

Commentary by Maxwell J. Mehlman:

Re: What is different about these technologies that make them different from a regulatory standpoint? What are the risks inherent in these technologies that are not susceptible to regulatory controls used for other technologies?

The regulatory issues raised by biomedical enhancement vary depending on the enhancement technologies in question. Some fall squarely within the purview of the FDA. For example, the agency has approved enhancement uses for a drug (Botox) and for several medical devices (liposuction, contact lenses, and breast implants). But even for these products, FDA oversight is limited. At most, FDA approval is based on efficacy and safety data from clinical trials, which do not reflect real world use. The agency is working to expand its ability to monitor how well drugs and devices work after they are approved, but so far it has made little progress. Moreover, in some cases, such as contact lenses for enhancement use, the FDA approves products without full-scale clinical trials.

More importantly, a physician lawfully may prescribe a product that has been approved for one purpose for any other purpose. A number of drugs, including HGH, EPO, and modafinil, are known to be used as enhancements in this “off-label” manner. In these cases, clinical studies that the FDA relied upon to approve the drugs for their therapeutic uses may not apply to their enhancement uses.

In addition, the FDA has either no authority or expertise to consider some of the most troubling ethical and social issues raised by enhancements under its jurisdiction. One is the risk that some people, including athletes, employees, members of the military, and children, may be forced or pressured to use enhancements that seem unreasonably dangerous. Another is the risk of social disruption if enhancements that were important for success were available only to the well-to-do. A third is the lack of ethical guidance on how to conduct enhancement experiments in human subjects. Even if the FDA attempted to respond to these challenges, its budget is tight, and it is not clear that it can fulfill its current missions adequately, much less take on significant new responsibilities.

Other enhancements are subject to even less regulatory oversight. Dietary supplements, such as creatine, may be marketed without FDA approval. Dietary supplement ads are subject to oversight by the Federal Trade Commission (as well as some state regulation), but again the available resources are limited. The FDA technically has jurisdiction over some aspects of genetic testing, including genetic testing for enhancement purposes such as ACTN3, but it has done little in this area. Finally, a major class of enhancement interventions is entirely beyond FDA jurisdiction because it is considered “the practice of medicine.” This includes cosmetic surgery (unless it involves the use of a new medical device). Despite this, the FDA has asserted jurisdiction over several medical practices, such as gene transfer and cloning, which might be used for enhancement purposes, but it is not clear that the agency’s position would survive legal challenge.