

Reduce Burdensome Regulation of Medicines and Medical Devices

Over the past century, American consumers have benefited from thousands of new pharmaceuticals and medical devices to help them combat disease, alleviate the symptoms of illness and infirmity, and improve their well-being. However, the public often demands that such treatments meet a near-perfect level of safety at bargain basement prices. In turn, Congress and the federal Food and Drug Administration (FDA) have steadily raised the regulatory hurdles that medical product manufacturers must clear before they can market a new treatment.

A strong dose of over-caution when the FDA approves new drugs and devices may sound like a virtue, but for patients in need of new treatments, regulatory over-caution can be deadly. Patients can be injured if the FDA approves a treatment that is later found to be unsafe, but they are also harmed when needed treatments are delayed by regulatory hurdles.

FDA, however, is predominantly focused on the first of these two risks, for political reasons. Agency approval of a drug or device that turns out to be unsafe will lead to front-page headlines and congressional hearings, while delay or denial of a needed new treatment stirs little public notice. Patients may suffer or die as a result of FDA delays, without them or their families ever knowing that a possible treatment exists, let alone that it was blocked by the

agency. As a result, the FDA is under constant pressure to assure the safety of new medical products, but under little pressure to speed up their availability.

Many doctors, patient groups, and public policy experts recognize that FDA's lengthy process for approving new drugs and devices often costs lives by denying patients potentially beneficial new treatments. Polls of medical specialists commissioned by the Competitive Enterprise Institute over the past 15 years have consistently found that majorities of doctors in various specialties believe that FDA is too slow in approving new medical products and that these delays mean that patients are not receiving the best possible care.

When making safety evaluations, the FDA is required, by statute, to determine the appropriate balance between patient safety and medical product effectiveness. But more thorough study of drugs and devices during clinical trials (both pre- and post-approval) has its own weaknesses. First, even very large clinical trials generally cannot include enough subjects to detect rare side effects. Second, large trials involve diverse populations with many subgroups that often are not easy to identify. Consequently, a few individual adverse events do not necessarily mean that a product is inherently unsafe for all patients. A given adverse event may not have

been caused by the treatment, or if it was, it may be confined to a small subpopulation.

Each patient is different from all others, both in physiology and in risk-level preference. Not only will a given drug or device affect each patient slightly differently, but each patient will place a different value on the product's benefits and the attendant risks associated with it. Therefore, treating the entire population of the United States as identical means that FDA inevitably makes regulatory decisions that will be too cautious for some and not cautious enough for others. Significant political pressure generally pushes the agency toward over-caution, and the end result is fewer new drugs and devices, as well as greater loss of life to what should be treatable illnesses. Those who view the FDA's approval process as too quick may freely choose to use only products that have been on the market for several years with a more well-established record of safety and efficacy. Unfortunately, those who seek access to medical products before the FDA has fully approved them have little or no choice.

Beginning in the early 1990s, the tremendous social cost of FDA overregulation had become apparent, so Congress and the agency took several steps to streamline the approval process. The Prescription Drug User Fee Act of 1992 sped up the drug approval process, saving an estimated 180,000 to 310,000 years of life for patients who relied on newly approved products. The 1997 FDA Modernization Act, for example, granted the agency authority to reduce the number of clinical trials needed for approval and to expedite the review of treatments

for serious conditions. But today, FDA is again under tremendous pressure from Congress and self-styled consumer advocates to slow down the approval process and to reject drugs that appear to offer only modest benefits or benefits for only small patient sub-populations.

In 2007, Congress passed the FDA Amendments Act, which provided the agency with additional authority to make pre- and post-market safety studies and clinical trials stricter. The Act also requires FDA to announce publicly even very minor or hypothetical safety concerns, which tends to raise undue alarm among patients. It also requires the agency to consider using Risk Evaluation and Mitigation Strategies for each new approved drug, which can restrict which doctors may prescribe new drugs, which patients may use them, and which pharmacies may fill certain prescriptions. Rather than increase drug safety, these changes, combined with the FDA's innate risk aversion, tend to harm patient health by reducing the availability of new medical products.

Individual patients and their doctors are in a far better position than the FDA to balance the risks and benefits of individual new treatments. The agency should focus on providing them with information rather than on restricting their choices. In forthcoming legislation, Congress should seek to accelerate the pace at which the FDA reviews new drug and device applications, and it should repeal many of the recent policies that make FDA regulation dangerously overcautious.

Greg Conko and Sam Kazman