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Restrictive Innovation: How Medical Device Manufacturers Confound Clinical Excellence

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Across industry, evidence of planned obsolescence is revealed a number of ways. Automobile manufacturers are known to provide a great example. Whether through frequent and unwarranted changes in design, a termination of spare parts supply or the intentional use of nondurable materials, consumers "get it" and have even come to accept it.

In healthcare, the practice is known as “restrictive innovation” and its effects are far more insidious. Under the guise of innovation, the industry's medical device manufacturers have become so brazen about introducing meaningless product changes that noted Princeton economist Uwe Reinhardt openly called them out, saying, “unnecessary innovation is one of the industry’s biggest cost drivers —a tax on the system that protects OEM profits and confounds customer [hospital] strategies to save money.” With device costs already running 60% of the total reimbursement tied to many procedures, the economics are unsustainable. Even worse, meaningless "innovation" adds cost pressures that ultimately hurt patients. Especially for hospitals that rely on Medicare/Medicaid-reimbursements, the effects invariably include a reduction in the number of patient procedures performed, meaning clinicians do not achieve the competency needed to increase success rates.

An Industry Example: Medical Device Reprocessing

The unnecessary and rapid launch of “new and improved” products designed to confound commoditization places constant pressure on hospitals to spend money on devices that aren’t any better. To fight back, many have successfully dealt with premium priced new technology adoption by leveraging FDA controlled device

reprocessing. By collecting used devices and working with commercial reprocessing companies to refurbish them at about half the cost of new, they achieve a blended device rate that is economically viable.

It would seem that all ships might rise on such a virtuous tide, but it's not the case. OEMs are responding by employing engineers whose specific job is to create designs that are more costly to reprocess. For example, the OEMs have recalled devices for the sole purpose of modifying operating codes so they lock after a single-use, offering no evidence of clinical improvements. They release "new and improved" versions where the only change is to make vital parts, like a chip controller, less accessible to re-program. Device company representatives will give away generic system parts, like cables, that are later discovered to only work with what they sell as single use. These same representatives are even known to withhold support from a physician who chooses to use the identical reprocessed version of the device that they sold --to the same doctor. The anecdotes are rampant and troubling. Beyond the added stress to healthcare's struggling economy, it's a shameful tug of war that is antithetical to the interests of patients.

A Hospital Example: The Electro-Physiology Lab

The restrictive innovation efforts of the OEMs are particularly egregious in the Electro Physiology sub category of cardiology, as the devices are notoriously expensive and the FDA has approved many of them for reprocessing. As mentioned, procedural cost pressures directly impact what hospitals do and who gets what. And because physicians don't become great at performing procedures that are economic losers for themselves and the hospitals where they operate, patients also lose.

Atrial Fibrillation ("A-Fib") Ablation provides an outstanding example, as demand for the procedure is high, yet the number being performed has slowed, meaning the improvements that the scientific evidence indicates are available are not being appropriately reflected in patient outcomes. Although the procedure has been shown to be more effective than medication therapies, it is still only 15% penetrated in the U.S., despite significant and known quality of life improvements. So, it is not a coincidence that there are a limited number of specialists. And, it should not be surprising that the physicians who are known to be particularly effective at this procedure tend to work in profitable EP labs where OEM tactics designed to confound value, like reprocessing, are not tolerated.

Rick Ferreira, CEO of Innovative Health, whose company is doing its best to drive cardiology device reprocessing, put it very plainly: "Technology innovation in AF Ablation has opened up the opportunity for us to revolutionize the treatment of heart disease, but its impact is confounded by commercial practices that effectively restrict rather than expand access."

We know that the medical device OEMs are under tremendous pressure to optimize their pricing for predictable, short-term gains. And we know that they do it well, as their

stock values have basically doubled over the last five years. Meanwhile, as a matter of survival, the care-provider market is consolidating. It’s a stunning juxtaposition, especially when considering that it has happened in a marketplace where supply grossly exceeds demand.

Hospital leaders must own the decisions that ultimately determine internal utilization, access and outcomes. They cannot allow them to be driven by OEM sales targets. As a starting point, they should direct their procurement staff to stop buying devices where the value-add is below the value-based reimbursement threshold. Value-based healthcare is transforming the care provider/payer/patient triad, so the idea that the industry's supply-side has somehow managed a "pass" is unacceptable.

Restrictive innovation is nothing short of a bully strategy against a vulnerable industry and patient populations that deserve better. And when considering that tax expenditures fund nearly two thirds of healthcare costs, the practice should not be tolerated.