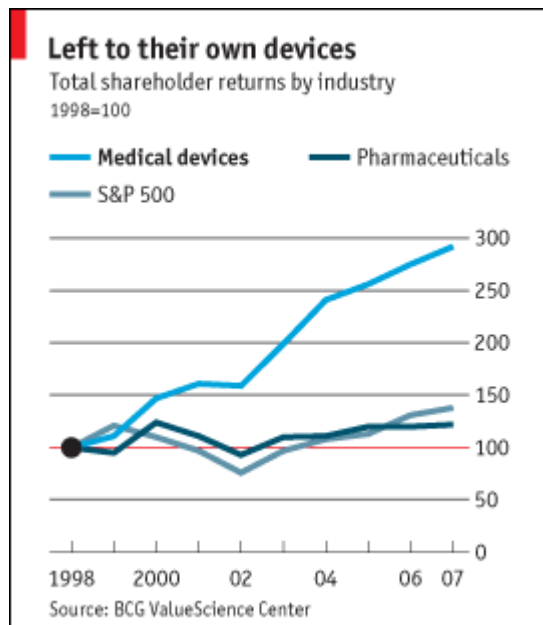


The bleeding edge

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The drugs giants are in trouble, but medical devices are booming



A GOLDEN age of medical innovation could be at hand—but only if the lawyers get out of the way. That, at least, is what champions of medical-devices firms argue. The industry has certainly been doing well lately. Thanks to the success of insulin pumps, heart stents and laparoscopic surgical tools, the industry's total shareholder returns have far outpaced those of the large drug companies—and, indeed, most other industries (see chart).

Proponents of medical devices point to such promising upstarts as Apollo Endosurgery, an American firm developing “natural orifice” surgical products that leave no scars. This approach, which involves inserting sophisticated surgical devices through orifices such as the mouth or anus, rather than slicing patients open, has already been shown to work in removing gall bladders. Apollo is convinced it can be adapted even to heart surgery.

But there is a snag. Santiago Horgan, a surgeon at the University of California in San Diego who advises Apollo, explains it is much easier to find suitable patients in his native Argentina than in hyper-litigious California. “I’ve turned down some ideal candidates, because I discovered they were lawyers,” he says.

Apollo's concerns about litigation echo those of other small device-makers in America. Even if their products have been deemed safe by the Food and Drug Administration (FDA), they have long faced the threat of liability lawsuits in state courts. Peter Lawyer of the Boston Consulting Group, a consultancy, has scrutinised the share valuations of firms in this field, and he reckons that those with stockmarket values of less than \$2 billion are being penalised by investors, who seem them as riskier. "The big multinationals are big enough to survive losing one of those liability suits, but the smaller innovators would be wiped out altogether," he says.

But now, after a landmark ruling by the American Supreme Court, the spectre of a blunderbuss of liability suits may have receded. On February 20th the court ruled that if a device's design has been ruled safe and effective by the FDA, then juries cannot say otherwise based on state law. A spokesman for AdvaMed, the devices-industry lobby group, cheered the decision as a sensible one that will prevent such lawsuits from "disassembling the innovation cycle" with contradictory rulings.

James Ralston of Smith & Nephew, a British device-maker, even argues that it will help America's regulators catch up with their counterparts across the Atlantic. Perhaps surprisingly, considering the grouching usually heard from drugs giants about European regulators, his firm has often found it faster and easier to launch new products in the Europe than in America.

If the ruling stands (and there are some rumblings among Democrats in Congress about overriding it), then the industry's boom seems likely to continue. Medical devices have already seen an influx of private-equity funds and venture-capital firms. Mr Lawyer also points to the "gathering wave" in Asia, including an unexpectedly strong cluster in Pakistan. FDA data on new-device applications shows that these low-cost innovators are rapidly evolving from making cheap tools to more sophisticated devices.

The long-term trends also look promising as the confluence of genomics, nanotechnology and high-speed computing make possible more elaborate devices. Futurologists at Deloitte, a consultancy, reckon the "medical home", chock full of new medical devices, will be a reality within five years. James Tobin, chief executive of Boston Scientific, an American devices giant, points to an ageing population, the proliferation of diseases, the demand for medical technology and the growing appetite for medical technology in emerging nations and insists "we're just beginning to scratch the surface."

It all sounds great—provided nobody asks who is paying for all of this. America's Congressional Budget Office recently released a study arguing that "the emergence, adoption and widespread diffusion of new medical technologies and services" were to blame for fully half of America's health inflation. Unlike in other industries, where new technology often leads to

productivity gains as inefficient older equipment is junked, new medical gadgets (such as MRI scanners) tend to be used in addition to today's technologies (such as X-ray machines). The industry may have the Supreme Court on its side, but it will now be watching carefully to see who wins the White House.