

Non-Therapeutic Uses and the FDA

Patricia J. Zettler

Associate Professor, Georgia State University College of Law
pzettler@gsu.edu

Abstract

Although debates about the FDA's premarket authorization of new drugs and devices often—and understandably—focus on the agency's oversight of important therapies for patients, the FDA's gatekeeping role also extends to non-therapeutic uses of drugs and devices. For example, technologies intended to enhance the cognitive or athletic performance of healthy individuals, breast implants intended as solely cosmetic improvements, drugs that eliminate frown lines, and recreational drugs used to produce a “high” or some other biological impact might all fall within the agency's jurisdiction. This Article explores how the FDA has implemented its premarket review authorities for such non-therapeutic uses of drugs and devices, arguing that, at least for appearance-enhancing uses, the agency has not treated non-therapeutic uses significantly differently than therapeutic uses. The agency has authorized non-therapeutic uses even when they are associated with small benefits, serious risks, or both, and will accept various forms of effectiveness evidence for non-therapeutic uses including subjects' own evaluations of the effects. This approach to authorizing non-therapeutic uses of drugs and devices, at first blush, may seem inconsistent with the FDA's role as a consumer protection agency charged with protecting and promoting the public health. This Article, however, argues that numerous different approaches to regulating non-therapeutic uses could be consistent with the consumer protection and information-related purposes of premarket review.