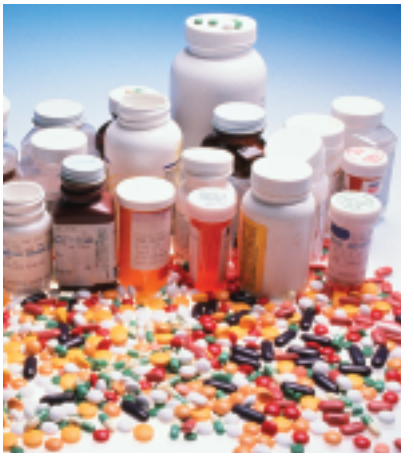
Curtis C. Verschoor, CMA, Editor

Ethics Issues Still Dog Pharmaceutical Industry

This editor believes it's time that the U.S. pharmaceutical industry rethinks a number of its strategies, including the apparent priority of "profits over people." This is needed not just to serve the public interest, but also because of the effects that continually increasing healthcare costs have on U.S. companies. In response to concerns about rising costs and continuing worries about patient safety, the U.S. Government Accountability Office (GAO) undertook several studies to examine issues relating to the pharmaceutical industry.

One 2006 GAO study, "New Drug Development: Science, Business, Regulatory, and Intellectual Property Issues Cited as Hampering Drug Development Efforts," investigated the cause of declining research productivity in the pharmaceutical industry. Though significant scientific advances continue to raise hope for the prevention, treatment, and cure of serious illnesses, the GAO reports that the number of completely new drugs being produced has actually been declining—despite steady increases in research and development expenditures. In the words of the Food and Drug Administration (FDA), the federal agency responsible for approving the sale of new drugs, "Innovation in the pharmaceutical industry has become stagnant." Yet industry profits continue at their extremely high level.

The GAO analysis shows that annual research and development expenditures increased in inflation-adjusted terms from nearly $16 billion in 1993 to nearly $40 billion in 2004, a 147% increase. At the same time, the number of new drug applications (NDA) increased by only 38% and actually declined in the most recent years. Even more alarming, the predominant, and increasing, proportion of NDAs has been for "me-too" drugs that have very few chemical differences from existing older, noticeably cheaper drugs already on the market. The net effect of this declining productivity is an



increase in drug costs to consumers in exchange for little or no incremental medical benefit. According to the GAO, the number of innovative drugs representing important therapeutic advances for treating disease—those that are new molecular entities (NME)—increased by only 7% during the same period.

Examples of NDAs that don't involve innovation include a new formulation of a previously approved drug, a new salt of a previously approved drug, a new combination of two or more existing drugs, and a new manufacturer. Many times, pharmaceutical manufacturers put up with the high costs of testing and guiding these "new" drugs through the FDA regulatory bureaucracy in

IMAGE: PHOTODISC, INC.

order to reap the benefit of extended patent coverage. With a new patent, a maker can charge the highly inflated prices for which the U.S. market is legendary.

Some of the more blatant and callous examples of these consumer-gouging business practices include AstraZeneca's (AZ) re-branding of Prilosec, the heartburn medication, as Nexium. This occurred just as Prilosec was about to become generic. AZ used an expensive marketing campaign to hail the "new" drug (now it's purple!) as almost being a medical breakthrough—despite the lack of medical evidence to back up such a claim. Such strategy appears to be within the ethical boundaries of this company. Eli Lilly, after losing its Prozac patent, introduced an exact copy with a new color and called it Sarafem. Schering-Plough salvaged part of the market for its drug Claritin (Loratadine) by making minor changes to formulate it into Desloratadine, calling it Clarinex, a "new" and patentable drug.

According to FDA protocols, an NDA may be approved for sale if it exceeds only the very low bar of being more effective than a placebo for treatment of a disease. Manufacturers don't have to demonstrate that a new drug has greater effectiveness than an existing drug. In other words, a company doesn't need to prove that its new drug is medically advantageous to the consumer.

Because of the alleged high cost of research, the pharmaceutical industry has placed great strategic emphasis on creating high-priced "blockbuster" drugs that have the potential for wide usage. Yet the industry frequently gets the benefit of research performed by the taxpayer-supported National Institute of Health or various research universities at little or no cost.

In other cases, manufacturers exercise total control over the research used by the FDA in the approval process. Manufacturers design the protocols for clinical research, with favorable results used as marketing materials while adverse findings may be kept from public view. Merck, for example, is still fighting numerous Vioxx cases in which it is accused of not disclosing unfavorable results. Medical critic Mike Adams believes "the FDA has become the marketing department [for pharmaceutical firms] and simultaneously an opponent of the public."

Calls for the FDA to expend greater efforts to regulate drug use in years after their approval seem to have had insufficient effect. A 2007 GAO report, "FDA Needs to Further Address Shortcomings in its Postmarket Decision-making Process," provides additional recommendations, including expanding the FDA's authority to require manufacturers to conduct post-market studies to collect data on safety concerns. According to *AARP Bulletin*, under the current voluntary program, drug-makers have failed to conduct 71% of the post-market studies they promised to perform on already approved drugs.

Another 2006 GAO study, "Improvements Needed in FDA's Oversight of Direct-to-Consumer Advertising," looked into marketing practices in the industry. It showed that, from 1997 to 2005, direct to consumer (DTC) advertising of prescription drugs increased twice as fast as the costs of promotion to physicians or research and development efforts. The GAO concluded that DTC advertising prompts consumers to request advertised drugs from their physicians, who are generally responsive to the requests. This has contributed to increases in prescription drug utilization and, hence, drug spending. The United States is one of only two countries globally to allow DTC.

Though conversations with your physician are considered a good outcome of DTC, despite the risk of self-diagnosis, the GAO found that heavy consumer advertising resulted in increased use of advertised drugs when alternatives may be more appropriate. As noted above, even a "new" drug is very likely to be a me-too version that is medically little better than the drug it aims to replace.

Another negative aspect of consumer advertising is the increased safety risk brought on by the fact that new drugs don't have long testing periods before their release. In its 2006 study, "The Future of Drug Safety: Promoting and Protecting the Health of the Public," the Institute of Medicine recommends DTC advertising be restricted during the first two years a new drug is marketed because some of the health risks of new drugs still aren't fully understood.

The GAO report on advertising makes a number of recommendations designed to increase the efficiency of the FDA's oversight, but it doesn't significantly challenge the very important premise that television advertising is unable to utilize the FDA's most important regulatory tools: the written labeling and accompanying disclosures. Matters of usage limitations, warnings of side effects, risks of use, and contraindications can't be communicated to a consumer in a TV spot. The labeling and information sheet is written for physician use, with technical language not suitable for consumer understanding. When the FDA requires a page or two of fine print disclosures to accompany every one-page

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magazine advertisement, it's hard to accept the adequacy of the soothing TV voice-over blandly indicating that a product "is not for everyone."

Healthcare is a critically important cost element for American businesses. Forecasts indicate that it could consume 20% of GDP if current cost trends continue. America vastly overpays for the healthcare it receives! Creative solutions need to be considered to address the many causes of this rapidly growing expense.

One solution is to provide consumers a higher level of ethics from companies that deal with our personal mortality! ■

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