US Health Officials propose greater transparency in clinical trials

By ACSH Staff — November 21, 2014

On Wednesday, the U.S. Department of Health and Human Services (DHHS) proposed a plan to significantly increase the information reported on clinical trials related to drugs, devices, and other interventions. The proposed plan would apply to the National Institutes of Health (NIH) publicly accessible database, ClinicalTrials.gov.

Currently, drug companies are allowed to withhold data, including results they consider unfavorable, from the public. Of the almost 180,000 studies registered on ClinicalTrials.gov, summary results are available for only about 15,000. Although a 2007 law requires drug companies to submit summary results within 1 year of the completion of a trial, this requirement only applies to drugs and devices approved by the FDA. Under the new plan, companies will also be required to report results for products that are not FDA approved.

The goal of the proposed requirements, says the HHS [1], is to make data available that could be useful to researchers to help them avoid duplicating trials, and also to fulfill the ethical responsibility to people who volunteer for trials. While Kay Dickersin, the director of the Center for Clinical Trials at the Johns Hopkins Bloomberg School of Public Health, praised the steps being taken towards better transparency, she states [2] there are still disappointments. For example, the proposals do not require researchers to reveal details of study protocols, such as what endpoints the study aims for.

It has been estimated that this proposal would add up to 150 extra summary reports per week to the database, on top of the 100 summaries currently being received each week, closing important gaps that are often left open in drug companies self-interest. [The proposed rule] would help eliminate unnecessary duplicative trials, advance biomedical innovation, and provide the public with a much richer understanding about the clinical trials for these products, says FDA Commissioner Dr. Margaret A. Hamburg.

ACSH’s Dr. Gil Ross had this comment: While in theory, shining light on the huge quantity of clinical trial data now hidden sounds like a benefit for scientists, the public and especially trial study subjects, I fear that the veritable information dump that will result will prove too unwieldy to
really add to our overall fund of knowledge. Of course, interested researchers and patients may find their way to the important nuggets of useful information buried in the mines of data, so the pluses may outweigh the minuses, which are basically the time and effort it will take to publish all that information.

I would like to add that I find it interesting that the DHHS is calling for more transparency, while the EPA’s stalwart defenders in the House of Representatives are fighting tooth and nail to keep that agency’s data secret. Maybe someone in authority should get them together.