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Breakthrough drugs and sponsorless CME
How the FDA can help

The FDA, with its complex and challenging mission, is constantly caught between Congress' scrutiny and the public's demands. It does not need nagging about doing more, but I'd like to suggest how the FDA could stimulate psychiatric drug discovery and encourage continuing medical education (CME). I propose 2 creative ideas as a long-time researcher with thorough knowledge of controlled clinical trials and an educator with extensive CME involvement.

Could extending pharmaceutical companies' patents give us innovative treatments and independent CME funding?

Reward innovation in drug discovery

Like all psychiatric clinicians, I am painfully aware that many DSM-IV-TR disorders have no FDA-approved medications. Within each of the existing classes of approved psychotropics—antipsychotics, antidepressants, and mood stabilizers—drugs tend to have similar mechanisms of action. Further, most available psychotropics are of limited effectiveness, and hardly any major therapeutic breakthroughs in psychiatry have been achieved in the past 50 years. Pharmaceutical companies seem content to settle for the safety of developing "me too" drugs and yet more formulations of existing agents.

Incentives can be powerful motivators for individuals and organizations to excel. So, to spur innovation by the pharmaceutical industry, I urge the FDA to extend the patent lives of breakthrough drugs (only those with completely new mechanisms of action) from the current 17 years to 25 years. I believe this very lucrative "carrot" will motivate every drug company to mobilize its resources and invest heavily in financially risky but innovative research and development.

Excellence deserves to be differentially rewarded, and outstanding drug discovery should be no exception. Promising an 8-year patent "bonus" extension could generate a tsunami of first-in-class drugs and cures for diseases that today's medications treat inadequately or not at all. Yes,

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the pharmaceutical companies would make higher profits, but the ultimate winners would be patients whose lives are improved and extended by these novel medications.

Support CME collaboratively

A second idea occurred to me after I read the Josiah Macy, Jr. Foundation's November 2007 report recommending the unthinkable: that CME be completely divorced from the financial life-blood of pharmaceutical sponsorship! More than 60% of financial support for accredited CME activities in medicine comes from pharmaceutical and medical device companies ($1.45 billion of a total $2.4 billion in 2006).[1]

The Macy Foundation's report acknowledges that "abrupt cessation of all such support would impose unacceptable hardship" on many professional organizations and institutions, and it proposes a 5-year phase-out period.[1] This ban on commercial support would include grand rounds and symposia organized by medical schools, which provide almost no funds for CME in their limited budgets.

How can the FDA help? I propose that the FDA support CME nationwide by pooling pharmaceutical company contributions in a not-for-profit independent fund and appoint the Accreditation Council for Continuing Medical Education (ACCME) as overseer. The ACCME would evaluate applications from all specialties and allocate funds to support meritorious CME programs.

For each year that a pharmaceutical company contributes to the CME fund, the FDA would grant a 3-month patent extension on all of the company's drugs. This extension could yield drug companies more than $1 billion in additional sales for blockbusters such as atypical antipsychotics.

CME could be adequately funded, but without today's perceived tarnish—whether deserved or not—of pharmaceutical influence. Pharmaceutical companies would no longer directly sponsor CME programs but would continue to be important philanthropic partners. Contributions from dozens of companies would fund the vital activities by which physicians and nurses keep pace with advances in the diagnosis and treatment of disease.

Your comments?

My suggestions are intended to start a dialogue about financial support for two critical needs in psychiatry: research to develop new psychiatric medications and support for continuing education. To advance, we must break with stale models and exploit reasonable solutions. I invite you to send your comments to me at henry.nasrallah@CurrentPsychiatry.com.

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Reference

1. Fletcher SW. Chairman's summary of the conference. *Continuing education in the health professions: improving healthcare through lifelong learning*. New York: Josiah Macy Jr. Foundation; 2008. Available at www.josiahmacyfoundation.org.