It is no surprise that federal and state laws and regulations often lag behind changes in technology. The fast-paced and diverse mobile health (mHealth) industry therefore must steer around inherent regulatory challenges. Because regulatory bodies typically take measured approaches and adopt longer time lines to address changes, the successful innovator must consider these limitations in addition to the opportunities presented by its new products for advancement of medical services.

The story of regulatory constraints facing new mHealth products is perhaps best told by how the Food and Drug Administration (FDA) first began regulating devices. The FDA’s evolved guidance on how it would regulate mHealth products also is an important lesson to understanding that there may be gaps in any regulatory authority of these products.

When Congress enacted the first national Food and Drugs Act in 1906, medical devices were not included. Indeed, the legislative history of the 1906 Act reveals no mention of medical devices. In its 1917 Annual Report, however, FDA recognized the need for regulation of medical devices, and every bill introduced to modernize the 1906 Act from 1935 to 1938 included medical devices. Initially, this legislation simply included devices within the definition of a drug. When it was pointed out that shoulder braces and crutches could not be regarded as drugs, however, Congress created a separate but very closely related definition of a device. Thus, the Federal Food, Drug, and Cosmetic Act was enacted in 1938 with parallel definitions of a drug and a device. The only difference was that a drug was described as an “article” and a device was described as an “instrument, apparatus, or contrivance.” Both were defined as “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” or as “intended to affect the structure or any function of the body.” These virtually
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duplicative definitions caused endless confusion and confrontation for FDA and the regulated industry.

The first legislation to amend the device provisions of the 1938 Act was introduced in 1962, but it was not taken seriously until 1969, when the Supreme Court held in the Bacto-Unidisk case that a simple antibiotic sensitivity disk could be regulated by FDA as a drug. In his 1969 Consumer Message, President Nixon ordered a thorough study of the need for new medical device legislation. The resulting Cooper Commission Report recommended a very different form of regulation for devices compared to the Investigational New Drug/New Drug Application (IND/NDA) process for new drugs. In the legislation that was prepared to implement the Cooper Committee Report, both FDA and the regulated industry agreed that a new definition of a device was needed in order to more clearly distinguish between a drug and a device. Thus, the Medical Device Amendments of 1976 amended the device definition broadly to mean (as further refined in the Safe Medical Devices Act of 1990) an “instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article” that is “intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease” or “to affect the structure or any function of the body.” This broad and all-inclusive definition was then limited, however, by providing that a device “does not achieve its primary intended purposes through chemical action within or on the body” and “is not dependent upon being metabolized for the achievement of its primary intended purposes.” It is this definition that now governs mHealth products.

Very simply, the first question is whether an mHealth product is a contrivance that is intended for use in the diagnosis, prevention, or treatment of disease or other health-related conditions. The second question is, if the relationship of an mHealth product to a disease or health-related condition is indirect and tangential and raises no safety concerns, rather than immediate and specific with significant potential safety concerns, should FDA exercise its discretion to exclude the product from the premarket review, approval,
and related provisions enacted in 1976. It is these and related questions that are the subject of chapter 2 of this book.

Other chapters analyze the many regulatory frameworks implicated by the evolving mHealth technology and highlight key considerations for each. Authored by recognized experts in these disparate regulatory disciplines, the book offers invaluable insights for anyone interested in mHealth products.