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ANNOTATIONS

Fry-Revere S, Malmstrom DB.

More regulation of industry-supported biomedical research: Are we asking the right questions? *Journal of Law, Medicine and Ethics* 2009;37(3):420-430. • According to Fry-Revere and Malmstrom, there is not strong evidence to suggest a correlation between industry-supported biomedical research and poor or inappropriate clinical outcomes. Alternatively, they argue that industry having a financial stake in the trial outcomes may in fact lead to better, more careful research. Attempts to limit industry financing of biomedical research could have many negative effects, including making drugs that could save lives less readily available. Critics often falsely conflate conflicts of interest with conflicts of obligations, thus leading some to assume that conflicts of interest are inherently problematic by virtue of the fact that conflicts of obligation can indeed be ethically difficult. The authors suggest patients should be better empowered to ask poignant questions, rather than assuming that physicians always know what is in their best interests.

Rabins P, Appleby BS, Brandt J, et al. Scientific and ethical issues related to deep brain stimulation for disorders of mood, behavior, and thought. *Archives of General Psychiatry* 2009; 66(9):931-937. • The authors reported on 16 consensus-created guidelines aimed at the design and implementation of clinical trials related to deep brain stimulation (DBS) for disorders of mood, behavior, and thought (MBT) and the protection of participants of such studies. The guidelines emphasize the need for continued research into the efficacy and safety of DBS in comparison to existing treat-

ments, the importance of multidisciplinary approaches to research, and the establishment of research protocols that are sensitive to the social and cultural perceptions of MBT disorders. In order to ensure appropriate consent, they recommend standardization of forms, the inclusion of a "close third" (such as a caretaker) in the consent process, and full disclosure of what is and is not currently known about DBS. Long-term studies of the safety of DBS and a registry of existing data will help to illuminate the prospects of effective DBS use. The implementation of these guidelines will require long-term commitment from clinicians, investigators, institutions, industry, funders, and government regulatory agencies.

Wynia M, Boren D. Better regulation of industry-sponsored clinical trials is long overdue. *Journal of Law, Medicine and Ethics* 2009;37(3):410-419. • Wynia and Boren argue that many recent studies show industry-funded trials tend to produce results that favor the company sponsoring the trial as a result of inappropriate trial design and misleading or incomplete analysis and reporting of results. Although regulatory practices—such as better training of clinicians and easier mechanisms for whistle-blowing—may help ensure accountability and safety of clinical trials, there is little to prevent manipulation to increase the likelihood of getting favored results. They contend that the best way to restore trust and promote high-quality, medically relevant clinical trials is to install a professional firewall between industry funding and final decisions about clinical trial design, conduct, analysis, and reporting.