PREFACE

Helpful Notes reflect thoughts and ideas, as described on the blog (www.bioanalyticx.com) by the author (Saeed Qureshi, Ph.D.) to clarify and address people's and experts' confusion about pharmaceuticals, including vaccines assessments and the practices in laboratories, and industry.

The focus is to explain the weakness and misunderstanding of the convoluted narratives presented as science under different names: such as medical, pharmaceutical, pharmacological, epidemiological, genetics (gene, DNA, RNA, etc.), molecular biology, immunology (antibodies, viruses, vaccines), illnesses or diseases (infectious or otherwise).

The critical aspect is that the subjects mentioned above utilize the fundamental science of testing (analytic chemistry). However, most testing has been developed in-house (medical and pharmaceutical-related facilities), authenticated by peers with little or no relevant academic training and/or working experience. Hence, this resulted in confusion and false claims about illnesses (e.g., COVID-19, pandemics) and treatments (pharmaceuticals and vaccines).

There is grave oversight of the medical and pharmaceutical-related professionals, including physicians and health authorities, resulting in the claims of non-existent viruses and the pandemic, which were predicted, early in the pandemic based on a lack of proper testing. Similarly, vaccines' lack of relevancy and efficacy was also described accurately even before the vaccine's introduction, using scientific (chemistry) logic and reasoning.

In addition, it has been argued for a much longer time that the claims of the quality of pharmaceutical products, in general, lack a scientific basis. But unfortunately, medical and pharmaceutical professionals are unaware of this dreaded oversight.

Medical and pharmaceutical professions rely on enforced non-validated tests, which fall into illegal practices but, for unknown reasons, are ignored by health authorities such as FDA, Health Canada, and others.

These issues have been explained and described with numerous scenarios and practical examples (as blogs) to address the weakness of current practices in simple language that is easy to understand without complex scientific training or expertise.

These notes are standalone versions that could be read mostly without internet access to avoid current unfortunate censorship practices and canceling valuable ideas.

These notes would benefit your scientific and business endeavors. In addition, they will help improve the public's understanding of the scientific principles and practices involved in developing, assessing, and manufacturing medicines.

Please consider purchasing it and recommending it to your friends and peers to provide desperately needed help in explaining the falseness of current scientific practices, which have caused untold damage to the health and wealth of the public around the globe.

About the author

Dr. Saeed Qureshi has a Ph.D. in fundamental science (chemistry) specializing in analytical chemistry, which covers the science of substances' isolation, identification, characterization, purification, tests developments, validation, and their uses.

Dr. Qureshi has been active as a scientist for at least 40 years in different areas, especially pharmaceuticals, food, microbiology, etc.

As a senior research scientist with Health Canada, Dr. Qureshi conducted experimental studies to assess drug applications for product marketing. In addition, he undertook hands-on experimental (scientific) studies in vitro and in vivo (animal/human).

He developed instrumental and mathematical methods/models to provide simpler and more efficient analytical approaches applicable to assessments and manufacturing quality products. Furthermore, he conducted international collaborative studies as a lead and a participant in evaluating regulatory standards for establishing the quality of pharmaceutical products.

While working with Health Canada for 30 years, Dr. Qureshi has developed a deep understanding of the underlying issues facing regulatory authorities and the pharmaceutical industry related to the assessment of products.

He reviewed drug applications and provided advice as an expert on the subject. In this regard, Dr. Qureshi maintains a full command of scientific aspects related to animal and human studies for developing and evaluating products. Such multifaceted knowledge and experience make him an unmatched and unique authority on the subject from both perspectives; manufacturing and regulatory.

He has extensively published in peer-reviewed journals and made numerous invited national and international presentations on the subjects.

He is an accomplished scientist from a regulatory organization, as reflected by several high-profile awards he has received, such as (1) the Lifetime Achievement Award (2015, Indus Foundation, India); (2) the 2007 Deputy Minister's (Health Canada) Award of Excellence in Science; (3) Excellence in Science Award (2007, Health Canada).

A copy of Dr. Qureshi's resume is available here.

Dr. Qureshi's expertise and experiences would greatly help any individual or organization seeking advice/consultation in designing study protocols, monitoring/observing studies, and interpreting and writing up studies, particularly for senior managers and decision-makers. In addition, Dr. Qureshi's abilities would shine in situations where there are complex issues of unexplained behaviors of products both in vitro and in vivo.

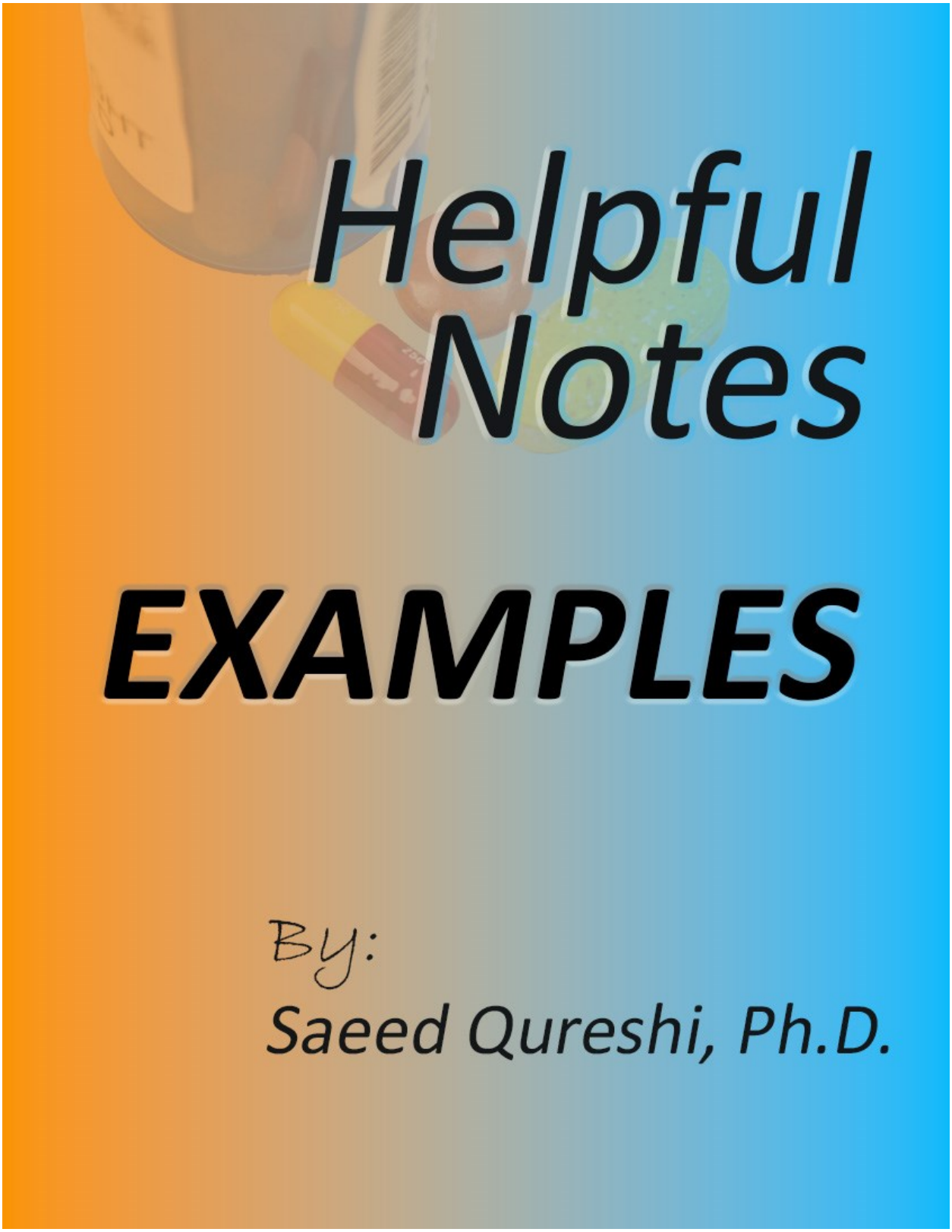

Helpful
Notes
EXAMPLES
By:
Saeed Qureshi, Ph.D.

Table of Content-Pharmaceuticals

Total number of blog posts = 372

Table of Content – Virus/Vaccines

Science at the authorities – tests which do not test!

October 25, 2020

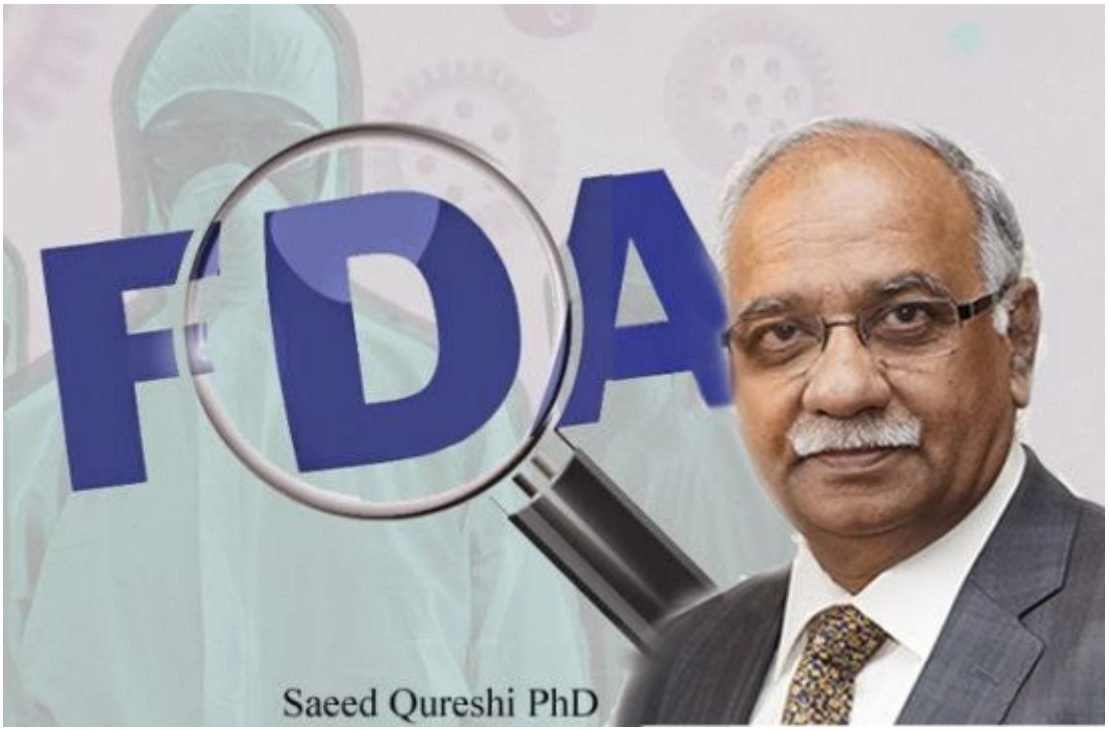
If scientists and health care professionals, including physicians and pharmacists, at the regulatory authorities had paid attention to false testing practices and requirements for pharmaceuticals, the current pandemic would never have happened. Instead, the basis of viruses and pandemics is "testing" developed and implemented by experts with no or limited expertise in the area of testing, resulting in false conclusions and declaration of the virus, just like the persistence of false claims about the quality (by extension safety and efficacy) of the approved and marketed pharmaceuticals (1, 2).

It is impossible to get out of this situation until analytical science (testing) and its principles are allowed to be followed. Fearmongering and censorship have always been tried to protect the status quo and the "experts"; however, they always fail – so will be this time.

Consider conducting testing based on relevant and valid scientific principles.

International Pharmaceuticals Expert Exposes Pandemic Fakery!

July 19, 2020



Link or Link

Do FDA and USP lie? Of course, all the time!

May 21, 2020

For example:

FDA claims that it establishes and monitors the quality of pharmaceutical products such as tablets and capsules. A lie – FDA neither defines the quality of the products nor its measurable parameter; hence it does not, or cannot, determine the quality of the products.

FDA claims that it establishes the safety and efficacy (as well as quality) of pharmaceutical products using valid clinical testing (e.g., bioequivalence assessment) and in vitro (drug dissolution) testing using USP apparatuses. But, again, this is a lie – these tests and associated testers have never been validated for the intended purpose. In fact, these tests are scientifically invalid and irrelevant to their intended purpose.

USP claims that it provides reference standards for establishing the quality of the pharmaceutical products such as tablets and capsules. A lie – USP never provides reference standards for any product. It provides powder or liquid samples of pure chemical compounds, not the products which patients use. However, it falsely promotes reference standards of medicines.

USP claims that it provides a valid analytical test for assessing drug release characteristics of the products for establishing and monitoring the quality of the products. A lie – the test has never been validated for the intended purpose. The test cannot determine any product's drug dissolution/release characteristics. It has been shown experimentally that the test provides irrelevant and highly unpredictable results/data with no relevance to product quality.

For more examples, please visit here. Manufacturers and patients should be cautious in accepting such claims from FDA, USP, and other national and international authorities, which often follow FDA/USP claims and guidelines.

Please consider accepting the Citizen Petition (under review with FDA for more than a year and a half, link) to address the underlying lies concerning product development, manufacturing, and regulatory approval.

Pharmaceutical products quality assessments – future!

May 17, 2020

What should one expect after FDA completely destroyed the credibility and usefulness as well as the need for bioequivalence assessment (aka clinical trials) by removing its requirement from ANDA approvals, at least for hydroxychloroquine (HCQ) and chloroquine (CQ) products to start with [1, 2]?

It is to be noted that bioequivalence assessments are scientifically invalid and irrelevant to establish the quality of the products based on their drug release assessment [3]. Furthermore, such studies put a large financial and personnel burden on the industry and regulatory authorities for the development, manufacturing, and approval of products and expose healthy human subjects, particularly young adults, to potent chemicals (a serious unethical practice).

Products can easily and accurately be assessed using drug dissolution testing. However, to implement its (drug dissolution testing) valid use, authorities, including FDA and USP, need to implement appropriate and scientifically valid dissolution testers and methods. Until then, authorities' claims regarding monitoring and establishing product quality will remain false and invalid.

The COVID-19 pandemic exposed the burdensome and unnecessary regulatory practices and requirements. It also provides an opportunity to simplify product development and manufacturing. Please consider the under-review Citizen Petition for removing the use of non-validated/non-qualified, hence non-GMP, USP drug dissolution testers/tests from regulatory requirements [4] and replace them with appropriate and scientifically valid tests and testers.

Clinical trials – credibility issue?

May 2, 2020

In general clinical trials are important and necessary. In any other area, one has to show that the "things" (in this case, medicines/treatments) work as expected – clinical trials serve such a purpose.

However, underlying scientific concepts and practices in medicine are extremely poor; hence "clinical trials" practices face credibility issues. For example, developing products (tablet/capsule) clinical trials (bioequivalence test – regulatory requirement) are conducted, lacking clinical relevance and usefulness. Therefore, it could be argued that such tests expose subjects, often healthy human volunteers, needlessly to potent chemicals in the name of medicine development. (link)

Similarly, relating to the Coronavirus pandemic, there appears to be a rush toward the development of medicines/vaccines. It may be argued that as the underlying analytical science is not well-established to monitor the virus and/or its "disease," it would be challenging to conduct appropriate and validated "clinical trials" (link)

In short, running clinical trials is a good idea. However, conducting appropriate and useful clinical trials remains challenging; that is where the confusion is.

Bye Bye – Bioequivalence testing? Long live drug dissolution testing! —– #2 (gift from heaven

April 16, 2020

I posted my view on the recent FDA guidance documents for chloroquine and hydroxychloroquine (link). I do not think people realize the long-term impact of this development, where BE studies have been replaced/substituted with drug dissolution testing. Let me explain:

1. Considering that guidelines are product specific is incorrect because chloroquine and hydroxychloroquine are drugs, not products. Products are tablets, capsules, often unknown and proprietary compositions of a drug, excipients, and manufacturing attributes (i.e., formulation and manufacturing attributes). Hence, guidances cannot be product-specific as assumed or suggested.

2. A drug dissolution test is conducted for products, not drugs. As product attributes are mostly unknown and propriety, as noted above, hence a dissolution test (or guidance) cannot be product specific but has to be independent "standard or universal."

3. Furthermore, it is to be noted that the product-specific guidance concept is invalid in principle. Drug dissolution testing is a scale used to measure the dissolution characteristics of a product. By definition, it (scale) has to be independent of the tested items. The point is that the guidance documents cannot be restricted to one or two drug products. These have to apply to ALL highly soluble drug products. It would not be possible for authorities, at least scientifically, to defend restricting to only one or two products. This decision could easily be challenged and won.

4. In addition, such a decision cannot be a one-time one, as many believe it may be taken under an emergency. It would not be possible to withdraw such a decision once taken, i.e., if the dissolution test alone can provide a quality assessment of the products. Then why would BE studies be needed and required on what basis, especially when BE studies are known to be irrelevant (link)?

5. This new development is a gift from heaven for underdeveloped countries where products and their manufacturing have always been labeled inferior because of a lack of BE studies. However, with dissolution testing only, manufacturers can confidently manufacture and promote (for local and/or international markets) their quality products.

Keep these thoughts in mind and proceed accordingly.

Bye Bye – Bioequivalence testing? Long live drug dissolution testing!

April 14, 2020

Recently FDA provided 1- and 2-pager guidance documents for chloroquine and hydroxychloroquine, respectively (link).

The most interesting part is that one can get product approval based on dissolution testing alone. This is what has recently been suggested in one of my recently published articles, i.e., product ("quality") assessment can easily and accurately be established with drug dissolution testing alone (link). Therefore, there is no need to conduct bioequivalence (BE) assessments. These (BE) assessment procedures have never been validated for the intended purpose. In fact, BE is scientifically invalid and can provide false conclusions and assurance about product quality. In addition, such testing exposes healthy human volunteers to highly potent chemicals under the disguise of medicine development.

On the other hand, switching to dissolution testing alone using currently recommended USP apparatuses is not valid either, at least scientifically. The recommended apparatuses are non-GMP compliant and can provide false and irrelevant results because of their intrinsic design and operation problems. Simpler and scientifically valid options can be used (link).

Result of using false (invalid) tests

November 19, 2022

Pushers of PCR, Rapid/antigen, and drug dissolution tests should pay attention.

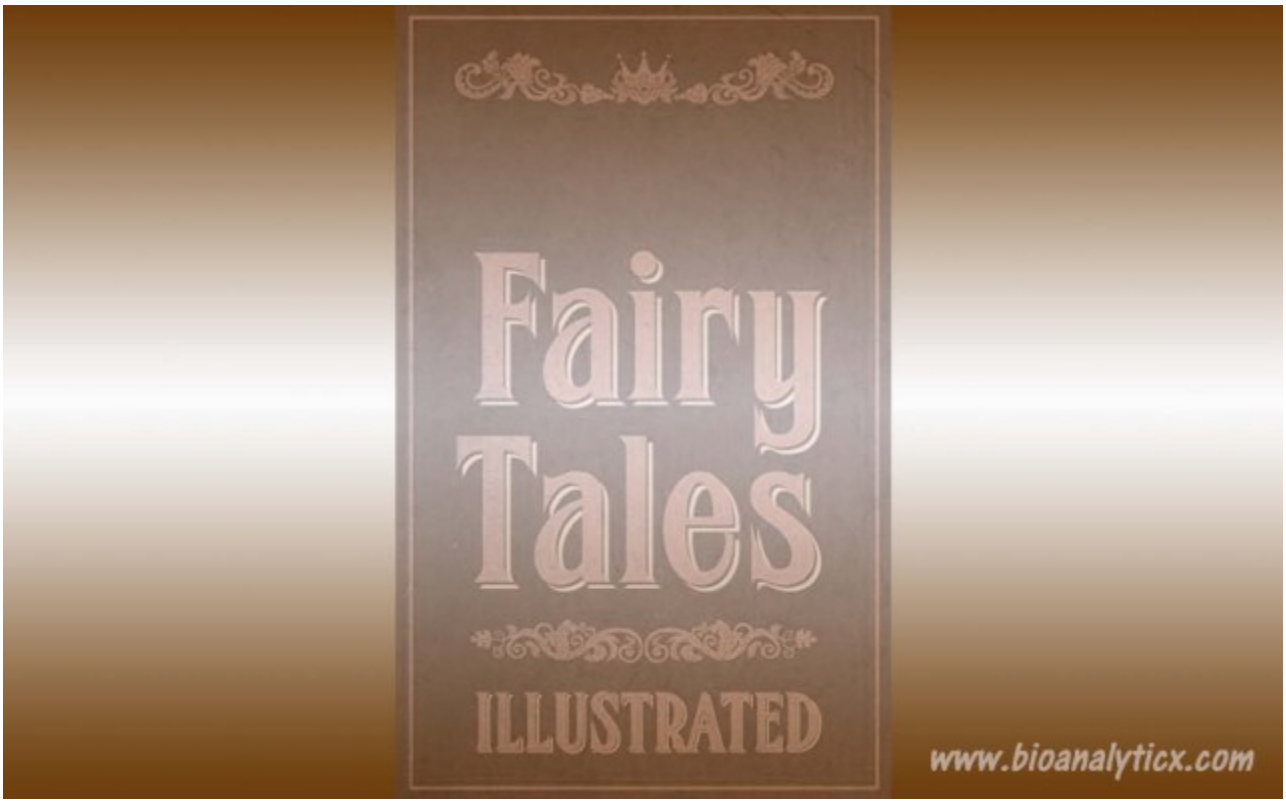
SAN JOSE, Calif., Nov 18 (Reuters) – A federal judge on Friday sentenced Theranos founder Elizabeth Holmes to 11 years and three months in prison for defrauding investors in her **now-defunct blood-testing** startup that was once valued at $9 billion.

"U.S. Attorney Stephanie Hinds said the sentence for Holmes "reflects the audacity of her massive fraud and the staggering damage she caused." (Link)

The PCR, Rapid/antigen and dissolution testing fall under the false (invalid) testing category. More details here (Link, Link, Link).

mRNA Vaccines: A Fantastic Fairy Tale

November 16, 2022

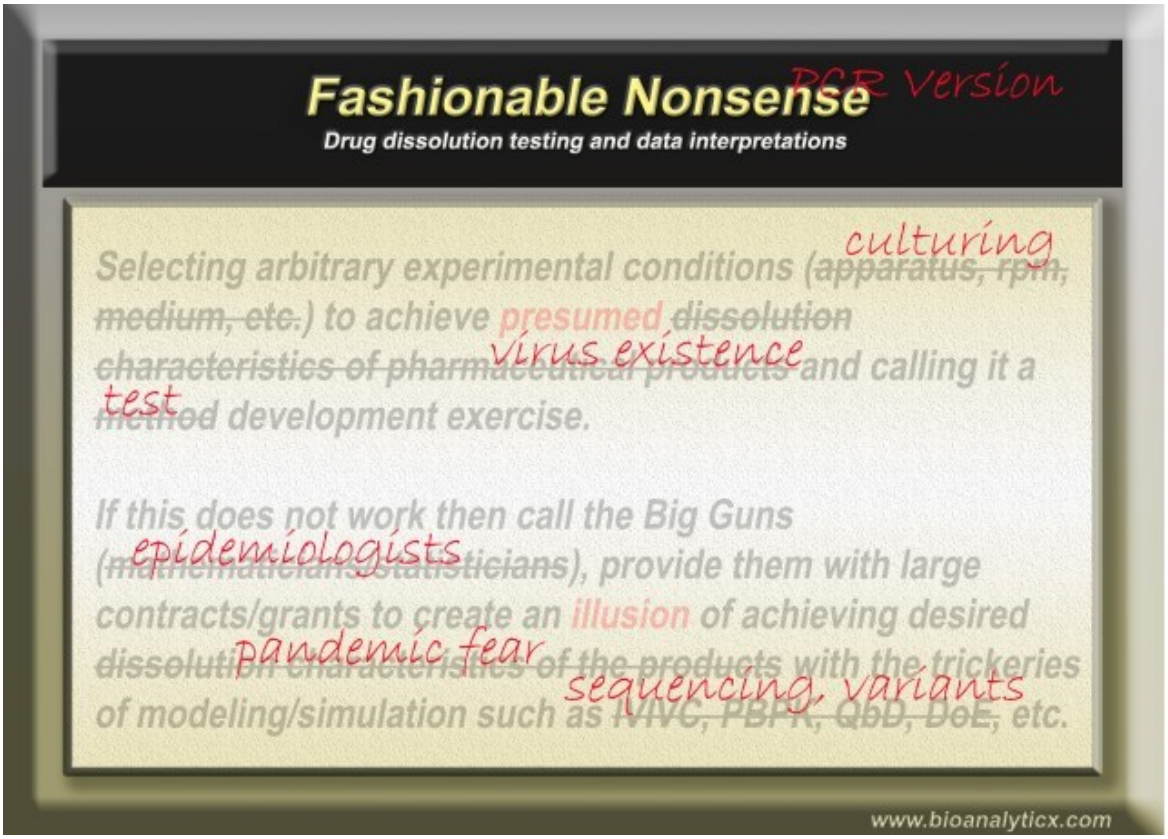


The following is a brief scientific explanation of mRNA technology, often presented as something new, advanced, or novel.

The literature described it (mRNA, messenger ribonucleic acid) as a chemical compound (a shorter version of nucleic acid or RNA), like a peptide molecule, compared to protein, the larger(chain or necklace) molecule. It may be impressive and overwhelming for medical professionals because of limited learning and understanding of science/chemistry; otherwise, nothing is unique or novel about its nature and characteristics as a chemical molecule/compound. (Continue here)

Fashionable Nonsense – PCR Version!

November 12, 2022



A little over six years ago, I wrote a blog describing the practice of nonsensical science for pharmaceutical evaluations at the regulatory authorities and the industry. My decades of experience seeing the "science" at regulatory authorities could be summarized as shown in the post here (Link).

In this regard, the "science" in the pharmaceutical area is based on a technique known as drug dissolution testing, which forms the basis of product quality assessments, particularly tablets and capsules. The testing is a mandatory requirement and is done worldwide.

Unfortunately, scientifically it is an invalid technique and should not be used for any purpose because it will provide a false assessment of the product quality and hence their safety and efficacy (Link).

Almost four years ago, I submitted a Citizen Petition to the FDA requesting to remove the invalid testers from the regulatory requirements. However, while acknowledging the invalidity of the testers, the FDA recently rejected the petition (Link).

It clearly shows incompetency in science at the authorities and disregard in addressing the issue related to assessing the safety and efficacy of pharmaceutical products.

If such a deficiency had occurred and been acknowledged by a manufacturer, it would have been shut down immediately, followed by legal ramifications – not so with the authorities or FDA.

The COVID-19 pandemic is a direct result of this ignorance and incompetence. The pandemic is also based on testing, which is known as PCR. The same problems have been noted with PCR testing, i.e., invalid testing that cannot detect viruses and their variants and vaccine efficacy (Link).

Therefore, by default, the pandemic becomes fake and false. Everything about viruses, vaccination, and the pandemic is based on flawed testing. Consequently, it has to be scientifically fake and false – period! However, authorities are promoting them as science-based, like the false claims of (high-quality) approved pharmaceutical products.

Moreover, like dissolution testing, highly confusing and irrelevant fancy technical jargon authenticated by high credential (mostly medical/pharmaceutical, not science) experts promoting the fake science of PCR-based viruses, testing, and vaccination (Link).

The problems associated with the virus, testing, and pharmaceutical products, including vaccines, are because of invalid testing (aka fake or pseudo-science), which requires immediate attention.

Science is missing – simple and clear!

November 7, 2022

To understand "viruses" or anything related to diseases and medicines logically and scientifically, one needs to study and understand the actual science (chemistry subject). But unfortunately, "experts" ignore this aspect and make false and fraudulent claims.

Considering a fundamental understanding of the science subject, it was clear (and described) from the beginning of the pandemic that there is no virus, testing is false, and vaccines have to be fake and potentially dangerous.

So, when you hear medical/pharmaceutical experts on the topics, keep the above-mentioned thought in mind; most narratives will be fake and false.

The following will help in clarifying the issues.

COVID-19: The virus does not exist – it is confirmed! (link)

(Video) Virus, COVID, pandemic, vaccine, and testing: fiction, not reality or science! (link)

Science for the pandemic at the authorities: false in fact fraudulent – requires urgent action! (link)

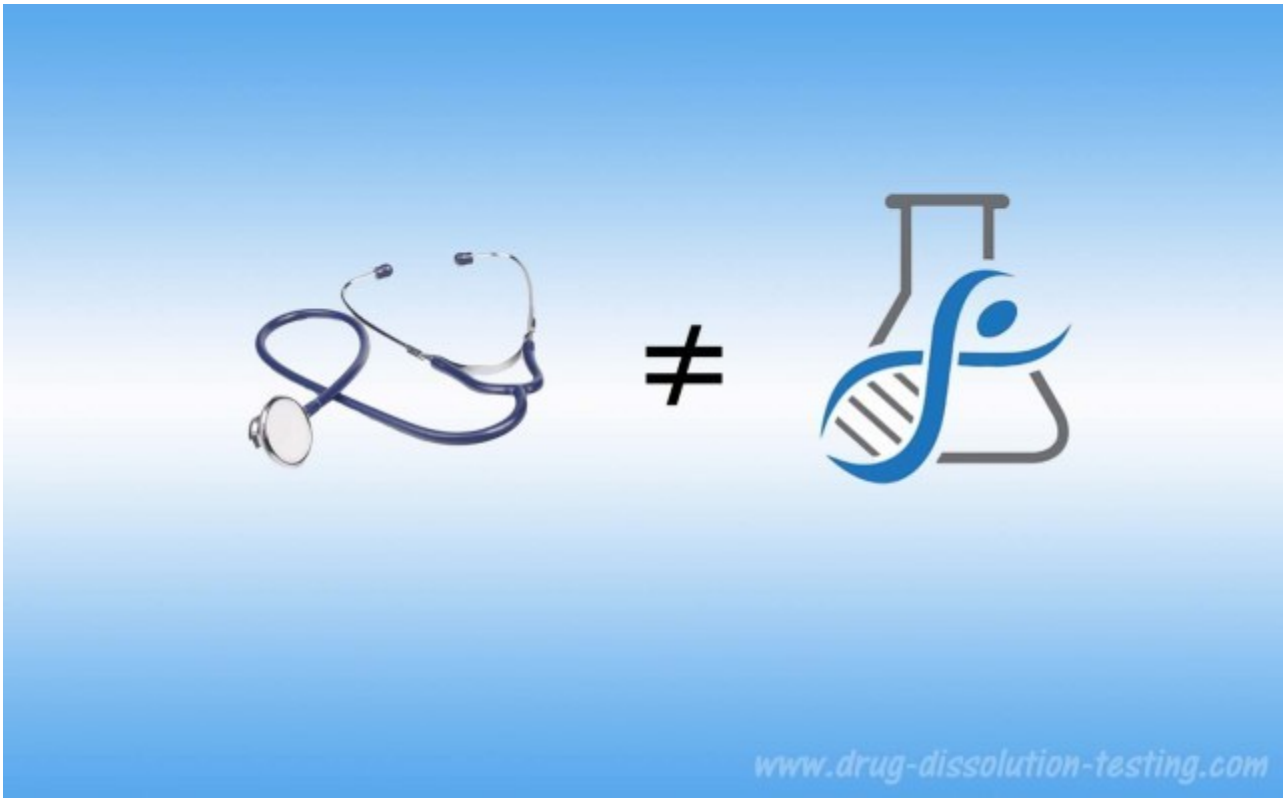
Facts and data-based science (link)

An M.D. degree is not a science degree! (link)

And much more here (link)

An M.D. degree is not a science degree!

November 3, 2022



It is critical to note that an M.D. degree is not a science degree. But unfortunately, holders of the degree are considered and promoted as scientists, which caused the erroneous claims of the viruses, testing, pandemic, and treatments (vaccines).

Most of the claims made in this regard, such as DNA/RNA, proteins, their isolation, purification, characterization, testing, and sequencing, belong to chemistry (science) subjects and should be part of such expertise and faculties.

There are indications that claims about the COVID-19 pandemic, made by experts with M.D. degrees and associated organizations such as CDC and FDA, are in retraction [link, link]. However, such (COVID-19, vaccination) aberrations are considered as rare, implying "science" is genuine and should continue as such for new and more viruses, illnesses, and vaccines.

When dealing with such claims, one should keep in mind that medical experts have never been able to show any evidence of the existence of the virus from any source, lab, or animal. Instead, their claims are based only on PCR testing or sequencing.

PCR testing is a scientifically invalid technique with no link to the virus/variants or illness. Further, the described sequencing technique is not sequencing but the opposite, i.e., assembling some chemical

molecules to obtain computer-based fictional RNAs (chemical compounds, not viruses) — a scientifically invalid and false claim and practice.

The only reason such studies and claims are published and accepted is that they are reviewed or authenticated by "peers/buddies" with similar flawed training and mindset. Independent third-party reviews of the published literature by scientists with expertise in the respective subjects have never been done. In this respect, it would be safe to assume that most of the published literature based on PCR testing and sequencing assessments for viruses and their related illnesses must be false and scientifically invalid and should be retracted.

Further, in the future, medical degrees should be considered a trade certification, not a science degree, which will help avoid future disasters of faulty testing and misdiagnosis.

For further details (link, link, link, link)