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FROM THE EDITOR

The US Food & Drug Administration has just released its highly anticipated framework for their real-world evidence program, which they were called upon to develop by end of 2018 as part of the 21st Century Cures Act. Knowing the importance of this framework for RWE generation, we selected the Cures Act as our theme for this issue of *Value & Outcomes Spotlight*.

Our feature article points out that it is not just FDA that has demonstrated interest and made accommodations for RWE, but the European Medicines Agency and other regulatory bodies around the world that have done so. This is in response to the growing recognition of an "efficacy-effectiveness gap" in the way in which interventions perform in highly controlled trials versus real-world clinical practice. The proliferation of electronic health records and other forms of real-world data as well as advances in statistical methods and computing power are increasingly making evidence generation more timely and reliable. Regulatory authorities are in tune to this and seeking to make use of RWE for decision making, just as payers have done for the past two or three decades.

But evidentiary standards for regulatory decision making are high and one thing that's clear from FDA's RWE Framework is that there is no intention of relaxing these standards when it comes to product labeling. The real question is not necessarily whether regulatory authorities will accept RWE, but rather will they accept evidence from the non-randomized study designs that typify much of RWE generation. The one exception is the pragmatic clinical trial, the only real-world research design that does include randomization to treatment assignment, so there is some speculation that this will become favored by regulatory and more widely used in the future.

Our ISPOR Central section contains a wide variety of material of interest to the ISPOR membership, including HEOR news, an update from the editors of ISPOR's highly successful flagship journal, *Value in Health*, individual and chapter awards, as well as reports and photo galleries from various ISPOR meetings, including our recently convened ISPOR Europe conference in Barcelona.

Finally, we include a memoriam for ISPOR's Founding Executive Director, Marilyn Dix Smith, whose passing we learned of this past October. It is impossible to overstate Marilyn's influence on the field of HEOR through the creation of our Society. She is the one individual whose dedication of time, energy, and resources brought the organization to the success and prominence it has enjoyed for so many years. She will certainly be missed.

All of us here at *Value & Outcomes Spotlight* wish you the best for the holiday season and new year. See you in 2019!

David Thompson, PhD
Editor-in-Chief,
Value & Outcomes Spotlight