

### References for Module 3

- Abboud, L. (2004, June 18). Drug makers seek to bar "placebo responder" from trials. *Wall Street Journal*, pp. B1, B5.
- Avorn, J. (2007). Paying for drug approvals—Who's using whom? *New England Journal of Medicine*, 356 (17), 1697-1700.
- Avorn, J. (2004). *Powerful medicines: The benefits, risks, and costs of prescription drugs*. New York: Knopf.
- Ballentine, C. (no date). *Taste of raspberries, taste of death: The 1937 Elixir Sulfanilamide incident*. Retrieved May 20, 2008 from: [www.fda.gov/oc/history/elixir.html](http://www.fda.gov/oc/history/elixir.html)
- Beutler, L.E., & Malik, M. (2002). *Rethinking the DSM: A psychological perspective*. Washington, DC: American Psychological Association.
- Breggin, P. R. (2002). Fluvoxamine as a cause of stimulation, mania, and aggression, with a critical analysis of the FDA approved label. *International Journal of Risk and Safety in Medicine*, 14, 71-86.
- Charney, D. S., Barlow, D. H., Botteron, K., Cohen, J. D., Goldman, D., Gur, R. E., Lin, K-M., Lopez, J. F., Meador-Woodruff, J. H., Moldin, S. O., Nestler, E. J., Watson, S. J., & Zalcman, S. J. (2002). *Neuroscience research agenda to guide development of a pathophysiologically based classification system*. In D. J. Kupfer, M. B. First, & D. A. Regier (eds.), *A research agenda for DSM-V* (pp. 31-84). Washington, DC: American Psychiatric Association.
- Cohen, D. (2002). Research on the drug treatment of schizophrenia: A critical appraisal and implications for social work education. *Journal of Social Work Education*, 38(2), 1-24.
- Cohen, D., & Jacobs, D. (2007). Randomized controlled trials of antidepressants: Clinically and scientifically irrelevant. *Debates in Neuroscience*, 1, 44-54.
- Emslie, G. J., Heiligenstein, J. H., Wagner, K. D. et al. (2002). Fluoxetine for acute treatment of depression in children and adolescents: A placebo controlled, randomized clinical trial. *Journal of the American Academy of Child and Adolescent Psychiatry*, 41, 1205-1215.
- Fisher, S., & Greenberg, R. P. (1993). How sound is the double-blind design for evaluating psychotropic drugs? *Journal of Nervous and Mental Disease*, 181, 345-350.
- Food and Drug Administration, Center for Drug Evaluation and Research. (1998). *Guidance for industry: Providing clinical evidence of effectiveness for human drug and biological products*. 6, 9. Available at:

<http://www.fda.gov/cder/guidance/1397fnl.pdf>

- Geddes, J., Freemantle, N., Harrison, P., & Bebbington, P. (2000). Atypical antipsychotics in the treatment of schizophrenia: Systematic overview and meta-regression analysis. *British Medical Journal*, *32*, 1371-1376.
- Gellad, Z. F., & Lyles, K.W. (2007). Direct-to-consumer advertising of pharmaceuticals. *American Journal of Medicine*, *120* (6), 475-480.
- Goozner, M. (2004). *The \$800 million pill: The truth about the cost of new drugs*. Berkeley, CA: University of California Press.
- Greenhill, L. L., Vitiello, B., Abikoff, H., Levine, J., March, J. S. et al. (2003). Developing methodologies for monitoring long-term safety of psychotropic medications in children: Report on the NIMH conference, September 25, 2000. *Journal of the American Academy of Child and Adolescent Psychiatry*, *42*(6), 651-655.
- Harris, G. (2004, December 6). At FDA, strong drug ties and less monitoring. *The New York Times*.
- Hawthorne, F. (2005). *Inside the FDA: The business and politics behind the drugs we take and the food we eat*. New York: Wiley.
- Healy, D., & Farquhar, G. (1998). Immediate effects of droperidol. *Human Psychopharmacology*, *13*, 113-120.
- Heres, S., Davis, J., Maino, K. et al. (2006). Why olanzapine beats risperidone, risperidone beats quetiapine, and quetiapine beats olanzapine: An exploratory analysis of head-to-head comparison studies of second-generation antipsychotics. *American Journal of Psychiatry*, *163*, 185-194.
- Hollon, M.F. (1999). Direct-to-consumer marketing of prescription drugs: Creating consumer demand. *JAMA*, *281*, 382-384.
- Hundley, K. (2007, July 1). Companies run trials of drugs they invest in: Critics say a conflict of interest couldn't be more clear, but the FDA doesn't think so. *St. Petersburg (FL) Times*.
- Jacobs, D., & Cohen, D. (1999). What is really known about psychological alterations produced by psychiatric drugs? *International Journal of Risk and Safety in Medicine*, *12*(1), 37-47.
- Jureidini, J. N., Doecke, C. J., Mansfield, P. R., Haby, M. M., Menkes, D. B., & Tonkin, A. L. (2004). Efficacy and safety of antidepressants for children and adolescents. *British Medical Journal*, *328*, 879-883.

- Lasser, K.E., Allen, P.D., Woolhandler, S.J., Himmelstein, D.U., Wolfe, S.M., & Bor, D.H. (2002). Timing of new black box warnings and withdrawals for prescription medications. *JAMA*, 287(17), 2215-2220.
- Lieberman, J. A., Stroup, T. S., McEvoy, J. P., Swartz, M., Rosenheck, R. A. et al. (2005). Effectiveness of antipsychotic drugs in patients with chronic schizophrenia. *New England Journal of Medicine*, 353, 1209-1223.
- Moncrieff, J., & Cohen, D. (2005). Rethinking models of psychotropic drug action. *Psychotherapy & Psychosomatics*, 74, 145-153.
- Moore, T.J., Cohen, M.R., & Furberg, C.D. (2007). Serious adverse drug events reported to the Food and Drug Administration, 1998-2005. *Archives of Internal Medicine*, 167(16), 1752-1759.
- Ng, R. (2004). *Drugs—From discovery to approval*. New York: Wiley.
- Quick, J. (2001). Maintaining the integrity of the clinical evidence base. *Bulletin of the World Health Organization*, 79, 1093.
- Rivas-Vazquez, R. A., & Mendez, C. I. (2002). Overview of the drug approval process. *Professional Psychology: Research & Practice*, 33 (5), 502-505.
- Safer, D. J. (2002). Design and reporting modifications in industry-sponsored comparative psychopharmacology trials. *Journal of Nervous and Mental Disease*, 190(9), 583-592.
- Sharav, V. (2007, March 20). The damaging impact of PDUFA and why it should be repealed. Infomail of the Alliance for Human Research Protection. Available at: <http://www.ahrp.org/cms/content/view/498/94/>
- Smith, R. (2005) Medical journals are an extension of the marketing arm of pharmaceutical companies. *PLoS Medicine*, 2(5), e138.
- Smith, R. (2003). Medical journals and pharmaceutical companies: Uneasy bedfellows. *British Medical Journal*, 326, 1202-1205.
- Strom, B. L. (2006). How the US drug safety system should be changed. *JAMA*, 295(17), 2072-2075.
- Turner, E. H., Matthews, A. M., Linardatos, E., Tell, R. A., & Rosenthal, R. (2008). Selective publication of antidepressant trials and its influence on apparent efficacy. *New England Journal of Medicine*, 358, 252-260.