my email before they got the first shot, the second shot, and booster shots..... The impacts of information laundering is far more than misleading people to their detriment, and have a magic effect of creating an immunity against truth. Those who conduct a search in Google likely gets hundreds of messages that the search engine wants to sell: commercial circulars, articles from the enterprise, articles from trade magazines, articles from drug companies, etc. They thus lose the last chance to avoid the dangers of the vaccines. When people reported serious problems like lasting fatigue, relapsed viral infection, lost thinking capacity, and lost energy, they still believe they could not have been caused by the vaccine. After medical information has been laundered for decades, consumers cannot be re-enabled to see problems in medicine and make sound decisions. The laundered information has actually ruined the population's thinking capacities by systematically altering background information necessary for conducting correct analysis. They do not know that the life model and everything revolving it is wrong. Thus, people are willing to take drugs, chemo, surgeries, and aggressive treatments for any claimed benefits.

Information laundering has impaired every aspect of our life. Flawed studies advanced by interest holders have persuaded people to accept all kinds of dangerous substances: use of fluorides in city water to damage the kidneys and bones of the population; installation of automatic traffic cameras to waste energy and generate massive durable wastes; people are persuaded to take vitamins supplements in mega dosages which are often hundreds of times of required daily needs; disinfectants are spread on buildings often resulting in dangerous vapor levels, CDC 6-foot rule has caused store owners to keep customers standing long lines under ruin, snow, and cold wind blow.... When people have trusted in junk science, they naturally accept all kinds of dangers like committing chronic suicides. Each dangerous idea can quickly find its way into the population, destroying their health.

Information laundering suppresses new discoveries supporting medical reform. By turning junk medicine into science, they eliminate the need for medical overhaul. By using their monopoly power, they can suppress all views urging for reform. By continuously swapping between junk science and true science, they eliminate new discoveries for starting reform. Thus, the flawed foundation of medicine cannot be improved, nor repaired, nor replaced, nor destroyed, and nor ignored. The reductionist approach continues controlling medicine. No existing laws and regulations have the force to compel the medical enterprise to practice science. Business is always driven by revenue; and consciousness for other lives and health is none of their business objectives. After the information laundering has molded every aspect of society, nothing can be done to improve medicine. Even federal agencies like NIH and CDC have become information laundering partners.

G. Junk Science Exerts Terminal Impacts on Humans and the Planet

I will show how the information laundering enterprise has exerted terminal impacts on public health, humankind, other species and the planet. I will show by how much the laundered information has written off the true toxicity of all toxic substances and how information launders have misled societies to act to the greatest detriment.

The flawed research model has made completely wrong prediction of the total toxicity of all toxic substances on the species on the planet. First, humans consider toxicity of synthetic chemicals only based on how they affect humans only. Thus, humans do not care whether a toxic chemical might kill a large number of non-human species. Many chemicals are found with higher lethal power to kill other species. Nature revenge by bringing all disasters from the destroyed ecosystem. Second, all drugs and chemicals are evaluated according to Independent Action Model and thus fail to see their combination toxicity. Third, the side effects or toxicity is determined by the symptom-based method, use of binary disease method in population trials or observations. Since each human being starts with huge vital organ functional reserves and can tolerate chronic poisoning without causing any symptoms during early exposure. All cellular damages that cannot be repaired pass down to daughter cells. Forth, each toxic substance can damage cells roughly proportional to its concentration and exposure time. When the substance is present in the body, damages happen in different locations of cells and different cells purely by chances; while damaged cells can be repaired by the immune system, some cells may lose cellular functional capacities or die, and thus organ functional capacities will decline with time. If the change is so small, its impact will be seen only after very long time. In other situations, exposure to toxic substances may continue if the toxic substances come from air, water, and soil. Even if exposure stops, damages continue being accumulated because those remaining in the body continue damaging cells with time. The total damages are proportional to time up to the life time of the host person. Most clinical trials cannot last personal life time, and thus massively write off damages by toxic substances.

Two factors that warrant discussion are lack of toxic symptom and combination interference effects of other weak factors. A well known fact is that people under chronic poisoning of kidneys, heart, liver lungs, etc. do not feel discomfort until the organ is unable to meet the required functional capacity, and most early cancers do not have subjective signs. Weak toxicity of nearly all toxic substances cannot be detected also due to interference of lifestyle factors. For example, most nutrients such as vitamin D have beneficial effects on some persons but toxic effects on others. Even though population data falsely show vitamin D has no effect due to canceling out between the positive effects and negative effects, it can interfere with any treatment in the personal level. The second factor, society fails to combine the toxic effects of all toxic compounds (by non-linear model, discussed below). While weak effects of drugs, chemicals, and compounds cannot be detected, each of which must cause cellular damages slowly. Because a person has a large number of cells, each chemical damage cells randomly. The overall damages must be the non-linear sum of all damages caused by all toxic sub-

stances. The total damages caused by a thousand compounds must be larger than the damage caused by one toxic compound. While the degree of damage by each chemical is small, their accumulated damages in each person's life time must be much larger than prediction based on independent action model. The total amount of cellular damages depends on the number of toxic chemicals and exposure of time.

If I correct all errors introduced by (1) intention to destroy other species, (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 persons, 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 disastrous and game-ending mistake that has an effect of putting humans and other species on brink of extinction.

I predict that when the total load of all toxic substances in human cells have reached certain levels, human being defined by current human genomes cannot survive like normal persons, and they must be re-selected in the continuous evolution. I believe that the total loads of toxic substances have exceeded thresholds for living normal life in some individuals, but will rapidly hit more and more people, and eventually cover all people in the population. The persons who cannot tolerate toxic substances will experience one or multiple cancers, CNS diseases, chronic diseases, or otherwise live miserable life. Human beings will die prematurely and probably miserably. No life can survive well over as predicted by my new model with the five corrections. Old people may escape from miseries by dying before the massive chemicals could reach them. The "forever chemicals" dispersion model implies that no one can escape no matter where the person lives. The adverse climate can bring toxic substances from oceans to lands. My model explains why species are rapidly extinct, humans are on the brink of extinction, and rescuing the current human genomes would require detoxification of the planet. To survive, everything in the remaining period of human species must revolve around environment, ecosystem and climate, or see everything rapidly degrading with time. Humans do not have another half a century of inaction.

Information laundering has gained the maximum destructive power by gaining monopoly power and forming the big enterprise. After having gained monopoly power, large corporation participants run their businesses like federal agencies according to their "established policies and processes".

The terminal impacts of information laundering are intensified by using automated computerized processes. The information laundering enterprise is like a huge machine, which presents and broadcasts junk science, flawed disease theories, danger-

ous drugs, and harmful treatments in a non-stop basis. All forms of media including search engines, websites, TV, radios, newspapers, movies, video, school lectures, etc. promote laundered information. To conduct tests, when I typed “mRNA vaccine risks”, all I got were how great the mRNA vaccines are. In response to early cancer diagnosis, all returned records urged me to seek doctors immediately. Junk medicine finds its way into all social fibers, all person activities, all human personal decisions, all social phenomena, and all kinds of physical objects such as textbooks, magazines, novels, etc. and intangible things such as language, vocabularies, songs, movies, plays, video games, etc. Junk science and laundered information thus run and influence all walks of life, business transactions, and legal processes. Junk science slowly ruins people’s thinking capability and helps them to develop “immunity” against any other health sciences and hurts people, species, and the planet perpetually.

When the population has developed immunity against true science, no media could and would promote “other sciences” that may disturb their paid audience and paid advertisers. Facebook, Google, Yahoo, Fox, etc. must promote only junk science to maintain their revenue streams from existing clients. Information launders have secured federal regulations to ban any claim of “treating or curing diseases”. All media participants rigidly honor this drug-protecting rule. The logic is like this: since drugs cannot cure diseases, nothing else could and thus no claim is allowed. By using the rule, they can raise drug’s relative benefits. By precluding even any attempt to find cures, their actions are like bringing death spells to themselves and humankind. The implication of the rule is that all diseases must be incurable.

Information launders have far more influences in science than NIH, FDA, CDC, etc. A rule set by a corporation may enable its automated computerized process to deliver flawed and fraudulent information millions to billions of times to poison the minds of the public. To promote their revenues, they must ignore, consciously disregard, and actively suppress thousands of important research articles by public interest groups. By monopoly or concerted actions, they use junk science to control medical practices, run human lives and businesses, and influence legislative processes. Misguided by junk science, each person’s activities may hurt self or others, each business transaction may harm the actor’s own health, other persons’ health, other species and even the planet. The laundered information has a collective effect of persuading billions of people to commit chronic suicides. No one told how the rapidly approved DES caused the worst nightmare in FDA history, no one told the truth the 1976 flu vaccination has hurt and killed people, and no one can have an article exposing flawed medicine published. If consumers can find risk information on mRNA vaccines, many of them could have chosen to avoid the vaccines, and thus avoided earlier deaths or future health uncertainty. Information laundering has cut off their every chance and sent all of them on destructive track.

Under influences of laundered information, medicine has developed a standard of care with a compelling force. In the U.S., junk science has found its ways into health

care laws and regulations, environmental laws and regulations, food and drug laws, federal tax laws, state tax law, state business law, hospital regulations, medical board regulations, etc. Junk science has controlled medical practices, influence health culture and personal belief, promoted dangerous vaccines and drugs, and spread voodoo spells. Information laundering is responsible for failure of medicine, lack of cures for chronic diseases, and uncontrollable medical spending [59-64]. Enhanced by legal power, junk science has inflicted damages to people, societies, species and the planet.

Information launders have expanded their monopolistic power through influencing the legal system. A similar plight was caused by elixir which tormented ancient people in China for thousands years, killing at least 12 emperors. However, society was unable to enforce the man-killing magic pills to all people. Thus, they did not have compelling effects, and the most likely victims of “longevity pills” were the rich and powerful. However, when junk medicine has been laundered as science-based medicine and enforced by laws and regulations, we find ourselves on the worst situation we can imagine. The enterprise has developed sophisticated devices for stifling innovations and stonewalling reform. No one can escape from the reach of laundered science.

Information laundering has impaired the daily actions of most federal agencies. When science and junk science has been swapped, we must see “travesty of science” and reproach of truth. Every federal agency that is supposedly run by science is now run by junk science; and every agency that supposedly promotes science actually promotes junk science. The U.S. patent system supposedly promotes science, but promotes synthetic drugs and provides little protection for natural products and nature-related processes [198-190]. Laundered junk science has caused NIH to distribute federal research funds to drug researches by a mismatched staff using flawed evaluation methods [187-188]. Junk science has caused FDA to establish flawed science framework which can inflate drug health benefits and massively write off drug injuries and latent side effects. Laundered information also turns NSF into a promoter of junk science rather science. When life model is wrong, nothing can be right.

As a result of information laundering, federal agencies and state agencies are promoting and enforcing junk science as the only science. The drug industry, the medical publishers, FDA and U.S. patent office jointly provides biggest incentives for developing, producing, and marketing synthetic drugs and chemicals while other federal and state agencies are participants. At the same time, the drug industry also buys monopolistic popular media to bloat drug benefits and suppress anything that could hurt drug selling revenues. They have fostered the population belief that only drugs can give health. Under this bizarre business and legal environment, genius, federal tax dollars, state tax dollars, private money and other social resources find their ways into this gigantic enterprise for developing, testing, and marketing synthetic drugs and toxic chemicals. When the foundation is wrong, reductionist science must exert terminal impacts on all species and the world.

Information laundering has fostered the drug-for-health culture. Misled by laundered information, people are willingly to ingest any drugs or to be exposed to any chemicals for any trivial or falsely claimed benefits in a way like committing chronic suicides. When people keep buying drugs and using things made of toxic chemicals, business success attributing to consumer purchases encourages more corporations to produce more and more dangerous drugs and chemicals. In the last half a century, toxic chemicals produced by corporations might have enough force to wipe out all species several times. Now, cancer is about to strike every human with a trend to find its way to newborns and fetuses, chronic diseases have inflicted more than half of the U.S. population, erratic climate keeps tormenting humans, ecosystem is in the process of irreversible ruining, and the planet has been crowned with a title of “toxic planet”, junk science still tells people that nothing needs to be done and provides corporation with incentives to develop more synthetic chemicals.

Information laundering has put the world is in a self-destruction process without fix. If a problem cannot be addressed by NIH, it cannot be corrected by any of other federal agencies or state agencies. When I predicted that mRNA vaccines would pose a large number of dangers and dramatically shorten human lives, I could not get any person's attention. My articles were suppressed by monopolistic media and search engines. The current information dissemination paradigm guarantees that the people must go through the worst plight. This human tragedy and all potential future ones have been built in the process-based business model. Whether the vaccine is safe could be determined by several unbiased experts in a matter of a few days, but the majority of controlling people have lost basic thinking capacity. With population health and national economy at risk, NIH could not determine what is right and what is wrong. NIH has to entrust the population lives to existing knowledge disseminated from published articles, which are the products by information laundering. By using this approach, NIH continues to endorse flawed disease theories, flawed researches, and biased opinions. NIH cannot conduct an initial determination of any critical issue even if the pandemic is about to destroy national economy and the world order. Similarly, FDA relies upon its established process to make its decisions. Despite the pressure for open science movements and all problems in publish-for-money publication, none of the federal agencies has done anything to make changes. The lives and health of billions of people must be decided by a few biased, incompetent peer reviewers.

Laundered information has convinced societies to keep producing drugs and toxic chemicals. By relying on clinical trials, symptom-based research method, and independent action model in toxicology, and short clinical trials, societies have been misled to believe all drugs and chemicals are safe. Societies failed to adopt necessary policies to limit synthetic chemicals long time ago. Wrong negative findings for a large number of chemicals provide excuses for keeping inventing and dumping toxic substances into the seas, oceans and lands. Societies are dumping 220 billion tons toxic chemicals [278] into the environment each year. By the time massive toxic chemicals have dispersed

into every corner of world, the toxic substances could have enough power to wipe out all species. Societies have not seen the seriousness of problems because monopolistic information launders keep promoting deeply flawed sciences. This gigantic information laundering system has gained an eternal life by precluding any challenge and contrary thinking. All aspects of human activities and social practices are controlled and run by monopolistic information launders, junk science has the absolute power to destroy civilization. The impact of information laundering is worse than that of any criminal act.

Laundered junk sciences have exerted terminal effects through the current business practices. For each culprit product, a large number of vendors are promoting the product often by using trade journals, search engines and popular media. It was inevitable forcing asbestos into everything including cigarette filters and clothing, creating a culture for abusing DES, promoting GMO in the world destroying food chain, selling chemotherapy, early cancer diagnosis, and over treatment of cancer to cancer patients, convincing governments to add renal toxins to public water; causing deployment of traffic cameras with little public safety benefits, creating the abusive cellular phone use culture to ruin public health, creating a new culture of ingesting mega vitamins to “achieve health”, and seeing a population of people willingly accepting dangerous mRNA vaccines. When a large number of monopolistic entities promote in the name of science, they can turn any dangerous product into health-givers or safety protectors. If history can be repeated, all personal injuries crises can be repeated with much more deaths and personal injuries, given the increased monopoly power and powerful internet marketing.

An example showing how business practices exert terminal impacts on human species is how businesses promote cellular phones. The business of millions of entities depend on cellular phone uses. Search engines have played the biggest role by turning each cellular phone into a point of marketing or reciprocal of laundered information. Phone users receive advertisements, marketing messages, commercial email, etc. and are induced to buy harmful products and services. They have jointly created a bizarre culture where people use their phones all times, on doorways, inside bathrooms, on crosswalks, during breaks, during driving, during sleep or even in dreams. Their daily phone use times may be more than 1 hour, 2 hours, 8 hours.... The more they use their phones, the more junk science, false information, and dangerous products they are exposed to. Naturally, toxic chemicals, hormones, antibiotics, emotional stress, and time burdens hit the users in combination. However, junk science tells the users that each of their products or services is safe, but never tell how the combination may hurt the users badly. With time passing, their metabolic pathways are altered, their hormone processes were disrupted, their circadian cycles are lost, and their immune systems are compromised by their combination effects.

The business practices have been developed long time before the factual findings of multiple factor disease model were published. After 1980, studies started revealing reductionist science is deeply flawed. That would give mankind an earliest

warning. Unfortunately, in parallel of those discoveries, the drug industry, trade medical journals, and popular media/search engines also slowly gain their monopoly power to launder medical information for their revenue. Thus, information launders have suppressed or disregarded important discoveries and prevent societies from addressing all big problems in effective ways. With all serious problems concealed, no one could have seen a need to consider why business practices are bad and what changes must be made in order to keep human species to survive. After societies have missed nearly half a century, now we suddenly see that the business practices influenced by reductionist science is an absolute destroyer of public health and all species.

The terminal impacts of the business practices can be traced to monopoly power and internet. It is well known that monopolistic businesses use fraudulent slogans, scam devices, predatory pricing, unproductive measures, stolen intellectual properties, etc. to keep their monopolistic positions. Monopolistic enterprise lacks motivation to do good for people and societies. With the internet, they can quickly find their partners to take concerted actions without signing on an illegal agreement. They can establish allies for promoting junk medicine, setting predatory prices for copyrights and patents, and using obsolete technologies. When one corporation issues a ban the claim of treating and curing diseases, all of them follow and thus create a voodoo spell climate for all. When monopolistic information laundering enterprise has formed, it must promote junk science, mold population's belief, and use deceptive and scandalous devices to defraud people and societies. The danger can be summarized in one sentence: Human health is maintained by a sophisticated process balance, the business practices of monopolistic entities under the influence of the reductionist junk science exert an absolute force to destroy the balance by the combination effects of their products and services.

Corrected against the enlarged monopoly power and internet effects, Asbestos, DES, Lead Paint, etc. would kill far more people if they were repeated. In addition, those died from asbestos would have died from other toxic substances, and all people must suffer from all kinds of damages whether they know or not. All monopolistic entities must seek maximum profits, but have no incentive to seek science and improve productivity with no concern for human species and the planet. The business practice model explains why cancer treatments and mRNA can be promoted for acceptance. As long as monopolistic medical journals and monopolistic media continue exist in the world, societies can never find solutions to all problems in environment, ecosystem and climate. Humans must live miserable life.

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, 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. It is under this junk science framework, from which dangerous mRNA vaccines were approved at the speed

of light, and then imposed on the population. It is under this junk science framework that FDA cannot evaluate the vaccines safety when the evidence of adverse effects is piped up.

LEGAL DEFECTS IN FDA APPROVAL OF MRNA VACCINES

A. Legal Standard for Approving Drugs and Vaccines

A drug product must be found to be effective and safe before it can be approved for marketing [108]. One of the essential elements that can fulfill the statutory requirements is that the use of clinical trials that permit quantitative comparison of the drug with a control. In the past, FDA relied on clinical trials because clinical trials were mistakenly believed to be the unbiased and valid evidence, 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 effective and safe conclusions. Express mention of this method is intended to use the highest standard but not 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]. I have 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 in 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. The legal standard does not preclude use of additional research methods. The new discoveries require that drug applicants to address flaws in clinical trials and seek better methods with higher accuracy.

FDA is the only agency that works as a gatekeeper for keeping out dangerous drugs and vaccines. Funded by tax dollars, FDA must always stand on the side of tax payers in enforcing the Public Health Act and FD&C Act. This implied duty is absolute and cannot be excused for any reasons. If the effectiveness and safety of the drug and the burden on drug sponsors cannot be reconciled, the effective and safety concern must trump. Those standards may not be lowered by tweaking research methods, data acquisition, data analysis methods, etc, and must be free of interference by personal opinions, political wills and medical publishers. If the drug industry's interest is in conflict with public interest, FDA must side with the public interest. An even higher standard

must be used for vaccines because vaccines would be used on the population. The actual danger in terms of total deaths and injuries increases with vaccines' injection frequencies. For the same reason, Applicants' statutory duty to provide evidence, particularly adverse evidence, must change with advancement of new knowledge, and cannot be limited by past practices and past standard.

B. Flaws in Evidence Relied Upon by FDA in Conducting Its Analysis

One of statutory requirements for approving Emergency Use Authorization for the vaccine is that "the known and potential benefits of the product outweigh the known and potential risks of the product..." [2]. The first EUA, issued Dec. 11, 2020 for the Pfizer-BioNTech COVID-19 Vaccine for individuals was based on safety and effectiveness data from a randomized, controlled, blinded ongoing clinical trial of thousands of individuals. FDA's approval of mRNA vaccines are based on sponsor's biologics license application (BLA). The agency conducts its own analyses of the information in the BLA to make sure the vaccine is safe and effective and meets the FDA's standards for approval. FDA stated "...FDA determined it is reasonable to conclude, based on **the totality of** the scientific evidence available, that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 12 through 15 years of age." Upon examining Pfizer's and Moderna's briefs for FDA Advisory committees, the decision is mainly based on their clinical trial data [5]. I will show that applicants failed to provide valid evidence.

FDA paid no attention to the concerted action of drug companies and controlling medical publishers, how they have formed this junk science landscape and how the junk science affects its regulatory action. FDA ignored my two articles on clinical trials even though articles refuted the validity of clinical trials. FDA did not address how those studies have affected the validity of clinical trials and did not address how the flaws affect its analysis and its conclusions. FDA gives unwarranted credibility to self-serving research findings and deeply flawed medical articles, but fails to pay attention to evidence from public domains, open access journals, open-science servers, patient stories, and reliable observations. FDA ignored the findings of organ reserve functions and all studies of refuting symptom-based evaluation methods. If FDA has considered all those studies, FDA cannot reach the same conclusions. FDA failed to consider whistle blower allegations. Pfizer's exit VP made serious allegations [230] about the safety of the mRNA vaccine. His allegations can shed light on how Pfizer might have tried to make the vaccine appear to be safer or more effective than it is. His stories may reveal what Pfizer's executives, scientists and internal staff really believes about the performance of the vaccine.

C. Mismatched Qualifications of FDA Advisory Committee Members

FDA decision is heavily influenced by the recommendation of its advisory committee [231]. FDA historically selected people who are known experts in medicine or field relevant to the drug under approval. However, when the foundation of medicine is found to be flawed [8-9], use of members trained in medicine is improper. When they have accepted population medicine, they cannot accept the challenge that population-derived indexes like 95% effectiveness rate, 3% death rate, etc. are all junk index values.

The biggest problem of drugs is latent side effects. Most voting members are not trained with knowledge for understanding the impacts of varying organ functions, multiple factors disease model, interference effects of lifestyle factors, and drug interactions with other compounds or materials. They all believe what is measured. Many of them are heavily influenced by dualism and reductionist approach and thus are predetermined to deny the roles of lifestyle factors and personal activities and believe that all complex life problems can be addressed by statistical analysis; some cannot appreciate how organs buffer conceal side effects, some may hold the unwarranted view that when symptoms are gone, no harm is done. Since vaccine long-term risk is not an issue for medical clinics, but an issue for biological and cellular biological pathways networks, the committee lacks the required qualifications for answering latent side effects. When FDA uses a panel of experts who simply lack matched expertise in system models, acute personal injuries, latent side effects, and reversibility, it is natural for FDA to prove the vaccine.

When problems under challenge are rooted on the foundation of medicine, few members in medicine can accept. Both organ functional buffer and the interference effects of lifestyle factors are different among any two persons, there is no average from a clinical trial that can be applied to all people. By accepting population medicine and use statistical model, they are not open to accepting correct concepts. While it is hard to find experts who can really appreciate nature of life and health model, people trained in system biology, system engineering, system optimization, integrated medicine, etc. may be closer. And people who understand organ reserve functions and their implications, and those who have done research on cellular damages of toxic substances and personal injury mechanisms may see the flaw of clinical trials. Millions of other experts could serve better if they are willing to accept new knowledge.

Another problem is FDA uses experts like NEJM editor as a member. Such an expert can influence research direction by selecting research articles for the journal and then influence FDA decision by his voting power.

D. FDA Failed to Explore Alternatives for COVID-19

Those 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. 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.

DEEP ANALYSIS OF SUBSTANTIVE DEFECTS IN FDA DECISIONS

A. Flaws in Vaccines' 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 article and can be found by anyone worldwide. FDA made no comment on those findings.

I found that, based on thousands of post-1980 studies, all key presumptions in medicine are invalid [9]. Medicine was established on deeply flawed foundation due to lack of understanding of life in the past. The clinical trials model is based on simplest system like goods weight and volume. The impacts of those studies are wiping out

nearly all research models, 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. Thus, Pfizer and Moderna cannot prove that the effectiveness from a clinical trial can be extended to nearly all people except by accident. They must disprove 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 review standard [1]. Medical knowledge on research models, disease theories, research evaluation methods, and medical practices has been promoted by controlling 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 is 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 to study cars such as Honda, Toyota, 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 attempted to use statistical model as a solution [106] and thus compound 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 that a population mean can be imposed on to any individual member. Statistical theory does 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 measurement violates the forbidden rule [9]: all health properties are process attributes that strictly tied to each person, and have no meaning outside the person. When personal numbers are added up, they have different scales and different significance. They are added up like adding apple, orange, watermelon and sesame to reach the total count 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 action 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 bio-

logical 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, exposure to all interference factors, and thus responds differently to any treatment.

The validity of means must be determined by the physical system or the human body. 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 function is 1. For his two-person population, we get death rate of 0.5. This number is a statistical representation 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 person 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 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 they all 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, pressure, concentration, enzymatic activities, and even structural strength cannot be added up. The structural failure stress in one person and that in another person must be distinctive. Even same numeric value in the same person can mean different things. The 10 mm Hg pressure increase in the range well below the structural failure point is immaterial. The same amount pressure increase will be-

come more and more legal when it is close to the failure point. Unit reduction in enzymatic activity controlling a critical path well below the threshold death is completely immaterial until when it is close to the crucial point. For this reason, most health properties cannot be modeled by classical mathematical operations.

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, use of the mean may be valid. A strict rule is that the mean cannot be used to guide treatment of diseases. In medicine, a vast of number of health properties are 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. This number cannot be imposed on persons who do not have this disease. When such numbers are extracted out of the person, they have no meaning. For example, 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 number 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 if treatments are strong effects. 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 at the same time, health or disease cannot be characterized by measuring 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 having a set of best values for all relevant factors or variables. In other words, value performance also 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 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 time would kill the person. However, a much worst problem is that all people (all similar John Does) 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 dream. Thus, some persons may take values to produce outcomes closer to their optimum points, and others may happen to be in the worst states. It is also possible that a particular value of factor is good for some persons, neutral for other, 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. This means that health problem cannot be studied by using population method just like cars and planes. The problem can be best explained that none of the factors is extensive due to tightly associated with each person and also interacts with other factors/variables. Exer-

cise can add huge burden on the vascular system; and a terrible dream and a great dream can have different impacts on the person's health state next day.

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

FDA vaccine safety conclusion for boost shots is based on a clinical trial, 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 serious side effects. In nearly similar time window, Senef et al. predicted a dozen potential risks based on biological and cellular mechanisms [237].

The safety 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 a long time delay [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 buffer, which conceals week side effects. Due to the buffering effects, drug A ruining 50% vital functional capacity, drug B ruining 5% 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 effects of toxicity. 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 effectiveness-to-risk ratio from clinical trials is grossly exaggerated. Measured values of health properties can be further interfered by a large number of factors in personal lifestyle, activities, emotional condition, environment, etc. Those two lines of studies explain that most acute injuries cannot be determined by observing the symptoms only.

All non-distinctive symptoms are "written off" as not having been caused by vaccines. Even though mRNA can cause an unlimited number of unpredictable side effects, medicine recognizes only a few distinctive symptoms. Due to this flaw, even death risks cannot be accurately determined. Since the vaccines can kill only 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, most deaths are written off by attributing deaths to other causes. After a super

majority of deaths have been written off, the death risk attributable to vaccines side effects is further reduced by improper averaging effect of a large number of healthy recipients who always survive. This averaging is done against a forbidden rule that death rate cannot be transferred from the at-risk people to no-risk people. The clinical trial actually attempts to use the large number of healthy people to hide the danger to the smaller number of vulnerable people, the symptoms based method can conveniently write off most acute injuries and latent injuries, and lifestyle and activities can further conceal delayed side effect and latent side effects. The final number of risks from such data is massively reduced. This number cannot be used as treatment guidance but creates misleading impression of safety.

The drug industry clings to clinical trials because they 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 whole population, and conceal most acute injuries and all latent injuries [1]. For COVID-19 disease, clinical trial expands the risk from the 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 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]. Based on known traveling properties [316-319], I must hold 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 dis-

tances [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 serve 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.

Deaths due to raised blood pressure and damaged heart. After vaccine is administered, 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, it causes 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. 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]. Thus, 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 must be maintained when protein synthesis 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 critical important in vital organ cell regeneration in lungs, kidneys, and liver [245-253]. Damages are felted in the weakest organs first in specific persons. Damages must be appraised from degraded performance of the vascular system. The mRNA must disrupt normal protein synthesis by affected local cells and 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. They must cause immunological damages based on observed cell death in COVID-19 patients (no need to find specific mechanism). The damages in vital organ cells thus reduce organ cell numbers, 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 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. 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 involved in normal metabolism, but alternation by DES (as well as many other drugs) turns out to be 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 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. Spike protein production triggered by mRNA vaccines must disrupt normal protein synthesis. If mRNA vaccines are administered 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.

Seneff et al. predicted a large number of 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 boost shot. Others risks they predicted include pathogenic priming, multisystem inflammatory disease, autoimmunity, idiopathic thrombocytopenic purpur (aplatelets 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 severe damages to the nerve system and the heart. They would strengthen each other's predictions. 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 side effects of DES and Roundup is very large even though they have no prectiable 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. If adverse effect is weak, it may show no symptom. If the acute injuries 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]. 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 [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, 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. 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 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 needs to find fast path to keeping out dangerous products.

FDA is not a scientific body and must exercise wisdom when scientific researches have failed or medical knowledge has been manipulated by information

launders. With the same evidence, agency decision depends on their review framework and the approach. EPA and IARC reached diametrically opposed conclusions on the genotoxicity of glyphosate-based herbicides [268]. FDA has used the same approval process which has failed time and again. Due to the huge buffering effects of organ functional reserves, the interference effects of lifestyle factors and selection biases, the real danger of any single drug is magnitudes more worse than nominal ratings from a clinical trial, and the total stress of all toxic chemical compounds is millions to billions of times of what reductionist science has predicted. Only the drugs with side effects that can stand out can be identified. A super majority of side effects can escape from flawed researches. All dangerous drugs and toxic chemicals work jointly to injure humans and species. The dispersion of “forever chemicals” [269-270] gave human a warning that no one can escape from the collective adverse impacts of all dangerous drugs and all toxic chemicals.

After the reductionist model is rejected, we should see humankind is in a hopeless situation. The scale of chemical release is estimated to be as high as 220 billion tonnes per year and still rapidly increase [278]. At current rates of progress, it will take over 100,000 years to evaluate all existing synthetic chemicals for human and environmental safety, and an additional 2,000 years to evaluate each year's new products [280]. Cribb discussed the great challenge to survive and how to clean up the planet [280-281]. I believe that total accumulated loads of all lasting toxic substances on the planet have surpassed the threshold for destroying life. Cancer is a problem reflecting cells based on human genes are unable to adapt to the environment [97]. When thousands of toxic substances are accumulated in cells, the cells cannot survive in the way they would in the long past. Thus, they must try to adapt to the toxic tissue by mutation. Some mutations may result in cells with high adaptability [284]. Based on the multiple factor disease model, the driving force of cancer is most probably total loads of all toxic substances and there is no way for humans to understand complete details. Based on the cancer from elderly persons [203-204], it is a disease of humans living in a misfit environment. The first cancer diagnosis ages are rapidly shifted toward to youths, teens and newborns. All of those risk-based disease models must be rejected as obsolete science; and it is just a matter of time for anyone to have cancer diagnosed as long as he is exposed to a sufficiently large load of total toxic substances and other cancer driving force.

No rescue is possible unless societies can correct flawed medicine and fix the planet. But society has developed all kinds of business practices which have severe tension with life. Whenever a research finds an innovative thing, this thing is quickly used by businesses to achieve revenue. By overreaching marketing, a monopolistic business can quickly turn the innovative thing around to achieve the harmful effects: stressing life and ruining the planet. When the world started tolerating monopolistic businesses, every business can grow bigger and bigger with a power to harm public health and the planet. Whether a business markets vitamins, drugs, poisons, appliances, or

materials, their decisions are always driven by the business judgment rule. Thus, life-destroying activities are seen in all personal activities, all social activities, all businesses activities, routines government actions, etc. The prevalence of prevalent monopolistic business entities has caused humankind abruptly to enter her doomsday. FDA could identify and study millions of things like adding fluoride into public drink water, spreading mosquitoes killers in public parks, abusing use of cellular phones, routine use of painkillers, unrestrained marketing of disposable products, production and sales of appliances with no obligation of repairs, widespread use of artificial additives, sales of highly-processed foods, abusive use of antibiotics, addition of hormones in animal feeds, etc. Each act is like throwing a small bomb to destroy life on the Earth.

Societies accept such acts because flawed medical researches have convinced societies that they are all safe. It is all the billions of little and routine activities that have dragged the humankind into the grave and preclude the young generations from living enjoyable life. Without correcting all model flaws in medicine, restructuring the business paradigm, and banning monopolistic business practices, societies will never solve any of big problems: public health, ecosystem, climate and environment. There is no other way to stop all activities that are rapidly pushing the human species into the grave. To attempt to alter human fate, FDA must start its urgent mission to place series of bans on synthetic chemicals and seek international cooperation in banning synthetic chemicals and dangerous drugs as the primary mission.

B. Key Evidence, 95% Effective Rate, Is Meaningless

Looking at the data in Table 6 in the FDA memorandum [3], 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 where were 162 COVID-19 infection cases in the control group of 18325 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 perform 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. The risk factors are often expressed as adjusted rate ratios, which may be infection or death rate of persons with a risk factor divided by the infection or death rate of normal persons. A high ratio means the risk factor has more severe effects. A study find: 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]. Independent factors associated with in-hospital mortality included ages 50-64, 65-74, 75-84, and ≥ 85 years versus 18-39 years (3.11, 5.77, 7.67, and 10.98, respectively); 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]. A

high frequency means more likely a person with the particular condition will be in hospitalization or die.

The risk model makes an assumption that infection, hospitalization and death are quantities that can be added. 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 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 things like bus tickets, hotel reservation, etc). Moreover, frequency has introduced averaging effect when it is used (even though no averaging operation is actually done). A frequency ratio 1.30 for sex implies males die at higher frequency than females. In reality, the 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. Death does not happen to the young, health, and responsible persons except by accident. With personal care, it is possible some of them can have even lower death rate. The numbers, diabetes (3.2), obesity (2.9), hypertension (2.8), cannot be used to predict personal risks even for people with those conditions.

The linear model used in risk assessment is very poor. Death happens when vital functional capacities cannot meet required minimum functional capacities and all burdens from all diseases and life activities. There are many variables that can be manipulated. I will show 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 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 rise, he may get over with the risk of 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 high chance to experience adverse event or death but this prediction can be easily defeated. Only when personal health condition is analyzed with current life factors, avoidance skills, personal behaviors, etc, we can 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 a specific person in specific circumstance.

Risk factors such as 2% death rate and 2000/million infection derived from population is only an abstract value for measuring the disease agent, the health condition of 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, we can get such a number but cannot apply it to any specific car at all. Im-

posing the population mean to any card 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 may be infected, severely disabled or die. The risk deduced from a population cannot be applied to even any of the persons in the clinical trials.

Ignoring all other problems in the 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 is based on small numbers and thus the 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 misleading. In reality, the un-vaccinated group just has only 162 cases. Thus, the low infection rate for the control group indicates that the disease is not bad. Finally, there are many other measures such as right lifestyle, avoidance skills, daily activities, etc. can offer similar and more reduction for most people.

The data imply that only less than one in every 100 persons would get infection. In reality, who gets infected is not decided by random probability but by their health, avoidance skills, lifestyle factors, and personal daily activities. 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% of 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. The effectiveness rate is most probably determined by the health characteristics of all people. The same 95% could be achieved by permuting the patients. If the 3 original patients were prevented by staying at home and any of other 3 patients are infected by intentional exposure. The trial would have got the same 95% effectiveness, and similarly, the 168 infections could be relocated to other persons by changing their personal behaviors in a number of different ways. Such a number represents an extreme model reduction and is irrelevant to the super majority of people including healthy and young people, healthy middle-aged people, healthy and old responsible persons.

Despite misleading impression, the number, 95%, does not prove that vaccine is the best measure because it cannot disprove each of hundreds of other life and preventive

factors. Temperature has more than 10 folds effects on national incidence rate [1]. When temperature is changed from worst to the best, 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 see data. Life skills for avoiding exposure and lifestyle factors [1, 232] would have similar or even higher effectiveness but they are not suitable subject for clinical studies. Deep breathing exercise, meditation, and right exercise at right time may have similar effectiveness ratio if they were studied. If some of those factors are used in combination, they can easily exceed the vaccine's short-term effectiveness.

One biggest problem is that this vaccine benefit 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 benefits must be weighted against the vaccine risks on all 18,198 persons in their life times. Thus, the risks of causing brain damage, heart damages and millions of unidentified damages are inflicted on the population. In contrast, good lifestyle, improved health, learned avoidance skills, etc. can have both short-term and long-term impacts without endangering 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, vaccines can keep those vulnerable persons forever in the vulnerable group while lifestyle measures can turn those vulnerable persons into those who can better resist the virus.

Lifestyle, avoidance skills, daily activities, body temperature management, etc are responsible for more than 100 times differences in infection rate and death rate. This observed facts imply that three predicted deaths could be prevented by using non-medical methods. This example shows population medicine flaws: transferring disease risks from a small number of persons to the population, inflating treatment benefits and extending 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 abused because it can turn the whole population as treatment subjects. However, it is grossly unfair to those (about 80% or 14,568 or more) healthy people because the risks of deaths of COVID-19 are completely irrelevant to them. The claimed treatment benefits are based on short-terms results and transferred from a small number of people to them. The benefits predicted by such flawed number can NEVER be realized if any of influence factors is altered. Even a very healthy person could have himself killed by do-

ing several wrong things in a relevant time window such as getting fatigue, exposure to very cold temperature, getting vaccine shot while exposure to the virus [1].

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 does 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 could fall within the CI range if the same research is repeated. In reality, the infection risk is not applicable to for those healthy persons; nor is the reduction in infection risk, and nor is the CI. The effective value and CI values will differ if a similar trial is done in different time of year, using different people, against a different variant, after change of health wisdom, etc. The CI creates a misleading impression that experimental errors can be estimated. The number is attributed to treatment effect. All lifestyle factors, personal activities and other diseases are bundled into the error or standard error. If we run a control to study the efforts of wearing mask, body temperature management, exercise, avoidance skills, etc, each could produce similar number like 90%. None of those factors could be regarded as errors. The model essentially is tailored to studying drug benefits and totally incompetent to model the multiple factors life and personal health.

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 organs. It is possible that the infection risk and disease severity rise more sharply 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.

Repairing cars/planes is NEVER a probability issue, and nor is curing diseases. Given the massive vital functional differences, death rate heavily depends on their 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. In reality, a super majority of people have a 0 death rate and a small number of people have nearly unit death rate if they are infected.

In one big clinical trial, the subjects were selected from many nations for determining which a cancer treatment should be used [82]. It must be assumed that how to treat cancer for women in the U.S. should depend on how to treat cancer patients in other nations. Evidence to prove flaw in this approach is the fact cancer is a disease greatly associated with culture, lifestyle, diet, and working environment. Each of those major types of cancer can vary by more than 5 to 10 times [282]. Similarly, COVID-19 is clearly associated with population health, diet, lifestyle, climate, preventive skills, etc. Medicine has no interest in controlling cancer by altering lifestyle, learning avoidance skills, giving up bad behaviors, making efforts of improving health, and avoiding wrong medications.

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 vaccinated group has 162 infection cases while both groups have similar persons. Their argument may have force only if the treatment has a strong effect like a gunshot for the ability to kill. When a treatment has a very strong effect, all people can be treated as identical units, those frequency data become useful estimates. A gun that can kill 80% target people on a single shot is predicted to kill four times of people than a small pistol that can kill only 20% persons. In this situation, personal differences can be dropped out, and each death can have one numeric value and frequency data is valid. In contrast, those vaccines are weak factors, and there is no identical basis for comparison 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 the practical reason, clinical trials cannot detect the impacts that are realized by long term. Thus, it is the best method for concealing drug side effects. Those vaccine trials last only several months to less than a year. Second, 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 are under very cold weather, the number of infections will both increase. However, the low temperature may disable the immune function and thus nullify the vaccine short-term benefits. If the virus has generated a new variant, it has more adverse impacts on the vaccinated group. Thus, activated partial immunity against the virus may be lost substantially. Such a trial precludes investigating multiple factors and their combination.

The population approach forces all people to accept mRNA vaccines that would damage vital organs, the blood brain barrier, the CNS and nerves, etc. While epidemiological study can estimate an anti-pandemic measure's ballpark performance or otherwise may be useful for other purposes, such a number cannot and should never be

used as treatment guidance. By clinging to flawed population research model, drug industry actually use the flawed models to transfer disease risks from distinctive vulnerable persons to the whole population, and thus force them to accept unnecessary and harmful drugs or vaccines. This time, flawed clinical trials have an effect of forcing the population to accept painful, dangerous, and reckless vaccine trials. 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 cause of deaths, etc.

The number 95% does not tell all vaccine risks. Since health outcome can be optimized only by tuning all relevant factors, failure to use them would have the same adverse effects of failing to achieve best performance. The predetermined use of the vaccines with a predetermined mind of precluding all other relevant factors most probably result in a pandemic outcome that is magnitudes worse than what could be brought by a holistic approach.

C. 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 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-induce inflammation, infection-induced inflammation and other damages can temporarily and permanently reduce such vital 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 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. Medicine never officially admits that adverse effects of drugs must have life-time impacts. This tradition has a magic effect of writing off all personal injuries that do not lead to deaths. The epidemiological model then turns around to use the death frequency (a quantitative value) as a risk factor. Ironically, both the binary disease model and deduced death frequency are wrong. The double wrongs do not make them right but make them worse. As I have shown, a deduced quantitative value like death risk 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; only vaccines can drain the battery to total death only in those worst circumstances. I must say that vaccine injury frequency must be 100%. Young people are like life-batteries with massive charged energy; you can keep draining their "life" by forcing them to accept vaccines and drugs.

The current method of counting vaccine deaths are also wrong:

(1) 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, increase in local flow resistance in all tissues and organs must contribute to a rise in systemic 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, kidney and lungs [1]. 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 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 vaccine in part even though there is no sign of vaccine injury based on flawed diagnosis method,

(2) All 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, its adverse impacts can continue affecting the person for much longer time. 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. This has an effect of early death with or without disease symptoms.

(3) Shortened life spans are caused by disturbed immune systems, disrupted protein synthesis in any vital organs, systemic damages to the vascular system, latent damages in the brain and vital organs, etc. Due to complexity, there are no distinctive symptoms. Most deaths caused by the vaccines are conveniently written off. By using 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 life-span. 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 diminished its regulatory capacity for the body, causing the person to die earlier. Lack of evidence does not mean it has no damage at cellular level.

(4) Deaths caused by weakened structure of body organs, bone, and blood vessels are also written off. Personal capability to survive from any 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. Over active immune system might kill more host cells that the body can replenish (ignoring accepted categorized immune disorders). Over active immune system and disrupted protein synthesis may collectively weaken the blood vessel structure. When failure point in a person’s vascular system is reduced from 300 mm Hg to 200 mm Hg, the person may die at more situations. Damaged bone structure may result in a diminished capacity of generating white blood cells. When the body needs more immune cells, the bone could not generate them. 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 with constraints, which cannot be freely ignored. 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.

For those reasons, death data and safety conclusions for mRNA vaccines must be rejected.

D. FDA Must Consider the Latest Data on mRNA Side Effects

Various sources of data point to the vaccine’s role in damaging the vascular system. Israel data [256], Gundry data [257] and Lab founder data [258] 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 death 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. The first fact is that more COVID deaths are associated with those first shots with the longer time lapse. 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 administering second and booster shots).

Based on the traditional view, the antibody concentration in a vaccinated person will go down with time, and so will the number of B and T cells. It takes time to slowly diminish personal ability to weather COVID-19 infection. Thus, a longer time delay would be associated with severe infection and high risk of deaths. This view is 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 a mRNA vaccine, its adverse impacts on vital organs and the tissue structure is realized with time. If neuron signal transmission 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. This is why the death rate will be high among those who have a longer time lapse from the first shot and COVID-19 infection.

I must find 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 shot is $57+4=61$, but the deaths among those with second shots are 1,790 for the >80 group. The total number of people with one shot must be more than the number of people getting two shots. Also, some people with a first shot have died or decide not to take a second shot, the number of people with two shots can be only smaller. Those numbers can be compared to estimate 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 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 body 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 general health [1] as I noted that organ's function capacity and body structure play even larger roles on personal capacity to survive from a disease. The active level of the immune system is only one factor which can slowly weaken the body structure. It is even possibly, an overly active immune system with excessive B and T cells can change the body in the direction of reducing the number of organ cells and reducing cell quality. A general rule is that sickness can progressively ruin health and vaccine-induced response is a severe illness.

Based on Table 6 [261], two vaccine shots did not reduce infection cases for all people from 30-79. 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 rough comparison: the two vaccine shots are responsible for observed increase in the 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 so that it would take longer time to see the adverse impacts of the vaccine on vital organ functions. My prediction is that if the trial can run for much longer time, young people will see high susceptibility to infection. This observed increase in the incidence rate is also consistent with the finding that Pfizer mRNA vaccine actually diminishes innate immunity [255].

Other UK death data in Table 6 concerns small frequency which cannot be reliably interpreted in light of overwhelming lifestyles, weather and environmental factors. Table 6 shows that vaccines can reduce death rates in the short-term follow-up period; however, the data cannot tell differences between those with one shot and those with two shots for a long term prediction. The data shows that vaccines only have short-term benefits 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 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 dangers of repeated vaccination are also reflected in side effect reports [307]. This study 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.

E. FDA Should Seriously Consider Alternative Preventive Measures

One condition is for approving the vaccines is that "no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition." Based on infection incidence patterns, one would find that lifestyle factors and temperature would cause 100 folds difference in the population data [1]. The drug industry is interested only in finding drugs and vaccines, but has no real incentive to ex-

plore better, safe, durable, and wide-spectrum alternatives. By relying on FDA EUA, most people are misled to believe the vaccines are safe and the best and nothing can substitute the vaccines. In reality, any of many other options such as use of mask, avoidance skills, well balanced diets, good lifestyle, exercises, proper body temperature management, etc. would have produced an abstract number like 95% except no body sponsor such researches and research findings would have been suppressed by the medical publishers and totally shadowed by popular media. I heard many reports that all fully vaccinated persons get infected as usual, and such vaccines have zero utility for putting an end to this pandemic.

NEW FRAMEWORK FOR EVALUATING MRNA VACCINES

When medical knowledge has been selected and falsified by information launders to accumulate junk science in the medical literature, FDA cannot make right decisions in its approval actions. FDA must examine how junk science has affected its approval framework and what changes must be made to fulfill its statutory mission. If junk science is not eliminated from the medical literature or the pool for FDA's use, whatever FDA does is meaningless, and its approved drugs must endanger the population like DES, and mRNA vaccines.

A. Several Changes Mandated by Medical Discoveries

To avoid repeating future health crisis, FDA must consider how DES crisis took place, and how the swine flu vaccination in 1976 hurt the population. The swine flu, influenza A virus subtype H1N1 caused one death and 13 hospitalization in January 1976 and led to a mass immunization program. FDA's Bureau of Biologics approved it on September 2, 1976. In very short time, approximately 24% of the population of the United States were administered the vaccine. It was soon found that the vaccine was associated with an increase in reports of Guillain-Barré Syndrome (GBS), which can cause paralysis, respiratory arrest, and death. The immunization program was ended abruptly. By 15 December, 1976, cases of Guillain-Barré syndrome (GBS) affecting vaccinated patients were reported in 10 states. On December 16, 1976, a one-month suspension of the vaccination program was announced and the vaccination program was not reinstated after. The Centers for Disease Control and Prevention states, "Those who received the 1976 swine flu vaccine had a slight increased risk for developing GBS of approximately one additional case of GBS for every 100,000 people who got the swine flu vaccine." Due to four big biases, nearly all damages were concealed. Some biological resources may have a hundred to a thousand times redundancy. The junk science enabled CDC to make an innocent conclusion to the world. In reality, nearly all damages that are not sufficient to cripple some relevant nerves or the part of the brain will not show up as vaccine injuries, but they consume the surviving capacities of the

vaccinated. In 1976, CDC were innocent because all new researches directed to life factors have not started yet. Even the role of Central Nervous System had not been explored. Today, it is entirely different. With the massive background discoveries, but laundered medical information is able to persuade more than 100 million Americans to receive the mRNA vaccines, which have not been specifically tested for safety. Millions of studies have proved again and again the role of multiple life factors and thrown out the reductionist treatment model by overwhelming evidence. The only thing that has not been done is synthesizing all relevant discoveries to come up with a new life model in place of reductionist junk models. This is not a science problem anyone.

FDA must accept an assumption that valid science cannot come out from researches performed by drug industry, trade researchers, enterprise researchers and actions of corporate boards. The bias in selecting research subjects is enough to bring scientific merit down to zero. The massive cited studies together with my analysis show that valid science can never be brought to the light of day by monopolistic commercial publishers and trade magazines. They cannot do it to ruin their revenues. To avoid being controlled by junk science, FDA must address this root problem. Based on problems from its past failures and mRNA approval, I propose several necessary changes: rejecting the drug-for-health hypothesis, adopting holistic analytic approach, nullifying the impacts of information laundering, and restructuring its advisory structure and member composition, and proactively seeking true science.

1. FDA must reject the drug-for-health hypothesis

I urge FDA to reject drug-for-health notion in medicine. I will summarily prove here the whole model of drug discoveries are flawed with zero (0) chances for success. The prevalent drug discovery model is funding a biochemical and cellular pathway for any chronic disease and then finding a chemical compound or a treatment measure to alter a disease driving pathway in a way to mitigate disease properties. I will show this approach has never worked in the long medical history, has failed consistently, and in conflict with most life experience, observations, clinical discoveries, common sense, and nearly all better disease theories. This finding has an effect of wiping out all drugs as far as they are used to treat chronic diseases.

Early researchers turned synthetic drugs into “medicines” around the same time evolution theory gradually gained its acceptance; and overwhelming facts about synthetic drugs were UNKNOWN. No body has ever vetted potential problems from changing medicines from natural products to synthetic drugs [9]. The early motivation of using synthetic drugs is clearly patent monopoly [189-190] and expected monopolistic revenues. However, synthetic drugs were not part of nature designs and medical researches have consistently found that drugs would not cure diseases [59-67]. It turns out that small differences between natural compounds and man-made compounds can cause catastrophic personal injuries as in the case of DES [198] and many man-made chemicals. Despite the repeated failures, lack of performance of synthetic drugs, and

severe side effects, medicine continues clinging to this hypothesis. The drug development history clearly shows that use of synthetic drugs was due to a short-circuit reasoning driven by monopoly: since natural compounds can cure diseases, synthetic drugs must have patent protection. More than a century later, drugs are promoted as the only medicines in place of the true medicines in nature. In reality, all attempts of using synthetic drugs to cure diseases have failed except by accident [69-80, 83] or have severe side effects [55, 100, 139-146, 211-212, 285-287]. FDA should review all drug performance articles to find that drug-for-health hypothesis has failed completely. Due to model flaws and the buffering effects of massive vital functional reserves, the side effects are concealed. There is no conceivable theory that a synthetic drug will not disturb the normal metabolic pathways in cells. Observed accidental benefits are most probably caused by roles of incidental lifestyle factors. FDA must find that no synthetic drug can cure chronic disease and cancer as a matter of fact.

Drug researchers naturally find working mechanisms to justify their uses. While exploring disease mechanisms can advance understanding of deep secrets of human life, what is wrong is to find a drug to intervene a single mechanism as an attempted cure. Assuming that all known metabolic pathways were right, it does not follow that a disease can be cured by using a single drug to block or accelerate a disease mechanism. I urge FDA to reject this hypothesis for many reasons.

First, the drug model is based on a completely wrong model in the physical world like cars and planes. A broken machine can be fixed by replacing the broken part. Millions of studies have shown that health is controlled by hundreds to thousands of factors, and disease-free condition can be achieved only upon sophisticated balances among all metabolic processes. Anything, even excessive oxygen, air and water can kill a person. However, the incentive for drug revenues has driven medicine to create a culture of using a synthetic drug to cure diseases. This unproved hypothesis has failed for more than a century and there is no theoretic basis to succeed.

Second, human health is based on a sophisticated balance. Synthetic drugs can always disrupt the established balance and thus ruin personal health as in an overwhelming number of cases. One reason is that each drug mechanism is coupled by a large number of metabolic pathways and there is no any conceivable possibility that one pathway (the mechanism) can be altered without disrupting others. This implies, sadly, drugs, as used in the reductionist treatment model, must ruin personal health in the long run. This can be understood by examining how traffic flow pattern in a traffic network can be disturbed by a road blockage. A correct presumption is that a synthetic drug must disrupt biological pathways with no possibility to cure diseases. All mechanisms used in the drug discovery model have failed and must fail also because they are unrealistic and oversimplified. Such mechanisms cannot explain how environmental, lifestyle, dietary, emotional, thinking, and behavioral factors affect outcomes. Additional findings in support of the multiple factors disease cause model can be seen in the references [288-297]. The drug working model may be used only for acute diseases for short

term estimate. It must be rejected for chronic diseases. If FDA can find a theory to explain how a drug can fix a single disease pathway, show it to the world.

Third, medicine has produced a track of failed records concerning all chronic diseases in the entire medical history. Failures reflected in published drug studies represent only a small number of attempted drugs. The biased publication practices have concealed a super majority (93%) of failed drug candidates [177-178] and thus prevent practicing doctors from knowing the extent of drug failures. FDA could identify a large number of failed drug trials that were not reported in medical literature. Most drugs can damage health in the long run, and a right presumption is that synthetic drugs are biggest hazards to public health and all species.

Forth, most research methods are fundamentally flawed or lack required accuracy. Assuming that the drug approach were correct, the methods for drug researches are wrong. Statistical models are misused. Per statistical theory, the mean of a sample from a population can represent the population. However, that does not follow that value of each individual person can be replaced by the mean from the treatment group. The representation used in statistical theory is totally different from running a patient's health metabolic process by the sample's or population's mean. All presumptions used in the clinical trials fails, and even statistical distribution simply does not exist for most medical research purposes. The use of a sample mean in a specific person crashes with overwhelming restrictions imposed by human bodies. Even adding up values of health properties across different persons is deeply flawed. Mean heart output or any other health properties cannot be applied to individual persons OR must ruin their health or kill them. Since all treatments from clinical trials are developed in violation of this forbidden rule, all treatments from the population medicine should be presumed to be dangerous as long as they are used for a sufficiently long time.

As a result of overwhelming flaws, most of the acute drug injuries and all latent side effects are concealed by massive organ functional reserves. The "success" of a small number of drugs is due to concealment of side effects as a result of inaccuracies in research models, biased review process, flawed evidentiary standard, distortion of data, and luck. While researches have exposed more and more drug problems, most non-distinctive side effects of approved drugs are concealed by massive organ reserves and interference of a large number of lifestyle and personal activity factors. The binary scale could introduce nearly 50% errors, regular exercises and well balanced diets would have far more (magnitudes) beneficial influence than drugs like therapeutic agents.

Finally, drug mechanisms cannot explain drugs' affects on vital organ reserves and body physical structure. Most drug studies focus on their effects on one or a few health properties. In reality, process attributes are only a very small part of the whole story (even assume they were right for the sake of argument). They seldom consider how drugs affect vital organ reserves, the structure of organs and cells, particularly

blood vessels structure. Organ functional reserves and body structure roughly set the longest life spans for each person. Making the immune system active is only one factor that affects the disease process. However, how an activated immune system affects organ functional reserves and body structure is a different story and has not been explored. A person's capacity to survive in all kinds of situations is determined by vital functional reserves. A young and strong person's vascular system may be tens to a hundred times more than that of a person who is near death. Even the overall structure of organs can have more effects on personal survival than a drug-altered process, which affects vital organs and body structure slowly. For example, some persons may be able to tolerate 350 mm Hg peak blood pressure without any problem, but another person may experience vascular failure at a peak pressure below 200 mm Hg. This problem can also be illustrated by a car lifespan: a car's operational parameters are not enough to tell whether the car can survive a crash or perform well in adverse driving conditions. Most drug induced changes in health properties are only a small factor in the full equation. FDA cannot take drug working mechanisms too seriously and must consider organ's functional reserve and the structure of the body.

FDA cannot trust drug working mechanisms for other reasons. Most drug working mechanisms are deduced from studies involving animals and human beings. Due to the effects of hundreds of influence factors, it is very hard to deduce the true working mechanisms. It is possible that the real mechanisms are so complex that there is no way for humans to understand and characterize. They are never like what can be written as several simple steps or shown in a graphic illustration. Even core mechanisms like ATP production and its use were subject to disputes. But the minority's voice was suppressed by influenced people. When personal reputation is at issue, absolute nothing can be trusted. If this theory were wrong, most metabolic pathways would have additional flaws. Even if they were right, they may only represent only a small part of reality. All drug mechanisms are deduced by relying on human experience with the physical world, but the life model is not what can be expressed in 3-D picture. All drug working mechanisms cannot explain the mind-body model involving brain axial in the gut microbiota [295]. The findings of recent studies imply that life is entirely different from any physical system we see in the world. It is possible that the method of deduction based on human 3-D experience may limit our ability to understand life. This is why each cancer theory cannot explain hundreds to thousands of factors but cancer can self resolve. The multiple factors disease causal model implies that drug working mechanisms generally cannot adequately represent human bodies. Most drug working mechanisms may be able to explain only one or a few strong influence factors while all other factors are omitted. That may be why drugs cannot give personal health even if they can have benefits to control symptoms. For this reason, FDA should distrust all drug discovery theories.

Using unproved theories for new drug discoveries are promoted by information launders for revenues, FDA should see that the merits of drugs have been promoted lit-

tle by little in more than a century. The benefits of synthetic drugs were originally found from antibiotics, anesthetic agents and painkillers. In the early time, no body could see great differences between drugs for killing bacteria, fungus and insects and drugs for altering human bodies. Without the millions of post-1980 studies, medicine mistakenly extended the benefits of antibiotics and painkillers to all other drugs. Medicine has never succeeded in treating chronic diseases. To diffuse lack of performance of drugs, medicine started using substitute properties in researches, added statistical analysis, and added conflict of interest declaration, all of which has an effect of evading the hard-to-answer question whether synthetic drugs can cure diseases. After the perfect information laundering system has fully established, medical researches do not need to directly tell whether a drug can cure a disease, but produce abstract numbers like risks, percents, significance levels, and confidence intervals, all of which have no bearing to real patients.

FDA should note that drugs are not best options for achieving health, and that most drugs actually ruin public health in the long run. Synthetic drugs are man-made and even drug mechanisms are created by man with little being right, they cannot fit into the nature designs for advancing personal health. One argument that nature accepts or tolerates only certain things that have been exposed in evolution, but reject things of man's creation. No one can approve why synthetic drugs do not infringe nearly 20,000 genes-encoded products and other metabolic intermediates. A better presumption is that drugs must ruin the immune system slowly [27] and the most important approach is using the multiple factors to improve immune system's current capacities [27]. My findings are suppressed even by preprint platforms because they would negatively affect drug sales revenue.

Correcting flaws in foundation is not the kind of researches that drug companies sponsor, but what some public interest researchers have done. Now, FDA can find massive evidence: all failed drug candidates, all removed drugs, drugs in product liability suits, all large drug review articles potentially in thousands, personal experiences potentially in millions, etc. Based on all factual evidence, I show the origins of using synthetic drugs were motivated for patent protection, the drug working mechanisms are man-made, no human-derived mechanisms can explain all influencing factors, and no plausible theory can explain why synthetic drugs will not destroy the integrity of known metabolic pathways in cells. Unless drug industry can show a plausible theory that a synthetic drug can cure diseases, FDA must reject the drug-for-health model, which has inflicted damages to public health and human species. I believe that the strength of evidence against use of synthetic drugs as medicines is thousands times more than that in support of their use. Even the few favorable findings in drug studies are a product of information laundering and flawed research model. Based on the totality of evidence, FDA should adapt a presumption that synthetic drugs cannot cure chronic diseases, and require drug sponsors to rebut the presumption before a drug can be approved for such

use. In establishing policies, FDA should favor nature-made products over synthetic drugs.

2. FDA must use a holistic analytic approach

FDA practices have been heavily influenced by the reductionist thinking, and are reflected in its policies. FDA believes that best evidence is a well controlled clinical trial for conducting a comparative study. Influenced by reductionist thinking, a treatment effect can be best determined by comparing a treatment group with a control. In an effort to defeat personal variables and lifestyle factors, it has been assumed that the net effects can be determined by finding means for the treatment group and the control group. The drug performance is based on how the drug affects health property, intermediate concentrations (bio-markers), symptoms, survival time and the number of deaths in a trial. This approach has been accepted for about three centuries, but is wrong. The discoveries of vital organ's redundant functions refute the symptom-based research method; the discoveries of cellular damages caused by various toxic substances in large number of studies reveal very long delays between exposure to harmful products and appearance of detectable symptoms and thus refute the validity of clinical trials on this ground, and discoveries of a large number of influence factors refute the clinical trials focusing on a single drug. Clinical trials improperly transfer disease risks from individuals to the population, extending treatment benefits from a small number of persons to the population, conceal most acute injuries, and conceal latent risks. The discoveries of role of massive lifestyle factors on personal health in the last half a century imply that health can be achieved only by a holistic approach. Since personal health depends on hundreds of factors, health can never be achieved by using one single factor at a time as imagined by reductionist theory, and health can be achieved only by using all of relevant influencing factors. The need to use holistic analytic approach in drug approval can be shown in several examples below.

The true bad effects of chemotherapeutic drugs can be found only if all relevant factors are considered. FDA approved cancer drugs that could extend mean survival time by several days [37] to several months [79-80] as compared with a control drug or treatment. All cancer drugs are approved in similar chain comparison. Over the years, it has been found that chemotherapy greatly accelerates aging of cancer survivors [100-101], impairs the mental state of cancer patients [83], and dramatically raises cancer spread speed [63] and accelerates aging process [100]. Meta drug reviews show that cancer drugs deliver little benefits in terms of long survival times [71-72, 79]. Only a small number of studies found marginal benefits; but if such benefits are corrected against the biases introduced by research models, organ redundant functions, and the slow-delivering nature of cellular damages [1], their true impacts on patients are most probably negative. The flaw is the misused comparative method. Each cancer is distinctive [102-103] requiring unique measures.

A large number of studies found that exercises can dramatically extend survival times of cancer patients [179-181, 291]. It is further found that all types of cancer could self resolve, and cancer can be prevented by major changes in lifestyle [27, 205]. In addition, even lifestyle and daily activities unrelated to cancer can affect cancer patient survivals by influencing the vascular system and the immune system [27]. When all relevant post-1980 studies are analyzed as a whole, no person in a reasonable mind could find that cancer drugs actually benefit cancer patients except by accident. Chemotherapy may contribute about 2-2.3% to five-year survival [72] while exercise (a very primitive form of exercise) would easily extend survival time by 40% [197-181, 291]. Based on all evidence, cancer drug benefits are “the tallest dwarfs from a room full of dwarfs.” It is certain that most of cancer treatments actually shorten patient lives [63].

The need to use the holistic approach is strongly indicated in difficulties in regulating cellular phones. I assume that excessive cellular phone use poses the worst danger in human history and no agency finds a way to regulate its use. The FDA shares regulatory responsibilities for cell phones with the Federal Communications Commission (FCC). However, FDA has limited its focus on radiation [185-186] but has not focused on all other potential risks from (1) reduced human-human interactions or social isolation [21-22], (2) reduced use of language, (3) diminished physical activities or increased inactivity degree [184], (4) adverse impacts on vision, (5) slow impairment of the body form due to extended use of certain body postures, (6) damaged elbow and shoulders from over uses, (7) increased stress on spine and its impacts on the whole body health [27], (8) potential impacts from lost balance in the usage of different neurons, (9) disrupted circadian rhythms from staying later at night, (10) impact of radiation on brain which is harmful by implication [225-226], and (11) increased exposure to radiation in body parts (e.g., when cell phone is placed in a pocket next to the body), etc. Each of them is a weak factor that cannot be reliably studied by the population-based model.

Thousands to millions of studies indirectly point to various health risks of this magic phone. Influenced by reductionist thinking, researchers have not paid attention to the health-ruining culture. Young people started owing cellular phones at very young ages and are not warned against chronic adverse health impacts. Misled by laundered information based on deeply flawed studies, all people believe cellular phone abuse is safe. People may constantly play phones in classrooms, door ways, elevators, breaks, crosswalks, etc. Some people use cellular phones even during driving. Many of those impact routes may strike each person in combination. The abusive use can disrupt their circadian rhythms [297]. Reduced speaking is one important factor. Speaking is an essential function for maintaining the lung health [294]. I assume that speaking is the best exercise for the brain. It is now believed that the brain and the body are communicated by many communication axes such as the gut-brain axis (GBA) [295] and lung-brain axis [294]; and those axes are connected to emotional center and cognitive centers in the brain. This means that emotion can affect those connected parts. Speaking must help maintain brain health because the speaker must think, interpret what others speak

and find right words to be used as response, etc. In addition, speaking must affect all nerves in the gut-brain axis and the lung-brain axis because the mechanical vibrations must affect the spinal cord and all surrounding nerve bundles. I safely assume that speaking is an essential exercise for maintaining nerve channel health, and the health of the emotional and cognitive centers. When a person lives in a cellular phone world, he is in isolation [21-22], he will lose language ability, lose part of the normal functions of the emotional and cognitive centers, and experience diminished communication efficiency.

I predict that, fifty years later, societies will see how the cell phone abuse culture impairs personal health, population health, personal life spans, and national economy. Some kids could grow up to be productive members if they actively interact with companions, but the cellular abuse may turn them into social rejects with all kinds of health and emotional problems. Injuries to hands, necks, vision, spine, etc. are not local and must have systematic impacts [27] contrary to the wrong hypothesis of reductionist medicine. FDA should see that cellular phone misuse could be the biggest health hazard for the population. Under the current analytic framework, FDA can do nothing. If FDA adopts a holistic approach, it could regulate phone uses to save or extend lives of a large number of people.

The need for using holistic analytic approach is also indicated in mRNA vaccines performance. By using a holistic approach, FDA could not have approved their use authorizations. Population based research model attempts to treat all persons as similar members. However, only a small number of people are at risk [276-277] and a super majority of people do not belong to those at risk. COVID-19 poses no material danger to at least 80% of the population, FDA must consider unnecessary dangers to them [1, 237] and viral mutation [298-300]. FDA should find that personal lifestyle factors such as diets, exercise, and body temperature management could dramatically affect infection and death risks [233-236, 301-302]. FDA cannot ignore the estimated 100 times differences in infection and death rates between the U.S. and other nations and the more than 10 times differences in infection/death rates in the U.S. between different times of the year [1, 232]. FDA must consider how organ functional reserves, delays in damage realization conceal adverse health effects of the vaccines [1, 8-9]. FDA needs to find how the vaccines affect different persons differently. FDA needs to understand how the vaccines reprogram the immune systems [1, 237, 255], disrupt protein synthesis [241-252], and promote viral evolution [253-254], etc. FDA must weigh short-term benefits against all predicted long-term adverse effects and their impacts on human ability to fight future pandemics. Since the stake is millions to billions of lives and their health, none of those issues are too small to be considered. FDA should have considered all issues that are unfavorable to the approval and consider that vaccine sellers are predetermined to endanger the population for their revenue.

3. FDA cannot rely on junk science produced by information laundering in violation of U.S. antitrust law and wire fraud statute

I must urge FDA to use a presumption that “science” from information launders may not be relied on. Whether FDA has right to rely on products brought by information launders was settled in Tang Dynasty in China more than 1400 years ago. It was well held that no one should trust greedy merchants. It was popular cultural belief that greedy merchants would do anything for money. FDA should find that money influence in medical publishing the modern time is much worse than in the ancient time. FDA is charged with the mission to protect public safety and our right to exist as the last gate-keeper. If NIH and CDC fails to do their jobs, FDA must make its last try to protect public interest. Millions to billions of people lives and the nation’s future depend on each of FDA actions. However, the mission of the information launders is diametrically opposite to the mission of FDA, and the biggest revenues can be achieved only by destroying public health, bringing miseries to patients, turning the whole population into revenue feeds, and ruining the planet. It is beyond any dispute that medical journals select articles for money, media speak for money, search engines present marketing messages for money, and their experts express opinions for money. The general media are the main conduit by which medical discoveries reach the public; and the public relies upon media to understand medical stories [303]. When both medical journals and media have gained monopoly power in the internet age, the information laundered for revenues have quickly ruined public health wisdom. FDA must treat their articles as trade knowledge. Many cited scandals show that none of them has ANY incentive to protect public health, human species and environment [147-175]. Controlled by their business needs, they must publish a drug article for a million dollars of reprint to crew up millions of patients, and reject one article teaching health lifestyle which could help save millions of people [110-115, 304]. Businesses do everything for money is what anyone should have seen half a century ago. How can FDA with all top ranking leaders failed to see it. I must find that FDA has no right to rely on “junk science” put forth by information launders for revenue. Over the last a few decades, U.S. antitrust law failed to contain the medical journals and popular media, and allow this enterprise to achieve power to exert terminal impacts on humankind, and at the same time, they are allowed to make fraudulent “science claims” to destroy public health wisdom. Relying on their “science” could also have an effect of encouraging their antitrust and wire fraud conducts with the worst damages to humankind in the human history.

FDA has made the biggest mistake that ancient people would not more than 1400 years ago. The failure of FDA in keeping dangerous drugs from the market can be traced to this mistake. If FDA cannot see the root problems of information launders, FDA should subpoena board minutes from all participants to see what they care about in their business actions. If FDA continues blindly relying on laundered junk science, FDA will repeat approving of things like DES and mRNA vaccines in the future.

From tracking all problems to the publication model, I believe that a solution for FDA is fixing the publication model. A solution could be creating an independent publication organization funded by tax dollars and public fund together with a statute of banning

the organization from receiving money from selling information and publishing articles. This organization may be jointly funded by multiple nations in the world. With as little as \$5 to \$50 billion dollars, future articles published by this organization can neutralize the influence of trade magazines and re-introduce true science to people and societies. This measure is perhaps the only effective and achievable measure for rescuing human species. Additional measures include enacting international laws or agreement forbidding trade journals from claiming science merit, imposing criminal sanctions for conduct of suppressing discoveries that could have impacts on public health, environment and human survival, and criminally punish information launders as the highest crime. While those measures may change the future slowly, they cannot solve the overwhelming problems threatened by the massive synthetic chemicals dumped at the rate of 220 billion tones a year. I hope FDA can see that they are in the process of burying civilization and our future.

FDA should explore other measures to nullify the acts of information launders. Information laundering has sent mankind to the brink of extinction, built overwhelming devices to block all paths to rescuing civilization, has substantially poisoned the population's minds, and fostered a drug-for-health culture. Information laundering is responsible for producing massive dangerous drugs and toxic chemicals. The world continues on its destructive course. FDA should conduct a comprehensive study to understand how information laundering affects public health, environment, ecosystem, and climate and why none of the problems can be fixed.

4. FDA should change its advisory committee composition, structure and use

Whether FDA can enforce the FD&C Act would depend on if FDA can escape from the controlling effects of junk science disseminated by the medical journals. One existing problem is that FDA consistently gives too much deference to advisory committees. If FDA finds that the foundation of medicine is flawed, FDA must independently determine scientific merits of research articles that could affect its daily approval decisions. In addition, FDA cannot select experts by using the current method which has been controlled by laundered medical knowledge.

Correcting any fundamental mistake is always difficult in the human history even in science discoveries [304]. Resistance was encountered in accepting the atom, the big bang, evolution theories, quantum mechanics, heliocentrism, etc. Biggest resistance was known in how societies accepted heliocentrism and quantum mechanics. When money was not a driver, society was able to correct past mistakes often taking hundreds to thousands of years. After junk medicine has been hijacked by monopolistic publishers and monopolistic media, sophisticated devices like peer review, content-based editorial review, monopolistic media, internet censorship, monopolistic search engines, etc, have been fully developed, it is impossible to correct junk science. Resistance can be traced to psychological activities, financial bias, monopolistic motivation, cultural biases, the momentum of established procedure and practice, operation of existing laws and regu-

lation, etc. Correction by using traditional way is impossible because such efforts can be easily defeated by the propaganda executed by automatic processes of monopolistic information launders. Every attempt will continue painting junk science as the best science and urge people commit mass chronic suicides. More than 100 millions of Americans are willing to sign the vaccine use agreement with a clear warning that nothing is known about vaccine's long-term side effects. By using powerful marketing tools, the information launders can repeat flawed theories millions of times, and suppress or ignore millions of new discoveries all together. After people have been bombarded with junk science, most people in medicine have lost ability to recognize junk science. That is why FDA cannot draw experts from medicine without testing their ability to recognize junk science.

5. FDA must proactively seek true medical science

FDA will never be able to enforce the FD&C and Public Health Act for tax payers if it cannot find true science. FDA cannot assume that science can be found from the medical literature because medical literature is a product of funding biases, research subject selection biases, publication biases, legislative biases, cultural biases, psychological biases, trade biases, professional biases, and monopolistic-motivated biases. A single source of biases would be enough to turn scientific merit into nothing. When there are so many biases, there is no point to even argue that medical art is a science.

FDA should see from the human history that science merits can be easily manipulated by money, political power, cultural belief and personal biases. While a wrong theory in the human history merely adversely impacted people and society on limited scales, the same mistake perpetuated by monopolistic information launders at this internet age has terminal adverse impacts. All aspects of human activities, legal systems and economic activities in the world have been integrated with junk science. FDA now must distinguish real science from trade art and tell true scientists from trade experts. If FDA continues to rely on junk science, corporations and drug companies will generate enough dangerous drugs and toxic chemicals to bury human species.

FDA cannot take what the information launders give but must search what it needs. FDA must take necessary measures to address the controlling impacts of monopolistic media such as Facebook, Google, Yahoo, Fox, TVs. etc. In this model, the drug industry has massive marketing budget; and the monopolistic media simply sell laundered information for money. Those two industries have more influences over living medical knowledge, health culture, and population health wisdom than any research organizations. For money, they will kill any new discoveries. To get money, they must promote junk science, harmful trade art and scam art. Their actions in promoting vaccines have an effect of talking 100 million of U.S. residents into receiving unproven and clearly dangerous mRNA vaccines even though they acknowledge unknown future risks.

FDA should conduct a comprehensive study to understand how double-blind peer review and content-based editorial review help to generate junk science and impact on FDA's actions. True science publishers lack funding for long-term survival. FDA should explore funding sources for supporting a workable publishing business.

FDA cannot wait for medical researchers to clean up the massive junk science. FDA must speedily address all fatal flaws. Natural law gives no respect for agency rules, laws and regulations, or leaders' wishes. If the research model is wrong, treatments from such a model must be bad and even endanger patients like all cancer drugs. If a disease theory is wrong, a treatment based on the theory must fail except by accident. If risk analysis framework is wrong, the nominal benefits-to-risks presented to FDA must be wrong. Unless FDA can reject the multiple factors disease causal model and millions study findings, FDA must reject the reductionist treatment approach.

FDA, together with other federal agencies such as NIH, CDC, DoD, NSF, etc. must address junk science in medical literature. Most studies may contain original data and would have some utility upon different interpretations. Thus, what must be done is to extract useful information from completed studies and published articles. Most articles may be amended in use scope and conclusions. The same research article may be valid for proving certain facts or certain aspects of a health issue, but invalid to prove a treatment or treatment strategy. Most articles may be used as evidence to reject existing disease theories and refute old medical practices. I believe that a large number of life secrets are found in various non-trade research articles. FDA should encourage researches to conduct large scale synthesis analysis by considering findings from the whole medical field. Perhaps, some researchers can quickly found new ways for addressing cancers and chronic diseases.

One biggest problem FDA must address is that research funding biases. Massive research funds have been directed to vaccine researches but none was intended to explore vaccine risks. NIH has spent more than \$40 billion research fund last year, but nothing on researches to explore the danger of vaccines. Some programs may sound to include both benefits and risks, but restrictions are placed to preclude any researches from investigating the side effects. The federal government has distributed multiple rescue fund for COVID-19, but not one penny has been directed to those working on fundamental problems and exposing risks of mRNA vaccines. The drafters of the legislation can think only enterprise researchers, existing businesses, and those with a track research records. They would not see that their lives and their family lives are in danger. All federal money must be thrown to failed programs that have failed for decades. This kind of narrow thinking is the main reason for seeing this massive vaccine human trial in the human history, with a clear sign to see the biggest human catastrophes. As a result of all biases in laws, regulations, culture, personal beliefs, psychology, etc, no fund is allocated to risk studies and disruptive studies. Among two comprehensive researches on mRNA vaccine risks, my research was unfunded and the other one was funded by a private company, Quanta Computers, Inc. Taiwan. Those two articles will likely map out all

risks, and will affect a large number of lives, population health and more than half of U.S. population, and could have an effect to stop imminent dangers to some people from booster shots, but the U.S. federal agencies, state governments, research foundations, non-profit organizations have paid nothing. The monopolistic media block those articles.... If the U.S. population must go through the worst plight, it is this kind of non-inclusive thinking and exclusive policies to bring the worst. It may shock the world that the U.S. government does not pay one penny for a vital project that is intended to protect the U.S. population the most, and yet a private computer company in Taiwan was paying for one research. Give all of those biases, FDA must struggle to find true science and avoid trade art put forth by information launders.

FDA must appraise whether the mRNA vaccines have real benefits to the users, how they increase SARS-Cov-2 infection susceptibility, and how they shorten people life spans. Having a huge staff, FDA cannot use any excuse to delay its corrective actions. FDA has an army of experts on its payroll and the U.S. government has even more scientists on its payroll. If two randomly selected reviewers are able to determine scientific merit for a research article, an independent review by a panel of unbiased and well matched non-trade experts must give much better determination. FDA must try to find a new approach to bypass the established review processes. If FDA cannot bypass junk science, FDA would repeat mistakes like DES and mRNA. If FDA fails to address the root problem, it is possible to see the worst plight for the U.S. residents.

6. FDA needs to reconsider approved drugs and products

The flawed research model has biases to write off most acute drug injuries and nearly all latent side effects, FDA must reevaluate all approved drugs or other approved products. FDA should note that many synthetic drugs and chemicals have tormented and will continue to torment people and societies. Each culprit product can keep injuring humans for decades to a century. Genetic modified foods raise omega 6/3 fatty acids ratio in the Western diet from near 1:1 to 30:1 or higher; a chemical can find its way to all human bodies, staying there "forever"; cancer is clearly about to strike each human in each person's lifetime. There is no foreseeable end date for each dangerous product. Now, we have gotten to a point that no one can have any assurance that she will not be exposed to many of hundreds to thousands dangerous chemicals. The news from our personal communications is often about new cancer diagnosis, recent cancer deaths, new diseases....

The side effects of nearly all drugs are not studied or unknown when they enter market [71, 79, 138, 266, 306, 309-312] and this practice is clearly wrong. To protect public health, FDA has massive clean-up for drugs that have been approved for chronic diseases and cancer, that are used regularly by a large number of people or that might be used by some people at fairly high frequency or long duration. All drugs for chronic diseases and cancer are approved by relying on flawed evidence. A faster remedial measure is that including label warnings to reflect flaws in clinical trials and misuse of

population data. In addition, new labels should tell whether approval is based on applicants' data, and whether applicant data can be influenced by the sponsor's funding. It may include allegations of whistle blowers and third-party information refuting drug validity and safety. Such information will allow patients to make informed decisions. The medicine is full of junk science; and FDA should not try to protect medical trade interest.

Drug safety is none of the business of drug companies, and thus FDA cannot expect drug sponsors to explore new approach for evaluating drug safety. FDA should conduct a comprehensive research to understand how dangerous products (many are regulated by other agencies such as EPA) currently under litigation will affect society in terms of costs to lives, national economy, species extinction, environmental pollution, destruction of ecosystem, and changes in climate. It will take decades to see each of those suits winding down. Now, each person in the U.S. is being exposed to a large number of drugs, toxic chemicals, and other harmful substances. Most of injuries will exhibit as one or more cancers, and many may develop multiple cancers in future. Without firmly controlling dangerous drugs and toxic chemicals, the young generations will live miserable lives.

All of those changes are necessary to determine drug's effectiveness and safety under the federal law. If FDA adopts those proposed changes, FDA can easily find that those mRNA vaccines pose unreasonable risks to the population and may recklessly endanger pregnant women and fetuses, and vulnerable people.

B. Determine mRNA Vaccines' Effectiveness and Safety

Based on the above analysis, FDA should take following actions:

1. FDA withdraw all mRNA vaccine use authorizations and reconsider vaccines safety and effectiveness in light of identified process defects, evidentiary flaws and analysis flaws. FDA approval is invalid also because FDA has relied on recommendation from mismatched advisory members, failed to consider relevant discoveries, failed to consider acute vaccine injuries, failed to study the latent side effects, accepted research data that dramatically "wrote off" side effects, failed to consider their impacts on viral evolution, failed to consider vaccines effects on cause of death.... Due to flaws in the foundation of medicine, FDA cannot blindly follow its policies and procedures used by other federal agencies such as NIH, CDC, etc.

2. FDA must find a way to bypass the effects of suppression of critical information by the medical publishers. Since FDA has no direct power to control medical journals and medical research practices, its only option is discrediting and disregarding their articles in FDA actions. By disfavoring trade articles and knowledge laundered to promote medical enterprise revenue, FDA can mitigate adverse impacts of junk science. In addition, FDA should sponsor research to understand how controlling medical publishers routinely manipulate medical science, knowingly publish false medical information and suppress discoveries that could hurt their revenues. FDA and DOJ should use antitrust

law and wire fraud statutes to punish those who have inflicted worst damages to human species and the planet. When a medical journal refused to review an article that clearly challenge the foundation of medicine, the action must be done with actual intention to endanger and kill millions to billions of people. The refusal to publish such an article is a prerequisite for eventual approval of dangerous mRNA vaccines. This action is much more culpable than refusing to publish an article exposing a failed drug trial.

3. FDA should restructure its advisory committees. FDA should establish a special committee for assessing acute and latent personal injuries, and select persons who have suitable expertise in appraising acute personal injuries and latent personal injuries. FDA cannot select persons trained in medicine and persons who are influenced by medical enterprise revenues. FDA cannot accept their recommendation unless the recommendation could be validated by independent non-trade experts. FDA should not consider recommendations issued by trade organizations. In addition, FDA should require serving members to be open to accept new theories that are contrary to accepted wisdom. For drugs that are intended to treat chronic diseases or imposed on the population, FDA should not approve them without extensive review and debates among all members of this special risk-management committee. In determining research merit, the only criteria is through extensive debates and active review, without giving any credibility to medical publishers, impact factors, peer review, and editorial policies, and article technicalities except that those may be used to discredit their science merit.

4. FDA should fully address acute vaccine injuries and latent side effects for mRNA vaccines. FDA should use an presumption that latent side effects cannot be detected due to expected long delays between exposure and appearance of the first symptoms and that most latent injuries cannot be detected due to the interference of a large number of lifestyle factors, personal activities and environmental factors. Its safety analysis cannot be based on clinical data only. FDA must rely on various types of studies in combination. Vital organ functional reserves cause one-way biased effects resulting in concealment of side effects. Thus, FDA should adopt the principle that a positive finding of side effects in animal studies or clinical trials can reliably predict side effects for a drug, but a negative finding cannot be used as credible evidence of lack of side effects, and further study must be conducted at cellular levels to predict latent side effects. By using combination risk-analysis approach and exploring the pattern of personal injuries, FDA will be in a much better position to predict latent side effects. FDA should demand drug sponsors to provide a theory for predicting drug safety and effectiveness. If the sponsor cannot give any plausible theory, the drug-for-health hypothesis should be rejected.

5. FDA should consider using a highest standard for vaccine approval. For example, it may several levels of evidence standards for different products: (1) strictly controlled drugs, (2) drugs for occasional use or prescription, (3) drugs that might be used by a substantial number of people at fairly high frequencies, and (4) vaccines or drugs that may be imposed on the whole population. For (1), the standards for both

acute and latent effects can be the lowest because they may be used in low frequency, for short terms, or as the last resort. The standards for (4) must be highest. The safety of vaccines should never be based on an assertion like “probably safe” or “appear to be safe” because a wrong decision may ruin the population or kill a large number of people.

6. FDA should expand the scope of evidence to be considered. FDA should adopt evidentiary standard used for patent examination. Vaccine defect can endanger millions to billions of persons. FDA should consider all relevant evidence under the Sun without being affected by suppression of research articles by the commercial publishers, applicant’s selection of references, sponsors’ biased funding efforts, etc. FDA should invite suitable persons to submit information to support or oppose approval of the drug under consideration.

7. In weighing conflicting evidence, FDA should consider the effect of revenues and money, funding biases and publication biases. FDA should give the least weights to sponsored research findings and articles from commercial medical publishers, and should give highest weights to studies done for public interest. Drug industry and the medical publishers have turned the medical system into a profit-optimizing enterprise. Now making profits and promoting public health are often in direct conflict, and medicine has evaded its responsibility by using substitute criteria having little to do with scientific merits of drugs. Based on money influences, FDA should regard NEJM, Nature, Lancet, Science, JAMA, BJM, as trade journals because they receive revenues from drug industry, getting “donation” from interest holders, are run and controlled by persons attached to medical enterprise, or receive substantial revenues from selling products that are owned, patented or trademarked. When money is the primary motivation, their articles cannot be relied up as the primary scientific evidence.

8. Since federal governments, societies and people heavily depend on science in making their routine decisions, there is a strong interest to stop monopolistic businesses from laundering science information. FDA, DOJ and other federal agencies should explore a new publish model and new information finding model. This task cannot be entrusted to board. If people search the internet for health information, current search engines return irrelevant, misleading, flawed or fraudulent, and harmful information. By relying on laundered information in search results, people may unknowingly make decisions leading to their deaths. When search engines have gained monopolistic standing, they naturally do everything to suppress information to create new business opportunities for selling formation. Even information like company addresses and contact information have disappeared from search results but appear in classified ads selling databases. Monopolistic search engines provide services with deception, intentional inefficiency, willful suppression, and marketing overreaching. FDA should conduct a study to see how search engines ruin public health, species and the planet. This may be the first instance that antitrust and wire fraud conduct can cause the biggest personal injuries and deaths. If search engines are not changed, all of those who have died would

repeat their outcomes by relying on the same laundered information. Due to strategic importance, federal government and public fund must run its own search engines and directly control search algorithms. It is necessary to ban private search engines from using ranking algorithms and using any science claims because they are used to achieve monopoly standing and defraud consumers. If one understands the magnitude of damages caused by search engines, no remedy can be excessive. Banning drug commercials is not enough. There is no remedy for the past personal damages caused by search engines. A public search engine must provide capability to find any subject like the old library index system. Reforming search engines cannot change the fake of those who have died from relying on search results, but changes can prevent information launders from doing further damages to lives, species and the planet.

9. As to those mRNA use authorizations, FDA decision was based on the effectiveness rate like 95%, a meaningless index number with a large number of flaws. FDA now can summarily reject this flawed index by noting the number does not show the vaccine safety and cannot be applied to any person.

Conclusion

FDA rapidly proved DES in 1941, swine flu vaccine in 1976, and now approved mRNA vaccines rapidly. To determine whether mRNA vaccines are safe and effective, FDA must determine whether vaccine evaluation researches are done by using a correct life model.

Based on all cited studies and my analysis, I summarize the life model here: Each multiple-cellular life being 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 those 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. Thus, 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 attended 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 it or reduce some of his life from it 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 model. The findings of half a century of researches provide irrefutable support to this life model. FDA cannot refute this model.

The proposed 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. FDA must see the severe limitations in bio-medicine. The usefulness of bio-medicine should be confined to exploring disease mechanisms for non-binding hints-generating purposes, and management of acute diseases, but should not be used as a direct guidance for formulating treatments for chronic diseases. When the life model in medicine is wrong, nearly all disease theories and all treatments must be wrong and dangerous. The biggest flaw is found in clinical trials, which attempt to transfer disease risks from a small number of distinctive individuals to the population, extend short-term benefits 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, and thus is wrong as a matter of law. FDA has a statutory duty to protect the health and life of all U.S. residents and the human species, FDA cannot avoid my challenge.

Unfortunately, true science has been suppressed by information laundering. 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 monopolistic medical publishers and then being disseminated as living medical knowledge by monopolistic media to ruin public health wisdom. Due to flawed in medicine, FDA approved DES on a fast track, hurting at least three generations of offspring of female users. FDA also approved Swine flu vaccine to cause 24% of population to receive dangerous vaccines in 1976. In this kind of information laundering environment, FDA approved mRNA vaccines to endanger the population. If information laundering is not firmly addressed, FDA is anticipated to approve even more dangerous drugs based on its action pattern involving DES, swine flue vaccine, and mRAN vaccines. Due to information laundering, hundreds of millions of U.S. residents are willing to receive such dangerous vaccines for little or imagined benefits. I must find that the population minds have been impaired by laundered information. If history can be restarted to run under the same flawed medicine, FDA would re-approve each of several hundreds of removed drugs, EPA would allow each of the banned chemicals, and those who died would die for the second times, third times....

Articles and knowledge disseminated for money have poisoned people's minds with an effect of blocking every path to reform. 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 for

the humankind, and inducing population or patients to commit chronic suicides. FDA must do whatever necessary to nullify the adverse impacts of laundered information. FDA must do its part to foster a new science publication model with zero money influences. All national governments, all societies, all organizations, and all citizens and residents must join force to dismantle this monopolistic information laundering enterprise. If FDA cannot address this vicious cancer, dangerous drugs and products will 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.

FDA approvals of mRNA vaccines are clearly invalid because the key evidence of effectiveness that FDA relied upon is invalid. FDA should have summarily rejected mRNA vaccine applications on any of the following grounds: vaccine effective rate representing an abstract concept, misuse of statistical analysis, data addition involving different scales and significance, failure to consider buffering effects of organ reserves, failure to address great differences in all persons, failure to take into account mRNA off-target expression, failure to address risk of interfering with immune system balance, failure to consider mRNA impacts on protein synthesis in vital organs, failure to consider vaccine-induced inflammation on the vascular system, failure to consider mRNA impacts on viral evolution, failure to consider vaccine damage reversibility.... If FDA sponsors a comprehensive study, it could find more problems. If FDA must prove use authorization, FDA should include strict use restrictions, require disclosure of all potential risks, and forbid their use on all people.

The business practices - publishing articles for money, speaking for money, and promoting ideas for money - have been accepted for long times even through it is considered an "unethical business", no one has seriously explored how the practices affect medicine, human species and the planet. Over the years, information launders become bigger and bigger or more have joined this giant information laundering enterprise, all for money. The drug industry, the medical publishers, social media, search engines, and general media have formed a long chain of monopolistic controlling points over medical information. Due to gradual nature in gaining their monopolistic statuses, they have escaped from the scrutiny of antitrust violation in all nations, particularly, in the U.S. After they have successfully suppressed truth, truth cannot be found. Thus, laundered information helps them to escape from the reach of wire fraud statute. They can sell useless knowledge, 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 promoted. Strangely enough, 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 must exert terminal impacts on public health, human species, all other species, and the planet.

It is well known that 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 because real cures for diseases do not support medical revenue, but maximum revenues can be found only by selling useless, disease-creating and dangerous drugs. In other words, 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 no money. In such a bizarre situation, this monopolistic information laundering enterprise must deliver the maximum destructive force to ruin public 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 have lost half a century to address environment, ecosystem and climate problems, and have suffered unprecedented damages.

Humans are in an evolutionary crisis. Human activities and business practices were developed under the influence of reductionist junk science. All human activities developed under influence of flawed medicine have a severe tension with life. Based on the current situation, human activities and business practices must destroy all lives on the planet. The massive toxic substances have polluted environment, ruined ecosystem's balance, and generated tormenting climate. Abnormal chemical profiles in human cells of persons and erratic climate must invite endless pandemics. The COVID-19 pandemic and human suicidal responses are just starting signs of this evolutionary crisis. Rapidly accelerated cancer incidences, rapid shift of the first diagnosis of cancer to young ages, and appearance of cancers in fetuses and newborns have been the signs of this evolutionary crisis for years. They cannot be seen because such information would be suppressed. If humans continue to make, sell and dump chemicals, whatever humans do to fix environment, ecosystem and climate will be futile. All of those big problems cannot be solved without firmly committed joint efforts of all governments, all businesses, all organizations, and all people.

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REFERENCES

(Not all references are directed cited in the text but relied upon)

1. Wu J. Expression of Concerns: Potential Risks and Unknown Effects of mRNA Vaccines On Population Health. March 17, 2021. Accessed from <https://osf.io/yudvh>.
2. FDA News Release. FDA Approves First COVID-19 Vaccine Approval Signifies Key Achievement for Public Health. Accessed from <https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine>
3. FDA. Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum. December 11, 2020 Retrieved from <https://www.fda.gov/media/144416/download>
4. FDA Pfizer-BioNTech COVID-19 Vaccine EUA Letter Authorization. May 10, 2021. Accessed from <https://www.fda.gov/media/144412/download> FDA Pfizer-BioNTech COVID-19 Vaccine EUA Letter Authorization. October 29, 2021, November 19, 2021 Retrieved from <https://www.fda.gov/media/150386/download>
5. Polack FP, Thomas SJ, Kitchin N, et al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. N Engl J Med. 2020;383:2603-15. DOI:10.1056/NEJMoa2034577
6. Moderna COVID-19 Vaccine EUA (Reissued February 25, July 7, August 12, and October 20, 2021) October 20, 2021. <https://www.fda.gov/media/144636/download/abstract=3502432>
7. Wu J. Expression of Concern: Medical Flaws and Failure Support the Presumption that Vaccine Boost Shots Are Dangerous. August 30, 2021. Accessed from <https://osf.io/ap43k>
8. Wu J, Zha P. Randomized Clinical Trial Is Biased and Invalid In Studying Chronic Diseases, Compared with Multiple Factors Optimization Trial. Preprints 2019, 2019110245. Accessed from <https://www.preprints.org/manuscript/201911.0245/v1>. DOI: <http://dx.doi.org/10.2139/ssrn.3480523>

9. Wu J, Zha P. Clinical Trials and Reductionist Approach Preclude Cures for Chronic Diseases Due to Flawed Presumptions. Preprints 2020, 2020090572 (doi: 10.20944/preprints202009.0572.v1). Accessed from <https://www.preprints.org/manuscript/202009.0572/v1>
10. Bortz WMT, Bortz WM 2nd. How fast do we age? Exercise performance over time as a biomarker. *J Gerontol A Biol Sci Med Sci*. 1996;51:M223–5.
11. Goldspink DF. Ageing and activity: Their effects on the functional reserve capacities of the heart and vascular smooth and skeletal muscles. *Ergonomics*. 2005;48:1334–51.
12. Sehl ME, Yates FE. Kinetics of human aging: I. Rates of senescence between ages 30 and 70 years in healthy people. *J Gerontol A Biol Sci Med Sci*. 2001; 56:B198–208.
13. Wu J, Zha P. A Multi-Factor Model for Estimating Relative Lifespans and Extending Health Spans (December 11, 2019). Available at SSRN: <https://ssrn.com/abstract=3502432>
14. Liu Y-Z, Wang Y-X and Jiang C-L. Inflammation: The Common Pathway of Stress-Related Diseases *Front. Hum. Neurosci*. 2017;11:316.
15. Steptoe A, Hamer M, Chida Y. The effects of acute psychological stress on circulating inflammatory factors in humans: a review and meta-analysis. *Brain Behav Immun*. 2007 Oct;21(7):901–12.
16. Webster Marketon JI, Glaser R. Stress hormones and immune function. *Cell Immunol*. 2008 Mar-Apr;252(1-2):16–26.
17. Pedersen AF, Zachariae R, Bovbjerg DH. Psychological stress and antibody response to influenza vaccination: a meta-analysis. *Brain Behav Immun*. 2009 May;23(4):427–33.
18. Pedersen A, Zachariae R, Bovbjerg DH. Influence of psychological stress on upper respiratory infection—a meta-analysis of prospective studies. *Psychosom Med*. 2010 Oct;72(8):823–32.
19. Walburn J, Vedhara K, Hankins M, Rixon L, Weinman J. Psychological stress and wound healing in humans: a systematic review and meta-analysis. *J Psychosom Res*. 2009 Sep;67(3):253–71.
20. Hawryluck L, Gold WL, Robinson S, et al. SARS Control and Psychological Effects of Quarantine, Toronto, Canada. *Emerg Infect Disv*. 2004;10 (7),1206-12.
21. Lutgendorf SK, Sood AK, Anderson B, et al. Social support, psychological distress, and natural killer cell activity in ovarian cancer. *Journal of Clinical Oncology*. 2005;23(28):7105-7113.

22. Lutgendorf SK, DeGeest K, Dahmouch L, et al. Social isolation is associated with elevated tumor norepinephrine in ovarian carcinoma patients. *Brain, Behavior, and Immunity*. 2011;25(2):250-255.
23. Moreno-Smith M, Lutgendorf SK, Sood AK. Impact of stress on cancer metastasis. *Future Oncology*. 2010;6(12):1863-1881.
24. Segerstrom SC, Miller GE. Psychological stress and the human immune system: a meta-analytic study of 30 years of inquiry. *Psychol Bull*. 2004 Jul;130(4):601–30.
25. Pennisi E. The human genome. *Science*. 2001;291 (5507): 1177–80.
26. Wikipedia, Human genome. Accessed at https://en.wikipedia.org/wiki/Human_genome. Accessed on May 17, 2020.
27. Wu J, Zha P. Immune Functional Capability Dynamics Determine Disease Outcomes as in Cancer, Heart Diseases, COVID-19, Etc. <https://osf.io/skf8e>
28. Atamna H, Tenore A, Lui F, and Dhahbi JM. Organ Reserve, Excess Metabolic Capacity, and Aging. *Biogerontology*. 2018 April; 19(2):171–184.
29. Gillis BS, Arbieva Z, Gavin IM. Analysis of lead toxicity in human cells. *BMC Genomics*. 2012; 13: 344. doi: 10.1186/1471-2164-13-344
30. Kim HS, Kim YJ, Seo YR. An Overview of Carcinogenic Heavy Metal: Molecular Toxicity Mechanism and Prevention. *J Cancer Prev* 2015;20:232-240 (Heavy metals induce oxidative stress, DNA damage, and cell death processes, which must proceed long before cancer is developed.)
31. Jaishankar M, Tseten T, Anbalagan N, et al. Toxicity, mechanism and health effects of some heavy metals. *Interdiscip Toxicol*. 2014;7(2): 60–72. doi: 10.2478/intox-2014-0009
32. Genchi G, Carocci A, Lauria G, et al. Nickel: Human Health and Environmental Toxicology. *Int. J. Environ. Res. Public Health*. 2020,17,679; doi:10.3390/ijerph17030679
33. Neal AP, Guilarte TR. Mechanisms of Heavy Metal Neurotoxicity: Lead and Manganese *J Drug Metab Toxicol* 2012, S5 DOI: 10.4172/2157-7609.S5-002
34. Caffo M, Caruso G, La Fata G, et al. Heavy Metals and Epigenetic Alterations in Brain Tumors. *Current Genomics*, 2014, 15, 457-463.
35. Gorini F, Muratori F, Morales MA. The Role of Heavy Metal Pollution in Neurobehavioral Disorders: a Focus on Autism *Rev J. Autism Dev Disord* (2014) 1:354–372 DOI 10.1007/s40489-014-0028-3

36. Romaniuk A, Lyndin M, Sikora V. Heavy metals effect on breast cancer progression. *Journal of Occupational Medicine and Toxicology* (2017) 12:32 DOI 10.1186/s12995-017-0178-1
37. Marth E, Jelovcan S, Kleinhappl B, et al. The effect of heavy metals on the immune system at low concentrations. *Int J Occup Med Environ Health*. 2001;14(4):375-86.
38. Sharma B, Singh S, Siddiqi NiJ. Biomedical Implications of Heavy Metals Induced Imbalances in Redox Systems Hindawi Publishing Corporation BioMed Research International. 2014, Article ID 640754, 26 pages <http://dx.doi.org/10.1155/2014/640754>
39. Brandt-Rauf PW, Li Y, Long C, et al. Plastics and carcinogenesis: The example of vinyl chloride. *J Carcinog*. 2012;11:5. doi:10.4103/1477-3163.93700
40. Sarkar D; Jung MK, and Wang HJ. Alcohol and the Immune System. *Alcohol Research: Current Reviews* 154:37(2),153-155.
41. Zheng D, Liwinski T, Elinav E. Interaction between microbiota and immunity in health and disease. *Cell Research*. 2020;30:492–506. <https://doi.org/10.1038/s41422-020-0332-7>
42. Peillex C, Pelletier M. The impact and toxicity of glyphosate and glyphosate-based herbicides on health and immunity. *Journal of Immunotoxicology*. 2020;17(1):163-174.
43. Cattani D, Oliveira Cavalli V, Heinz Rieg CE. Mechanisms underlying the neurotoxicity induced by glyphosate-based herbicide in immature rat hippocampus: Involvement of glutamate excitotoxicity. *Toxicology* 2014;320:34–45.
44. Pu Y, Ma L, Shan J, et. al. Autism-like Behaviors in Male Juvenile Offspring after Maternal Glyphosate Exposure. 2021 Aug 31;19(3):554-558. doi: 10.9758/cpn.2021.19.3.554.
45. Thongprakaisang S, Thiantanawat A, Rangkadilok N, et al. Glyphosate induces human breast cancer cells growth via estrogen receptors. *Food Chem Toxicol*. 2013;59:129-36. doi:10.1016/j.fct.2013.05.057
46. Portier CJ. A comprehensive analysis of the animal carcinogenicity data for glyphosate from chronic exposure rodent carcinogenicity studies. *Environ Health*. 2020;19:1-18. doi:10.1186/s12940-020-00574-1
47. de Souza JA, Laureano-Melo R, herai RH, et al. Maternal glyphosate-based herbicide exposure alters antioxidant-related genes in the brain and serum metabolites of male rat offspring. *Neurotoxicology*. 2019;74:121-131. doi:10.1016/j.neuro.2019.06.004

48. Zeliger HI. Lipophilic chemical exposure as a cause of cardiovascular disease. *Interdiscip Toxicol*. 2013; Vol. 6(2): 55–62. doi: 10.2478/intox-2013-0010
49. Diethylstilbestrol (DES) and Cancer. Wikipedia. Retrieved from <https://www.cancer.gov/about-cancer/causes-prevention/risk/hormones/des-fact-sheet#what-is-des>
50. Reeda CE and Fentona SE, Exposure to Diethylstilbestrol during Sensitive Life Stages: A legacy of heritable health effects. *Birth Defects Res C Embryo Today*. 2013 Jun; 99(2): 10.1002/bdrc.21035. doi: 10.1002/bdrc.21035
51. Baker SG. The detached pericyte hypothesis: A novel explanation for many puzzling aspects of tumorigenesis. *Organisms. Journal of Biological Sciences*. 2018;2(1):25-41. DOI: 10.13133/2532-5876_3.10.
52. Yonemoto, Junzo (2000). The Effects of Dioxin on Reproduction and Development. *Industrial Health*. 28 (3):259–268. doi:10.2486/indhealth.38.259.
53. Veterans and Agent Orange: Update 11 (2018). National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Population Health and Public Health Practice; Committee to Review the Health Effects in Vietnam Veterans of Exposure to Herbicides (Eleventh Biennial Update). Washington (DC): National Academies Press (US); 2018 Nov 15.
54. Zamora-León P. Are the Effects of DES Over? A Tragic Lesson from the Past *Int J Environ Res Public Health*. 2021 Oct; 18(19): 10309. doi: 10.3390/ijerph181910309
55. List of withdrawn drugs. Wikipedia. Retrieved March 6, 2021, from https://en.wikipedia.org/wiki/List_of_withdrawn_drugs
56. Gao Y, Feng J, Kang L, et al. Concentration addition and independent action model: Which is better in predicting the toxicity for metal mixtures on zebrafish larvae. *Sci Total Environ*. 2018;610-611:442-450. doi: 10.1016/j.scitotenv.2017.08.058.
57. Metabolic pathway. Wikipedia. Accessed from https://en.wikipedia.org/wiki/Metabolic_pathway
58. Wu J, Zha P. Lung Damage Mechanisms For COVID-19 and Other Lung Infections and Driving Force in Leukocyte Recruitment and Migration. Preprints 2020, 2020090209. Accessed from <https://www.preprints.org/manuscript/202009.0209/v1>. <http://dx.doi.org/10.2139/ssrn.3689090>
59. Cole T. Failures of Medicine. *British Medical Journal*. 1875; Nov. 6; 579-582.
60. Green AR. Why the disease-based model of medicine fails our patients. *West J Med*. 2002 Mar; 176(2): 141–143.

61. Advisory Board, Precision medicine fails for up to 93% of patients. Are its proponents selling 'false hope'? September 21, 2018, Accessed from <https://www.advisory.com/daily-briefing/2018/09/21/precision-medicine>
62. Wikipedia. List of incurable diseases. Accessed from https://en.wikipedia.org/wiki/List_of_incurable_diseases. Accessed on May 17, 2020.
63. Wu, JQ and Zha, P. Surgery, Chemotherapy and Radiotherapy Promote Cancer Growth Speeds and Shorten Patient Lives (November 14, 2019). Available at SSRN: <https://ssrn.com/abstract=3487080> DOI: 10.13140/RG.2.2.17967.28321
64. Tackling the burden of chronic diseases in the USA. *Lancet*. 2009;373(9659):185. Accessed at [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(09\)60048-9/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(09)60048-9/fulltext)
65. DeVol R. and Bedroussian A. An Unhealthy America: The Economic Burden of Chronic Disease. October 2007. Milken Institute Report. Page 1-35.
66. Kresser C, Two Reasons Conventional Medicine Will Never Solve Chronic Disease, Accessed from <https://kresserinstitute.com/two-reasons-conventional-medicine-will-never-solve-chronic-disease/>
67. Keehan SP, Cuckler GA., Poisal JA, et al. National Health Expenditure Projections, 2019–28: Expected Rebound In Prices Drives Rising Spending Growth. *Health affairs* 39(4):704-714 doi: 10.1377/hlthaff.2020.00094
68. Li J, Blakeley D, Smith RJ. The failure of R0. *Comput Math Methods Med*. 2011;2011:527610.
69. Ashdown ML, Robinson AP, Yatomi-Clarke SL, et al. Chemotherapy for Late-Stage Cancer Patients: Meta-Analysis of Complete Response Rates, Version 1. *F1000 Res*. 2015; 4:232.
70. Albero A, López JE, Torres A, et al. Effectiveness of chemotherapy in advanced differentiated thyroid cancer: a systematic review. *Endocr Relat Cancer*. 2016 Feb;23(2):R71-84.
71. Davis C, Naci H, Gurpinar E, et al. Availability of evidence of benefits on overall survival and quality of life of cancer drugs approved by European Medicines Agency: retrospective cohort study of drug approvals 2009-13, *BMJ* 2017;359:j4530.

72. Morgan G, Ward R & Barton M. The contribution of cytotoxic chemotherapy to 5-year survival in adult malignancies. Clin. Oncol. (R. Coll. Radiol.) 2004; 16, 549–560.

73. Na Z, Qiao X, Hao X, et al. The effects of beta-blocker use on cancer prognosis: a meta-analysis based on 319,006 patients. OncoTargets and Therapy 2018;11 4913–4944.

74. Yap A, Lopez-Olivo MA, Dubowitz J. Effect of beta-blockers on cancer recurrence and survival: a meta-analysis of epidemiological and perioperative studies. Br J Anaesth. 2018 Jul; 121(1):45-57.

75. Bai ZG, Zhang ZT. A systematic review and meta-analysis on the effect of angiogenesis blockade for the treatment of gastric cancer. Onco Targets Ther. 2018 Oct 17; 11:7077-7087.

76. Li Y, Zhou Y, Hong Y, et al. The Efficacy of Different Chemotherapy Regimens for Advanced Biliary Tract Cancer: A Systematic Review and Network Meta-Analysis. Frontiers in Oncology. May 2019, Volume 9, Article 441.

77. Dos Santos MA, Pignon JP, Blanchard P, et al. Systematic review and meta-analysis of phase I/II targeted therapy combined with radiotherapy in patients with glioblastoma multiforme: quality of report, toxicity, and survival. J Neurooncol. 2015 Jun;123(2): 307-14.

78. Su J, Cai M, Li W, et al. Molecularly Targeted Drugs Plus Radiotherapy and Temozolomide Treatment for Newly Diagnosed Glioblastoma: A Meta-Analysis and Systematic Review. Oncol Res. 2016;24(2):117-28.

79. Maeda H and Khatami M. Analyses of repeated failures in cancer therapy for solid tumors: poor tumor-selective drug delivery, low therapeutic efficacy and unsustainable costs, Clin Transl Med. 2018; 7: 11.

80. Tournigand C, André T, Achille E, et al., FOLFIRI Followed by FOLFOX6 or the Reverse Sequence in Advanced Colorectal Cancer: A Randomized GERCOR Study. J Clin Oncol. 2004; 22:229-237. (Median survival was 21.5 months in 109 patients allocated to FOLFIRI then FOLFOX6 versus 20.6 months in 111 patients allocated to FOLFOX6 then FOLFIRI (P =.99))

81. Chang SC, Liu KH, Hung CY et al. Adjuvant Chemotherapy Improves Survival in Stage III Gastric Cancer after D2 Surgery. Journal of Cancer 2018; 9(1): 81-91.

82. Sparano JA, Gray RJ, Makower DF, et al. Adjuvant chemotherapy guided by a 21-gene expression assay in breast cancer. *N Engl J Med* 2018;379(2):111–121.
83. Ahles TA, Root JC, Ryan EL. Cancer- and cancer treatment-associated cognitive change: An update on the state of the science. *J Clin Oncol.* 2012;30:3675–86.
84. Colleoni M, Sun Z, Price KN, et al. Annual hazard rates of recurrence for breast cancer during 24 years of follow-up: Results from the international breast cancer study group trials I to V. *J. Clin. Oncol.* 2016;34, 927–935.
85. Cheng L, Swartz MD, Zhao H, Kapadia AS, Lai D, Rowan PJ, Buchholz TA, Giordano SH. Hazard of recurrence among women after primary breast cancer treatment—A 10-year follow-up using data from SEER-medicare. *Cancer Epidemiol. Biomarkers Prev.* 21, 800–809 (2012).
86. DeVita VT Jr, Chu E. A history of cancer chemotherapy. *Cancer Res.* 2008 Nov 1;68(21):8643-53.
87. Krall JA, Ferenc R, Mercury OA, etc. The systemic response to surgery triggers the outgrowth of distant immune-controlled tumors in mouse models of dormancy. *Sci. Transl. Med.* 10, eaan3464 (2018).
88. Demicheli R, Retsky MW, W. Hrushesky JM, Baum M. Tumor dormancy and surgery-driven interruption of dormancy in breast cancer: Learning from failures. *Nat. Clin. Pract. Oncol.* 2007; 4,699–710.
89. Solinas G, Marchesi F, Garlanda C, et al. Inflammation-mediated promotion of invasion and metastasis. *Cancer Metastasis Rev.* 2010;29:243–248.
90. Hüsemann Y, Geigl JB, Schubert F, etc. Systemic spread is an early step in breast cancer. *Cancer Cell* 2008;13,58–68.
91. Tohme S, Simmons RL, Tsung A. Surgery for Cancer: a trigger for metastases. *Cancer Res.* 2017;77:1548–1552.
92. American Cancer Society. Early Theories about Cancer Causes. Accessed at <https://www.cancer.org/cancer/cancer-basics/history-of-cancer/cancer-causes-theories-throughout-history.html>. Last Accessed on November 8, 2019.
93. Brücher B, Jamall IS. Somatic Mutation Theory - Why it's Wrong for Most Cancers. *Cell Physiol Biochem* 2016;38:1663-1680.
94. Nowell, P. C. The clonal evolution of tumor cell populations. *Science.* 1976:19

4 (4260): 23–28.

95. Attolini CS, Michor F. Evolutionary Theory of Cancer. The Year in Evolutionary Biology 2009: Ann. N.Y. Acad. Sci. 2009;1168: 23–51.

96. Hanahan D. & Weinberg R. The Hallmarks of Cancer. Cell, 2000 January; Vol. 100, 57–70.

97. Hochberg, ME & Noble RJ. A framework for how environment contributes to cancer risk. Ecology Letters. 2017;20, 117–134.

98. Howard J. Minimum Latency & Types or Categories of Cancer. October 17, 2012, Revised: May 1, 2013. Revised: November 7, 2014. World Trade Center Health Program

99. Ericsson M, Hardel L, Carlberg M, Åkerman M. Pesticide exposure as risk factor for non-Hodgkin lymphoma including histopathological subgroup analysis. Cancer. 2008;123(7):1657-63. doi:10.1002/ijc.23589

100. Cupit-Link MC, Kirkland JL, Ness KK, et al. Biology of premature ageing in survivors of cancer. ESMO Open. 2017 December 18.

101. López-Otín C, Blasco MA, Partridge L, et al. The hallmarks of aging. Cell 2013;153:1194–217.

102. Ogino S, Fuchs CS, Giovannucci E. How many molecular subtypes? Implications of the unique tumor principle in personalized medicine. Expert Rev Mol Diagn. 2012;12(6): 621–8.

103. Ogino S, Lochhead P, Chan AT et al. Molecular pathological epidemiology of epigenetics: Emerging integrative science to analyze environment, host, and disease. Mod Pathol. 2013;26(4): 465–84.

104. Wu, JQ and Zha, P. Public Health Intervention Framework for Reviving Economy Amid the COVID-19 Pandemic (2): Use of Personalized Mitigation Measures Beyond the Epidemiological Model Limits. <https://osf.io/preprints/wzjp9/>

105. Krauss A. Why all randomised controlled trials produce biased results. Ann Med. 2018;50:312–322.

106. Bhatt A. Evolution of Clinical Research: A History Before and Beyond James Lind. Perspect Clin Res. 2010 Jan-Mar; 1(1): 6–10.

107. FDA Emergency Use Authorization of Medical Products and Related Authorities. Guidance for Industry and Other Stakeholders. Retrieved from <https://www.fda.gov/media/97321/download>
108. Katz R. FDA: Evidentiary Standards for Drug Development and Approval. *NeuroRx*. 2004 Jul; 1(3):307–316. doi: 10.1602/neurorx.1.3.307
109. Smith R. Medical journals are an extension of the marketing arm of pharmaceutical companies. *PLoS Med*. 2005 May;2(5):e138.
110. Smith R. Lapses at the New England Journal of Medicine. *J R Soc Med* 2006;99:380-2.
111. Armstrong D. Bitter pill: how the New England Journal missed warning signs on Vioxx. *Wall Street Journal* 2006. May 15:A1.
112. Herper, M. (2005). David Graham On The Vioxx Verdict. Retrieved from: https://www.forbes.com/2005/08/19/merck-vioxx-graham_cx_mh_0819graham.html
113. Grant, B. (7 May 2009). Elsevier published 6 fake journals. *The Scientist*. Accessed at <https://www.the-scientist.com/the-nutshell/elsevier-published-6-fake-journals-44160>. Last accessed on May 26, 2020.
114. Wikipedida, *Australasian Journal of Bone & Joint Medicine*. Accessed at https://en.wikipedia.org/wiki/Australasian_Journal_of_Bone_%26_Joint_Medicine. Accessed on May 20, 2020.
115. Hagan, K. (23 April 2009). Merck accused of 'ghost writing' medical article. *The Age*. <https://www.theage.com.au/national/merck-accused-of-ghost-writing-medical-article-20090422-afdk.html?page=-1> Last accessed on 20 May 2020.
116. Dunn A. The Conversation (April 3, 2012) Pharma's influence over published clinical evidence. Accessed from <https://theconversation.com/pharmas-influence-over-published-clinical-evidence-5325>
117. Singh A and Singh S. The Connection Between Academia and Industry. *Mens Sana Monogr*. 2005 Mar; 3(1): 5–35. doi: 10.4103/0973-1229.27876
118. Smith R. Curbing the influence of the drug industry: a British view. *PLoS Med*. 2005 Sep;2(9):e241.

119. Campbell EG, Louis KS, Blumenthal D. Looking a gift horse in the mouth: corporate gifts supporting life sciences research. *JAMA* 1998;279:995–9.
120. Llamas M. (April 24, 2015 Last Modified: September 24, 2021) Big Pharma's Role in Clinical Trials. Retrieved from <https://www.drugwatch.com/featured/clinical-trials-and-hidden-data/>
121. Als-Nielsen, B. et al. (2003). Association of funding and conclusions in randomized drug trials: a reflection of treatment effect or adverse events? Retrieved from <https://www.ncbi.nlm.nih.gov/pubmed/12928469>
122. Begley, S. (2010, August 5). Some Pharmaceutical Clinical Trial Results are Buried, Study Shows. Retrieved from <https://www.newsweek.com/some-pharmaceutical-clinical-trial-results-are-buried-study-shows-71561>
123. Chopra, AM, S. S. (2003). Industry Funding of Clinical trials: Benefit or Bias? Retrieved from <https://jamanetwork.com/journals/jama/fullarticle/196846>
124. Cormack, L. (2017). Big pharma funding biases drug trials in favour of a sponsor's product: review. Retrieved from <https://www.smh.com.au/healthcare/big-pharma-funding-biases-drug-trials-in-favour-of-a-sponsors-product-review-20170220-gugr0d.html>
125. Whoriskey, P. (2012). As drug industry's influence over research grows, so does the potential for bias. Retrieved from https://www.washingtonpost.com/business/economy/as-drug-industrys-influence-over-research-grows-so-does-the-potential-for-bias/2012/11/24/bb64d596-1264-11e2-be82-c3411b7680a9_story.html?utm_term=.8c554c8d6336
126. Lundh, A. et al. (2017). Industry sponsorship and research outcome. Retrieved from <https://pubmed.ncbi.nlm.nih.gov/28207928/>
127. Sandle, T. (2015). Most clinical trials today are funded by Big Pharma. Retrieved from <https://www.digitaljournal.com/tech-science/most-clinical-trials-today-are-funded-by-big-pharma/article/452974>
128. Rennie D. Thyroid storm. *JAMA* 1997; 277:1238–1243.

129. Perry, S. (2012, July 31). Private-sector physicians run clinical trials mostly for the money, study finds. Retrieved from <https://www.minnpost.com/second-opinion/2012/07/private-sector-physicians-run-clinical-trials-mostly-money-study-finds/>

130. Fisher, J.A. & Kalbaugh, C.A. (2012). United States Private-Sector Physicians and Pharmaceutical Contract Research: A Quantitative Study. Retrieved from <https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001271>

131. Rout, Milanda (9 April 2009). Doctors signed Merck's Vioxx studies. The Australian. Archived from the original on 6 May 2009. <https://web.archive.org/web/20090506064629/http://www.theaustralian.news.com.au/story/0,25197,25311725-5013871,00.html> Accessed on May 20, 2020.

132. House of Commons Health Committee (2005) The influence of the pharmaceutical industry. Available at: <https://publications.parliament.uk/pa/cm200405/cmselect/cmhealth/cmhealth.htm>. Accessed on May 7, 2020.

133. Schwartz LM, Woloshin S. Medical marketing in the United States, 1997-2016 [published January 8, 2018]. JAMA. 2019;321(1):80-96. doi:10.1001/jama.2018.19320.

134. Van Praet, N. (2014). The new drug dilemma: Does big pharma have a duty to humankind – or its shareholders? Retrieved from <https://financialpost.com/investing/the-new-drug-dilemma-does-big-pharma-have-a-moral-duty-to-humankind-or-its-shareholders>

135 Peart, K.N. (2003, January 21). Financial Conflicts of Interest Can Influence Biomedical Research Outcomes, Yale Researchers Show. Retrieved from <https://medicine.yale.edu/news-article/2999/>

136. Wolford, B. (2014, November 13). Big Pharma Plays Hide-the-Ball with Data. Retrieved from <https://www.newsweek.com/2014/11/21/medical-science-has-data-problem-284066.html>

137. Weintraub, A. (2016). Why Big Pharma Gets A Failing Grade On Clinical Trial Transparency. Retrieved from <https://www.forbes.com/sites/arleneweintraub/2016/08/17/why-big-pharma-gets-a-failing-grade-on-clinical-trial-transparency/#437150406cbd>

138. Olowofela AO, Isah AO. A Profile of Adverse Effects of Antihypertensive Medicines in a Tertiary Care Clinic in Nigeria. *Ann Afr Med*. 2017 Jul-Sep; 16(3): 114–119.
139. Friedman GD, Udaltsova N, Chan J. Screening pharmaceuticals for possible carcinogenic effects: initial positive results for drugs not previously screened. *Cancer Causes Control*. 2009 Dec; 20(10): 1821–1835. doi: 10.1007/s10552-009-9375-2
140. Chang C, Gershwin ME. Drug-induced lupus erythematosus: incidence, management and prevention. *Drug Saf*. 2011;34:357-374.
141. Vasoo Sheila. Drug-induced lupus: an update. *Lupus*. 2006; 15:757-761.
142. Araújo-Fernández S, Ahijón-Lana M, Isenberg DA. Drug-induced lupus: Including anti-tumor necrosis factor and interferon induced. *Lupus* 2014; 23:545-553.
143. Borchers AT, Keen CL, Gershwin ME. Drug-induced lupus. *Ann N Y Acad Sci* 2007 Jun; 1108; 166-82.
144. Pearce A, Haas M, Viney R, et al. Incidence and severity of self-reported chemotherapy side effects in routine care: A prospective cohort study. *PLoS ONE* 2017; 12(10): e0184360. <https://doi.org/10.1371/journal.pone.0184360>.
145. Cornelius VR, Perrio MJ, Shakir SA, Smith LA. Systematic reviews of adverse effects of drug interventions: a survey of their conduct and reporting quality. *Pharmacoepidemiol Drug Saf*. 2009 Dec;18(12):1223-31. doi: 10.1002/pds.1844.
146. Golder S, Loke Y and McIntosh HM. Room for improvement? A survey of the methods used in systematic reviews of adverse effects. *BMC Medical Research Methodology* 2006;6:3.
147. Horton R. The dawn of McScience. *New York Rev Books* 2004; 51(4): 7–9.
148. Thompson J, Baird P, Downie J (2001) The Olivieri report. The complete text of the independent inquiry commissioned by the Canadian Association of University Teachers. Toronto: Lorimer. 584 p.
149. Smith R. The highly profitable but unethical business of publishing medical research. *J R Soc Med*. 2006;99:452–456.

150. Smith R. Peer review: a flawed process at the heart of science and journals. *J R Soc Med* 2006;99:178–182.
151. Lock S. *A Difficult Balance: Editorial Peer Review In Medicine*. London: Nuffield Provincials Hospital Trust, 1985.
152. Godlee F, Jefferson T (2003) *Peer review in health sciences*, 2nd ed. London: BMJ Publishing Group. 367P;
153. Godlee, F, Gale, CR, Martyn, CN. Effect on the quality of peer review of blinding reviewers and asking them to sign their reports: a randomized controlled trial. *J. Am. Med. Assoc.* 1998; 280, 237-240.
154. Smith R, Feachem R, Feachem NS, Koehlmoos TP, Kinlaw H. The fallacy of impartiality: competing interest bias in academic publications. *J R Soc Med*. 2009 Feb;102(2):44-5.
155. Peters D, Ceci S. Peer-review practices of psychological journals: the fate of submitted articles, submitted again. *Behav Brain Sci* 1982;5:187–255.
156. Smith R. Conflicts of interest: how money clouds objectivity. *J R Soc Med*. 2006 Jun;99(6):292-7.
157. Krinsky S, Rothenberg LS, Stott P, Kyle G. Scientific journals and their authors' financial interests: a pilot study. *Sci Eng Ethics* 1996;2: 395–410. (authors may be peer reviewers of others).
158. Bekelman JE, Li Y, Gross CP. Scope and impact of financial conflicts of interest in biomedical research: a systematic review. *JAMA* 2003;289:454–65.
159. Sobkowicz P. (2015) Innovation Suppression and Clique Evolution in Peer-Review-Based, Competitive Research Funding Systems: An Agent-Based Model. *Journal of Artificial Societies and Social Simulation* 18 (2)13
<https://www.jasss.org/18/2/13.html>. DOI: 10.18564/jasss.2750
160. Braben D, Dowler R. (2017) Peer review processes risk stifling creativity and limiting opportunities for game-changing scientific discoveries. Accessed from <https://blogs.lse.ac.uk/impactofsocialsciences/2017/09/17/peer-review-processes-risk-stifling-creativity-and-limiting-opportunities-for-scientific-discoveries/>

161. Angell M. (2005) The truth about drug companies: How they deceive us and what to do about it. New York: Random House. 336p.
162. Kassirer JP. (2004) On the take: How medicine's complicity with big business can endanger your health. New York: Oxford University Press. 251p.
163. Haivas I, Schroter S, Waechter F, Smith R. Editors' declaration of their own conflicts of interest. *Can Med Assoc J* 2004;171:475–6
164. van Rooyen S, Godlee F, Evans S, Black N, Smith R. Effect of open peer review on quality of reviews and on reviewers' recommendations: a randomised trial. *BMJ* 1999;318:23–7.
165. Carroll AE. Nov. 5, 2018. Peer Review: The Worst Way to Judge Research, Except for All the Others. <https://www.nytimes.com/2018/11/05/upshot/peer-review-the-worst-way-to-judge-research-except-for-all-the-others.html>
166. Smith R. Commentary: the power of the unrelenting impact factor--is it a force for good or harm? *Int J Epidemiol.* 2006 Oct;35(5):1129-30.
- 167 Measuring Your Impact: Impact Factor, Citation Analysis, and other Metrics: Journal Impact Factor (IF). Accessed at <https://researchguides.uic.edu/if/impact> Accessed on May 17, 2020.
168. Smith R. Journal accused of manipulating impact factor. *BMJ.* 1997;314:461.
169. Seglen PO. Why the impact factor of journals should not be used for evaluating research? *BMJ.* 1997;314-9.
170. Gabehart ME. An analysis of citations to retracted articles in the scientific literature. Available at: <http://hdl.handle.net/1901/199>. Accessed on September 3, 2006.
171. Pfeifer MP, Snodgrass GL. The continued use of retracted, invalid scientific literature. *JAMA* 1990;263:1420–23.
172. Tramèr MR, Reynolds DJM, Moore RA, McQuay HJ. Impact of covert duplicate publication on meta-analysis: A case study. *BMJ* 1997; 315: 635–640.

173. Huston P, Moher D. Redundancy, disaggregation, and the integrity of medical research. *Lancet* 1996; 347: 1024–1026.

174. Rochon PA, Gurwitz JH, Cheung M, et al. Evaluating the quality of articles published in journal supplements compared with the quality of those published in the parent journal. *JAMA* 1994;272: 108–113.

175. Cho MK, Bero LA. The quality of drug studies published in symposium proceedings. *Ann Intern Med.* 1996;124: 485–489.

176. 18 U.S. Code § 1343 - Fraud by wire, radio, or television

177. Joober R, Schmitz N, Annable L, Boksa P. Publication bias: What are the challenges and can they be overcome? *J Psychiatry Neurosci.* 2012 May; 37(3): 149–152. doi: 10.1503/jpn.120065

178. Pharma Intelligence. 2021 Clinical Development Success Rates. Accessed from <https://pharmaintelligence.informa.com/resources/product-content/2021-clinical-development-success-rates>

179. Cormie P, Zopf EM, Zhang X, Schmitz KH. The Impact of Exercise on Cancer Mortality, Recurrence, and Treatment-Related Adverse Effects. *Epidemiologic Reviews*, Volume 39, Issue 1, January 2017, Pages 71–92.

180. Holmes MD, Chen WY, Feskanich D et al. Physical activity and survival after breast cancer diagnosis. *JAMA.* 2005;293(20):2479–2486.

181. Meyerhardt JA, Heseltine D, Niedzwiecki D et al. Impact of physical activity on cancer recurrence and survival in patients with stage III colon cancer: findings from CALGB 89803. *J Clin Oncol.* 2006;24(22):3535–3541.

182. Toy, J. The Ingelfinger Rule: Franz Ingelfinger at the New England Journal of Brücher Medicine 1967-77. *Science Editor.* 2002; 26: 195–198.

183. Tipton CM. The history of “Exercise Is Medicine” in ancient civilizations. *Adv Physiol Educ.* 2014;38(2):109–117.

184. Booth FW, Roberts CK, Laye MJ. Lack of exercise is a major cause of chronic diseases. *Compr Physiol.* 2012;2:1143–1211.

185. Ehrhardt, S. et al. (2015). Trends in National Institutes of Health Funding for Clinical Trials Registered in ClinicalTrials.gov. Retrieved from <https://jamanetwork.com/journals/jama/fullarticle/2475454>
186. NIH, Grants and Funding: Peer Review. Accessed at <https://grants.nih.gov/grants/peer-review.htm>. Accessed on April 16, 2020.
187. Negative Impacts of NIH Funding Policies On the Global Health Landscape and Required Changes (online published). 9/1/2020
188. Wu J. Fundamental Flaws in Academic, Employment and Professional Tests Test Score Misuses Are Responsible for Ruined Student Health, Social Injustice and Diminished Competitiveness. Accessed from https://www.researchgate.net/publication/351607841_Fundamental_Flaws_in_Academic_Employment_and_Professional_Tests_Test_Score_Misuses_Are_Responsible_for_Ruined_Student_Health_Social_Injustice_and_Diminished_Competitiveness
189. USPTO, 2106 Patent Subject Matter Eligibility [R-08.2017], Accessed from https://www.uspto.gov/web/offices/pac/mpep/s2106.html#ch2100_d29a1b_139db_e0. Accessed on May 24, 2020.
190. Alice Corp. v. CLS Bank International, 573 U.S. 208, 134 S. Ct. 2347 (2014).
191. Egger M, Bartlett C, Juni P. Are randomised controlled trials in the BMJ different? BMJ 2001; 323: 1253. (the high percentage of clinical trials were conducted to investigate drugs effects).
192. Dobson, R. NEJM failed its readers by delay in publishing its concerns about VIGOR trial. BMJ. 2006; 333 (7559): 116.
193. Angell M. (January 15, 2009). Drug Companies & Doctors: A Story of Corruption. The New York Review of Books. Retrieved May 18, 2020.
194. Couzin J, Unger K. Cleaning up the paper trail. Science. 2006;312:38–43 (scientists use fake data).
195. Sarwar U and Nicolaou M. Fraud and deceit in medical research. J Res Med Sci. 2012 Nov; 17(11): 1077–1081.
196. Department of Justice. (March 25, 2019) Duke University Agrees to Pay U.S. \$112.5 Million to Settle False Claims Act Allegations Related to Scientific Research Misconduct. Accessed from <https://www.justice.gov/opa/pr/duke-university-agrees-pay-us-1125-million-settle-false-claims-act-allegations-related>

197 Author Manuscripts in PMC Accessed at <https://www.ncbi.nlm.nih.gov/pmc/about/authorms/>. Accessed on May 15, 2020.

198. USA (August 16, 2018) 75% of Physicians in the World Refuse Chemotherapy for Themselves. Accessed from <https://usareally.com/1129-75-of-physicians-in-the-world-refuse-chemotherapy-for-themselves>

199. Behl D, Jatoi A, What Do Oncologists Say about Chemotherapy at the Very End of Life? Results from a Semiquantitative Survey. *J Palliat Med.* 2010 Jul; 13(7): 831–835. doi: 10.1089/jpm.2009.0414

200. Draisma G, Etzioni R, Tsodikov A, et al. Lead time and overdiagnosis in prostate-specific antigen screening: importance of methods and context. *Journal of the National Cancer Institute.* 2009; 101:374–83.

201. Welch HG, Black WC. Overdiagnosis in cancer. *J Natl Cancer Inst.* 2010 May 5;102(9):605-13.

202. Aguirre-Ghiso JA. Models, mechanisms and clinical evidence for cancer dormancy. *Nat Rev Cancer.* 2007;7:834–846.

203. Stemmermann GN. Undiscovered cancer in elderly Hawaiian Japanese: an autopsy study. *Hum Pathol.* 1982 Nov;13(11):1039–1044.

204. Jahn JL, Giovannucci EL, Stampfer MJ. The high prevalence of undiagnosed prostate cancer at autopsy: Implications for epidemiology and treatment of prostate cancer in the prostate-specific antigen-era. *Int. J. Cancer.* 2015;137:2795–2802.

205. Anand P, Kunnumakara AB, Sundaram C, et al. Cancer is a Preventable Disease that Requires Major Lifestyle Changes. *Pharmaceutical Research.* September 2008;25(9). DOI: 10.1007/s11095-008-9661-9.

206. Aune D, Giovannucci E, Boffetta P, et al. Fruit and vegetable intake and the risk of cardiovascular disease, total cancer and all-cause mortality-a systematic review and dose-response meta-analysis of prospective studies. *Int J Epidemiol.* 2017;46(3):1029-1056. doi:10.1093/ije/dyw319

207. Giovannucci E, Harlan DM, Archer MC, et al. Diabetes and Cancer: A consensus report. *Diabetes Care.* 2010 Jul; 33(7):1674–1685.

208. Sloan EK, Priceman SJ, Cox BF, et al. The sympathetic nervous system induces a metastatic switch in primary breast cancer. *Cancer Research* 2010;70(18):7042-7052.

209. Yeung PK, Wong JT. Inhibition of cell proliferation by mechanical agitation involves transient cell cycle arrest at G1 phase in dinoflagellates. *Protoplasma*. 2003 Mar; 220(3-4):173-8.
210. Levine EM & Robins EB. Differential temperature sensitivity of normal and cancer cells in culture. *Journal of Cellular Physiology*. 1970;76(3):373–379.
211. Diethylstilbestrol (DES) and Cancer. Wikipedia. Retrieved from <https://www.cancer.gov/about-cancer/causes-prevention/risk/hormones/des-fact-sheet#what-is-des>
212. Amerio A, Gálvez JF, Odone A, et al. Carcinogenicity of psychotropic drugs: A systematic review of US Food and Drug Administration–required preclinical in vivo studies. *Australian & New Zealand Journal of Psychiatry*. 2015;49(8) 686–696.
213. Kim HS, Kim YJ, Seo YR. An Overview of Carcinogenic Heavy Metal: Molecular Toxicity Mechanism and Prevention. *J Cancer Prev* 2015;20:232-240 (Heavy metals induce oxidative stress, DNA damage, and cell death processes, which must proceed long before cancer is developed.)
214. Jaishankar M, Tseten T, Anbalagan N, et al. Toxicity, mechanism and health effects of some heavy metals. *Interdiscip Toxicol*. 2014;7(2): 60–72. doi: 10.2478/intox-2014-0009
215. Brandt-Rauf PW, Li Y, Long C, et al. Plastics and carcinogenesis: The example of vinyl chloride. *J Carcinog*. 2012;11:5. doi:10.4103/1477-3163.93700
216. Roundup. Wikipedia. Retrieved March 6, 2021, from [https://en.wikipedia.org/wiki/Roundup_\(herbicide\)](https://en.wikipedia.org/wiki/Roundup_(herbicide))
217. Zhang L, Rana I, Shaffer RM, et al. Exposure to glyphosate-based herbicides and risk for non-Hodgkin lymphoma: A meta-analysis and supporting evidence. *Mutat Res*. 2019;781:186-206. doi:10.1016/j.mrrev.2019.02.001
218. Nogueira LM, Yabroff R, Bernstein A. Climate change and cancer. *CA: A Cancer Journal for Clinicians* 2020;70(4):239-244 <https://doi.org/10.3322/caac.21610>Citations
219. Zheng D, Liwinski T, Elinav E. Interaction between microbiota and immunity in health and disease. *Cell Research*. 2020;30:492–506. <https://doi.org/10.1038/s41422-020-0332-7>
220. Galán JE. Bacterial toxins and the immune system: show me the in vivo targets. *J Exp Med*. 2005 Feb 7; 201(3): 321–323.
221. Cannon WB “VOODOO” Death. *Am J Public Health*. 2002 October; 92(10): 1593–1596.

222. Matsuyama R, Reddy S, Smith TJ. Why do patients choose chemotherapy near the end of life? A review of the perspective of those facing death from cancer. *J Clin Oncol*. 2006;24:3490-3496.

223. Mackillop WJ, Stewart WE, Ginsburg AD, Stewart SS. Cancer patients' perceptions of their disease and its treatment. *Br J Cancer*. 1988;58:355-358.

224. Beadle GF, Yates PM, Najman JM, et al. Beliefs and practices of patients with advanced cancer: implications for communication. *Br J Cancer*. 2004;91:254-257.

225. Mathews JD, Forsythe AV, Brady Z, et al. Cancer risk in 680000 people exposed to computed tomography scans in childhood or adolescence: data linkage study of 11 million Australians. *BMJ* 2013;346:f2360.

226. Zondervan RL, Hahn PF, Sadow CA, et al. Body CT scanning in young adults: examination indications, patient outcomes, and risk of radiation-induced cancer. *Radiology*. 2013;267(2):460-9.

227. *Ballard v. Arie*, 41 Cal. 3d 564, 572 n.6 (1986). In this oft-cited footnote, the Court stated: "[A] court's task — in determining 'duty' — is not to decide whether a particular plaintiff's injury was reasonably foreseeable in light of a particular defendant's conduct, but rather to evaluate more generally whether the category of negligent conduct at issue is sufficiently likely to result in the kind of harm experienced that liability may appropriately be imposed on the negligent party."

228. Pandit MS. and Pandit S. Medical negligence: Coverage of the profession, duties, ethics, case law, and enlightened defense - A legal perspective. *Indian J Urol*. 2009 Jul-Sep; 25(3): 372–378.

229. Judicial Council of California. Retrieved 27 December 2013. California Civil Jury Instructions: 1900. Intentional Misrepresentation.

230. Delaney P. (Wed Apr 7, 2021) Lifesite News. EXCLUSIVE - Former Pfizer VP: Your government is lying to you in a way that could lead to your death. Retrieved from <https://www.lifesitenews.com/news/exclusive-former-pfizer-vp-your-government-is-lying-to-you-in-a-way-that-could-lead-to-your-death/>

231. FDA. Vaccines and Related Biological Products Advisory Committee October 26, 2021 Meeting Document. Accessed from <https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-october-26-2021-meeting-announcement#event-materials>

232. Worldometers database. Incidences and death data for various nations. See both incidences and death pattern for most nations. Accessed from <https://www.worldometers.info/coronavirus/>

233. Evans SS, Repasky EA, Fisher DT. Fever and the thermal regulation of immunity: the immune system feels the heat. *Nat Rev Immunol*. 2015 June; 15(6): 335–349. doi:10.1038/nri3843.

234. Tzampoglou P, Loukidis D. Investigation of the Importance of Climatic Factors in COVID-19 Worldwide Intensity. *Int. J. Environ. Res. Public Health*. 2020; 17, 7730.

235. Wu, J, Zha P. Proactive Body Temperature Management Protocol and Lifestyle Interventions as Predictable Cures for COVID-19 Disease: Curative Protocols Discovered from a Century of Medical Discoveries. Retrieved from <https://osf.io/pcfna>, DOI: 10.31219/osf.io/pcfna

236. Wu, J, Zha P. Mask Is a Double-edged Sword in the Fight Against COVID-19 Pandemic (March 28, 2020). SSRN. Retrieved from <https://ssrn.com/abstract=3563851> or <http://dx.doi.org/10.2139/ssrn.3563851>

237. Seneff S, Nigh G. Worse Than the Disease? Reviewing Some Possible Unintended Consequences of the mRNA Vaccines Against COVID-19. *International Journal of Vaccine Theory, Practice, and Research*. 2021; 2(1):38-78.

238. Fallon JR, Taylor AB. (15 May 2013) Protein Synthesis in Neurons. Retrieved from <https://doi.org/10.1002/9780470015902.a0000050.pub2>

239. Mofatteh M. mRNA localization and local translation in neurons. *AIMS Neuroscience*, 7(3): 299–310. DOI: 10.3934/Neuroscience.2020016

240. Rhea EM, Logsdon AF, Hansen KM, et al. The S1 protein of SARS-CoV-2 crosses the blood–brain barrier in mice. 16 December 2020. (intravenously injected radioiodinated S1 (I-S1) readily crossed the blood–brain barrier in male mice)

241. Nafee N, Gouda N. Nucleic Acids-based Nanotherapeutics Crossing the Blood Brain Barrier *Curr Gene Ther*. 2017;17(2):154-169. doi: 10.2174/1566523217666170510155803.

242. Boado RJ, Pardridge WM. The brain-type glucose transporter mRNA is specifically expressed at the blood-brain barrier. *Biochem Biophys Res Commun*. 1990 Jan 15;166(1):174-9. doi: 10.1016/0006-291x(90)91927-k

243. Schreiber, SS, Evans CD, Oratz M, Rothschild Ma. Protein Synthesis and Degradation in Cardiac Stress. *Circulation Research* 1981;48(5):601-611.

244. Yuan CL, Sharma N, Gilge DA. et al. Preserved protein synthesis in the hea

rt in response to acute fasting and chronic food restriction despite reductions in liver and skeletal muscle Am J Physiol Endocrinol Metab. 2008 Jul; 295(1): E216–E222. doi: 10.1152/ajpendo.00545.2007 10.1152/ajpendo.00545.2007

245. Kasinath BS, Feliers D, Sataranatarajan K, et al. Regulation of mRNA translation in renal physiology and disease. Am J Physiol Renal Physiol. 2009 Nov; 297(5): F1153–F1165. doi: 10.1152/ajprenal.90748.2008: 10.1152/ajprenal.90748.2008

246. Kasinath BS, Mariappan MM, Sataranatarajan K, et al. mRNA Translation: Unexplored Territory in Renal Science. J Am Soc Nephrol 2006;17:3281–3292. doi: 10.1681/ASN.2006050488

247. Kren BT, Steer CJ. Posttranscriptional regulation of gene expression in liver regeneration: role of mRNA stability. FASEB J. 1996 Apr;10(5):559-73. doi: 10.1096/fasebj.10.5.8621056.

248. Bai H, Jin W, Guo J, et al. IncRNA Expression Reveals the Potential Regulatory Roles in Hepatocyte Proliferation during Rat Liver Regeneration. Hindawi BioMed Research International Volume 2019, Article ID 8597953, 11 pages. <https://doi.org/10.1155/2019/8597953>

249. Airhart J, Arnold JA, Bulman CA, Low RB. Protein synthesis in pulmonary alveolar macrophages. Source of amino acids for leucyl-tRNA. Biochim Biophys Acta. 1981 Mar 26;653(1):108-17. doi: 10.1016/0005-2787(81)90109-x.

250. Liu X, Liu H, Jia X, et al. Changing Expression Profiles of Messenger RNA, MicroRNA, Long Non-coding RNA, and Circular RNA Reveal the Key Regulators and Interaction Networks of Competing Endogenous RNA in Pulmonary Fibrosis. Frontiers in Genetics 2020. Volume 11 Article 558095

251. Fraser JD, Price PA. Lung, Heart, and Kidney Express High Levels of mRNA for the Vitamin K-dependent Matrix Gla Protein. The Journal Of Biological Chemistry. 1988;263(23):11033-11036.

252. Hoernes TP, Huttenhofer A, Erlacher MD. mRNA modifications: Dynamic regulators of gene expression? RNA Biology 2016;13(9)760–765. Doi: 10.1080/15476286.2016.1203504

253. Boots M. The Need for Evolutionarily Rational Disease Interventions: Vaccination Can Select for Higher Virulence. PLoS Biol 2015;13(8):e1002236. doi:10.1371/journal.pbio.1002236

254. Read AF, Baigent SJ, Powers C, et al. Imperfect Vaccination Can Enhance the Transmission of Highly Virulent Pathogens. *PLoS Biol* 2015;13(7): e1002198.doi:10.1371/journal.pbio.1002198
255. Föhse FK, Geckin B, Overheul GJ, et al. The BNT162b2 mRNA vaccine against SARS-CoV-2 reprograms both adaptive and innate immune responses. doi: <https://doi.org/10.1101/2021.05.03.21256520>
256. Mordechai S. (Feb 18, 2021) Vaccination in Israel: Challenging mortality figures? Analysis by infectious disease specialist claims mismatch between data published by authorities and reality on the ground. Retrieved from <https://www.israelnationalnews.com/News/News.aspx/297051>
257. Mangiaracina E. (Aug 18, 2021) Lab founder shows damage COVID jab's spike protein inflicts on vital organs. Retrieved from <https://www.lifesitenews.com/news/lab-founder-shows-damage-covid-jabs-spike-protein-inflicts-on-vital-organs/>
258. Gundry S. Abstract 10712: Mrna COVID Vaccines Dramatically Increase Endothelial Inflammatory Markers and ACS Risk as Measured by the PULS Cardiac Test: a Warning. https://www.ahajournals.org/doi/10.1161/circ.144.suppl_1.10712
259. Blumenthal KG, Robinson LB, Camargo Jr CA, et al. Acute Allergic Reactions to mRNA COVID-19 Vaccines. *JAMA*. March 8, 2021;325(15):1562-1565. doi:10.1001/jama.2021.3976
260. Soucheray S. Experts: mRNA COVID-19 vaccines likely tied to heart inflammation. News Reporter CIDRAP News. Retrieved from <https://www.cidrap.umn.edu/news-perspective/2021/06/experts-mrna-covid-19-vaccines-likely-tied-heart-inflammation>
261. Hoft J. November 20, 2021 UK Health Security Agency Releases Data Shows Most COVID-19 Deaths in England are Fully Vaccinated. <https://www.thegatewaypundit.com/2021/11/uk-health-security-agency-releases-data-shows-deaths-england-fully-vaccinated/>
262. Hoft J. November 21, 2021 Shocking UK Study Stuns Medical Community: Vaccinated People 60 and Younger Are Twice As Likely to Die as Unvaccinated People. <https://www.thegatewaypundit.com/2021/11/shocking-uk-study-stuns-medical-community-vaccinated-people-60-younger-twice-likely-die-unvaccinated-people/>
263. Hoft J (Joe). November 21, 2021 HUGE: CDC and Big Pharma Data Confirm that More Children will Die from COVID Vaccine than from the COVID Virus. <https://www.thegatewaypundit.com/2021/11/shockingly-insane-cdc-big-pharma-data-show-save-lives-less-50-children-covid-5000-children-will-die-vaccine/>
264. Aripaka P. (August 11, 2021) EU looking into new possible side-effects of mRNA COVID-19 shots. Accessed from <https://www.reuters.com/business/healthcare->

pharmaceuticals/eu-drugs-regulator-looking-new-possible-side-effects-mrna-vaccines-2021-08-11/ (mentioning rare heart inflammation)

265. Radcliffe S. (August 25, 2021). Health News. Healthline. FDA Is Reportedly Looking Again at Heart Inflammation Linked to Moderna Vaccine. Retrieved from <https://www.healthline.com/health-news/fda-to-add-warning-on-mrna-covid-19-vaccines-about-rare-heart-related-side-effect>

266. Classen JB, Classen DC. Public should be told that vaccines may have long term adverse effects. *BMJ* 1999;318:193-193.

267. Bardage C, Persson I, Ortqvist A. Neurological and autoimmune disorders after vaccination against pandemic influenza A (H1N1) with a monovalent adjuvanted vaccine: population based cohort study in Stockholm, Sweden. *BMJ*. 2011 Oct 12;343:d5956. doi: 10.1136/bmj.d5956.

268. Ozonoff A, Nanishi E, and Levya O. Bell's palsy and SARS-CoV-2 vaccines. *Lancet Infect Dis*. April 2021;21(4):450–452. doi: 10.1016/S1473-3099(21)00076-1

269. Moghadas SM, Vilches TN, Zhang K, et al. The impact of vaccination on COVID-19 outbreaks in the United States. *Clin Infect Dis*. 2021 Jan 30: ciab079. doi:10.1093/cid/ciab079

270. Qualls N, Levitt A, Kanade N et al. Community Mitigation Guidelines to Prevent Pandemic Influenza — United States, 2017. Carrie Reed *MMWR Recomm Rep*. 2017 Apr 21; 66(1): 1–32. doi: 10.15585/mmwr.rr6601a1.

271. Benbrook CM. How did the US EPA and IARC reach diametrically opposed conclusions on the genotoxicity of glyphosate-based herbicides? *Environmental Sciences Europe*. 2019;31(2). doi:10.1186/s12302-018-0184-7

272. EWG. APRIL 3, 2003 PFCs: Global Contaminants. Assessed from <https://www.ewg.org/research/pfcs-global-contaminants>

273. Beans C. (2021 Apr 8) News Feature: How “forever chemicals” might impair the immune system. *Proc Natl Acad Sci U S A*. 2021 Apr 13; 118(15): e2105018118.

274. CDC, Severe Outcomes Among Patients with Coronavirus Disease 2019 (COVID-19) — United States, February 12–March 16, 2020. The report was posted online on March 18, 2020 as an *MMWR Early Release*. *Weekly/March 26, 2020/69(12)*;343-346.

275. Verity R, Okell LC, Dorigatti I, et al. Estimates of the severity of coronavirus disease 2019: a model-based analysis. *Lancet Infect Dis* 2020. Published Online March

30, 2020. Available from [https://doi.org/10.1016/S1473-3099\(20\)30243-7](https://doi.org/10.1016/S1473-3099(20)30243-7)

276. Ko JY, Danielson ML, Town M, et al. Risk Factors for Coronavirus Disease 2019 (COVID-19)-Associated Hospitalization: COVID-19-Associated Hospitalization Surveillance Network and Behavioral Risk Factor Surveillance System. Clin Infect Dis. 2021 Jun 1;72(11):e695-e703. doi: 10.1093/cid/ciaa1419.

277. Kim L, Garg S, O'Halloran A, et al. Risk Factors for Intensive Care Unit Admission and In-hospital Mortality Among Hospitalized Adults Identified through the US Coronavirus Disease 2019 (COVID-19)-Associated Hospitalization Surveillance Network (COVID-NET). Clin Infect Dis. 2021 May 4;72(9):e206-e214. doi: 10.1093/cid/ciaa1012.

278. Naidu R, Biswas B, Willettd IR, et al. Chemical pollution: A growing peril and potential catastrophic risk to humanity. Environment International 2021;156

279. Cribb J. Poisoned planet: How constant exposure to man-made chemicals is putting your life at risk. Allen & Unwin Book Publishers, New South Wales (2014)

280. Cribb J. Surviving the 21st century- Humanity's ten great challenges and how we can overcome them Springer International Publishing, Switzerland (2017)

281. Cribb J. Earth Detox: How and why we must clean up our planet. Cambridge University Press, Cambridge (2021)

282. Sung H, Ferlay J, Siegel RL, et al. CA: A Cancer Journal for Clinicians Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries ACS Journals. <https://doi.org/10.3322/caac.21660>

283. American Institute for Cancer Research, Global cancer data by country. Exploring which countries have the highest cancer rates. Accessed from <https://www.wcrf.org/dietandcancer/global-cancer-data-by-country/>

284. Adjiri A. DNA Mutations May Not Be the Cause of Cancer Oncol Ther. 2017 Jun; 5(1): 85–101.

285. Zaman SB, Hussain MA, Nye R. A Review on Antibiotic Resistance: Alarm Bells are Ringing. Cureus. 2017 Jun;9(6): e1403.

286. Hongchao P, Richard P, et al. WHO Solidarity trial consortium. Repurposed antiviral drugs for COVID-19 –interim WHO SOLIDARITY trial results. MedRxiv Preprint. doi: <https://doi.org/10.1101/2020.10.15.20209817> (These Remdesivir,

Hydroxychloroquine, Lopinavir and Interferon regimens appeared to have little or no effect on hospitalized COVID-19, as indicated by overall mortality, initiation of ventilation and duration of hospital stay.)

287. Björnsson ES. Hepatotoxicity of Statins and Other Lipid-Lowering Agents. *Lancet* 2017 Feb;37(2):173-178.

288. Virtanen JK, Mursu J, Virtanen HE et al. Associations of egg and cholesterol intakes with carotid intima-media thickness and risk of incident coronary artery disease according to apolipoprotein E phenotype in men: the Kuopio Ischaemic Heart Disease Risk Factor Study. *American Journal of Clinical Nutrition*, 2016; DOI: 10.3945/ajcn.115.122317

289. Mariamenatu AH, Abdu EM. Overconsumption of Omega-6 Polyunsaturated Fatty Acids (PUFAs) versus Deficiency of Omega-3 PUFAs in Modern-Day Diets: The Disturbing Factor for Their “Balanced Antagonistic Metabolic Functions” in the Human Body. Volume 2021 Article ID 8848161 <https://doi.org/10.1155/2021/8848161>

290. Simopoulos AP. The omega-6/omega-3 fatty acid ratio: health implications. *OCL* 2010;17(5):267–275.

291. Li T, Wei S, Shi Y et al. The dose-response effect of physical activity on cancer mortality: findings from 71 prospective cohort studies. *Br J Sports Med*. 2016;50(6):339–345.

292. Gick ML, Nicol JJ. Singing for respiratory health: theory, evidence and challenges *Health Promotion International*, 2016;31:725–734.

293. Pedersen AF, Zachariae R, Bovbjerg DH. Psychological stress and antibody response to influenza vaccination: a meta-analysis. *Brain Behav Immun*. 2009 May;23(4):427–33.

294. Mumaw CL., Levesque S, McGraw C. Microglial priming through the lung–brain axis: the role of air pollution–induced circulating factors. *FASEB J*. 2016 May; 30(5):1880–1891.

295. Carabotti M., Scirocco A, Maselli MA, Severi, C. The gut-brain axis: Interactions between enteric microbiota, central and enteric nervous systems. *Ann. Gastroenterol*. 2015, 28, 203–209.

296. Lowen AC, Steel J. Roles of Humidity and Temperature in Shaping Influenza Seasonality. *Journal of Virology*. July 2014; 88:14,7692–7695.

297. Buijs RM, Scheer FA, Kreier F, Yi C, Bos N, Goncharuk VD, Kalsbeek A. Or

ganization of circadian functions: interaction with the body. *Prog Brain Res*. 2006;153:341-60.

298. Domingo E, Holland JJ. RNA Virus Mutations and Fitness for Survival. *Annual Review of Microbiology*. 1997;51:151–78.

299. Harvey WT, Carabelli AM, Jackson B, et al. SARS-CoV-2 variants, spike mutations and immune escape. *Nature Review Microbiology*. July 2021;19: 409-427.

300. Maxmen A. (23 April 2021) One million coronavirus sequences: popular genome site hits mega milestone: GISAID's impressive effort to understand the spread of COVID-19 has seen scientists upload sequences from most nations on Earth. *Nature News*. Retrieved from <https://www.nature.com/articles/d41586-021-01069-w>

301. Wu, JQ and Zha, P. Treatment Strategies for Reducing Damages to Lungs In Patients with Coronavirus and Other Infections (February 6, 2020). Available at https://www.researchgate.net/publication/339077708_Treatment_Strategies_for_Reducing_Damages_to_Lungs_In_Patients_with_Coronavirus_and_Other_Infections

302. Wu, JQ and Zha, P. Preventive, Mitigating and Treatment Strategies for Containing or Ending The COVID-19 Pandemic (a first update) (February 25, 2020). Available at SSRN: <https://ssrn.com/abstract=3544428> or <http://dx.doi.org/10.2139/ssrn.3544428>

303. Smith R. Medical journals and the mass media: moving from love and hate to love. *J R Soc Med*. 2006 Jul;99(7):347-52.

304. Elsevier Press Release. Statement from Michael Hansen, CEO Of Elsevier's Health Sciences Division, regarding Australia based sponsored journal practices between 2000 and 2005.

305. Fang H. An explanation of resisted discoveries based on construal-level theory. *Sci Eng Ethics* 2015 Feb;21(1):41-50. doi: 10.1007/s11948-013-9512-x.

306. Zadeh NM, Mashinchi Asl NS, Forouharnejad K, Mechanism and adverse effects of COVID-19 drugs: a basic review. *Int J Physiol Pathophysiol Pharmacol* 2021;13(4):102-109 www.ijppp.org /ISSN:1944-8171/IJPPP0127950

307. Chapin-Bardales J, Gee J, Myers T. Reactogenicity Following Receipt of mRNA-Based COVID-19 Vaccines. *JAMA*. 2021;325(21):2201-2202. doi:10.1001/jama.2021.5374

308. Lancet Editorial. Where next for randomised controlled trials in global health? www.thelancet.com Vol 394 October 26, 2019.

309. Schwalm J-D, McCready T, Lopez-Jaramillo P, et al. A Community-Based Comprehensive Intervention to Reduce Cardiovascular Risk in Hypertension (HOPE 4): A Cluster-Randomised Controlled Trial. 2019 Oct; 5;394(10205):1231-1242.

310. Sacks FM, Pfeffer MA, Moya LA, et al. The effect of pravastatin on coronary events after myocardial infarction in patients with average cholesterol levels. Cholesterol and Recurrent Events Trial investigators. N Engl J Med. 1996;335:1001–9.

311. Beigel JH, Tomashek KM, Dodd LE et al. Remdesivir for the Treatment of Covid-19 — Preliminary Report. May 22, 2020 England Journal of Medicine. DOI: 10.1056/NEJMoa2007764

312. Fry AM, Goswami D, Nahar K et al. Efficacy of oseltamivir treatment started within 5 days of symptom onset to reduce influenza illness duration and virus shedding in an urban setting in Bangladesh: a randomised placebo-controlled trial. Lancet Infectious Disease. 2014;14:2,109-118.

313. Dreier S. (May 9, 2021) 1,000 Lawyers and 10,000 Doctors Have Filed a Lawsuit for Violations of the Nuremberg Code Covid-19 Health. Retrieved from <https://sorendreier.com/1000-lawyers-and-10000-doctors-have-filed-a-lawsuit-for-violations-of-the-nuremberg-code/>

314. Wu J, Zha P. The Central Nervous System's Adaptive Changes Make Chronic Diseases Incurable. Preprints 2019, 2019110287. DOI: <http://dx.doi.org/10.2139/ssrn.3480562>

315. Lu R, Zhao X, Li J. et al., Genomic characterisation and epidemiology of 2019 novel coronavirus: implications for virus origins and receptor binding. Lancet (London, England) 2020;395:565–574.

316. Wadhwa A, Aljabbari A, Lokras A, et al. Opportunities and Challenges in the Delivery of mRNA-Based Vaccines. Pharmaceutics 2020;12,102; doi:10.3390/pharmaceutics12020102

317. Diken M, Kreiter S, Selmi A, et al. Selective uptake of naked vaccine RNA by dendritic cells is driven by macropinocytosis and abrogated upon DC maturation. Gene Ther. 2011;18:702–708.

318. Selmi A, Vascotto F, Kautz-Neu K, et al. Uptake of synthetic naked RNA by skin-resident dendritic cells via macropinocytosis allows antigen expression and induction of T-cell responses in mice. Cancer Immunol. Immunother. 2016;65, 1075–1083.

319. Lorenz, C. et al. Protein expression from exogenous mRNA: uptake by receptor-mediated endocytosis and trafficking via the lysosomal pathway. *RNA Biol.* 2011;8:627–636 .
320. Sendera R, Bar-Ona YM, Gleizera S, et al. The total number and mass of SARS-CoV-2 virions. *PNAS* 2021;118(25):1-9 e2024815118 <https://doi.org/10.1073/pnas.2024815118>
321. 1976 swine flu outbreak, Wikipedia, Accessed from https://en.wikipedia.org/wiki/1976_swine_flu_outbreak
322. Wu J, Zha P. Public Health Intervention Framework for Reviving Economy Amid the COVID-19 Pandemic (1): A Concept. Preprints 2020, 2020040270. Accessed from <https://www.preprints.org/manuscript/202004.0270/v1>. DOI: <http://dx.doi.org/10.2139/ssrn.3571775>
323. Wu J, Zha P. Public Health Intervention Framework for Reviving Economy amid the COVID-19 Pandemic (2): Use of Personalized Mitigation Measures Beyond the Epidemiological Model Limits. Preprints 2020, 2020050049. Accessed from <https://www.preprints.org/manuscript/202005.0049/v1>. <http://dx.doi.org/10.2139/ssrn.3592067>