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LETTER FROM THE EDITOR

This issue of *Value & Outcomes Spotlight* comes on the heels of ISPOR's 22nd Annual International Meeting in Boston. Approximately 4,200 attendees enjoyed a wide ranging program of short courses, plenaries, issue panels, workshops, oral presentations, and posters. Though not a native-Bostonian, I have resided in the greater-Boston area for more than 30 years and consider New England my home—which made this year's ISPOR meeting all the more special.

The meeting theme was "*Evidence and Value in a Time of Social and Policy Change*." If that sounds like a nod to the current global political environment, then the first plenary session did not disappoint. With the provocative title, "*Where Is US Health Policy Going?*" the panel discussion included four health economists who have counseled US policymakers across the political spectrum, with former ISPOR President Peter Neumann moderating. Despite the intended balance, the discussion soon focused on the perils of Obamacare repeal, not only from the standpoint of loss in health insurance for more than 20 million Americans but also from the perspective of what a political hot potato the issue has become for Republicans and Democrats alike.

We carry that policy theme into this issue, though our focus is not on the provision of health insurance coverage, but rather the evolving relationship between regulatory policy and real-world research. In our last issue we talked about the "topsy-turvy" nature of this relationship at present, with regulatory authorities in the US and Europe now in a position to impact the creation of real-world evidence after more than a century of real-world evidence impacting the creation of regulatory policy.

The first article addresses aspects of the US 21st Century Cures Act that relate to the dissemination by manufacturers of health-care economic information (HCEI), which has spurred the Food & Drug Administration to provide—finally, according to the author—guidance to manufacturers on best practices for communication of non-misleading HCEI to health care system stakeholders. The second article considers the "adaptive pathways" schema for accelerated regulatory approval put forth by the European Medicines Agency (EMA), which permits early approval in a limited in size, well-defined population accompanied by a milestone-based plan for continued evidence generation—this brings challenges in demonstrating product value, highlighted by the author. The third article draws attention to the particularities of medical devices, providing insights into the challenges of assessing product value from industry, payer, and regulatory perspectives.

Finally, we come back to the Boston meeting with a variety of features, including a report from the ISPOR student chapter leadership on their activities at the meeting; a summary of social media activity and other connections during the conference; a listing of award winners; and a photo gallery of all the happy attendees.

Best regards,

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

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