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# WHITE PAPER




# How Will the Affordable Care Act Impact Medical Products?

By Dennis Burns and James Woodward

*The Patient Protection and Affordable Care Act (ACA) is already affecting the way health care providers (HCPs) operate, but how will the recent Supreme Court decision impact your medical product sales in 2013? Equally important, the new FDA user fee law signed on July 9 should accelerate regulatory reviews for medical devices and drugs.*

The hyper-politicized US media has been emphasizing the uncertainty caused by the recent Supreme Court decision and the upcoming elections. But you cannot wait. To quote an expert from a recent PWC webinar: "The doubts about the ACA are quickly fading and the time to act is upon you". Some 3 million new US customers will be joining the healthcare system by 2014 (25 million by 2020). Key implementation steps are moving forward and ACA programs are changing the way medical care is delivered now. Here are some key points to consider for your 2013 plans if you currently sell medical products in the US or want to enter the US market.

## The Supreme Court decision confirms that ACA is legal

The Supreme Court sided with the key Obama administration argument: Congress had the power to enact the ACA law – healthcare access will increase and its provisions will go forward. Hospitals and other health care providers are moving from the old US model of "fee-for-service" to a new "outcome-based" approach. Structural reforms are proceeding and you need to be planning for them whether you are a large or small medical products company. Only one aspect of the ACA was disallowed by the Supreme Court: the ability to force the states to enact Medicaid changes.

The rejection of the federal government's "universal" Medicaid (state insurance) requirement will disrupt programs for the poor in some areas (e.g., governors in Texas and Florida have refused to support the ACA due to fears of budget cuts). But 75% of the other states are already moving forward so insurance and hospital groups cannot take a "wait and see" approach. Politicians will find it hard to cut popular ACA provisions, such as coverage for older children, expanded drug reimbursement for seniors and the prohibition against excluding citizens with preexisting illness. Acting now to better meet your customers' new business requirements is smart before your competition does this smart.

## Health care customers have a new emphasis on quality outcomes

The emphasis on value and outcomes is a major change that payors and health care providers are adopting quickly. More than ever, products need to demonstrate their impact on patient care and costs, which gives companies with innovative cost solutions an advantage. Just another me-too offering will not work. Overall efficiency in medical offices, treatment facilities and hospitals will be a critical focus as various HCP groups consolidate into new unified Accountable Care Organizations (ACOs) and expand their managed care networks to seek more profit. These developments have driven a surge in hospital and practice acquisitions with well known "brands" like Mayo, Johns Hopkins, Cleveland Clinic and Duke expanding beyond their original locations. The overall cost of care and quality of life are now more important outcomes to these integrated systems as is their capability to connect. Before your reps can close a sale, they must discuss the effect on the customer's entire system and they will be expected to help the clinicians and management with:

**Defined cost advantages and a clear reimbursement strategy are critical for your US products as the ACA provisions go forward because regulatory approval is no longer sufficient in the new environment.**

- A superior value proposition for all health care provider groups
- IT connectivity solutions that have adaptable interfaces for different settings
- Detailed outcome information for offices and hospitals
- Unique ways to expand data access via wireless and electronic records (EMR)
- Collaborations with the growing EMR vendors (Meditech, Cerner, McKesson, Epic, Siemens etc.)
- Programs that translate to patient usage benefits

Marketing and sales goals for drugs and devices are changing dramatically – prepare your team for the new US marketplace.

## New medical products with cost-effective innovations will succeed

Defined cost advantages and a clear reimbursement strategy are critical for your products as the ACA provisions go forward because regulatory approval alone is no longer sufficient. An early example of the new emphasis is the Patient-Centered Outcomes Research Institute (PCORI), created in 2010 to conduct comparative effectiveness research. While not as powerful as its UK counter-part, the National Institute for Health & Clinical Experience (NICE), it will be increasingly influential. Along with the decisions of the Centers for Medicine and Medicare Services (CMS), PCORI will help codify cost solutions for federally funded medical care (now more than 60% of the US system) as well as for the new ACOs trying to treat overall disease more effectively.

Some experts have suggested that European medical device makers may be better prepared for the new US focus on total patient care and cost control. However, they will only be successful if they can apply their system knowledge from Europe and modify their products to match the evolving US environment. All company R&D programs and new product plans must include cost models to move away from the old "unit" selling and towards an integrated "solution" model. Sim-

ply stated, you want payors to more readily reimburse your HCP customers for your product compared to your competition. You need devices and drugs that lower overall costs with fewer and shorter office visits and hospital stays. Your customers will increasingly focus on these metrics because these will increasingly determine how their performances will be evaluated.

This new environment provides opportunities for products that emphasize wellness, prevention, diagnosis and quicker therapy such as:

- Point of care (POC) diagnostics
- Unique primary care products
- Preventive care and better home care solutions
- Patient monitoring aids
- Drug delivery systems that improve compliance

## The medical device tax challenge

All of us are concerned about the economic impact of the new 2.3% excise tax; and frankly, we are outraged by the unfair financial burden to our industry. Most Congressional Representatives oppose it; and in a normal political environment, it would be repealed. But 2012 is not a normal year with debates about the global economic stress, the US deficit, the looming debt ceiling debate and expiring tax programs all at the same time that political campaigns ramp up.

The excise tax will put financial strain on device companies, especially on new companies. It will probably encourage more US start-ups to begin commercialization in Europe to fine tune their business model before marketing in the US. Our industry associations are telling us to keep fighting the tax, but begin to begin designing systems to collect it properly starting next year (unless your devices are patient/consumer oriented which are exempt under ACA). Obviously, programs to reduce product costs should be given priority this year.

## The FDA Safety and Innovation Act

On July 9, the FDASIA was signed by President Obama after strong bipartisan support in Congress. It updates both the MDUFA and PDUFA medical device and drug user fee programs while requiring reforms and policy changes (including how FDA approves clinical trials and a de novo pathway for devices). Most industry executives are pleased with the final Act because $595 million from higher user fees will fund 240 additional FDA reviewers and provide more scientific training. In addition, it sets new performance metrics on 510ks and PMAs, which the FDA must meet to receive the extra funding. Hopefully, this new law will be a ”win-win” for both industry and the FDA with more predictability in the approval process so companies can bring life-saving devices to market quicker.

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