The Recent Court's Decision Provides Hope For Addressing Incompetence And Fake Science At Government Agencies.

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In a major ruling, the Supreme Court sharply reduced the power of federal agencies to interpret the laws they administer and ruled that courts should rely on their own interpretation. (link.)

The court overruled its landmark 1984 decision, which gave rise to the doctrine known as the Chevron doctrine. Under that doctrine, if Congress has not directly addressed the question at the center of a dispute, a court was required to uphold the Agency's interpretation of the statute as long as it was reasonable. In a 35-page ruling by Chief Justice John Roberts, the justices rejected that doctrine, calling it "fundamentally misguided."

The FDA has been using the Chevron doctrine to dictate its opinion through numerous Guidance documents, as Congress's intent, and law, for example (link), stating:

"Guidance documents represent the Agency's current thinking on a particular subject. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public."

However, in practice, not only does the industry have to accept the decision to get their products approved for marketing, but courts also accept it as a valid, unbiased, and final opinion on the topic. The fundamental assumption is that the Agency's opinions are valid, unbiased, and science-based (or scientific). However, the missing aspect is knowing whether the opinion providers or decision-makers have valid and relevant expertise. It is where the problem is.

In the Agency's view, a physician with an M.D. degree becomes the expert and final voice on the science subject for developing, assessing, and manufacturing medicines/pharmaceuticals, including vaccines. It is to be noted that an M.D. degree is a typical non-science undergraduate degree without any gained knowledge or training in the area of science, particularly chemistry, as medicines/pharmaceuticals are chemicals. This loophole of falsely designating scientists or science experts has created many unintended "scientists" without proper expertise and training in actual science subjects.

Therefore, they ("scientists") frequently make erroneous and scientifically invalid claims about tests used in medicine/pharmaceutical developments

– the backbone of the practice of medicine and assessment of pharmaceutical products.

For example:

(1) Most safety, efficacy, and quality of medicines/pharmaceutical products assessments, particularly oral dosages such as tablets and capsules, are based on a drug dissolution test and correspondingly using a drug dissolution tester. However, the testers have never been validated for their use, i.e., can they determine the products' valid and relevant drug dissolution characteristics? It has been repeatedly shown that this tester cannot provide valid and relevant results, hence the quality of the products and, by extension, safety and efficacy. However, the test and its requirements continue as per FDA Guidance documents (contrary to Congress's intent of producing quality products). In real life, if anyone uses a non-validated test, it is considered illegal/crime, and the promoter is usually dealt with immediately and swiftly, but not the agencies (link).

In a challenge to this practice, a Citizen Petition to the US FDA was submitted requesting the discontinuation of the practice and its requirements. However, after four years of evaluation, the flaw (lack of validation of the testers) in FDA-recommended dissolution testers was acknowledged, as highlighted in the Petition. Unfortunately, the Petition was denied based on irrelevant discussion and arguments on dissolution method development and validation, not on apparatuses/testers validation – the subject of the Petition. It clearly shows a lack of understanding of the subject/science of product evaluation at the Agency (link). Therefore, agencies have final authority in making logically and scientifically false decisions that are not in line with lawmakers' intent, and this needs to be addressed.

(2) Clinical tests (called clinical trials) are considered the gold standard for evaluating pharmaceuticals. This sledgehammer approach establishes the superiority of medical "science" over others, as no one can do or is allowed to do the clinical trials but physicians. Have these tests/trials been

validated to be scientific and produce relevant or valid results or data? The simple answer is no.

Let me explain this with an example of evaluating or comparing generic products against brand-name ones. They are done based on clinical trials called bioequivalence studies. Here, healthy human volunteers are given separate doses of brand-name products vs generics. Blood drug levels (markers of dosage efficacy) are measured and compared with each other. If the drug's blood levels fall within the "accepted" range (roughly plus/minus 20%). Then, the products are considered similar, which means they will be equally safe and effective and can be interchangeably prescribed. The assumption is that if the blood levels fall outside the accepted range, the product will be considered inferior to the brand name. In short, bioequivalence tests are done to establish the quality of the product to see if products are similar (with a 20% difference). Where does the 20% difference come from, and can the bioequivalence test see this 20% difference? The answer to both is no regarding the 20% difference (a number out of a hat) and whether the method can see a 20% difference.

In a study, it is established that the bioequivalence method itself can provide 20% and higher variability in testing (link). It cannot see the difference in product variability, often less than 20%. In reality, the method considers the variability of the test itself, not that of the product as presumed. In simple terms, one is trying to establish the weight and accuracy of a small jewelry item with a large weighing scale having a much higher tolerance than the weight of the jewelry piece. This is an excellent example of a lack of understanding and competency in science/chemistry. However, the situation cannot be corrected as, in the Agency's view, it is "science" and valid and can be used to apply for product approval. This clearly misrepresents Congress's intent to provide safe and effective drug products.

(3) A recent example of such misrepresentation is the "science" behind COVID-19, its pandemic, and its vaccine development. It is

> important to note that the diagnosis of any illness is established by a test specific to it or its cause; in this case, it is a virus called SARS-COV-2. It is critical to note that a test cannot be developed for something if its sample (reference) is unavailable. No sample of SARS-COV-2 is available. Hence, it is impossible to develop a diagnostic test for it. Hence, scientifically, it is clear that there is no virus or illness, and the suggested tests are simply a scientific lie. The nation or the world is in the grip of a false virus and is treated with vaccines for a non-existent illness.

The only reason such erroneous and scientifically incorrect standards/methods are allowed is the belief that the Agency's experts know and practice the science, which is a wrong assumption. These decisions or interpretations are made mainly by medical and pharmaceutical experts who do not study science, and no auditing mechanism is available to correct the situation.

The recent court decision should allow the courts to conduct independent evaluations or audits. It also provides opportunities for academic and industry scientists, often unheard and suppressed, to seek independent audits of the science at the Agencies. Not only will it save a huge amount of resources, but more importantly, it will allow people to live and interact with one another freely without fear of non-existing illnesses and avoiding unnecessary medicines, including vaccines.