The Innovation and Evolution of Medical Devices

S. Abbas Shobeiri
Editor

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Vaginal Mesh Kits

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Editor
S. Abbas Shobeiri
INOVA Health System
Falls Church, VA
USA

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On behalf of my contributing authors, we would like to dedicate this work to patients and those who share their journeys with them.

This book is our attempt to understand and appreciate the perspective of each entity involved in the production and utilization of a medical device. We pledge to continue our journey together to improve the process to achieve the creation of zero harm medical devices.

To my trainees, I can teach you things. But the important thing, the only important thing, how to listen, how to see things through the patients' eyes, how to feel their sorrows, how to have unconditional empathy and compassion, should have started at home long before you met me. Be humble and always practice evidence-based innovation that places patients' well-being first and foremost.

Lastly, this book is dedicated to my family, the most and the only important thing.

Preface

In the distant past, when there were no antibiotics and surgeons were mere glorified barbers, trials and chronic catastrophes were part of a surgeon's existence. It was not unusual for a gynecological surgeon to perform 30 vaginal fistula procedures and to have all fail. From today's ethical point of view, we look at past experimentations on patients and marvel at how barbaric they were only 100 or 200 years ago. While preoccupied with surgical success in the absence of antibiotics and anesthesia, these surgeons increased patients' suffering. James Marion Sims—whose statue was recently taken down from New York City's Central Park, whose disgrace caused the American Urogynecologic Society to retire the annual lectureship in his name, and who was every gynecologists' hero—experimented on slave women "given" to him by their owners at Sims' expense to find a cure for vesicovaginal fistula. In his day what Sims did was perhaps noble and heroic. There were no medical standards, laws or regulations to motivate Sims to behave otherwise. Just as the concept of consent was different in Sims' time and now, future generations will look at us in amazement at how we failed on multiple levels by allowing what they would view as practical experimentation with medical devices that lacked appropriate design or adequate scientific evidence for their use. The experimentations with medical devices today is much different than the experimentations that surgeons performed 200 years ago. While the motivation of the surgeon has always been to simply cure disease, the motivation of a medical device innovation process is much more complicated and culminates in a modern corporation's fiduciary responsibility to the shareholders. The experimentations still go wrong despite many advances over the past 200 years, advances such as more refined ethical standards, evidence-based medicine, regulatory processes from the US Food and Drug Administration, and local hospital peer review and safety initiatives.

Although in this book we use vaginal mesh kits as a case study of a nearly failed gynecological product, the failed medical device corollaries can be found in any organ system from cardiac stent to orthopedic hardware. This book aims to understand the process of medical device approval and to examine why years after a product is approved, the device is withdrawn from the market for either lack of efficacy or for causing harm to the patients. The bar for approving medical devices

is being raised everyday constantly moving. With recent loosening of some regulatory processes in an attempt to bring lucrative manufacturing jobs to the United States, patients and the health care system in general may pay a hefty toll in exchange. Once a medical device has hit the market, investors are anxious to reap the benefits, and there is simply no incentive to perform efficacy trials. The product is sold to as many and as quickly as possible before the device is inevitably withdrawn from the market and litigation ensues.

In the face of financially driven medical innovation and loosening federal and local regulations, there remains evidence-based medicine, taught in medical schools, as the only hope for patient safety. Although medical societies have taken some leadership to demand hard data by creating registries and sponsoring randomized controlled trials to protect their patients, the fee-for-service system rewards physicians who use the devices the most. While double-blind studies such as those performed for drugs may be seen as difficult for medical devices, it is imperative for us to change the way we approve and oversee medical devices if we are to achieve zero harm to our patients. Furthermore, the current system rewards the quantity of procedures performed, not the quality of patient outcomes. We need more robust monitoring and demand for improved outcomes data by the insurers.

Historically, medical devices were produced by the industry and "consumed" by the surgeons and hospitals. The medical device industry has had a better price-to-earnings ratio with 23–25% operating margin compared to other major stock market indices. The current changes in technology and the development of new disruptive frontiers have resulted in the breakup of well-entrenched industries, value chains, and value-creating strategies. Technological advances have made the metamorphosis of commercial models possible, favoring centralized purchasing, contracting, and call points.

This book discusses the disruptive forces that will determine the medical device industry's direction in the near future. Although it is estimated that market forces will greatly decrease the value generated by each dollar for the research and development of new medical devices, the forecast depends on shifting from a fee-for-service to a value-based healthcare model. This book discusses medical device innovation, the regulatory process, and the ethics of medical device marketing in detail and adds the largely lost patient perspective. The book emphasizes the fact that the sectors that produce, approve, and utilize medical devices operate with a silo mentality and not necessarily in the patients' best interest. The system should change such that innovators, industry, regulators, physicians, patients, and hospitals communicate in a way that improves patient outcome and eliminates suffering by utilizing evidence-based medicine principles while enhancing the product life cycle and go-to-market strategies that are in the interest of the investors.

Falls Church, VA, USA S. Abbas Shobeiri

Contents

Contributors

Pakeeza A. Alam Section of Female Pelvic Medicine and Reconstructive Surgery, MedStar Washington Hospital Center, Departments of Obstetrics/Gynecology and Urology, Georgetown University School of Medicine, Washington, DC, USA

Jonia Alshiek, MD, MSc Department of Obstetrics and Gynecology, Gynecologic Subspecialties, Inova Women's Hospital, Virginia Commonwealth University, Falls Church, VA, USA

Tel Aviv Sourasky Medical Center, Sackler Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel

Elizabeth T. Brown, MD, MPH Department of Urology, MedStar Georgetown University Hospital, Washington, DC, USA

Laura Chang-Kit, MD Department of Urology, Albany Medical Center, Albany, NY, USA

Roberta N. Clarke, MBA, DBA Health Care Management Program, Questrom School of Business, Emeritus Boston University, Boston, MA, USA

Roger R. Dmochowski, MD, MMHC Department of Urology, Vanderbilt Medical Center, Nashville, TN, USA

Tanaz Ferzandi, MD, MBA, MA Division of Urogynecology and Pelvic Reconstructive Surgery, Department of Obstetrics and Gynecology, Tufts Medical Center, Boston, MA, USA

Farzeen Firoozi, MD Center for Female Pelvic Medicine & Reconstructive Surgery, The Arthur Smith Institute for Urology, Northwell Health, Lake Success, NY, USA

Zucker/Northwell School of Medicine of Hofstra University, Hempstead, NY, USA

Howard B. Goldman, MD Glickman Urological and Kidney Institute, Cleveland Clinic, Cleveland, OH, USA

Cheryl B. Iglesia, MD Section of Female Pelvic Medicine and Reconstructive Surgery, MedStar Washington Hospital Center, Departments of Obstetrics/Gynecology and Urology, Georgetown University School of Medicine, Washington, DC, USA

Melissa R. Kaufman, MD, PhD Department of Urology, Vanderbilt Medical Center, Nashville, TN, USA

Katrina Knight, PhD Department of Medicine, School of Medicine, University of Pittsburgh, Pittsburgh, PA, USA

Neeraj Kohli, MD, MBA Boston Urogynecology, Newton-Wellesley Hospital/ Brigham and Women's Hospital, Wellesley, MA, USA

Department of Obstetrics and Gynecology, Harvard Medical School, Boston, MA, USA

Rui Liang, MD, MSc Department of Obstetrics, Gynecology and Reproductive Sciences, University of Pittsburgh, Pittsburgh, PA, USA

Vincent R. Lucente, MD Department of Obstetrics and Gynecology, St Luke's University Health Network, Bethlehem, PA, USA

Pamela Moalli, MD, PhD Division of Urogynecology and Pelvic Reconstructive Surgery, Department of Obstetrics, Gynecology and Reproductive Sciences, Magee-Womens Hospital of UPMC, Magee-Womens Research Institute, University of Pittsburgh, Pittsburgh, PA, USA

Miles Murphy, MD, MSPH The Institute for Female Pelvic Medicine and Reconstructive Surgery, North Wales, PA, USA

Sherrie J. Palm Association for Pelvic Organ Prolapse Support, Mukwonago, WI, USA

Bruce Patsner, MD, JD Department of Obstetrics and Gynecology, Virginia Commonwealth University School of Medicine, Richmond, VA, USA

Quality and Patient Safety, Inova Fairfax Women's Hospital, Falls Church, VA, USA

Department of Obstetrics and Gynecology, Inova Fairfax Women's Hospital, Falls Church, VA, USA

Ghazaleh Rostaminia, MD, MSc Female Pelvic Medicine and Reconstructive Surgery NorthShore University Health System/University of Chicago, Skokie, IL, USA

S. Abbas Shobeiri, MD, MBA, FACS, FACOG, CMPE INOVA Health System, Falls Church, VA, USA

Michael Ting, MD Division of Minimally Invasive Gynecologic Surgery, Department of Obstetrics and Gynecology, St Luke's University Health Network, Bethlehem, PA, USA