

Has the FDA become less industry-friendly?

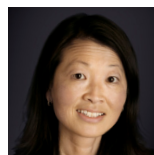
The Food and Drug Administration (FDA) played a prominent role in 2020 as health care companies rushed to develop diagnostics, therapies and vaccines to address the COVID pandemic. The agency responded by working closely with the industry and expediting approvals to facilitate desperately needed solutions. However, even prior to the pandemic, it appeared that the agency's relationship with the industries it oversees was undergoing changes.

The pharma and biotech industries have enjoyed a collaborative environment with the Food and Drug Administration (FDA) over the past four years. Dr. Scott Gottlieb entered as Commissioner of the agency in May 2017 and was charged by Congress and the Trump Administration with streamlining and accelerating the regulatory approval of medical products. An example of this was the creation of the Breakthrough Therapy Designation (BTD), which was designed to allow more interactions between the FDA and the company sponsor during the development and review process for drugs that treat serious conditions.

The pace at which the FDA has granted Emergency Use Authorizations (EUA) for Covid-19 diagnostics, therapeutics and vaccines over the past year is unprecedented. For non-Covid-related drug approval applications, the situation is quite different. As expected, some companies have encountered delays in approval, as FDA inspectors were unable to perform in-person inspections of manufacturing facilities that were necessary for approval. However, numerous drugs over the past year have received Complete Response Letters (CRL) – letters which indicate that the FDA has completed its review of the new drug application and cannot approve it in its present form – which have caught companies by surprise.

One major issue is that correspondence between the FDA and sponsors are confidential, so we must rely on corporate management teams to truthfully disclose the contents of

the CRL and any prior communications. Reasons cited by the FDA for not approving the drugs include the need for longer-term data and issues with safety, efficacy and data analysis. Frustrated corporate executives have indicated that the FDA changed requirements (after previously agreeing to a study design or analysis) and/or they had no indication that the FDA had concerns about safety and/or efficacy until they received notice that the FDA was unable to commence product labeling discussions, which is typically the last step in the review process. In one instance, this was quite shocking because the drug had received BTD so earlier indications of the FDA's concerns should have emerged. One sponsor went as far as to chronologically detail their interactions with the FDA on a webcast, during which they received no indications that their application was insufficient for approval.



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It is too soon to conclude that the FDA has become “less industry-friendly”. Similar to the rest of world, the agency had to adapt to working in a primarily remote environment and resources have shifted to Covid-related reviews. Telephone calls between the FDA and management do not provide the non-verbal cues available at in-person meetings. Most importantly, it is imperative that companies submit applications with strong datasets – once again, we rely on management to fully disclose details and sometimes these issues do not come to light until the receipt of a CRL or during an FDA Advisory Committee meeting. A good example is a biotech company’s recent disclosure that the

data they revealed to investors two years ago was incorrect. An upcoming FDA decision on an Alzheimer’s disease drug (June 7, 2021) could provide some insights into the FDA’s disposition – Alzheimer’s is a significant unmet medical need and this drug would be the first to slow disease progression. However, the clinical data set was mixed, with one study demonstrating efficacy while another did not. A panel of FDA advisors voted against approval in November 2020. It should also be noted that Janet Woodcock became Acting Commissioner of the FDA in January with the incoming Biden Administration. As such, the true direction of the FDA may be unknown until a permanent Commissioner is appointed.

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