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Preface

This book was originally conceived as a way to raise the level of awareness among regulatory professionals of the many activities – often simultaneous, usually complex, and always high stakes – that are involved in the development and maintenance of healthcare product labeling. The extent and impact of this function, and the professionals performing the role, remain underappreciated owing to a lingering impression that the focus of this role is on a single, relatively brief document. The reality of multiple manuscripts, myriad operational activities, and a multifaceted audience frequently astounds those who become acquainted with the full scope of the labeling function – including regulatory professionals.

Industry professionals tasked with "doing the labeling" for a healthcare product or for a development candidate, who may not appreciate the extent of the assignment or know where to begin, should find value in this text. Other readers may be interested in better understanding the scope and detail of the labeling function as it relates to their own responsibilities. This text should also prove valuable to anyone beginning a career in this specialty by presenting a thorough background to the discipline that will facilitate their understanding of their new role.

To serve the varied needs of these target readers, each chapter features an overview of its topic as well as guidance to relevant resources for further exploration.

This second edition updates the fundamental material and expands the scope into other topics of relevance, including the labeling of investigational products for clinical trials and the labeling recommendations for cannabis and CBD. As with the original version, the subject of this updated reference should be considered as dynamic as the sources on which it is based. The reader is advised to use this book as an introduction to important concepts before proceeding to current details found in the helpful resources and references identified in each chapter.

This publication represents the efforts of many knowledgeable, experienced professionals. Its purpose is to illuminate the scope and depth of the labeling function in providing a critical component of healthcare products.

Cathleen O'Connell, PhD, MS, RPh
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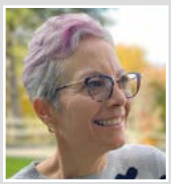

After beginning her professional life as a hospital pharmacist, Cathleen O'Connell, PhD, MS, RPh, had a long career in the pharmaceutical industry, where her responsibilities over the years included drug information, medical writing, and international regulatory affairs. She spent more than a decade in labeling roles, reaching the executive level at several multinational pharmaceutical companies, where she designed and led global labeling departments. A driver of several industry-wide initiatives relating to packaging and drug information, Dr. O'Connell also co-founded the Drug Information Association Labeling and Packaging working group.

Moving into academia, she became associate professor and valedictory program director of Biomedical Writing at the University of the Sciences in Philadelphia (now part of Saint Joseph's University).

Dr. O'Connell is a rated pilot of several aircraft, including helicopters, hang gliders, and paragliders.