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LETTER FROM THE EDITOR

The world is topsy-turvy in so many ways these days it's difficult to keep up. In sports, did the Chicago Cubs really win the World Series after 108 years of heartbreak, and did Leicester City really beat 5,000-to-1 odds to win the Premiership? In movies, did La La Land just win the Oscar for best picture or was it Moonlight? In politics, did … well, let's not even go there.

In our realm we have our own topsy-turvy example to point to, in that after more than a century of real-world research driving changes in regulatory, we're now entering a period in which changes in regulatory are poised to drive real-world research. Consider how things have unfolded …

One can identify influences of real-world research in the origins of the US Food & Drug Administration, beginning with the "muckraking" journalism of Upton Sinclair in the early 1900s, which exposed unsanitary conditions and harsh treatment of immigrant labor in America's meat packing plants (his classic novel, *The Jungle*, details it all). Later, in the 1930s, real-world research pinpointed the product, Elixir Sulfanilimide, as the cause of hundreds of deaths (mostly in children), leading to legislation allowing FDA (for the first time!) to require manufacturers to demonstrate product safety before obtaining marketing approval. And then in the 1960s it was real-world data linking severe birth defects to the drug, thalidomide, that led to further stiffening of regulatory requirements and demonstration of product safety and (for the first time!) efficacy for FDA approval. No one was talking about real-world data in those days but make no mistake in each of these examples that's exactly what was driving these changes in the regulatory apparatus.

Now, with the 21st Century Cures Act in the US and changes to clinical trial regulations in Europe, the tables have turned and it will be regulatory driving changes in the conduct of real-world research. Cures, passed in December 2016, encompasses a variety of provisions "to accelerate the discovery, development and delivery of 21st century cures" in the US. Included among these provisions are instructions for FDA to consider real-world evidence as a potential factor in approval and labeling decisions. In Europe, new regulations on clinical trials include a new category for the "low-intervention clinical trial," with streamlined safety monitoring requirements versus conventional randomized controlled trials. By all appearances, it seems this new category is intended to be occupied by the pragmatic clinical trial, the real-world analog to the conventional RCT. Provisions from these new regulations in the US and Europe are being phased in over time, so their immediate impact may be minimal. But it will be interesting to see how these regulations, which on paper clearly favor expanded conduct of real-world research, change the nature of the work we do in the years ahead. It's a topsy-turvy situation to think about.

You know what else is topsy-turvy? For the first time ever, ISPOR is coming to Boston! This issue of *Value & Outcomes Spotlight* should arrive in your inbox just as you're making final preparations for the 22nd Annual International Meeting in May.

See you there!

Sincerely,

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

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