Foreword

The Center for Devices and Radiological Health (CDRH) is the part of the U.S. Food and Drug Administration concerned with the regulation of medical devices. It owes its existence to the Medical Device Amendments of 1976, signed into law by President Gerald Ford on May 28, 1976. CDRH was created by the merger of two Bureaus: the Bureau of Medical Devices and the Bureau of Radiological Health.

The mission statement for the Center for Devices and Radiological Health (CDRH) is a well-crafted document, comprised of three sections: Mission, Vision, and Shared Values. It assures the reader that CDRH makes decisions based on sound science; they maintain the public trust by acting with integrity and honesty; they hold themselves accountable for the actions they do and do not take; they acknowledge their errors and learn from them. From my experience over the past decade, these objectives are sometimes forgotten. The one page document can be seen in Appendix A.

This book presents several examples where CDRH personnel failed to live up to the ideals of the mission statement.

The title *Unaccountable Too* is a tribute to Martin Makary's 2009 book *Unaccountable* which is a remarkably candid recitation about the dangers to the public health from bad doctors and greedy hospital administrators. Makary and Michael Daniel's 2015 article in the British Medical Journal asserts that medical mistakes are the third leading cause of death in the United States.

When the Medical Devices Amendments were enacted in May, 1976, the Food and Drug Administration was given very broad authority to regulate the medical device industry. At the outset, the agency was faced with the challenge to understand the medical device industry, and with industry's willing assistance, the agency compiled data on the many devices then on the market. The law adopted recommendations from the "Cooper Report" including the idea that devices are different from drugs. The law defines three "classes." Class I devices are subject to a set of requirements known as General Controls. Class II devices originally would be subject to a performance standard in addition to General Controls. Class II was later changed to Special Controls. Class III devices are subject to Premarket Approval, in addition to General Controls.

I got involved because a particular device in which I had an interest was in Class III although I believed it should be in Class II. In a remarkable turn of events, CDRH agreed with me, and even changed the name of the device as I recommended. However, there are other issues – notably the need to revise and retain the Classification Questionnaire – which is a major theme of this book.

As my interaction with the FDA continued, I began to better appreciate the bureaucratic culture. People were unwilling to answer basic questions or to offer an opinion on anything. Freedom of Information requests were ignored or the responses delayed and incomplete. I observed that legitimate inquiries even from members of Congress were ignored. A little research shows that CDRH people command good salaries, and they get paid whether or not they are responsive to inquiries, criticism, or

constructive ideas. The delays in handling submissions from industry for new or changed devices and premarket approval applications grew to the point that industry agreed to pay millions of dollars per year in fees. Hence, my suggestion that CDRH is a kleptocracy.

Save the CQ

This book deals extensively with the General Device Classification Questionnaire, a document which has been used for decades by the Food and Drug Administration. It is usually referred to as the Classification Questionnaire which I've abbreviated it to CQ for this book. The CQ is also known as Form FDA 3429.

The CQ's purpose is to identify to which of the three regulatory classes a medical device should assigned. The CQ consists of a series of questions, a list of the possible answers, and directions depending upon the answers. In 2012, I discovered a serious logical flaw in the CQ and petitioned the Commissioner of the FDA to correct the flaw. Instead, the FDA deleted the logical directions, arguing that the Form was confusing and needed to be simplified. In 2014, the FDA decided to discontinue use of the Form. However, they have not finalized that action, instead obtaining permission to extend the expiration date on the Form until September 30, 2021.

The book is also concerned with two devices that were misclassified into Class III by the FDA and were thus slated for Premarket Approval, even though they did not satisfy the definition of Class III. Chapter 1 deals with one of these devices.

Read on to learn how I got involved in my campaign to "Save the CQ."