Editorial

Prudence before profit—safety issues and new products

It would be a safer world if all products used on humans were thoroughly tested clinically before being put on sale for use on, or by, the public. The recent Dow Corning silicone breast implant scandal highlights the dangers, and the potential improprieties, that can challenge the ethical and moral issues involved.

Regrettably, market pressures accelerate the market path for some materials. Dental materials that will be used on humans require little testing before they are marketed. However, most reputable companies initiate some clinical testing before deciding when to go to market. The hope is that at the very least some preliminary clinical results will be available before the actual product launching day. Less-reputable companies callously carry out their clinical research by listening to anecdotal reports, and, eventually, complaints from the marketplace, after the profits have started to roll in.

From presently available reports, it appears that Dow Corning was negligent in failing to initiate appropriate scientific studies to document safety of silicone breast implants. Thus, women who have received implants in the past 20 years would not have been fully informed of the possible consequences. Apparently the company was also less than forthcoming with early reports of silicone leakage and subsequent health problems.

So now a federal agency has had to step in. An advisory committee to the US Food and Drug Administration recently recommended sharp restrictions on the use of silicone gel implants. Cosmetic implants would be restricted. Necessary reconstructive surgery would be permitted, but only under strict research guidelines. (It is likely the government will act on this recommendation before this editorial appears in print.)

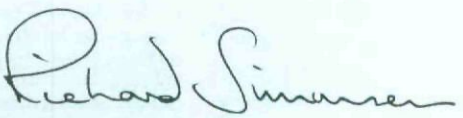
Why were scientifically rigorous clinical tests not initiated by Dow Corning before the implants were marketed? Millions of women could have been spared the agony of doubt and fear that now pervades this issue. Additionally, many may have been saved from having implants at all. Then, however, sales would have been lost.

Similar dilemmas are faced in dentistry. Market pressures essentially force even highly ethical companies to go to market with new materials before the results of clinical studies are fully available. We should be cautious about accepting this trend. As Dow Corning discovered, inadequate attention to safety issues can result in catastrophe for a company, let alone the far more serious individual consequences for those afflicted by the product in question. A company that markets a product without adequate scientific studies completed, or at the very least underway, is flirting with disaster, apart from skirting the clearcut ethical issues.

Remember Kadon, one of the early resins? This product had to be withdrawn from the market since it was thought to cause pulpal death. In fact, it is more than likely that the material itself was not harmful to the pulp. But the technique of application, without etching either enamel or dentin, meant that restorations placed with Kadon leaked—and, as it turned out, leaked fatally for the pulp. So the material was blamed, when the technique was at fault. Appropriate clinical testing would have detected the problem and saved many patients from unnecessary root canal treatment.

What do we really know about dental implants? While some have admirable scientific support over many years of study, other systems are going along for the ride without the necessary studies. Prudence must come before profit.

Any material for use in or on the human body, whether dental, medical, or simply cosmetic, should undergo scientifically rigorous clinical testing. Preliminary results should be available prior to market introduction. Failure to adequately document safety is irresponsible, greedy, and socially unacceptable.



Richard J. Simonsen
Editor-in-Chief