

Science for the pandemic at the authorities: false in fact fraudulent – requires urgent action!Saeed A. Qureshi, Ph.D. (www.drug-dissolution-testing.com)

Also published as "COVID-19: Vaccine 'Not Possible' for a Virus Not Yet Quantifiable" On Principia Scientific International site ([link](#)).

It is often claimed and promoted by the regulatory authorities, in particular CDC/FDA, that the current Coronavirus (SARS-CoV2/COVID-19) pandemic, particularly in the USA, is based on science and the associated data or facts. It is claimed that the virus causes the infection, which causes or may cause human deaths, potentially millions. Furthermore, it is also claimed that a viral disease (COVID-19) can only be treated with a vaccine, which currently does not exist, and must be developed urgently and made available to the public worldwide.

Let us evaluate these claims on a scientific basis. First of all, let us see if the virus exists in humans, and perhaps more importantly, how it is measured reflects its disease, which causes the alleged deaths.

In general, the presence or absence of COVID-19 in humans does not, or cannot be, determined effectively and efficiently because of technical (scientific) difficulties. Therefore, in most cases, in fact, in almost all cases, the presence/absence of a virus is established by indirect testing. These indirect tests are commonly known as PCR and antibody tests. Without going into technical details, one may consider that these tests monitor specific types of proteins or related chemicals. However, they are produced by the presence of viruses, not only SARS-CoV2 or COVID-19 but all pathogenic viruses as a defense mechanism to get rid of the viruses and/or protect human bodies from their ill effects. It is important to note here

that when someone refers to virus testing, one does not determine a virus but a marker (such as protein). The irony is that these markers are not specific to COVID-19 but generic to viruses the body is exposed to. Alternately, these tests are not sufficiently specific - and scientifically speaking, should never be relied upon for declaring the presence of a particular virus, including COVID-19. Obviously, if a virus cannot be monitored reliably, then the associated disease or deaths cannot be established accurately and scientifically. Hence, confusion and inaccuracies in predicting the death rate that is no higher than average and natural attrition rates.

In a simpler and daily life example, one may explain the situation as establishing the safety of cars by monitoring the tires' air pressure levels (marker). Someone noted that deviation in car tire pressure could be of safety concern. It is quite possible (by chance) that variation in tire pressure can be dangerous to cars' performance/safety. However, it is not accurate or logical to use tire pressure monitoring as an overall car safety criterion and keep rejecting the cars for tire pressure deviation, which may be the tires' issue. Unfortunately, authorities decided that car safety will be monitored only based on tire pressure levels. Now, this would become a "Regulatory Compliance Requirement" or the law for car safety assessment. On top of this, the irony is that authorities provide their version of tire pressure gauges, which shows failures of otherwise perfectly acceptable cars as unsafe and useless.

This is precisely the situation here in the case of pandemic and COVID-19 monitoring. A regulatory

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compliance requirement has been made that COVID-19 will be established based on PCR/antibody testing, which, as noted above, is not specific at all to COVID-19. Furthermore, only to use the tests which are suggested ("approved/authorized") by the authorities. It is important to understand that it (testing) is based solely on a regulatory compliance requirement, not a scientific requirement. However, it is promoted as scientific. The believers and promoters of this requirement are usually experts from the areas: of pharmacy, epidemiology, virology, genetics, microbiology, immunology, medicines, and biochemistry, to name a few. However, the test by definition, falls in the category of analytical chemistry. The multiple disciplines named are the test users and should not claim to be the test developers and/or validators – they lack the needed expertise. It is just like a baker uses agricultural products (e.g., flour) and cooking equipment (e.g., oven) to make bread but does not claim to develop and manufacture the items used to make the bread.

If one sees the issue from an analytical chemistry perspective, it will become evident that testing is entirely bogus, hence all the associated claims. The testing should be considered bogus because these tests do not meet the fundamental requirements of science (analytical chemistry), which is the tests' validation. This validation step is commonly based on establishing four parameters: (1) accuracy, (2) precision, (3) specificity, (4) references used to validate the test. No analytical test is accepted without meeting these validation requirements – they must meet the scientific requirements. However, no COVID-19 test is available or used which is validated. This practice should be considered a cardinal sin in the scientific world. Scientists often argue that seeking

a specific test for COVID-19 or its associated disease is like seeking "absolute truth" or causing hindrance in providing available and "acceptable" testing and/or science. This, unfortunately, is the most deceptive or fraudulent view/argument presented, often supported and promoted by the regulatory authorities. Therefore, at present, regulatory authorities are not implementing true scientific principles in the pharmaceutical areas but based on self-created and arbitrary science of "regulatory compliance requirements" with various flashy and catchy marketing phrases.

If the COVID-19 cannot be determined, and by extension, the pandemic, what vaccine is being developed for? Again it is just a regulatory requirement because regulatory authorities are asking for it. Therefore, it needs to be developed. On the other hand, it is impossible to develop a proper vaccine because, as noted, one cannot monitor the virus or disease and then how the vaccine's effectiveness will be established. It cannot be! Therefore, a fake vaccine will most likely be developed to satisfy the regulatory wish and calm down the created public hysteria and fear. Unfortunately, such vaccines, if developed and administered, will undoubtedly create potentially dangerous side effects, without any presumed benefits, by interfering with the body's immune system and other related physiological processes.

The regulatory compliance requirement syndrome is not associated with COVID-19 only or new; it is widespread in other pharmaceutical areas. For example, the compliance-based approval of traditional pharmaceutical products such as tablets and capsules for the past at least three decades, has ruined science and pharmaceutical product development and manufacturing. All kinds of regulatory requirements have been

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developed and implemented with force to establish and monitor the manufactured products' quality. The irony is that authorities have never defined what they mean by a "quality product" with some (scientifically) measurable parameter/criteria. However, there is a huge battery of compliance requirements (such as regulatory guidance documents) available from authorities, in particular FDA. The requirements and guidance are enforced with or without numerous unrelated testing requirements. They have never been validated for their intended purpose or claim. Still, the industry must follow if it has to survive, and the public must accept, assuming it is receiving "quality" pharmaceutical products.

In short, at present, a serious and fatal flaw exists in the practice of science at the authorities in regulating the areas of pharmaceutical product development and assessment. This can only be addressed by critically evaluating and implementing appropriate scientific principles from relevant scientific disciplines and expertise.

PS: If one requires specific references to the views presented here, they can be obtained by visiting the site (www.bioanalyticx.com) or directly contacting the author principal@pharmacomechanics.com.

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