PART V

Medical and Legal Oversight of Medical Devices Introduction

Carmel Shachar

Part V of our volume, "Medical and Legal Oversight of Medical Devices," can be thought of as the part that tries to address the question of "what now?" Previous parts have grappled with the regulation of medical devices as they are developed and come onto the market. Part IV considered the impact that devices may have on patients and family members once they are approved for us. Part V takes that focus a step further to consider how we should monitor, evaluate, and regulate medical devices once they are approved and on the market.

This is an important question because, despite the best efforts of regulators to evaluate products before they reach patients, not all medical devices will prove themselves entirely safe. Sometimes, flaws or challenges in a medical device will only be revealed when there are a wider number of users, beyond the scope of any clinical trial. Therefore, it is critical that the medical system develop methods of flagging concerns with approved devices, and that the legal and regulatory system be able to respond to these concerns. This is a challenging task for both the medical and legal systems, however. It essentially asks how we put the rabbit back in the hat. The rabbit, in this case, being the approval and availability of medical devices post-initial approval.

The authors of the chapters in Part V consider the challenge of monitoring the "rabbit," following up on concerns regarding the rabbit, and regulating the rabbit from different perspectives. Some chapters focus on the regulatory system as the actor who can properly supervise and deal with the rabbit. Sanket Dhruva, Jonathan Darrow, Aaron Kesselheim, and Rita Redberg open the part with "Ensuring Patient Safety and Benefit in Use of Medical Devices Granted Expedited Approval." They flag that with a more flexible and streamlined approval process comes an increased chance of unforeseen risks to patients. Therefore, it is necessary to update postmarket requirements to require fuller studies. Efthimios Parasidis and Daniel Kramer likewise turn to the regulatory system to provide sufficient postapproval oversight in their chapter, "Compulsory Medical Device Registries: Legal and Regulatory Issues." While Dhruva et al. argue for postmarket studies, Parasidis and Kramer support the use of registries to track patient experiences with approved medical

devices. They note that registries are perhaps underdeveloped as a tool to monitor medical devices, especially around data governance.

David Rosenberg and Adeyemi Adediran close Part V by considering the interplay of the regulatory system and market pressures in their chapter, "Strengthening the Power of Health Care Insurers to Regulate Medical Device Risks." Similar to the Dhruva and Parasidis chapters, this piece turns to regulatory solutions to solve postapproval problems. This chapter is different, however, in that it focuses on using regulatory solutions to harness the market power wielded by insurers to adopt or avoid certain medical devices. This chapter highlights for the reader that once medical devices are approved by regulatory agencies, we move beyond a relationship focused tightly on the manufacturer and the regulator, to add in payors and patients.

The other two chapters in Part V are less focused on putting the rabbit back in the hat and more focused on the role of the medical system in monitoring and responding to postapproval issues. Anthony Weiss and Barak Richman look to how the medical profession can incorporate medical technology into physician self-regulation mechanisms, namely peer review. Their chapter, "Professional Self-Regulation in Medicine: Will the Rise of Intelligent Tools Mean the End of Peer Review," flips the focus in the part. From considering how we can continue to supervise and regulate medical devices, Weiss and Richman instead ask how can we use medical devices to supervise and regulate human practitioners of medicine? Megan Wright and Joseph Fins, in their chapter, "Regulating Post-Trial Access to In-Dwelling Class III Devices," consider the ethics of risky medical devices embedded in the human body. While Wright and Fins touch on regulatory best practices for following up on study subjects with these implanted devices, they focus strongly on the ethical implications of leaving or removing these devices posttrial.

Overall, the authors of Part V remind us that regulatory approval to bring a medical device to market is not a "happily ever after" or even a final chapter in a story. Instead, approval can be considered a midpoint or inflection point. The subsequent story, of how to monitor, identify problems, and address challenges in approved medical devices, raises significant questions. Our authors grapple with the right mechanisms to tackle these challenges, including the legal and medical systems.