Biotechnology Innovation Organization

# AN OPEN LETTER TO THE BIOPHARMACEUTICAL INDUSTRY

September 03, 2020

The biopharmaceutical industry is at the center of the world's fight against Covid-19, leading the effort to develop new vaccines, therapeutic medicines and diagnostics.

Over time, we expect these efforts to be successful, resulting in a range of new healthcare products for the benefit of the entire world. These new products will need to be manufactured in large quantities and distributed rapidly to all segments of our society. Physicians, public health officials, patients and healthy citizens will need to be educated as to their safety, efficacy, and risk/benefit. Their widespread adoption will be based on trust in the integrity of the scientific and public health principles governing their development and approval.

If this is done correctly, we will halt the pandemic, save lives, reignite our economy and enable a return to a more normal life. We will emerge from this pandemic better prepared to address and react to future biological threats.

As data begin to emerge from clinical trials of an array of vaccines and therapeutics, we believe that it is important for us in the biopharmaceutical industry to articulate the principles we see as essential for assessing these data and determining their potential value. We believe that public health, and the public's trust in new medical products, are dependent upon the integrity, transparency and objective assessment of new data as they emerge.

Accordingly, we are articulating the following principles:

1. Clinical trials should be conducted according to best practices to assure credibility of the data, as well as the ethical participation of a diverse population of subjects.

2. Companies should disclose important clinical data via well-respected scientific meetings or rigorous, independent peer review journals. The disclosure of key scientific and clinical data through meetings and journals is the gold standard. However, companies may need to release some clinical data in advance of publication. In these instances, companies should approach any pre-publication press activity thoughtfully, and data should not be released by press release alone. Sponsors should ensure that data included in any press statement are clear and include accurate descriptions of key data points while reinforcing that the full data will be submitted for peer review.

3. FDA should maintain its historic independence as the gold-standard international regulatory body, free from external influence. This will assure the public that the FDA review process will adhere to the highest standards of scientific and medical integrity, and that any approved products therefore will meet the required standards of safety and efficacy.

4. The appropriate use of any new products should be data-driven. Different sub-populations are likely to react differently to different medicines. These differences will begin to be revealed in larger long-term studies. The public should be assured that only rigorously considered data will dictate the subsequent use of any product. Distribution of any vaccines should be done with these considerations in mind.

5. Political considerations should be put aside by Republicans and Democrats alike. Our nation's leaders should reassure the public that politics will not influence the development and approval of new medicines. Conclusions about both the safety and effectiveness of such medicines should be based on rigorous collection and assessment of data by all the appropriate bodies, and their distribution should be based on sound public health considerations. This approach is all the more vital considering the unprecedented pace and scale of the effort to develop treatments and vaccines for Covid-19.

We urge all parties involved in the development, review, approval, and distribution of COVID-19 therapeutics and vaccines to commit themselves to these principles.

Sincerely,

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