LETTER FROM THE EDITOR

Since being signed into law in the United States in December 2016, the 21st Century Cures Act has garnered considerable attention from the ISPOR community, as reflected in the many contributions to the program of our 22nd Annual International Meeting as well as the pages of various publications, including Value & Outcomes Spotlight. In fact, this issue features an article (see page 7) on this topic developed around a plenary session from the May meeting.

The attention is not surprising given the prominence of two topics—real world evidence and health care economic information—that are near and dear to our hearts. The legislation calls for the US Food & Drug Administration to develop plans and guidance for the consideration of RWE in regulatory decision making and outlines expansion in communication channels of HCEI between manufacturers and health system stakeholders. These and other provisions are designed “to accelerate the discovery, development and delivery of 21st century cures” in the US, which is the stated objective of the law.

Taking a global perspective, it’s not easy to reconcile these efforts in the US with other countries, where the provision and financing of health care and the evaluation of medical technologies are all done so differently. Is America leading the world in advancing treatment innovation in the 21st century, playing catch-up, or sidestepping the most pressing issues? Looking at the health technology assessment (HTA) bodies that exist around the world—NICE in the United Kingdom, IQWiG in Germany, CADTH in Canada, PBAC in Australia, ZIN in the Netherlands, CONITEC in Brazil, the list of acronyms goes on—there is widespread acceptance outside the US that governmental and quasigovernmental bodies such as these should play a prominent role informing decisions regarding the adoption, reimbursement and pricing of new medical technologies.

This approach seems clear headed and fiscally responsible and though not perfect works reasonably well in these countries. In contrast, the very idea of government-imposed limitations on patients’ access to a medicine based on pharmacoeconomic criteria is essentially against the law in the US and we have no US-equivalent to NICE. The Institute for Clinical & Economic Review (ICER) has attempted to fill the void but in so doing has generated criticism from seemingly all directions—from academics, who take issue with their methods; from manufacturers, who take issue with their results; and from patient advocacy groups, who take issue with potential restrictions on medication access. Another common criticism is that ICER provides information to support payers’ negotiations with manufacturers over drug prices and decisions regarding reimbursement. But how many of the HTA bodies listed above do not do the exact same thing?

Which brings us back to the 21st Century Cures Act. Certainly the objective of getting breakthrough therapies in the hands of patients quicker and with less regulatory red tape is commendable. But other countries have recognized that it’s not simply a matter of managing the entry of new treatments into the medical-care system, it’s also their usage is commendable. But other countries have recognized that it’s not simply a matter of managing the entry of new treatments into the medical-care system, it’s also their usage of those treatments which the HTA bodies listed above do not do the exact same thing?

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