International Pharmaceuticals Expert Exposes Pandemic Fakery!

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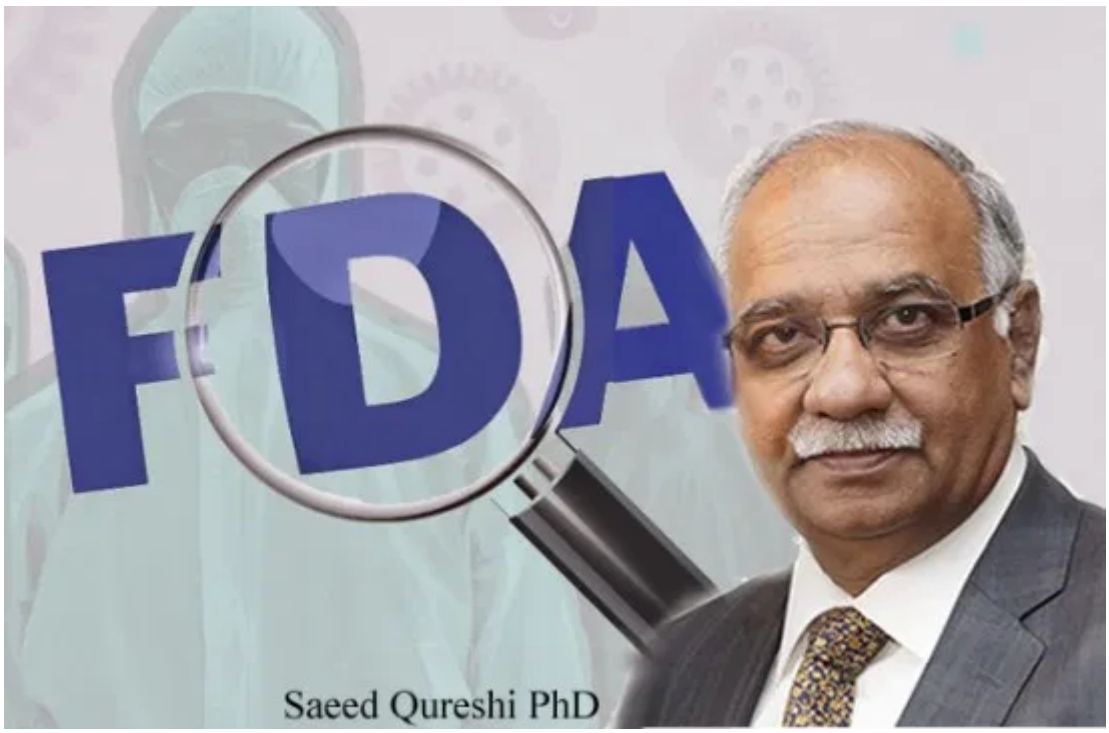
Written by John O'Sullivan



In a scathing assessment of governmental responses to the COVID-19 pandemic a respected former pharmaceutical assessor for Health Canada condemns systemic **"lies"** about antibody testing which, he says, "**lacks scientific validity**."

Saeed Qureshi, Ph.D. is a top pharmaceuticals expert with over 30 years in the industry. He conducted hands-on and multi-disciplinary laboratory research for regulatory assessment purposes while working with Health Canada.

Heaping particular criticism on the FDA approved under Emergency Use Authorization or EUA, Dr Qureshi condemns the testing kits widely used as ineffective and "**such tests should be avoided in making predictions or projections about the infection and its spread. It certainly is a false science.**"

We cite sections of Dr Qureshi's findings below:

"Considering the statements below, from a randomly selected fact sheet FDA approved under Emergency Use Authorization or EUA, the current antibody testing lacks scientific validity. This is really sad that such tests [kits] are being promoted or used to establish COVID-19 [1]. As noted below the test monitors protein levels commonly known as [IgM, IgA and IgG] not specifically COVID-19. Logically data obtained from such tests should be avoided in making predictions or projections about the infection and its spread. It certainly is a false science.

1. *"A positive result with VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack test may not mean that an individual's current symptoms are due to COVID-19 infection."*
   2. "However, a negative result does not rule out COVID-19."
   3. "The absolute sensitivity of the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack test is unknown."
   4. FDA statement [2] "This limits the test's effectiveness for diagnosing COVID-19 and why it should not be used as the sole basis to diagnose COVID-19."
   In addition, if vaccines would be developed based on such antibody tests, which does not appear to be sufficiently validated as noted above, then how reliable and valid vaccines would be? Please be cautious with claims in this regard.

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

For example:

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

FDA claims that it establishes 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. A lie – these tests, along with associated testers, have never been validated for the intended purpose. In fact, these tests have been shown to be scientifically invalid and irrelevant for their intended purpose.

USP claims that it provides reference standards for establishing 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 falsely promotes as reference standards of medicines.

USP claims that it provides a valid analytical test for the assessment drug release characteristics of the products for establishing and monitoring quality of the products. A lie – the test has never been validated for the intended purpose. The test cannot determine drug dissolution/release characteristics of any product. 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 and USP as well as other national and international authorities which often follow FDA/USP claims and guidances.

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

Can we say?

1. *Flu came and gone!*
2. *Why it was called a pandemic – not clear*
3. *Discredited the bench top science – as disease state monitored with charts and their shapes (humpy or dumpy) with protocol/testing developed on the fly*
4. *Discredited the medicines approval system with the approval of medicines without requiring established protocols*
5. *Treatments could be suggested and implemented without having knowledge or expertise in the area of medicine.*
6. *Exposed the great weakness, perhaps more accurately ignorance, of "science" at the authorities!*
7. *Hope we learnt something not to repeat in future*

(1) Coronavirus pandemic: Public/patients deserve better!

The unfortunate situation created by this Coronavirus pandemic is providing a serious opportunity for reassessing the current regulatory approaches in pharmaceutical products development as well as their manufacturing so that in future such irrelevant discussion can be avoided and patients can have access to modern and multiple options to treat ailments. Hopefully in the future patients will be treated with well-established products rather than products developed on the fly or with the use of disposable gowns, masks, washing hands and/or staying home policy which certainly are not the treatments – patients expect and deserve something better from us as scientists, physicians and regulators. Follow the link for complete article (link)

(2) Authorities (including FDA) and pharmacopeias (including USP) never establish quality of products!

Reasons:

(1) They do not define quality of the products, hence it cannot be measured and/or established (link).
(2) Suggested methods and procedures lack scientifically relevancy and validity (link)
(3) GMP practices, including inspections, are about operation of manufacturing not per se reflection of products quality (link).

(3) Is Coronavirus really causing abnormally higher number of deaths?

Mortality in the United States, 2018 (as of January 2020, link).

"The age-adjusted death rate decreased by 1.1% from 731.9 deaths per 100,000 standard population in 2017 to 723.6 in 2018." i.e. death rate is about 0.7236%

For the USA, having population of 331 million (link), normal/standard death (attrition) rate should be 199,593 deaths/month. Now compare this number with the reported number of deaths caused by Coronavirus pandemic, which are 21,435 in about a month's time as of April 12, 2020 (link) which is far less than normal/standard death (attrition) rate.

The death rate, therefore, does not appear to support the thesis that the pandemic is killing people with abnormally high numbers.

***About the author: Dr. Qureshi** gained extensive (30+ year) experience in conducting hands-on and multi-disciplinary laboratory research in pharmaceutical areas for regulatory assessment purposes while working with Health Canada.*

He is an internationally recognised expert in the areas of pharmacokinetics, biopharmaceutics, drug dissolution testing, analytical chemistry as related to characterization of pharmaceuticals, in particular, based on in vitro (dissolution) and bioavailability/bioequivalence (humans and animals) assessments.

At present, Dr. Qureshi provides teaching, training and consulting services, in the area of his expertise as noted above, for improved pharmaceutical products development and assessments. Dr. Qureshi can be reached by email (principal@pharmacomechanics.com) or Tel (+1 613 797 9815)

Read more at www.drug-dissolution-testing.com

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Ed D.

July 10, 2020 at 1:17 pm | # | Edit

According to its website , the American Red Cross says, “The Red Cross is using the FDA-authorized Ortho Clinical Diagnostics VITROS® Anti-SARS- CoV2 Total Test, which is SPECIFIC to COVID-19.” (capitalization is mine)

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