

# FORWARD

During my tenure as Director of the FDA Center for Drug Evaluation and Research (CDER), advisory committees provided essential input in the product review process. These committee meetings remain as critical to the Agency today.

With the explosion of new medical product categories including gene therapies, bi-functional molecules, and live virus oncolytics, the FDA must frequently rely on outside experts, in the form of FDA advisory committees, to help assess product efficacy and safety.

It is hard to overstate the importance of these meetings, or the challenges that advisory committee members face in trying to provide a fair recommendation to the FDA. In addition to their “day jobs,” these clinicians, academicians, and patient representatives have only days to pour through a sponsor’s briefing book and assess years of data; a few hours to hear both the FDA’s and sponsor’s analyses of the data; and even less time to ask the sponsor and the Agency questions.

While I was at FDA, I saw case after case of sponsors who either weren’t effective in putting forth the true benefit of their product, were not confident when answering committee member’s questions, or went too far in making statements and conjecturing in ways that couldn’t be supported by their data. However well-intentioned, they lost credibility and often an advisory committee member’s positive recommendation.

Because the FDA almost always follows the advice of its advisory committee members, their recommendations are critical to public health. As a result, it’s essential that sponsor companies take charge of their portion of the meeting and skillfully moderate their session. They must present their data in a clear, credible, and convincing way, and confidently answer advisory committee members’ questions—to satisfy both the company’s interests and serve the greater good.

During my post-FDA career at Amgen, I worked with 3D Communications and leveraged the preparation process outlined in this book. I experienced firsthand why extensive and rigorous preparation is necessary when sponsor companies develop materials and presentations for advisory committee meetings. It's challenging for company teams, which often have other responsibilities and areas of expertise, to meet strict FDA deadlines and execute a time-consuming and disciplined preparation process on their own.

While companies have invested decades of work, hundreds of millions of dollars, countless resources, and know more about their program than anyone else, it is sometimes difficult for them to critically evaluate their data. They often lack a larger-lens perspective on their positions and data going into advisory committee meetings.

A proven external process, like the one in *The FDA Advisory Committee Survival Manual*, and the outside experience of advisory committee preparation experts, can help sponsors address that gap. A company like 3D brings experience, focus, technology platforms, and an efficient process to help companies successfully prepare. This includes: providing sponsor teams with a front-line perspective on how the FDA and advisory committee members will see the data and the sponsor's presentation; ensuring the presentations and the written materials are clear and streamlined; and coaching those delivering the data so that even seasoned presenters are ready to stand up to scrutiny at this unique, and often contentious, public meeting.

A strong presentation, along with skilled moderating and confident Q&A, may tip the scales toward approval of product, communicating supportive information that may not be apparent in the written documentation available to a committee. In contrast, a poorly executed presentation may adversely influence an advisory committee and increase the chances that FDA will not approve the submission.

Over the last two decades, 3D has worked with hundreds of pharmaceutical, biotech, and medical device companies preparing them to be successful at FDA advisory committee meetings. This book, and the process detailed in it, are the result of that experience.

– Steven Galson, MD, MPH  
Former Director, FDA CDER

# CONTENTS

Acknowledgments .....	1
Introduction.....	2
<b>ANALYSIS</b>	
Chapter 1: Prepare Early .....	14
Chapter 2: Convene the Team .....	24
Chapter 3: Target the Audience .....	35
Chapter 4: Engage Stakeholders .....	41
Chapter 5: Dissect the Data .....	49
<b>CONTENT DEVELOPMENT</b>	
Chapter 6: Build the Right Foundation .....	55
Chapter 7: Make a Good First Impression .....	63
Chapter 8: Tell the Story.....	71
Chapter 9: Visualize the Data .....	77
Chapter 10: Be Ready with Backup.....	91
Chapter 11: Check It. Check It Again .....	98
<b>TESTING &amp; TRAINING</b>	
Chapter 12: Stand and Deliver .....	104
Chapter 13: Respond and Resolve.....	111
Chapter 14: Get a Reality Check .....	123
Chapter 15: Speak to the Street.....	131
Chapter 16: Amplify the Message .....	139
<b>FINAL PREPARATION &amp; MEETING EXECUTION</b>	
Chapter 17: Game On!.....	146
<b>CLOSING</b>	
Chapter 18: A Final Word .....	153
<b>LOGISTICS &amp; CONTEXT</b>	
Appendix I: Listing of the FDA’s Advisory Committees.....	155
Appendix II: Rx-to-OTC Switches .....	158
Appendix III: New Drug Application (NDA) Review Process.....	162
Appendix IV: Legislative and Regulatory Considerations .....	163
Appendix V: Glossary.....	164

## Acknowledgments

A book is never the work of one person, and that is especially true in the case of this updated version of *The FDA Advisory Committee Survival Manual*.

The methodology detailed here is the result of more than 20 years of 3D Communications guiding companies across the finish line for one of their most important and stressful events—going before an FDA advisory committee. Each of those companies and projects improved our processes and helped us create the book you see today.

As a result, our first acknowledgment is to our clients. Without these brilliant, committed, and hard-working people trusting us with their important programs, this book wouldn't be possible.

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We proudly offer this book to our existing and future clients, with the hope it will help them do what they do best—get important treatments to the people who need them.

– **Jim DiBiasi and Cindy DiBiasi**  
Co-Founders, *3D Communications*

# INTRODUCTION

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## Getting Started



### **Understanding the Rules of the Road**

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