

Drugs in the News 7/8/09 -The Value of FDA New Drug Approval Packages

A Commentary in this morning's *Journal of the American Medical Association* (JAMA) about Food and Drug Administration (FDA) approval packages for new drugs concludes:

“At the time they are performed, regulatory agency reviews are the most complete and accurate syntheses of clinical trial data available—it is time to make better use of them.”¹

The Center for Drug Information and Research (CDIR) has long held the view that it is no longer possible to conduct an independent review of the therapeutic value of a new drug by relying exclusively on the peer reviewed medical literature because of the high probability of publication bias. Recent research indicates that only about 50% of the randomized clinical trials (RCTs) submitted to the FDA as part of new drug approval process are ever published. Those that are not published are generally negative.² This results in a body of published literature that gives an overly optimistic impression of the therapeutic value of new drugs placing in question the validity of systematic reviews, meta analyses, and clinical practice guidelines.

The utilization of FDA documents is required for the Capstone Course students at the Erie campus in their evaluations of the therapeutic value of new drugs.

The JAMA Commentary is attached using the Fair Use provisions of US Copyright Law.

Reference List

- (1) O'Connor AB. The Need for Improved Access to FDA Reviews. *JAMA* 2009; 302(2):191-193.
- (2) Rising K, Bacchetti P, Bero L. Reporting bias in drug trials submitted to the Food and Drug Administration: review of publication and presentation. *PLoS Med* 2008; 5(11):e217.

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