Support AllTrials Essential Call for Data Disclosure

Advocates from the Treatment Action Group (TAG) explain why results of clinical trials should be more transparent.

August 12, 2013 By Tim Horn and Richard Jefferys

When your doctor prescribes you a drug, you'd like to think that his or her decision is informed by results from all of the clinical trials that were conducted prior to the drug's approval. But that is not always the case. There are many examples of pharmaceutical companies keeping less favorable data under wraps, leaving a sunnier picture of safety and efficacy in public view, while clouds of uncertainty remain hidden behind the horizon of corporate confidentiality.

Ben Goldacre, a British physician and researcher, describes the problem in detail in his 2012 book, Bad Pharma. He notes that while pharmaceutical companies are generally required to present all available data to regulatory agencies, such as the U.S. Food and Drug Administration (FDA), when they seek approval for a drug, that's generally where the legal responsibilities end—the data do not need to be published in journals read by researchers or health care providers, results do not need to be shared with other health agencies responsible for public health initiatives, and additional studies conducted after approval may never be reported to the FDA.

Currently, roughly half of all clinical trials conducted and completed never get published; clinical trials with positive results are about twice as likely to be published compared with studies yielding negative results; and less than one in four clinical trials required to be listed with clinical trials registries (e.g., ClinicalTrials.gov) and report synopses of results within a year of completion actually do so.

The AllTrials initiative, launched earlier this year, aims to resolve this unacceptable situation by making sure that all clinical trial results are reported. The initiative is the brainchild of Ben Goldacre and several collaborating organizations, and has already received a multitude of high-level endorsements. Many HIV/AIDS organizations have signed up in support, including amfAR, Test Positive Aware Network, Stop AIDS Campaign, the AIDS Treatment Activists Coalition, the European AIDS Treatment Group, HIV i-Base and Treatment Action Group. To read full list of supporters, click here.

So far, however, only one major pharmaceutical company is listed: GlaxoSmithKline (GSK). (Boehringer Ingelheim has suggested it will move to comply with the call for data transparency, but stopped short of an endorsement.) Of greater concern, a July 21 article in the Guardian newspaper by Ian Sample reported on a leaked memorandum indicating that the two main pharmaceutical trade organizations—the European Federation of Pharmaceutical Industry Associations (EFPIA) and the Pharmaceutical Research and Manufacturers of America (PhRMA)—are crafting a strategy to oppose AllTrials, including "mobilizing patient groups" to oppose the initiative.

Although several companies, including GSK, Roche and Boehringer Ingelheim, have distanced themselves from this last-ditch attempt to maintain the status quo, the scenario of the trade associations stepping up to do the industry's dirty work is a familiar one for AIDS activists. A little over a decade ago, when the battle for access to cheap generic HIV drugs in the developing world was being fought, the trade associations representing brand-name pharmaceutical companies relentlessly generated spurious talking points with the aim of undermining activist efforts.

PhRMA went so far as to create a specific website—world.phrma.org—to promote this shameful propaganda; the site is happily now defunct, but thanks to the Wayback machine, click here to view its self-serving claims. The website is no more because PhRMA lost this battle, and millions of lives are now being preserved because of global access to generic HIV drugs.

Activists are working to ensure that any rearguard action against AllTrials by pharmaceutical trade associations will be similarly doomed. News of the scheming by PhMRA and EFPIA has provoked an immediate response from the European Patients Forum, the European AIDS Treatment Group, the European Cancer Patient Coalition and a broad coalition of HIV/AIDS advocates and advocacy organizations. To read the sign-on statement, click here.

We urge all readers to visit the AllTrials website. Click here to learn about the initiative and click here to sign up in support.

Richard Jefferys and Tim Horn are staff members of the Treatment Action Group (TAG). Jefferys is the coordinator of the Michael Palm Basic Science, Vaccines and Prevention Project. Horn is the HIV project director. Bad Pharma: How Drug Companies Mislead Doctors and Harm Patients by Ben Goldacre is published in the United States by Faber & Faber.

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http://beta.docker.poz.com/article/alltrials-initiative-24368-2801