Data Release in the Public Interest

Clinical trial data informs just about everything we do as physicians. There have been several instances where the results from a controlled clinical trial in a large population of patients led to a rapid change in the way retinal diseases are managed. The Macular Photocoagulation Study and ETDRS easily come to mind, as well as seminal work by the DRCR.net—in each instance, the standard of care was either established or altered for the betterment of patient care.

At the recent American Academy of Ophthalmology (AAO) Annual Meeting, data from yet another critical study, DRCR.net Protocol T, trickled into the pubic sphere. Unlike the data releases from the majority of previous studies, however, the data were shared with the study's corporate cosponsors, which then in turn prepared press releases to inform the public (or, more appropriately, investors) of the top-line outcomes.

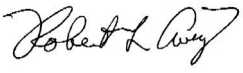
What we retina physicians heard was that the DRCR.net shared its data with the company sponsors because they had a right to review the data before it was published. However, once the companies were made aware of data that might have a material effect on its stock price, they felt obligated to inform investors (to obviate insider trading). Yet, per a rule of the National Eye Institute (NEI), which also sponsored the study, the full data could not be presented before publication so as to reduce the potential for bias.

What resulted is that we physicians, the end users of the products being studied, and the ones who must make informed decisions every day in the clinic, were only able to interpret the data through the prism of corporate press releases—and yet, a core principle of studies supported at least in part by tax payer money is that they are designed to reduce the potential for industry influence. The confused release of this critical data wound up creating rather than preventing bias, especially because the press releases were not consistent—for example, reporting differing accounts of the number of injections needed with the different agents.

The substantial confusion was reminiscent of the data release from the CATT, when investigators and coordinators were informed a few days before planned publication and release, but due to leaked information to the lay press, the publication date had to be moved up and announcement plans cancelled.

What is most frustrating in this scenario is that the presentation of only the top-line results through the lens of conflicting corporate press releases without proper context could influence physicians' decision making. The NEI's rule to prevent presentation of any results until full publication is well intentioned; however, had the DRCR.net been able to present the data as a late breaker at the AAO Annual Meeting, we clinicians would have much more clarity and would know how to interpret the results. Asking physicians to make decisions with incomplete data stitched together from conflicting corporate press releases is reckless, and it is certainly not in the best interest of the public.

Simply put, there needs to be a better system for releasing data from large-scale clinical trials. Protecting against insider trading is crucial. Ensuring that companies cannot influence outcomes of clinical trials is essential. But the NEI's rule preventing presentation of results before publication has once again backfired, and its policy needs to be revisited. ■



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