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Musings on the Role, Value, and Risks of New Technology in Spine Surgery

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For 45 years I've been chasing the next great medical technology—beginning in the mid-1980s on Wall Street, then since 2005 as the publisher of *Orthopedics This Week*. Recently, I've started interviewing the creators of modern spine surgery and also re-reading old patents, regulatory filings, and clinical studies.

In my interviews and readings, I came to find that before 1960, virtually nothing that spine surgeons do today existed. After 2010, virtually everything today's spine surgeons do existed in one form or another. Those 50 years of innovation revealed, I think, 3 ground rules for all medical innovation. Ground rules that are applicable even to the coming tsunami of digital and software-based innovation.

1. Innovation must *materially* improve patient outcomes.

Not just for obvious reason, but also, equally importantly, for economic reasons. The connection between pricing, profits, and patient outcomes may be denied by companies seeking market share, but it is an immutable, unbreakable link—which exerts power over the intermediate to long term. The 70-year landscape of spine technology is littered with devices that were someone's fervent dream in search of a market—yet failed because they did not *materially* improve patient outcomes.

2. Innovation must *materially* improve the logistics of patient care.

To a large extent, the economic success of innovative pain management products is rooted in the logistics—cutting the number of days a patient stays in the hospital by 50% or more, for example.

The promise of the rapidly accelerating digital revolution is to address such major logistics issues as patient record keeping, coding, contracting and reimbursement, and, ultimately, providing a level of smart guidance that would elevate, standardize, and de-risk the act of spine surgery itself. The value of these digital technologies will be measured in terms of fewer hours in surgery, streamlined planning, faster and more accurate coding

and billing, and reduced readmissions—in short, the logistics of spine care.

3. Innovation must fit into the natural monopolies that exist in medicine.

Medicine generally, and back pain specifically, comes with a low elasticity of demand—meaning that the patient demand for care is not, from the patient's perspective, price dependent. Layered over that is the legal monopoly of the patent system. This was the foundation for Gary Michelson's legendary billion-dollar litigation win a couple of decades ago.

The second monopolistic layer is the regulatory system. InFuse's Pre-Market Approval (PMA), for example, effectively blocked competition for decades. Reliance on a 90-day 510(k), sets up the conditions for fast follower competition—witness the speed with which manufacturers have been able to bring 3D-printed implant designs to the market.

An innovation that materially improves patient outcomes, materially streamlines spine surgery logistics, is patent protected, and has emerged from the PMA gauntlet (level 1 clinical study), is valuable by any measure. Unfortunately, the coming digital revolution is vulnerable in this area. Software is routinely obsolete. Hardware is vulnerable to Moore's law. Today's large robotics systems could well become tomorrow's recycling material.

There are, however, natural monopolies available in data. Each hospital has monopolistic ownership of its patient data. Each researcher or institution owns its clinical study data. Each payer owns its own data. If a co-op of data generators were ever launched, it would be leveraging these natural data monopolies. Under U.S. law, co-ops are legal monopolies. And when viewed as an information business, spine surgery has a built-in legal monopoly in terms of the data it generates.

In conclusion, innovation is like a river. While it may change direction, it never stops flowing. Spine surgery, as an implant and instrument business, is mature. Spine surgery as an information business is in the early stages

of an innovation revolution. It's an exciting time, but one that, I believe, is still subject to the 3 immutable rules of innovation in medicine.

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