

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

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

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

In general, 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, presence/absence of 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 which are produced by the presence of viruses, not only by SARS-CoV2 or COVID-19, but by all pathogenic viruses as a defence mechanism to get rid of the viruses and/or to protect the human bodies from their ill effects. It is important to note here that when someone refers to testing of virus, one does not determine virus but a marker (such as protein). Irony is that these markers are not

specific to COVID-19, but generic to viruses, body exposed to. Saying it differently, these tests are not sufficiently specific - and scientifically speaking should never be relied upon for declaring presence of a specific virus including COVID-19. Obviously, if a virus cannot be monitored reliably, then the associated disease or deaths cannot be established reliably and accurately, at least scientifically as well. Hence, confusion and inaccuracies of the predicted death rate which is no higher than normal and natural attrition rate.

In a simpler and daily life example, one may explain the situation as establishing safety of cars by monitoring air pressure levels of the tires (marker) because someone noted that deviation in car tire pressure could be of safety concern. It is quite possible (by chance) that deviation in tires pressure can be dangerous to cars performance/safety. However, it is not accurate or logical using tires pressure monitoring as overall cars safety criteria and keep rejecting the cars for tires pressure deviation, which may be issue of tires themselves. Unfortunately, authorities end up deciding that cars safety will be monitored only on the basis of tires pressure levels. Now this would become a “Regulatory Compliance Requirement” or the law for cars safety assessment. On top of this, irony is that authorities to provide their own version of tire pressure gauges leading to showing of failures of otherwise perfectly acceptable cars as unsafe and useless.

This is exactly the situation here in the case of pandemic and COVID-19 monitoring i.e. a regulatory compliance requirement has been

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made that COVID-19 will be established based on PCR/antibody testing which, as noted above, is not specific at all to COVID-19 - and further only to use the tests which are suggested (“approved/authorized”) by the authorities. It is important to understand that it (testing) is solely on regulatory compliance requirement basis not a scientific requirement, however, it is promoted as scientific. The believers and promoters of this requirement of testing 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 users of the tests and should not claim being developers and/or validators of the test – 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 do not claim developing and manufacturing the items used to make the bread.

If one sees the issue from analytical chemistry perspective, it will become immediately obvious that testing is completely bogus and hence all the associated claims. The reason that the testing should be considered bogus is that these tests do not meet the basic and fundamental requirements of science (analytical chemistry) which is validation of the tests. 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 – the must scientific requirements. However, at present no COVID-19 test is available or used which is validated. This practice should be considered as a cardinal sin in the scientific world. The 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.

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

The regulatory compliance requirement syndrome is not associated with COVID-19 only or new, it is wide spread in other pharmaceutical areas as well. For example, for the approval of traditional pharmaceutical products such as tablet and capsule – it has been imposed for the past at least three decades, which certainly has ruined the science as well as pharmaceutical products development and manufacturing. All kinds of

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regulatory requirements have been developed and implemented with force in the name of establishing and monitoring quality of the manufactured products. Irony is that authorities have never ever defined what they mean by a “quality product” with some (scientifically) measurable parameter/criteria. However, there is 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, never been validated for their intended purpose or claim but the industry must follow if it has to survive and public must accept assuming it is receiving “quality” pharmaceutical products.

In short, at present, there is a serious and fatal flaw exists in the practice of science at the authorities in regulating in the areas of pharmaceutical products 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 could be obtained by visiting the site ([www.drug-dissolution-testing.com](http://www.drug-dissolution-testing.com)) or directly contacting the author at [principal@pharmacomechanics.com](mailto:principal@pharmacomechanics.com).

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