Legal Opinion Letter

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DON'T DILUTE DRUG APPROVAL PROCESS WITH NON-SCIENTIFIC CRITERIA

by
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A recent article in the *Baltimore Sun* expressed overtly what some have been contemplating in smaller policy and academic circles: the federal Food and Drug Administration (FDA) is not devoting enough attention to our spiritual needs, concentrating as it does on purely scientific issues of drug safety and efficacy. Jonathan D. Rockoff, *Critics weigh in on FDA decisions*, BALTIMORE SUN, Jan. 9, 2006, at 1A. The article refers to unnamed critics who believe that the FDA should be taking non-science-based factors into its approval equation when deciding the worth of a new drug.

The FDA has already been severely criticized for not accomplishing its stated mission: to determine, based on the medical evidence accumulated over years of clinical trials, whether or not a new pharmaceutical entity warrants entry into our marketplace. Yet, the rumblings from "a growing number of critics" assert that there should be more to this decision than the mere summing up of benefits and risks of a drug, more than trying to figure out how many will be safely helped as opposed to the unknowable risk of adverse drug reactions. They call upon the FDA to take less firm criteria into account, under the headings of "ethical concerns" and "costs."

Ethical concerns on both ends of the ideological spectrum would come into play — some say these parameters have already infiltrated the agency. "Environmentalists" have deeply-held concerns about "cloned animals" producing meat, milk and even drugs. Many believe that new gene-splicing technologies are somehow unethical, and demand that these methods be abandoned. Activists of both the conservative and liberal camps espouse concern that new drugs might lead to behavioral changes in some segments of our population of which they do not approve. Issues already causing havoc because of the overlap of science and ethics include the Plan B "morning after pill," the new human papillomavirus vaccine against sexually-transmitted cervical cancer (which should be administered to adolescent girls to be most effective), and silicone breast implants, among others. In the not-too-distant future, the approach towards evaluating stem-cell treatments is going to be difficult enough if it remains science-based — if moral, religious and ethical issues intrude into the evaluation process, it is likely the discord provoked will cause the whole process to simply grind to a halt.

The FDA has been the last bastion of science-based public health policy over the years, in contrast to such politically-correct agencies as the Environmental Protection Agency, whose agenda has largely been dictated by popular whim since its inception in 1972. This is so because the issue of how many micrograms of what pollutant kills how many rats is of little concern to the public at large, while everyone either takes or will take some FDA-approved drug at some point. Thus, the intricacies of drug approval is of concern to all Americans to a greater or lesser degree, depending on their health and that of their loved ones.

Therefore, when someone tries to persuade us that we would benefit from the FDA leaving the true science path and venturing out into the uncharted waters of "ethics," as this concept pertains to drug

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evaluation, it becomes big news. Those folks — primarily bioethicists and environmental activists — say that the crescendo of new medical advances in recent years warrants taking these formerly peripheral issues into account. It appears that they believe there is now too much science at the FDA, and the agency needs to focus on philosophical issues, rather than sticking to the "mundane" concerns of liver toxicity and gastrointestinal bleeding from ADRs (adverse drug reactions, commonly called "side effects").

The notion that the FDA needs to consider more than drug safety and efficacy is absurd. They have their hands full trying to get the science right; thankfully, despite the bad publicity since the Vioxx withdrawal in September 2004, they get it right much more often than not. For this, we should all be thankful: our FDA is the most stringent regulatory body in the world, which largely accounts for the fact that our pharmacopeia is so safe and contributes to our enviable record of longevity and good health.

Of course, this being America, many will demand that our drugs be completely safe, always effective, and cheap. That will never happen, of course — nothing is completely safe, no matter how many studies are done. The risks that will accrue after a drug is released to the marketplace cannot be known in the small, earlier stage trials. Mistakes happen, drugs are withdrawn, but the tried and true FDA evaluation system works well. In 2000, a diabetes drug called Rezulin was in wide use, although it was known to be associated with some liver toxicity under certain circumstances. However, it was the only drug of its kind available and it helped many diabetics live healthier lives. So-called "consumer advocates" called for the drug's withdrawal, but the FDA resisted. When two new, similar drugs were approved, with better safety profiles, Rezulin was pulled from the market. That is how the FDA is supposed to work, for the greatest good of the greatest number.

There are already too many non-science factors working on FDA drug professionals. Recent pressures have come from unexpected quarters: Congress and local officials demanding cheap imported drugs want the FDA to ignore federal laws on this subject, failing to be cognizant of the fact that importing drugs necessarily also imports foreign price controls, which would send our robust pharmaceutical industry in the direction of the moribund drug developers in the EU and Canada. The intrusion of "ethics" into the drug evaluation process would lead to increased regulation of the drug industry, probably to the point of regulating it out of existence.

Expected political activity comes from the plaintiffs' bar, which has largely decimated the vaccine industry over the past forty years. Vaccine makers have been forced out of business in droves due to strict liability concerns. Paradoxically, the rampant bird flu hysteria has lent the FDA some political cover for relaxing the vaccine-approval regimen. This, combined with the new federal policy regarding tort reform in general, and vaccines specifically, may allow vaccine research and manufacturing to recover some of its losses. How would ethics apply to the FDA approval process in the face of a viral pandemic?

When the slippery slope of "bioethics" is added to this mix, the possibilities for mischief abound. Whose ethics will be applied? Are the ethics of a professor of bioethics of a higher plane than those of the commonfolk? Who will make these decisions at the FDA, and where in the approval process will it be inserted? Most assuredly, majority does not rule when it comes to making scientific assessments, although the FDA does have public commentary as part of the process.

And as for the cost of new drugs to society, how will it be determined if a new cancer or AIDS drug is "worth it?" How much is a human life worth? Sometimes such decisions do indeed have to be made — but certainly not as part of the drug approval process. These decisions must be made by the patient and his or her family, and also by insurers, including Medicare and Medicaid. Costly end-of-life treatments may be worthwhile in some circumstances, but not in others, for many reasons. But not if the drug is not available at all, due to a rejection for excessive cost by the FDA.

Let the FDA be the FDA — they have a full plate of critically important work to do. And now they have to deal with the new "transparency" of publishing early-stage clinical trial data, and the new Drug Oversight Board looking over their shoulder, aiming for unattainable perfection. To those who say that drug science is too important to be left to the scientists, we say it's too important not to be.

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