Neurology and Medical Devices

Medical devices are becoming more important in the diagnosis and treatment of neurological diseases. In the 1980s and 1990s, diagnostic technologies, in particular, computed tomography and magnetic resonance imaging, improved the accuracy of neurological diagnosis and helped to define new diseases. Now, medical devices are becoming an important part of the treatment armamentarium for neurological diseases. The most obvious examples are in the treatment of stroke. Coiling of aneurysms; angioplasty and stenting of carotid, vertebral, and intracranial arteries; extraction of thrombus in patients with acute stroke; and closure of patent foramen ovale are some prominent examples. Outside the vessels, deep and surface brain stimulators have been used for a variety of conditions, and neuroprostheses are also coming to the fore. Clearly, devices are changing the way we practice neurology.

Overall, medical device companies have outperformed pharmaceutical companies in the past decade, with a 1.5-fold greater return on investment.[1] The pace of device approvals by the US Food and Drug Administration (FDA) is much greater than for drug approvals, which may partially explain the difference. During the past decade, 1,375 devices have received FDA approval after review by neurology advisory panels, whereas only 76 neurological drugs were approved during the same period.[2] Furthermore, whereas rates of approval for drugs have declined, device approvals have tended to increase (Fig).

Simply comparing the number of approved devices and drugs is potentially misleading. Many approved devices have had only minor impact on medical care and health, such as neurosurgical tools and electrodes and other sensors. Furthermore, most neurological devices have been approved through the 510k mechanism, which covers devices that represent incremental advances on existing approved devices and does not require proof of efficacy. Of course, one could argue that most approved drugs are incremental advances over existing drugs, such as the numerous "triptans" and acetylcholinesterase inhibitors,[3] and many important devices have been approved, even using the 510k mechanism.

The lower bar for device approvals certainly contributes to the pace of development. Most devices are approved without evidence of efficacy from a randomized trial, whereas drugs require evidence of efficacy from randomized trials. This is partly explained by the broad definition of devices, which includes things such as surface electrodes for electroencephalography and surgical sutures; it appears unnecessary to subject these to randomized trials. However, when approvals are given for substantially new indications, things get more complicated and controversial.

One of the most controversial examples of a device approved by the 510k mechanism was the Merci Retriever, a "corkscrew" device that was approved for endovascular removal of thrombus in patients with ischemic stroke. No randomized trial was performed, but based on results of a large uncontrolled case series, the manufacturer argued that the device was safe and that it was substantially equivalent to one already approved for retrieving errant coils.[4] The retriever is now widely used in treating patients with stroke, whereas intraarterial prourokinase, shown to be effective in a randomized trial, never gained approval for the same indication.

Critics have argued that the advantage for devices in the approval process is unfair, and that many devices are then used inappropriately for unproven indications. For example, many patent foramens are being occluded with devices, whereas data showing that these reduce risk for stroke are completely lacking. Patent foramen ovale closure for migraine prophylaxis, in the absence of definitive clinical trials for this indication, is equally problematic. In another example, neurologists are well aware of the lack of adequate placebo-controlled trials supporting numerous devices used to treat chronic back and neck pain syndromes, including discography, artificial discs, and electrical stimulation. Utilization of devices without evidence of efficacy will certainly increase costs, perhaps with little or no benefit. Contrary to this argument, economists estimate that the majority of the improvements in health in the past 20 years are due to advances that were not tested in randomized trials.[5] Early approval of coronary stents allowed practitioners and device manufacturers to perfect them and the procedures involved and to define the most appropriate indications in an organic fashion, learning from observational data and their own experience. Such advances would have been much slower if a randomized trial was required for each new advance. More broadly then, the easier mechanism for device approval may actually accelerate the development of new therapies by allowing more rapid testing in actual use.

Once a device is approved, there are often strong incentives to use it. Procedures that involve devices are very well reimbursed, with hospitals and physicians generally profiting from them. For example, an endovascular surgeon can bill about $1,600 in professional fees to Medicare for a 2-hour cerebral aneurysm coiling, whereas hourly rates for outpatient evaluation to

Published by Wiley-Liss, Inc., through Wiley Subscription Services

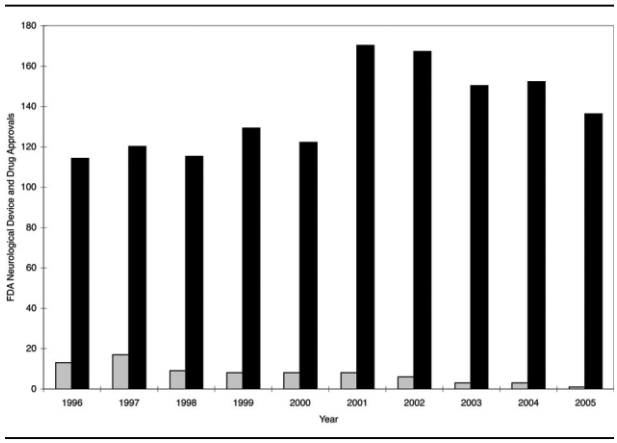

Fig. Approvals of neurological devices (black bars) *and drugs* (grey bars) *by the US Food and Drug Administration (FDA) 1996 through 2005. For devices, new premarking approvals and 510k approvals are included.*

consider whether treatment is actually indicated are about one tenth this. This premium on procedures has been well protected. A recent attempt by the Center for Medicare and Medicaid Services to reduce reimbursement for device-related procedures was quickly thwarted by subspecialty groups and device industry lobbyists. Thus, the financial incentives that promote implementation of new devices are likely to remain into the foreseeable future.

These realities, coupled with current levels of reimbursement for "cognitive" activities that are inadequate to sustain traditional freestanding neurological practices, have increased the pressure to expand the armamentarium of devices used in the clinic. Transcranial Doppler and transthoracic echocardiography for neurovascular indications, evoked potentials and optical coherence tomography for multiple, and an increased use of traditional electrophysiologic diagnostics (electroencephalography, electromyography) are but a few examples. Although all of these procedures provide useful information that can inform decision making, a legitimate concern is that their excessive use may reduce the physician's focus on the need to have a personal relationship with the patient. It appears clear that a balance needs to be restored between the value placed on physician–patient interactions that do not involve application of expensive technology and those that do. Without a level playing field, malaligned incentives encourage behavior that is not in the patient's best interest.

With the financial success of device companies, a quicker and cheaper path to approval, and strong incentives for implementation, the pace of development is likely to accelerate. Advances in diagnosis and treatment will be exciting to watch. How these advances will change the clinical practice of neurology will depend very much on whether the field sits on the sidelines, as with neuroimaging, or embraces these new devices as part of the armamentarium of neurologists. More than simply transforming itself into a procedural specialty, however, neurologists also need to play an important role in assessing the value of new technologies and ensuring that evidence-based clinical decision making governs their application. This challenge represents not only an obligation, but also an outstanding opportunity for the future of the field.

S. Claiborne Johnston, MD, PhD
Executive Vice Editor

Stephen L. Hauser, MD Editor

References

1. Moses H 3rd, Dorsey ER, Matheson DH, Thier SO. Financial anatomy of biomedical research. JAMA 2005;294:1333–1342.
2. PMA and 510(k) device approvals. US Food and Drug Administration. Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/search/search.cfm. Accessed August 24, 2006.
3. Johnston SC, Hauser SL. Can industry rescue the NIH? Ann Neurol 2006;60:11A–14A.
4. Becker KJ, Brott TG. Approval of the MERCI clot retriever: a critical view. Stroke 2005;36:400–403.
5. Heidenreich PA, McClellan M. Biomedical research and then some: the causes of technological change in heart attack treatment. In: Murphy KM, Topel RH, eds. Measuring the gains from medical research. Chicago: University of Chicago, 2003: 163–205.