Technology, Regulations, and Value in Health

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It was a pleasant surprise for those of us in the Outcomes Research community to see a health economist lead the Food and Drug Administration (FDA) albeit for a very short time. In this issue, Value in Health presents its transcript of a speech Dr Mark McClellan gave at ISPOR last year [1].

The speech was part of a plenary session on real world databases in health care. Dr McClellan has been a pioneer in the use of such databases. Several of his earlier publications related to his using them in innovative ways to examine the costs and effectiveness of various technologies [2–5].

Given his background, was Dr McClellan intending to incorporate cost-effectiveness into the FDA approval process? He explicitly addressed this question, and his answer was “no.” Instead, he brought to the FDA a vision about the opportunity of information technology to improve the performance of the agency and reduce health-care costs.

Dr McClellan is aware of both the high cost of medications and the high cost of drug development. Cost pressures in both arenas drive the search for new efficiencies, and Dr McClellan’s background has led him to identify several important opportunities.

He first addressed the role of the FDA in drug development. Dr McClellan developed initiatives to prevent repeat cycles in FDA reviews, share best practices within the FDA, and provide better public guidance. Hopefully these initiatives will lead to more efficient investment in research.

Dr McClellan also developed initiatives to expand the use of information technologies in drug prescribing. The FDA proposed a new rule to require a universal bar coding system for prescription medications and blood products. This offers the potential to prevent a large number of costly adverse events.

Third, he initiated pilot programs expanding the use of real world databases in post-market surveillance. One project involved several leading academic medical centers sending adverse event data to the FDA in an automated fashion. Another project has involved systematic collection of data on medical devices in real time, permitting the FDA to quickly identify and address issues of public safety.

So it should be no surprise that the President of the United States has recently spoken on the need to computerize American health care. George W. Bush said “. . . Medicine ought to be using modern technologies in order to better share information, in order to reduce medical errors, in order to reduce costs to our health-care system by billions of dollars [6].”

These statements by the President are completely in line with the focus and vision of Dr McClellan. While some health economists focus on health-care rationing, Dr McClellan has placed his focus instead on facilitating innovation, adopting new technologies, and increasing efficiency. It is a great way to promote value in health.

References