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Preface

Welcome to the inaugural edition of RAPS' *Lifecycle Management Through the Rx-to-OTC Switch: US Considerations and Perspectives to Advance Self-Care*. This book is a culmination of my involvement in switches, learning from the few available guidance documents, and most significantly, interacting with highly experienced regulatory professionals. The increased relevance of over-the-counter (OTC) or self-care products to consumers and patients alike was also a driver in developing this practical reference manual for the regulatory community.

The availability of OTC medicine, relative to prescription alternatives, provides significant value to the US healthcare system—\$102 billion in annual savings—or, on average, every dollar spent on OTC medicine results in \$6-7 in value for the US healthcare system as a whole.¹ In addition, the US OTC market is expected to grow from its \$25 billion in annual sales in 2013 to approximately \$42 billion in 2024, a sales increase of 68%.² Part of that growth will be the result of Rx-to-OTC switches creating new commercial opportunities for pharmaceutical manufacturers. OTC product development also has been on the rise since the enactment of the *21st Century Cures Act*³ in 2016 and the *Cares Act* in 2020.⁴

Through a series of case studies, a group of highly respected regulatory experts illustrates the basic requirements for implementing a switch to increase availability of, access to, and adoption of OTC medications, thus enabling more consumers to avail themselves of proven therapies.

This is a new book topic for RAPS. It is intended for newcomers and seasoned professionals, ranging from those working in product development and marketing, to those in regulatory affairs. *Lifecycle Management Through the Rx-to-OTC Switch* is a valuable resource for any regulatory professional interested in learning about or pursuing a switch.

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