

## **Assessment of Clinical Trial Reporting for COVID-19 Vaccines Developed by BioNTech/Pfizer, Moderna, and AstraZeneca/Oxford**

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### **Abstract.**

Recently, Pfizer/BioNTech, Moderna and AstraZeneca/University of Oxford announced with great fanfare that their candidate vaccines that target the Spike protein of SARS-COV-2 were ~92%, ~94% and 90% effective respectively. At around the same time, the N.F. Gamaleya Center For Epidemiology and Microbiology of the Russian Ministry of Health also announced that their candidate vaccine termed "Sputnik V" was also over 90 % effective. The response to the announcements of Pfizer/BioNTech, Moderna and AstraZeneca/University of Oxford by the scientific community, so-called pundits and experts, including the influential Nature and Science Magazines, Government Officials and the Western Media at large was generally and resoundingly favorable and extremely enthusiastic while the response to announcement of the N.F. Gamaleya Center For Epidemiology and Microbiology of the Russian Ministry of Health was extremely reticent and derisive. The responses to the announcements of the above entities are not understandable because none provided any scientific data to support their un-scientific conclusions. It is not clear how the values of over 90% effectiveness of the candidate vaccines were arrive at. It is submitted that the announcements of Pfizer/BioNTech, Moderna, AstraZeneca/University of Oxford and N.F. Gamaleya Center constitute Dishonest Scientific Reporting that are calculated to mislead. The limited results reported by Astra/Zeneca/University of Oxford also constitute Data Falsification

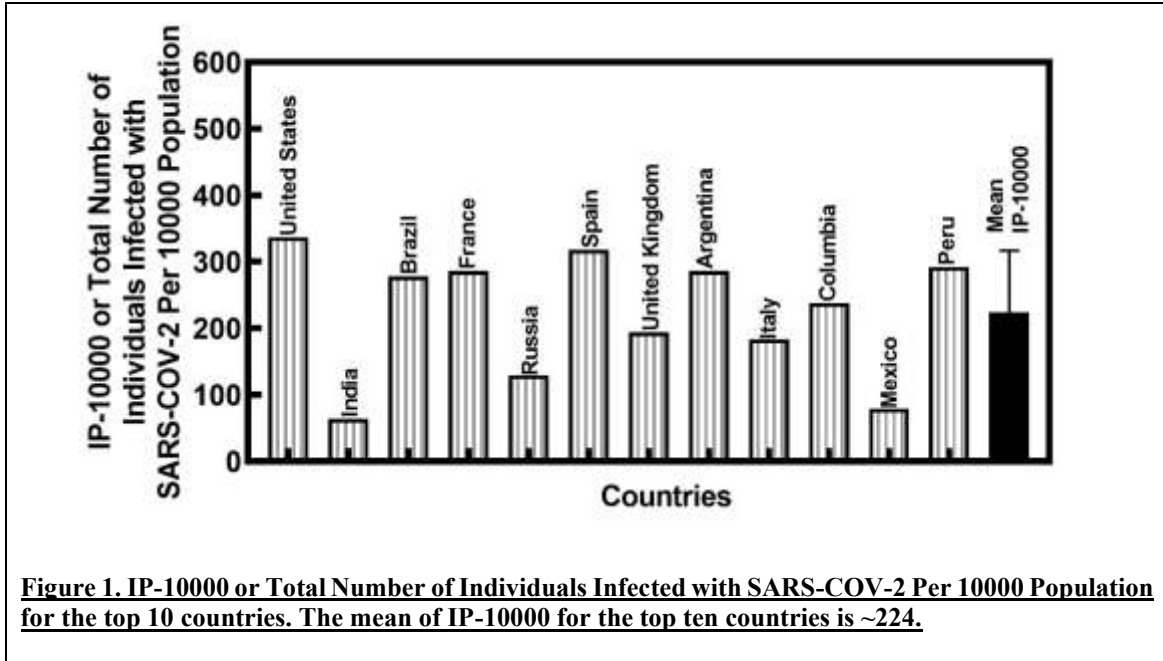
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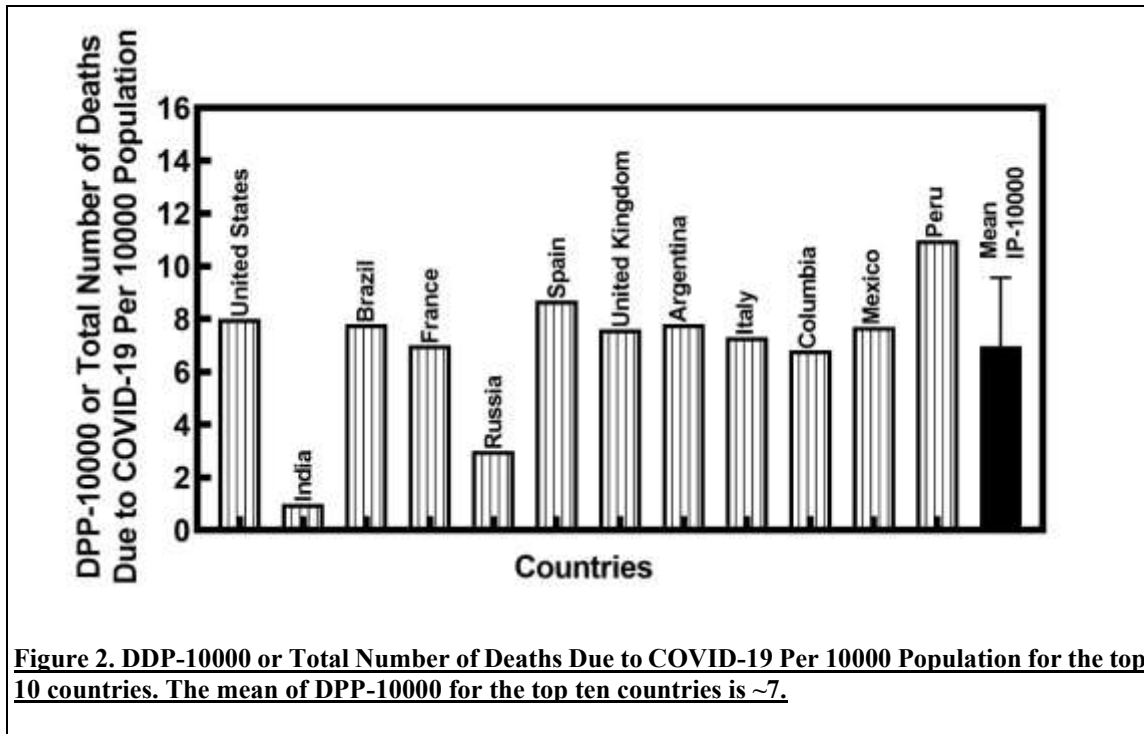
Recently, the entities, including Pfizer/BioNTech, Moderna and AstraZeneca/University of Oxford announced with great fanfare that their candidate vaccines that target the Spike protein of SARS-COV-2 were ~92%, ~94% and ~90% effective respectively [1-9]. At around the same time, the N.F. Gamaleya Center For Epidemiology and Microbiology of

the Russian Ministry of Health also announced that their candidate vaccine termed "Sputnik V" was also over 90 % effective [10]. It is not clear why the response to the announcements of Pfizer/BioNTech, Moderna and AstraZeneca/University of Oxford by the scientific community, so-called pundits and experts, including the influential Nature and Science Magazines, Government Officials and the Western Media at large was generally and resoundingly favorable and extremely enthusiastic [4-9] while the response to the announcement of the N.F. Gamaleya Center For Epidemiology and Microbiology of the Russian Ministry of Health was extremely reticent and derisive [10]. It is not clear how the values of greater than ~90% effectiveness of the candidate vaccines were arrived at. It is also not clear how the values of effectiveness provided by Pfizer/BioNTech, Moderna and AstraZeneca/University of Oxford can be considered legitimate while that provided by the N.F. Gamaleya Center For Epidemiology and Microbiology of the Russian Ministry of Health is considered illegitimate.

Pfizer/BioNTech reported that based on a total number of 43000 subjects, 162 confirmed cases of symptomatic COVID-19 in the placebo group and 8 among those who were vaccinated with their candidate vaccine, their candidate vaccine was 95% effective. It is not clear how and what scientific data they used to arrive at the value of 95% effectiveness. The scientific data is flimsy at best and dishonest at worse. The values appear to have been made up out of thin air. The average infectivity rate or IP-10000 Number (or Total Number of Individuals Infected Per 10000 population) for the top 10 countries, including United States, India, Brazil, France, Russia, Spain, United Kingdom, Argentina, Italy, Columbia, Mexico and Peru, can be estimated to be ~224 (Figure 1). This imply that based on 50% (21500) of the total individuals who took part in the Clinical Trial of Pfizer/BioNTech and who were not vaccinated with their candidate vaccine (Control Group), ~482 individuals who were not vaccinated with the candidate vaccine should have been infected with SARS-COV-2.



The DPP-10000 Number (or Total Number of Deaths Due to COVID-19 Per 10000 populations) for the top for the top 10 countries, including United States, India, Brazil, France, Russia, Spain, United Kingdom, Argentina, Italy, Columbia, Mexico and Peru, can be estimated to be ~7 (Figure 2). This imply that based on 50% (21500) of the total individuals who took part in the Clinical Trial of Pfizer/BioNTech and who were not vaccinated with their candidate vaccine (Control Group), ~15 individuals who were not vaccinated with the candidate vaccine should have died due to severe COVID-19 symptoms.

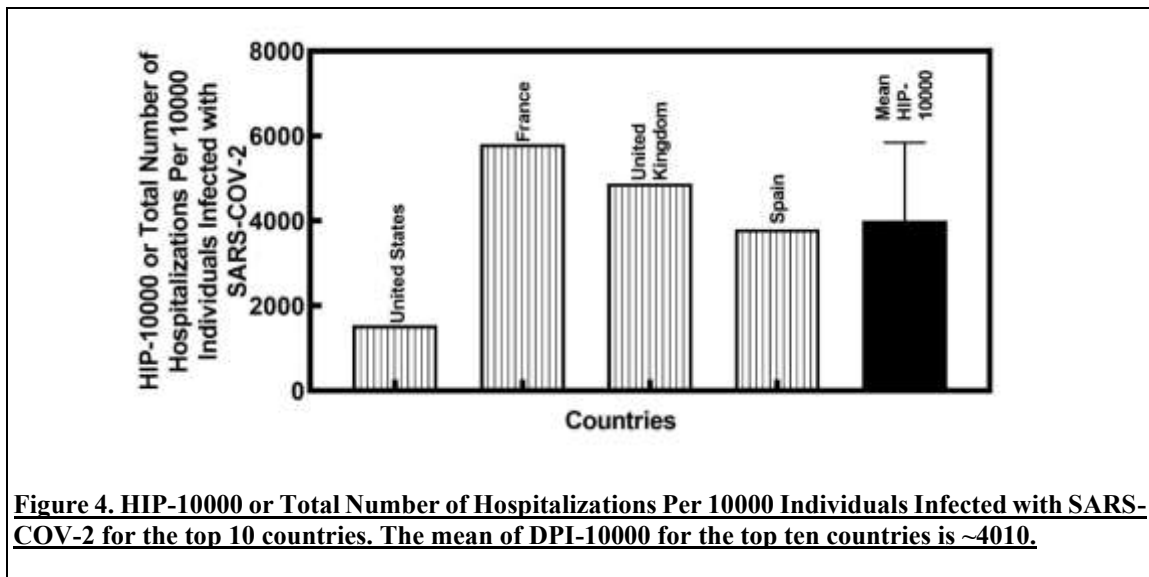
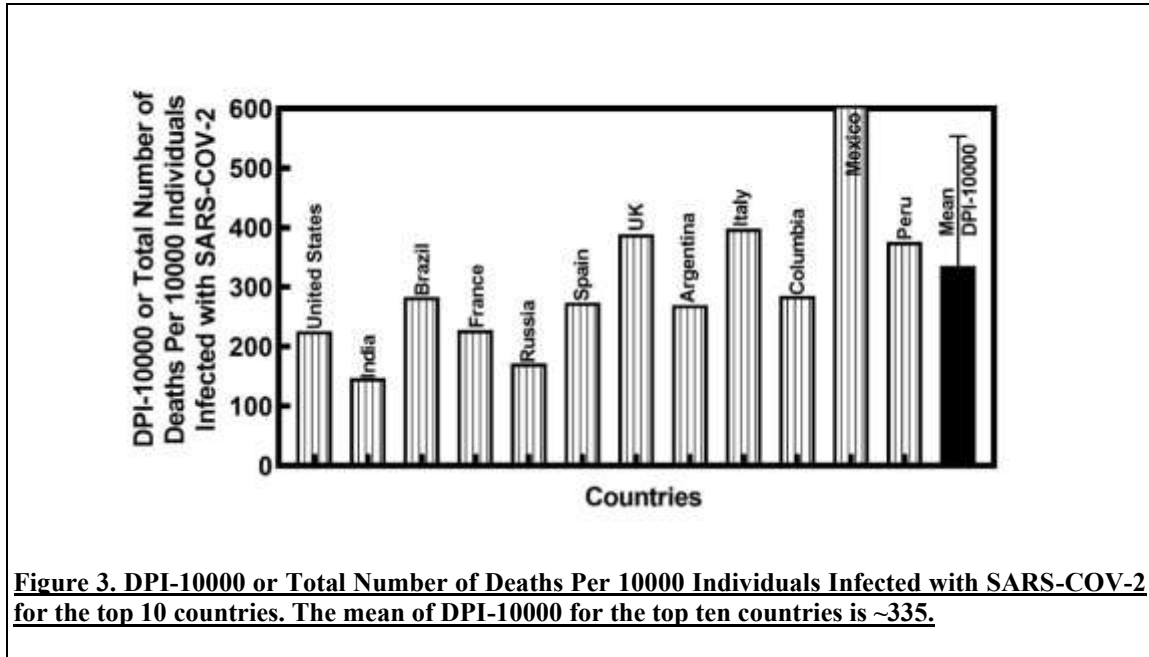


**Figure 2. DPP-10000 or Total Number of Deaths Due to COVID-19 Per 10000 Population for the top 10 countries. The mean of DPP-10000 for the top ten countries is ~7.**

The DPI-10000 Number (Total Number of Death Per 10000 Individuals Infected with SARS-COV-2) for the top for the top 10 countries, including United States, India, Brazil, France, Russia, Spain, United Kingdom, Argentina, Italy, Columbia, Mexico and Peru, can be estimated to be ~7 (Figure 3) can be estimated to be ~335. This implies that based on 50% (21500) of the total individuals who took part in the Clinical Trial of Pfizer/BioNTech and who were not vaccinated with their candidate vaccine (Control Group), ~16 individuals who were not vaccinated with the candidate vaccine should have died due to severe COVID-19 symptoms.

Because the average HPI-10000 Number (or Total Number of Hospitalizations Per 10000 Individuals Infected with SARS-COV-2) can be estimated to be ~4010 (Figure 4), it can be calculated that ~194 individuals infected with SARS-COV-2 would be experiencing severe symptoms of COVID-19. The reported figure of 162 is far below that of prevailing pandemic conditions. The total absence of reported death in the Pfizer/BioNTech clinical trial makes it high suspicious for two reasons. First, there may have been Data Falsification and Dishonest Scientific Reporting or the Clinical Trial has not been

conducted scientifically under current prevailing pandemic conditions which makes the whole process a farce and Scientific Fraud [13,14].



Moderna has stated in their press releases that based on the unsealing of only 95 cases of SARS-COV-2 and COVID-19 symptoms, and on the fact that five individuals who were vaccinated with the candidate vaccine were infected with SARS-COV-2 and developed symptoms of COVID-19, and 90 individuals who were not vaccinated with the candidate

vaccine were infected with SARS-COV-2 and developed symptoms of COVID-19, and 11 of the 90 individuals who were not vaccinated with the candidate vaccine also experienced severe symptoms. In their latest drip-drip press release, Moderna [11,12] stated that out of 30,000 participants, 15,000 were not vaccinated with their candidate vaccine and 196 participants developed symptoms of COVID-19. 30 of the non-vaccinated individuals developed severe symptoms of COVID-19 and 1 of the non-vaccinated individuals died while 11 of the vaccinated individuals develop symptoms of COVID-19 and none of the vaccinated individuals developed severe symptoms of COVID-19. It is also stated that there were 7000 participants who were over 65 years old. It suggests that 23,000 of the 30000 participants were under 65 years old and that most probably 11,500 participants were not vaccinated with the candidate vaccine. The IP-10000 (or Total Individuals Infected with SARS-COV-2 Per 10000 Population) can be estimated to be ~224 (Figure 1). If the clinical trial of Moderna was conducted scientifically and was reflective of the current pandemic prevailing conditions, ~257 individuals who were not vaccinated with Moderna's candidate vaccine should have become infected (Figure 1), and among them there should have been ~8 or 9 deaths (Figures 2 and 3). Among the 7000 participants who were over 65 years old, 3500 probably were not vaccinated with Moderna's candidate vaccine. Simple calculation would show that ~78 participants who were over 65 years old should have been infected with SARS-COV-2 and among them ~3 would have died. However, because the Infection Fatality Risk for individuals over 65 years old can be as high as 9%, it can be calculated that there could be ~7 deaths among the 3500 participants who were over 65 years old and who were unvaccinated. The latest limited data released by Moderna strongly suggests that the Moderna's clinical trial to determine the efficacy of its candidate vaccine has not been performed scientifically and did not reflect current pandemic prevailing conditions. It is not clear whether the participants were chosen at random and whether there were any bias (It is possible that individuals who volunteered to participate in Moderna's clinical trial were much healthier than the average population. The only scientific way to determine the effectiveness of a candidate vaccine is to enroll participants who are willing to accept being infected on purpose!). Also, whether a total of 30,000 participants in a clinical trial that has lasted from July 27, 2020 to October 30,

2020 is enough to determine its efficacy is highly debatable. All the above points to Dishonest Scientific Reporting and possibly Data Falsification [13,14].

The candidate vaccine of AstraZeneca/University of Oxford [3] is a lot more problematic as no reliable scientific data was provided and the number of participants is so small (only 2800 participants were injected with the candidate vaccine in the clinical trial(s) that supposedly gave greater than 90% efficacy) that it can be said that the clinical trial conducted by AstraZeneca/University of Oxford is a farcical unscientific exercise. First, it is not clear where the results come from exactly as they appear to be derived from several clinical trials. There was no standard dosing. The initial dose was  $5 \times 10^{10}$  virus particles. However, it appears that it could in fact be between  $3.5$  to  $6.5 \times 10^{10}$  virus particles (It is not clear what method was used to determine the number of virus particles). Secondly, there was no consistency in the treatment modality. The control group in the United Kingdom received a meningococcal vaccine while the control group in Brazil were given saline. Thirdly, a simplistic calculation was used to arrive at the percentage of efficacy. Apparently, fewer than 2,800 volunteers got the dose that resulted in their "92% effective" value. Worse, the dose given to the 2,800 participants was arrived at by mistake. According to the very limited scientific that was made available, 131 symptomatic cases were recorded. What proportion of 131 symptomatic cases came from the 2,800 subjects? It is in the realm of science fiction to be able to determine the effectiveness of a candidate vaccine from these numbers. The drip-drip information from AstraZeneca/University of Cambridge does not lend credence with respect to transparency, credibility, accuracy and safety of their clinical trials. The combination of results from several trials with different dosing and controls is akin to data manipulation which would constitute Data Falsification and Dishonest Scientific Reporting [13,14]. Cutting corners is not only unscientific but also dangerous.

To state that the candidate vaccines developed by BioNTech/Pfizer, Moderna and AstraZeneca/University of Oxford were greater than 90% effective is at best misleading and at worse dishonest. In order to arrive at the conclusions that the candidate vaccines developed by BioNTech/Pfizer, Moderna and AstraZeneca/University of Oxford were

greater than 90% effective, the investigators of BioNTech/Pfizer, Moderna and AstraZeneca/University of Oxford would have to unseal sets of data of individuals who were and were not vaccinated with the candidate vaccine, analyze them separately and calculate the percentage of infections in each group. Only when large data sets are unsealed or upon completion of a clinical trial can definite conclusions on the effectiveness of a clinical treatment be made. The sensational, un-scientific conclusions of the investigators at both BioNTech/Pfizer and Moderna are unwarranted, misleading at best and dishonest at worse. There used to be a time when press releases would be made after complete scientific data (not drip-drip communications!) was analyzed and divulged to the scientific community

Perhaps, the biggest drawback of the candidate vaccines concocted and manufactured by Pfizer/BioNtech, Moderna and Astra Zeneca/University of Oxford is that they do not prevent individuals from being infected with SARS-COV-2. A vaccine against SARS-COV-2 is supposed to prevent SARS-COV-2 infections and not just the symptoms of the diseases that it causes. The candidate vaccines do not prevent SARS-COV-2 infections which makes them suspicious at best and dishonest at best since they were made to elicit immune response that targets the SARS-COV-2 Spike protein. If the immune response that is elicited by the candidate vaccines was truly targeting SARS-COV-2 Spike protein, prevention of SARS-COV-2 infections should have been their primary mechanism of action (SARS-COV-2 should not in principle be able to enter and infect cells). The fact that the candidate vaccines do not prevent SARS-COV-2 infections make the claims of more than 90% effectiveness dubious, misleading at best and dishonest at worse. As stated above, no verifiable scientific evidence is available to show that the candidate vaccines concocted and developed by Pfizer/BioNtech, Moderna and Astra Zeneca/University of Oxford are more than 90% effective. The only way to know anything about the effectiveness of the candidate vaccines is to analyze the data towards the end of the clinical trials in 2022 or to completely unseal the data for all the participants now. There is also no study of the long-term effects of the candidate vaccines. Again, one cannot cut corners when it comes to proving the effectiveness of a candidate vaccine and whether it is dangerous or not.

What is even more surprising and incomprehensible is that Science Magazine through one of its non-scientific staff writers (Jon Cohen) who knows next to nothing about vaccines, clinical trials and vaccine protocols wrote gloriously about the success of the candidate vaccines of Pfizer/BioNTech and Moderna [5,6,8,9]. That Science Magazine under its Editor in Chief, Holden Thorpe has become a mouth-piece for commercial entities is an understatement. Science Magazine does not seem to know how to conduct unbiased scientific critiques anymore. What does the Editor in Chief of Science think of the candidate vaccines of Pfizer/BioNtech and Moderna? The same can be said of Nature magazine and its Editor in Chief. The discipline of Statistics can be quite informative and useful which it is conducted scientifically, honestly and rigorously. However, Statistics can also be quite misleading and dangerous when it is not conducted scientifically, honestly and rigorously. What is quite disturbing and does not bode well for the legitimacy and openness of science is the large number of "Scientific Researchers" and so-called scientific experts and pundits have lauded the un-scientific conclusions as scientific facts either out of ignorance and incompetence or they just did not want to rock the boat. Very few Scientific Researchers have questioned the validity and usefulness of the conclusions on the effectiveness of the candidate vaccines made by Pfizer/BioNTech and Moderna. Only a few Scientific Researchers have objected to the limited and dubious results of AstraZeneca/University of Oxford.

It is clear that unless Scientific Protocols are followed to the letter, no honest and useful conclusion can be made with respect to the investigations of whether the candidate vaccines developed by Pfizer/BioNTech, Moderna and AstraZeneca/University of Oxford are effective or not. Also, if the investigation is not conducted properly with respect to the questions that are asked and must be answered, no valid scientific conclusions can be made on the effectiveness of a treatment. In most valid clinical trials, data of individuals who receive and do not receive the treatment are segregated until an end point that is established scientifically and analyzed separately. It is un-scientific to mix untreated and treated groups, and come up with conclusions by analyzing them together. Because in the investigation of the candidate vaccines developed by

Pfizer/BioNTech, Moderna, and AstraZeneca/University of Oxford, the data of individuals who were and were vaccinated with the candidate vaccines were analyzed together and not segregated, conclusions that are at best misleading and at worse dishonest have been made and peddled as scientific facts to incompetent or corrupt governmental officials and regulatory agencies. It is unfortunate that regulatory agencies, including the United States Federal Drug Administration (US FDA) has become a Political Agency as opposed to a Scientific Regulatory Agency (Was it not the US FDA that gave emergency approval to Hydroxychloroquine, Remdesivir and Dexamethasone when all scientific data showed that they were/are not only ineffective but also dangerous [15-17]).

In conclusion, the statements that the candidate vaccines developed by BioNTech/Pfizer, Moderna and, the N.F. Gamaleya Center For Epidemiology and Microbiology of the Russian Ministry of Health are more than 90% effective is misleading at best and dishonest at worse. That these entities and their investigators have committed Scientific Dishonest Reporting is an understatement. In addition to indulging in Dishonest Scientific Reporting, AstraZeneca/University of Oxford have also committed Data Falsification. Their actions were calculated to mislead and quite dangerous.

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