"Coming of Age" for Device Technology

Medically related hoaxes and quackery have been with us for many, many years. The American Medical Association's principal activity during the late 19th century and early 20th century was to expose and debunk such phoney remedies and their fraudulent promoters. Subsequently, after the predecessor to the present-day U.S. Food and Drug Administration was established in 1906, that federal agency assumed national leadership for monitoring the promotion of devices and gadgets claimed to have therapeutic properties or diagnostic value. Other groups—including the American Pharmaceutical Association in particular—provided strong support to these efforts, as well as conducting their own educational programs and professional projects.

Copper bracelets for arthritis sufferers probably have been the most common and well-known hoax, but there have been hundreds and perhaps even thousands of others. The FDA had a museum—a so-called "Chamber of Horrors"—in which its collection of the more unusual and ingenious such items had been exhibited. The agency made wide use of that exhibit in conjunction with its educational campaigns to warn the general public about the uselessness—and, in some cases, even the potential hazard—of such devices.

Those of us educated in the sciences, and especially in the medical and pharmaceutical sciences, recognize the lack of any plausible scientific basis for expecting these devices to have any curative value. But to the average lay person, who is at best only casually schooled in the sciences, the claims appear to be within the realm of possibility. And when one is desperate for a cure—due to the absence of other proven remedies, coupled with pain or a fatal prognosis—that person is quite receptive to the pitch of a medical charlatan.

For years, the FDA has so relentlessly pursued this activity, so dramatically exposed the devices as fraudulent, so widely publicized their worthlessness, and so vigorously prosecuted those people who promoted them, that one might reasonably question whether the agency has been able to adequately retain its objectivity in the matter. In other words, if some seemingly exotic device or treatment came along that did indeed do what was claimed for it, would the FDA be able to recognize its worth, and publicly acknowledge its usefulness? The krebiozen and laetrile episodes were fueled by just such doubts on the part of the public and some of the medical community.

Well, in our view, any such question can now be put to rest.

We recently saw the April issue of the *FDA Consumer*—which is the Agency's magazine for lay readers.

The lead article was entitled "Sealing Teeth to Prevent Cavities." And rather than expose the procedure as a hoax, or even as a well-intended but worthless effort by dentists to protect against the ravages of caries, the article gave a ringing endorsement to the procedure! The FDA staff writer explained in easy-to-understand language the susceptibility of tooth fissures to dental decay, the theory behind the sealants, how they are applied, their relative safety, and the clinical test results recorded for them. The general message of the article can best be conveyed by the writer's own abstract-summary: "*A group of experts recently agreed that sealants can be effective in protecting teeth of youngsters, particularly those teeth that are pitted and have fissures.*" The article itself stated that "*the occurrence of pit and fissure cavities was reduced by approximately 95 percent at the end of one year and at least 50 percent at the end of five years.*"

Then, later on in that same April issue of *FDA Consumer*, was an article discussing a heat-generating device that has been promoted as a treatment of cancer. Our initial reaction was: "*Old hat! FDA has been debunking such devices, and hounding their promoters for as long as we can remember!*"

But, again, this was another case of "man bites dog!"

The FDA staff author described how a new medical device that uses controlled microwave energy to treat certain kinds of cancer has won FDA approval for marketing. The microwave energy produces hyperthermia and is now approved specifically for treatment of four types of malignant tumors: melanoma, squamous carcinoma, adenocarcinoma, and sarcoma.

The article points out that hyperthermia has certain limitations and is a palliative treatment rather than a true cure. But just to suppress and halt the growth of a malignant cancer is a great achievement with respect to this terrible disease. Also described are the clinical test results (with full to partial regression of 83 percent of tumors in one major study), the theoretical basis of the device's principle of activity, the technique employed in utilizing the device, the specialists who will initially employ the device and where it will be available, and the technique that manufacturers will use in testing and standardizing the machines they produce without needing to use human subjects in the testing process.

This FDA author's own abstract-summary also conveys very well the general message of the article: "*A recently approved device offers a new way to treat four types of cancer. In a process called hyperthermia, cancer cells are destroyed by microwave-type heat.*"

And less than a week earlier, we had read that, effective March 30, FDA had granted approval for the general marketing of nuclear magnetic resonance (NMR) imaging equipment for medical diagnostic purposes. NMR is expected to be very useful for *in vivo* pathological analyses as well as more effective three-dimensional visualization than can be achieved by currently available CAT scanning. Other exotic diagnostic applications are anticipated in the near future, and there is a good possibility that certain therapeutic or treatment applications will be approved eventually.

All of this is welcome news in the overall health care picture. New drug discoveries will continue to be important, but there is a growing recognition that pharmaceuticals alone are not sufficient to provide the most efficient and effective treatment for many diseases.

What we are seeing is the emerging era of applied technology. Although, as in the case of drugs, we have long enjoyed some benefits of device technology, they have been very limited and elementary when compared to the new gadgetry, electronics, and computer systems now becoming available.

And even in the pharmaceutical field, the present research and development emphasis is shifting more and more toward sophisticated drug delivery systems and away from exclusive interest in new drug entities. Again, this is applied technology.

In conclusion, what we are witnessing is truly a medical revolution. A field that just a few years ago had been full of phoniness and quackery has now been transformed by modern technology into one of hope and promise. For all of us who are involved, or even just witnessing these events, these indeed are exciting times!

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