It is increasingly clear that new medical devices, including surgical implants, are not always better than existing technology. Unfortunately, this often becomes clear only after widespread use. Widely publicized recent examples include the Ancure aortic endograft (faulty delivery device, 12 deaths not reported to FDA), and the pulmonary artery catheter in ICU care (used for decades, but RCTs show no improvement in mortality, increased complications). In orthopedics, devices such as stand-alone interbody spine fusion cages and the Menaflex knee implant have raised recent questions, and many insurance carriers still do not cover artificial discs.

The FDA estimates 300,000 deaths and injuries a year are associated with medical devices. In 2006, complications from medical devices, implants and grafts resulted in over 634,000 hospitalizations, with hospital bills alone totaling more than $27 billion.

One reason for these discouraging events is that scientific evidence is increasingly manipulated by marketing, media pressures, political maneuvering, and wishful thinking. The problems are illustrated by recent revelations of extensive suppression of unfavorable data on new drugs; multiple publications of the same data with different authors and no reference to other publications; selection of comparison interventions or patients that increase the likelihood of favorable results; and selective reporting of measures that are favorable. Some industry sponsored-articles put a favorable “spin” on findings by having articles ghostwritten by hired writers, but attributed to academic authors. In some cases, government funding agencies have come under political attack by professional or industry groups displeased by certain research findings.

In addition, conflicts of interest on the part of researchers and practicing physicians have become increasingly apparent. One manufacturer of spinal implants recently settled with the government for $40 million over allegations of “sham consulting agreements, sham royalty agreements, and lavish trips to desirable locations.” Five makers of hip and knee prostheses paid $310 million in fines to settle accusations of kickbacks to surgeons. Several surgeons conducting a trial of an artificial disc for FDA approval were found to be major investors in the company, with equity interests of $25,000 to $500,000. Further, there is growing literature documenting that industry-sponsored research yields more favorable results for the sponsor’s product than does independent research. Conflicts of interest by surgeons and researchers may lead to unwarranted enthusiasm, biased research, overuse, and choices based on loyalty to a company rather than the patient.

The consequences of such manipulations include exposing patients to unnecessary risks; discouraging independent research on controversial topics; slowing the creation of new knowledge; pushing researchers to seek funding sources with conflicts of interest; and allowing vested interests to determine acceptable questions and results. Correcting these problems will require reforms in academia and
regulatory agencies, closer attention to university-industry agreements, and better protection of the peer-review process.

Implications for practice are that physicians should avoid consulting agreements or travel that are disproportionate to effort; encourage well-informed patient participation in research, rather than “jumping the gun”; and avoid off-label uses of devices (which may constitute research without informed consent). Practitioners also need to be familiar with the principles of evidence-based medicine, to help distinguish solid evidence from unfounded claims. For researchers, it is important to avoid ghost authorship; avoid ghost management of research; insist on making all publication decisions; retain control of all data and data analyses; and avoid equity interest in companies whose products are being studied.

Surgeons have a reasonable expectation of compensation for time and intellectual contributions to device development. Their involvement in device innovation and testing is critical. However, conflicts of interest erode confidence in the scientific base underlying innovations. To assure safety and affordability of health care, complete transparency and limits on industry involvement in research and practice are needed.