



THINKING BIGGER:

BROADENING REGULATORY STRATEGY FOR NEW MEDICAL DEVICES BY PLANNING FOR BOTH REGULATORY AND REIMBURSEMENT APPROVAL

One day, Michelangelo entered Raphael's studio, and looked at one of young artist's early works. After studying the small painting for some time, Michelangelo wrote across the top of the canvas 'Amplius,' meaning 'greater' or 'larger.' On a small canvas, Raphael's composition was too crowded and narrow, and its impact could only be felt through an expanded composition.

To succeed in bringing new medical technologies to market, manufacturers developing their regulatory strategy would do well to heed Michelangelo's advice: Think Bigger. Specifically, to meet the demands of the "New Health Economy,"¹ a more expansive regulatory strategy must consider reimbursement to ensure the best, most efficient outcome.

Among the many disruptions occurring in the life sciences industry, changes to reimbursement models are placing new pressures on medical device manufacturers. To be sure, enabling speedier patient access to novel innovative devices and demonstrating their value in an already crowded market top the list of challenges.

The concept proposed in this article—combining reimbursement considerations into the development of a regulatory strategy for approval of new medical devices—may not, in and of itself, be novel. However, rapidly evolving reimbursement models lend a new sense of urgency to examining it as a concept and adopting as a tactic.²

I. FROM “VOLUME TO VALUE”: THE MOVEMENT AWAY FROM FEE-FOR-SERVICE AND TOWARD VALUE-BASED PRICING IS CREATING NEW BARRIERS TO ACCESS OF INNOVATIVE MEDICAL DEVICES

A. CHANGING PAYMENT MODELS FOR HEALTHCARE SERVICES AND PRODUCTS

A growing trend has emerged over how payers reimburse health care providers for their services: payers are moving away from the traditional fee-for-service model, and instead are basing coverage decisions on health outcomes, financial metrics, or some combination.³ Known as “Pay-for-Performance” or a “Value-Based,” such payment models are “the wave of the future.”⁴ While “value” in health care products and services may lie in the eye of the beholder

i.e., demonstrating that a new technology is an improvement over the existing standard of care, and “economic value”—when ethical and if the economic impact is significant.⁸

Second, who makes utilization decisions is changing. Under the conventional fee-for-service model, payers act as the gatekeeper to patient access of new medical devices, with health care providers assuming a “countervailing patient advocacy role” to ensure access to new devices.⁹ Under a value-based model, providers are, to a degree, reimbursed based on health outcomes and efficiencies.¹⁰ Consequently, a value-based model may actually lead to providers as gatekeepers, resisting adoption and use of new technology.¹¹

Third, payers are requiring more evidence and using new metrics to assess new technology and to make coverage decisions.¹² To ensure coverage by payers and utilization by providers, manufacturers of new medical devices will be called upon to demonstrate “evidence across

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(patient, doctor, payer), in the New Health Economy, “value” means reducing costs and improving health outcomes.⁵

This change has significant implications for introduction of new medical devices and can be addressed through development of an expanded regulatory strategy development. First, uncertainty regarding reimbursement is rising.⁶ Payers are imposing more onerous evidentiary requirements to secure coverage of new medical technologies.⁷ Increasingly, manufacturers will need to present evidence of “clinical value”—

the spectrum of care management and delivery, including outcomes studies, and analyses and evaluations and patient and population-level of alternative care pathways.”¹³ Likewise, development, selection, and validation of financial and quality-related metrics, and application of evidence to those metrics, will become of paramount importance to the success of new medical devices in a changing industry.¹⁴

To adapt to this changing landscape, proactive regulatory planning must include early consideration and of gathering the necessary data to support broad reimbursement.





II. “WE HAVE CLEARANCE CLARENCE”¹⁵ ... BUT WHAT ABOUT REIMBURSEMENT?

FDA approval or clearance is a precondition to any public or private payer reimbursement for a new medical device. However, “clearance is no guarantee of coverage”¹⁶ by either CMS or private payers, and more importantly, it is “not equivalent with patients getting access to that device.”¹⁷

Ultimately, decisions regarding regulatory approval or clearance and reimbursement alike depend on evidence gathered to support those decisions. However, the type of evidence gathered at each phase necessarily varies.

A. REGULATORY APPROVAL OR CLEARANCE

FDA approval or clearance is a prerequisite to legally marketing a new device, and the manufacturer must present evidence demonstrating that the device is safe and effective for its intended use. Regulatory strategy for identifying the appropriate path to regulatory approval or clearance is vital to a new product’s success, both pre- and post-launch.

Implicit in that regulatory strategy is creating a sound plan for gathering the evidence necessary to submit in support of approval. Clinical trial design, including development and identification of appropriate clinical trial end-points, identification of the targeted patient population, identification of the risks associated with the device and mitigation of those risks, are all within the purview of regulatory strategy.

B. THIRD-PARTY REIMBURSEMENT

FDA approval or clearance is the first significant hurdle that a device manufacturer must overcome on the path to market and patient access, but it does not end the inquiry. Unlike regulatory approval, coverage decisions are ultimately concerned with real-world clinical outcomes, and the costs associated with achieving those outcomes.¹⁸

To ensure coverage by CMS’ Medicare program, for example, a manufacturer must demonstrate that the item covered is “reasonable and necessary for the diagnosis and treatment of illness or injury ...”¹⁹ Thus, to be covered by Medicare, a product, or service must fall into one of the statutorily defined benefit categories and be approved or cleared by the FDA.²⁰ For private payers as well, a focus on optimizing health outcomes for a defined population and within budgetary constraints leads to collection of evidence different from evidence collected to ensure regulatory approval or clearance.²¹

III. THINKING WITH THE END IN MIND: ENSURING QUICKER PATIENT ACCESS AND REIMBURSEMENT WITH AN EXPANDED REGULATORY STRATEGY

A. SEQUENTIAL VERSUS PARALLEL REGULATORY AND REIMBURSEMENT STRATEGY

Traditionally, the processes of seeking FDA approval or clearance and securing third-party payer coverage are done sequentially.²² Following FDA’s device approval or clearance, payers then assess the new technology and render a



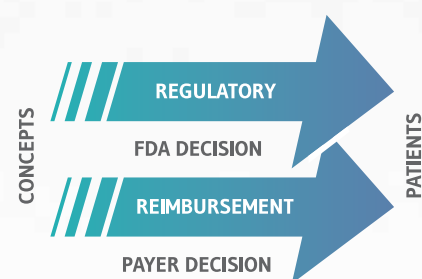
coverage decision, as depicted in the diagram below.²³

As described above, the type of evidence necessary to achieve regulatory approval is different from evidence necessary to secure reimbursement—demonstrating safety and efficacy versus establishing that a new device is reasonable and necessary. What is more, the timing of seeking a coverage decision —after securing regulatory



approval or clearance is different.²⁴ As a result, this “serial” review process extends both patient access to and a coverage decision regarding a new medical device.²⁵

To shorten an otherwise protracted process and to address demands posed by the New Health Economy such as value-based reimbursement, a new tactic has emerged in which regulatory and reimbursement strategy are implemented in parallel, as depicted below.²⁶



Effective execution of this strategy requires broader consideration and proactive planning to gather the requisite evidence necessary to collect and to do so earlier. Consequently, the widespread adoption of value-based reimbursement should drive development of a broader regulatory strategy in the New Health Economy.

B. “IT’S ALL ABOUT GATHERING EVIDENCE”: FDA’S PARALLEL REVIEW PILOT PROGRAM

As described above, both FDA approval or clearance and third-party payer coverage rely on evidence developed, gathered and analyzed during different phases of the medical device product development cycle. Forming a regulatory strategy that timely accounts for gathering evidence to support both regulatory approval and third-party payer coverage for new devices can lower the barriers to early market access posed by value-based reimbursement models. Indeed, both the FDA and CMS have recognized the importance of this new strategy.

During a November 21, 2014 presentation, FDA’s Ken Skodacek presented the slide²⁷ above, explaining that for FDA, “it’s all about gathering evidence,” and “if you’re gathering evidence for FDA to meet certain needs ... I want you to think about gathering evidence for other stakeholders along the way.”²⁸

Such information gathering had been underscored on October 7, 2011, when FDA and CMS announced their joint “Parallel Review” pilot program. “Under the ... program,

CMS and FDA offer concurrent review of medical devices for FDA approval and Medicare coverage.”²⁹ FDA described the goal of the pilot program as follows: “Both agencies rely on clinical data in reaching their decisions, and while the two agencies have distinctly different regulatory responsibilities, parallel review can reduce time between FDA approval and Medicare national coverage determinations.”³⁰ Indeed, the program’s “linchpin” is the “increased interaction between the primary stakeholders, ideally leading to a clinical trial that meets the needs of all parties involved.”³¹ Importantly, Parallel Review is designed to reduce the lag between regulatory approval and determination of CMS coverage by as much as six months.³²

Although innovative, Parallel Review has limitations. Not only is the program voluntary, it is also only available “for qualifying new medical device technologies.” Further, only five devices per year can participate in the program.³³ Recently renewed, the program is set to expire on December 18, 2015.³⁴ Of course, nothing about the pilot program changes the “existing separate and distinct review standards for FDA device approval and CMS coverage determination.”³⁵

To date, only one device has been approved through the parallel review program. On August 11, 2014, FDA approved Exact Sciences’ “Cologuard,” the first stool DNA-based colorectal cancer screening test, and simultaneously, CMS issued a national coverage determination (NCD).³⁶

C. PARALLEL REVIEW WITH PRIVATE PAYERS: THE FDA REIMBURSEMENT TASK FORCE

In addition to the Parallel Review program, FDA has created a task force on reimbursement, the mission of which is to “[s]treamline the pathway regulatory clearance or approval to reimbursement to support patient access to innovative medical devices.”³⁷ To do so, FDA is working to “[d]evelop a voluntary process that facilitates earlier interactions with payers ... about evidence to support coverage and reimbursement.”³⁸ Similar to Parallel Review, FDA is proposing a mechanism whereby device manufacturers can request a pre-submission, confidential meeting with FDA and one or more private payers to shorten the time between device approval and a coverage decision.³⁹

Like Parallel Review, nothing about this mechanism changes the method by which FDA evaluates safety and effectiveness.⁴⁰ Moreover, the program is voluntarily for manufacturers and payers, with manufacturers inviting payers to attend the pre-submission meeting and otherwise participate in the process.⁴¹

The benefits of these voluntary initiatives are far-reaching and signal FDA's understanding that all stakeholders need to adapt to industry-wide changes. For patients, FDA's initiatives represent an effort to fulfill its goal of enabling "[e]arlier access to innovative technologies."⁴² For payers, these programs represent a chance to obtain earlier information about new technologies, understand the FDA review process, and offer meaningful input into the data and analyses most useful in making coverage decisions.⁴³ For device manufacturers, they have an early opportunity to understand payers' evidentiary needs in making coverage decisions, evaluate and address coverage-related issues sooner in the regulatory process, and obtain earlier reimbursement decisions.⁴⁴

CONCLUSION

Systemic changes in the New Health Economy are having ripple effects throughout the spectrum of health care. In particular, a shift to value-based reimbursement models means that all stakeholders must identify strategies for reducing costs and improving health outcomes.

For manufacturers developing innovative medical devices in this environment, their regulatory strategy should incorporate reimbursement considerations. Indeed, the two gatekeepers for entry to market—FDA and CMS—have signaled a combined willingness to facilitate the success of new medical technologies by encouraging parallel review of both regulatory approval and coverage. Adopting a broader regulatory strategy to plan for gathering evidence to simultaneously meet the demands of both approval and coverage is an important tactic in establishing and demonstrating the "value" of new medical technologies. ■

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