

WHEN MEDICAL DEVICES FAIL, WHO PAYS?

Christopher O'Connor, Esq.
Associate General Counsel,
Lancaster General Health



INTRODUCTION

Repeated media reports about recalled medical devices that require replacement due to safety concerns have recently focused national and international attention on the growing problem of failing devices. In one of the most visible recent examples, the FDA recently requested additional safety data concerning metal-on-metal hip replacements which are failing prematurely at an alarming rate, as described not only in the medical literature, but in a major news article in the *New York Times*.¹ Also notable in the news is a recent report in Europe of a higher than normal leak rate in breast implants manufactured by a now-defunct manufacturer who used industrial rather than medical-grade silicon because of its lower cost.² World-wide, the implants may have been inserted in as many as 300,000 women, though they were never approved in the U.S.

Device recalls may be initiated for any of several reasons. In this country there are mandatory recalls initiated by the United States Food and Drug Administration (FDA), or voluntary recalls initiated by device manufacturers. Sometimes recalls are the result of safety and efficacy concerns that have only been identified in early research publications, but these concerns have been magnified by patient anxiety which gives them a life of their own.

Regardless, numerous issues now surround the complex process that often leads to the decision to replace a device that has the potential to fail. Individuals with a suspect implanted device must be identified, the need for replacement of the particular device must be determined, and responsibility for the costs associated with the replacement must be allocated. These conundrums have generated significant discussion among manufacturers, providers, insurance companies, and patients.

In this column I will deal principally with the question of responsibility for the often considerable cost of replacing these flawed medical devices. Similarly troubling questions have been raised by many earlier

recalls, such as the failures of defective cardiac valve prostheses going as far back as the 1960s, but for one reason or another, perhaps because these problems were less frequent or were not in the media spotlight as they are now, they did not arouse as much discussion. Still, insurance companies had to decide how to share the financial burden with the manufacturers.

In the case of the hazardous breast implants which were inserted in approximately 30,000 French women, the government of France paid for their removal, though not—interestingly—for the actual prosthetic replacements, and only in cases where the implants had been done for reconstructive rather than for cosmetic purposes.³ In England, the National Health Service said it would pay to have the implants removed from women who received them as part of reconstructive care provided by the publicly funded National Health Service. Women who paid for cosmetic implants from private clinics would not be eligible for government funded care in most cases, but the government expressed its “hope” that private practitioners would also pay for the removal of implants if patients requested it.⁴

LEGAL ANALYSIS

In the U.S. there is as yet insufficient state and federal legislation to conclusively resolve these issues, but many insurance companies, including Medicare, have developed payment policies that specifically address payment of the costs associated with replacement of medical devices.

Historically, device manufacturers have only provided the actual replacement devices and have reimbursed patients for any out-of-pocket costs to purchase the devices; third party payers have paid the hospital and physician charges. This historical approach is shifting, however, in response to insurance company pressure and revised payment policies. Now, most manufacturers—if they assume responsibility for payment—will pay those hospital and physician charges that are directly related to device replacement. But even so, the situation is not as simple as it may seem.

As noted earlier, the reason for replacement of a device may be an FDA recall, a voluntary recall by the manufacturer, a defective device, or the patient's request. Since responsibility for payment is typically determined by the reason for replacement, in most cases it is reasonably obvious who is responsible, but it is not necessarily obvious which hospital and physician charges are directly related to replacement of the medical device and which are not.

Manufacturers of the device typically pay for replacement costs in the following circumstances:

- In the event the FDA recalls a medical device in response to safety or efficacy concerns. Medicare, in fact, revised its billing rules to exclude payment for medical devices that are replaced in response to a recall. Many other insurers maintain a similar billing policy, although there are some variations about hospital and physician charges.
- If a manufacturer initiates a voluntary recall of a medical device, oftentimes the manufacturer will cover the costs associated with replacement of the device. Again, in the absence of federal and state laws, variations exist between manufacturers in what costs are actually reimbursed.
- If replacement of a single device is necessary, not because of a generic flaw, but because a specific patient's device is defective or requires replacement prior to the end of its useful life, the manufacturer's device warranty may include responsibility for replacement and payment of associated costs. Once again, Medicare payment policy excludes reimbursement for defective devices or those that require replacement prior to the end their useful lifecycle, and the device manufacturer is responsible for payment.

But though these responsibilities for payment to replace the devices are well defined, what if the patient requests replacement of a medical device as a result of reading research publications that question the safety and/or efficacy of a device and develops anxiety about having the device in their body? Or, what if the FDA inquiry is in an early stage, and the FDA has only requested additional data on a medical device because of the potential for problems, but this is sufficient to arouse the patient's anxiety? Situations such as these do occur in which there has been no official FDA

recall and the manufacturer has not initiated a voluntary recall. Indeed, even in the case of the French breast implants, an individual patient would only experience a problem if the device ruptured, which—though more likely than usual—was not certain. The patients were advised by the French government that removal was advisable, but was not mandatory and was not an emergency.

To choose a more relevant example here in the U.S., there is evidence that metal-on-metal hips fail more often than hip implants manufactured with other materials, but not inevitably so. The FDA has requested additional data and investigations to determine the safety and efficacy of metal-on-metal hip implants, and these reports have led many patients whose devices have not yet failed to request preemptive replacement of their metal-on-metal hip. The legal responsibility for reimbursement of medical costs associated with replacement under these circumstances is opaque, at best. Further, even if the manufacturer accepts responsibility, there may be disputes, as noted, about which costs are included in the reimbursement.

Not surprisingly, in our litigious society with aggressive plaintiff's attorneys, there is a proliferation of lawsuits filed by patients about possibly defective devices. Aside from any other reasons for the lawsuits, among the contentious issues is reimbursement for costs incurred when devices are replaced at the request of the patient. If complications ensue, the costs can become staggering, but since the majority of these cases are settled out of court, scant legal precedent has been created. I suspect that over the next few years as the use of medical devices continues to increase (along with medical costs in general), there will be better definition of the legal framework for determining responsibility for payment to replace a medical device.

The fact that a number of lawsuits have ended in settlement indicates that when a manufacturer accepts the costs of replacing a medical device in response to patient concerns about safety and/or efficacy, it is purely a business decision instead of a response to a legal mandate. In specific cases, a device manufacturer may simply determine that the cost to replace the device is the most prudent choice to protect itself from the expense and the adverse publicity of litigation.

CONCLUSION

Except for situations that involve recalls initiated by the FDA or the manufacturer, or replacement of

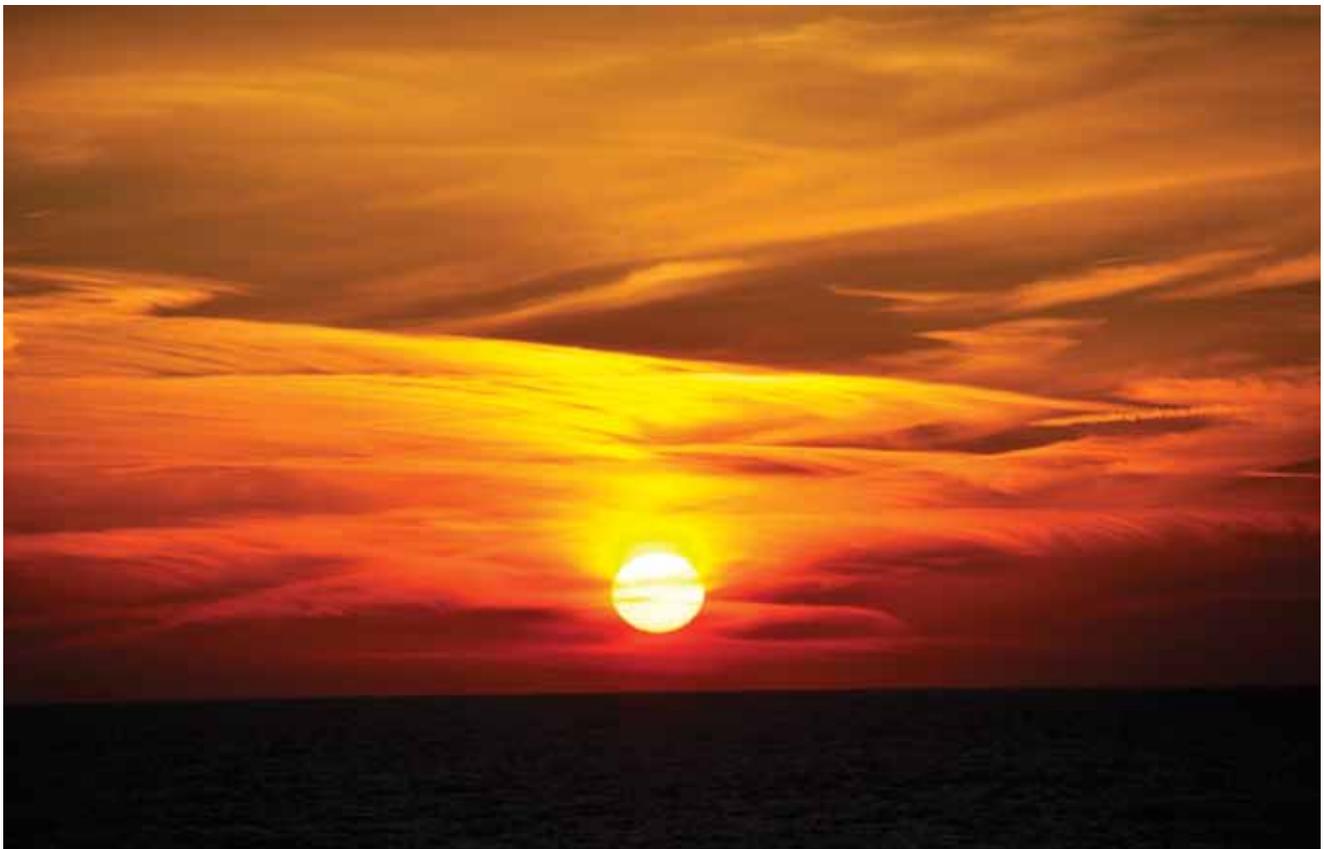
a defective device, there is scant legal precedent that defines responsibility for reimbursement of medical costs associated with replacement of a device. However, the law evolves constantly, and as medical devices garner increased attention from regulators, insurance companies, media, and the general public,

I suspect the law will provide guidance, either through statutory or regulatory means, or court precedent. In the interim, responsibility for medical costs associated with replacement of medical devices is likely to be determined by payment policies of insurers, and business decisions of manufacturers.

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Christopher M. O'Connor, Esq.
Associate General Counsel
Lancaster General Health
555 North Duke Street
PO Box 3555
Lancaster, PA 17604
717-544-1390
cmoconno@lghealth.org



Sunset from Norwegian Cruise Ship off the coast of North Carolina. - Debra Milne, Peach Bottom, PA