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When silence is not golden

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As the debacle involving Johnson & Johnson's metal-on-metal (MoM) hip implants has recently illustrated, silence is not golden when it comes to potential problems with medical devices or treatments. According to Barry Meier of the *New York Times*, Johnson & Johnson's DePuy orthopedic unit was warned by multiple consultants that an artificial hip it was marketing was failing at excessive rates and injuring patients. One letter was particularly blunt: The device was so poorly designed that the company should slow its marketing until it could determine why patients were getting hurt.

According to the Food and Drug Administration, MoM hip implants have unique risks in addition to those present in all hip implants. In a MoM implant, the metal ball and cup slide against each other during hip movement, which can cause metal particles to be sloughed off the device. According to the Australian Department of Health and Aging, the body's natural joint lubricating fluid can react with these metal particles, or metal ions from these particles, and cause pain and inflammation at the site of the implant. This local inflammation can lead to premature failure and the need to replace the device.

The damage around a MoM implant can add up over time and increase the risk of complications with revision surgery. In addition, chromium and cobalt ions from the metal particles shed by MoM implants may enter the bloodstream and cause side effects at sites remote from the implant.

The device referenced in the letter to DePuy was its Articular Surface Replacement (ASR) system. According to the *Times*, the letter was written by a consulting orthopedic surgeon two years before the company finally recalled the device in 2010. That warning was not the only one the company received from paid consultants. Notwithstanding warnings from its own paid consultants, however, the company continued marketing and selling the device. What is most troubling, though, is the fact that none of the concerned consultants went public. Dr. Harlan Krumholz, a Yale professor quoted in the *Times* article, says that questioning the status quo in medicine is not easy. Doctors may fear that speaking up will get them sued or may dismiss a potential product problem as an aberration or chalk it up to their own mistake in technique. The FDA relies on reports from physicians regarding adverse patient reactions to monitor the safety of drugs and devices. According to Krumholz, however, doctors usually do not file these reports with most stating they are too busy for the paperwork. Robert Hauser, a cardiologist who sounded the alarm in 2005 over a defective heart implant, says that the standard in the medical community is not to report.

One of the reasons for this disconnect between ethical duty and actual practice may be money. Financial ties to a drug or medical device manufacturer seem to exert a corrosive effect on a physician's objectivity. George Loewenstein, a Carnegie Mellon professor who has studied medical conflicts of interest, believes that money can shift a physician's sense of loyalty: If someone has been paying you or employing you, it is very difficult to blow the whistle, because it offends our sense of loyalty.

Which is not to say that all or even many of the recipients of payments from manufacturers are consciously dishonest. According to Krumholz, such relationships create a sense of loyalty between the physician and the company's executives. Over time, the physician will begin to view these relationships as friendships and may begin to subconsciously identify with the executives interests instead of the patients.

Theoretically, problems with medical devices or drugs are communicated to fellow professionals and the public through the publication in peer-reviewed journals of articles summarizing clinical research. According to Ben Goldacre in another *Times* article, up to half of all clinical trials conducted are never published in academic journals. Trials with positive or favorable results are about twice as likely to be published — this statistic holds true for both academic and industry studies.

An antiviral drug, Tamiflu, is a good example. According to several sources, including a 2012 *British Medical Journal* article, Roche, the drug's maker, has failed to supply data that supports the efficacy of the drug. The *Journal* originally published in 2009 a review by Cochrane Collaboration researchers which found inadequate evidence that the drug reduces the risk of flu complications. The authors noted that eight of the 10 clinical trials examining that issue were not published. Roche promised to provide that data but never followed through even after repeated requests from various researchers.

The fear is that data that does not support the efficacy of the drug has been suppressed, skewing the results. As Goldacre puts it, if you toss a coin 20 times but hide the result every time it comes up tails, it appears that you always get heads.

The reluctance of physicians to speak up about dangerous medical devices or treatments and the tendency to hide unfavorable data puts us all at risk. For patient safety, silence is definitely not golden. ■

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