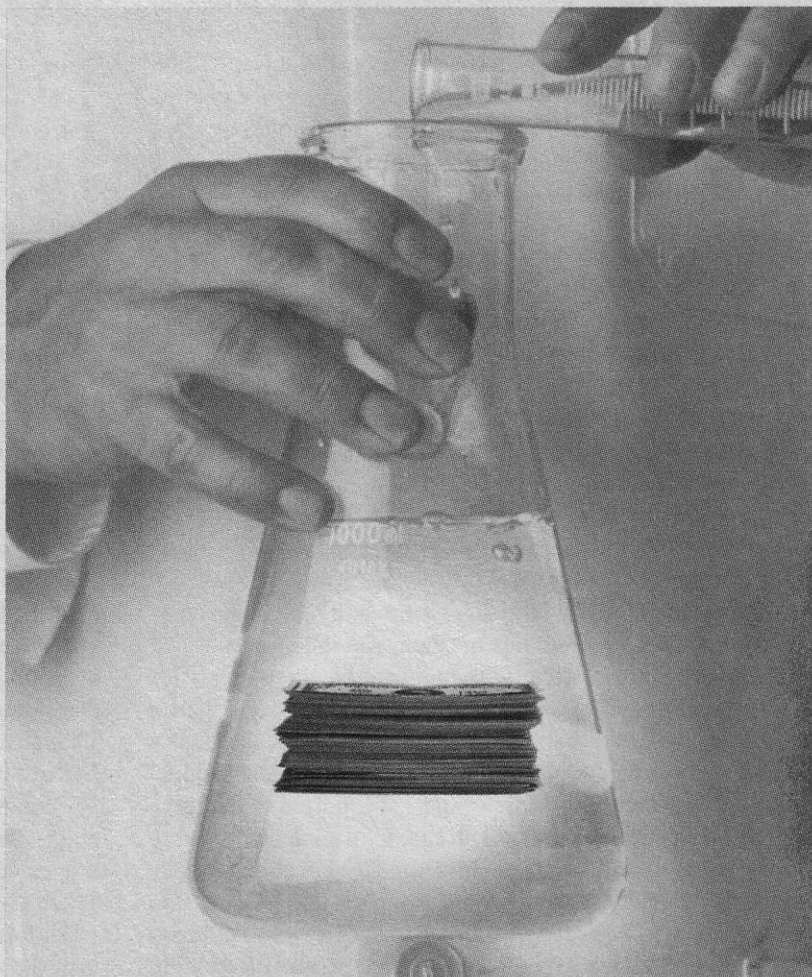


ARTICLES

Money + Science = Ethics Problems on Campus

by DAVID SHENK



The third most dispensed drug in the United States is a thyroid medication called Synthroid. Eight million Americans suffering from hypothyroidism take Synthroid every day, paying a premium for Knoll Pharmaceutical's top-selling brand name rather than buying the much less expensive generic alternative. As is the case with most brand leaders, Knoll's enormous success with Synthroid is entirely dependent on its continuing ability to convince its users and the healthcare community that its drug is worth the extra cost. This the company has done brilliantly for decades, despite any real proof of Synthroid's superiority.

In the late eighties, the company (then known as Boots Pharmaceutical) had good reason to believe it was on the verge of obtaining such proof. A clinical pharmacist at the University of California, San Francisco, named Betty Dong published a limited study that strongly suggested Synthroid would beat out its competitors in a blind, randomized trial. The company approached Dong, offering her the full \$250,000 needed to pay for such a long and complex study.

Alas, the study backfired on the company. To the surprise of nearly everyone, including Dong, the results suggested that Synthroid was no more or less effective than three much cheaper

competitors. All four were what scientists call "bioequivalent."

But the company had a trump card. As the study's sponsor, it had not only been able to design the protocols of the drug trial; it also had exclusive access to the prepublished results of the study as well as final approval over whether the study could ever be made public. Not surprisingly, with the results so threatening to its marketing efforts, Knoll set out to thwart the study. In addition to delaying its publication in a scientific journal by many years, effectively destroying the relevance of its data, the company also undermined the study's message by pre-emptively publishing the UCSF data in a different journal with a different (much friendlier) conclusion. Then Knoll waged a massive PR campaign against the real study, "Bioequivalence of Generic and Brand-name Levothyroxine Products in the Treatment of Hypothyroidism," by Betty J. Dong et al., after it was finally published in the spring of 1997 in the eminent *Journal of the American Medical Association (JAMA)*.