The Decline of Medical Innovation in the United States

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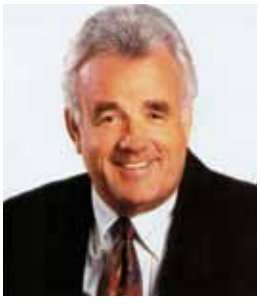
If arthroscopic surgery were to make its appearance on the medical scene today, it is possible that it would be deemed experimental, and, therefore, not approved or paid for. Its early adoption in North America, heralded by Robert Jackson, MD, and many other pioneers too numerous to mention, was met with some skepticism and push back. Eventually, the procedures were accepted and reimbursed and the era of minimally invasive surgery (MIS) was born. Our arthroscopic procedures are quicker, have fewer complications, and are less expensive than traditional open surgery, and they are of immeasurable benefit to the patient. It is one of the 3 most important advances in the world of orthopedics in the last century, next to joint replacement and open reduction and internal fixation of fractures.



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Were we to introduce the arthroscopic technique today, our hurdles might be insurmountable. The Food and Drug Administration (FDA) would not consider a 510(k) clearance appropriate, as there would be no predicate orthopedic device. Level 1 outcome studies would commence, but they could be too inconclusive to give the insurance companies or Centers for Medicare and Medicaid Services (CMS) reason to consider arthroscopy anything other than experimental, and, in turn, they would deny reimbursement. You may recall the flawed study on arthroscopy for osteoarthritis of the knee and the rather prompt response by CMS and private insurance companies to deny reimbursement.

A recent reversal of a previously FDA-approved meniscal implant has left the sports medicine knee surgeon without a viable option for patients with symptomatic post-partial meniscectomy syndrome. A meniscal allograft is not a reasonable alternative. Twenty years of research and clinical trials as well as a published Level 1 study apparently were not enough for the FDA. This meniscal implant has been used successfully in Europe for the past 7 years.

Advances in MIS, arthroscopy, and, in general, the world of medicine, are being threatened as never before. Our European and Asian colleagues currently are performing procedures approved in their countries that have little chance of being approved in the United States for years to come, if at all. Major orthopedic industries will be moving their new product launches to Europe and Asia as the FDA tightens its policies. The FDA's recent increase in regulatory control is being advertised as a patient care initiative, when, in truth, it is another move to increase bureaucratic government control.

There are innumerable examples of conservative treatment modalities approved in Europe and Asia that have been proven to be effective alternatives to more costly surgical procedures. A good example of this is ESWT (extracorporeal shock-wave therapy); there is significant scientific support for its safety and efficacy. The refusal by the insurance industry to pay for these procedures is forcing patients into costly surgical procedures.

We are entering into an exciting era of biologics in orthopedics. The cost of development and the regulatory process may make these products more expensive than they should be, and, in some cases, not available in this country. This would be a great disservice to our patients and our profession.

The quandary now exists of increasing medical care needs and the development of new techniques and therapies that are either not approved or not affordable. Reducing the burden of regulatory control and advancing tort reform would go a long way toward helping to reduce costs.

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