THE RETURN OF THE SNAKE OIL SALESMEN

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I have seen a medicine
That’s able to breathe life into a stone
Quicken a rock, and make you dance canary... ... All’s Well That Ends Well
William Shakespeare

It’s the time of the year when an annual editorial is due. Thinking about possible topics, I noticed the extraordinary amount of media advertising going on directed to the public concerning new medical tools. Today radio and television ads directly discuss prescription medications and their potential benefits (never the down side) and finish with the comment, “Ask your doctor.” Obviously, vendors and drug companies have decided to target their products directly to patients and hope that a patient interaction will intimidate the unwitting physician to write the prescription.

At a recent conference on intensity-modulated radiotherapy (IMRT), I was amazed to see a representative of one of the vendors take approximately 30 minutes in a formal presentation to discuss explicitly with radiation oncologists and hospital administrators how they should advertise and market IMRT to get the public’s interest and entice the patient to facilities with this new technology. Not a single word was expressed concerning the lack of long-term data or the potential down sides associated with this new treatment approach, which actually conflicts with several principles of radiation biology that I would have thought were well known and accepted before this present era. Those principles have been reviewed (1), and need not be discussed here. In this editorial, I would like to focus on the efforts of vendors for both drugs and devices that appeal directly to patients and their families, most of whom are in no position to be able to evaluate the message received.

Formal use of the media as a means of selling such medical drugs and devices directly to the consumer seems to be a phenomenon of the last 15–20 years. There was a time when technologic and pharmacologic information was considered too complex for patients, and there was an attitude of patronization exclusively with respect to physicians on these issues. Not any more.

Another factor relates to present-day Darwinian competition, not only among physicians, but also among hospitals. Many of today’s hospital administrators presume that they know the issues better than physicians, but the issue of most concern seems to be the issue of revenues. Some simply smell the aroma of profits with a very low threshold. Is there any other way to interpret hospital advertisements such as one that was clipped from The New York Times and recently sent to me? One of the New York hospitals advertised publicly a “quantum leap” in the improvement of the treatment of lung cancer because of the development of respiratory gating! There are obviously no data on lung cancer to demonstrate a quantum leap of any kind associated with gating, irrespective of any theoretical rationale for potential benefit. It remains a research area and one in which the major justification centers upon the desire to use IMRT for the treatment of mobile intrathoracic neoplasms, largely presupposing improvement from dose escalation. The mo-
tion problem is a serious confounding factor for the calculation process for dose associated with IMRT.

It will take well-designed clinical trials and considerable time to clarify this issue, if investigators can admit they don’t really know, but simply suspect, there may be some improvement. Those patients in whom the prognosis is poor are reasonable candidates for prospective and careful investigation of these new technologies. On the other hand, patients who are expected to live a long time (e.g., breast cancer, pediatric cancers, etc.) may manifest some of the unforeseen, but nonetheless predictable, morbidities and complications that are not yet being reported, but ultimately will be, simply because these patients will live a long period of time in which to do so. The big question is whether these trials to evaluate IMRT objectively will ever be done or not; it may well be too late, inasmuch as there appears to be a veritable stampede for such treatment. Does this not remind you of the bone marrow transplant euphoria for patients with breast cancer?

Today, the advertisements from hospitals, physicians, and vendors are too one-sided. Unsubstantiated claims are directly made to the general public, and no acknowledgment is given to potential hazards associated with these new developments. What this has led us to is a situation in which many community hospitals have invested heavily in new technologies and equipment, and they intend to recoup their investments quickly. They are competing for patients with major medical centers and are unknowingly carrying out confirmatory clinical research based on the preliminary initial reports from a few medical centers. All this is being done in the name of patient care, because no one wishes to call this treatment “research” for fear that third-party carriers will not pay for it (even though there are no published long-term data that conclusively indicate survival improvement). Investigators present updates at virtually every meeting, thereby confirming that this is ongoing research, regardless of how it is labeled. Every effort appears to be aimed at equating high-tech treatment with high-quality treatment to the lasting confusion of both patients and third-party payers alike; these are not necessarily the same thing.

Even the doctors are getting into the media act. You can find sites on the Internet advertising high-technology treatment with claims of “95% success.” It is unclear to me to what that “success” refers. Are we talking cure? Are we talking local control? Or are we talking about the ability of the patient to get off the table at the end of the course of treatment?

Now there are some who say that FDA approval means it is not research but standard of practice. Not so. The approval by the FDA for a device is not the same as for a drug. A drug will not receive FDA approval without evidence of both safety and efficacy, usually a Phase III study. Approval of a device merely means that mechanical safety of hardware and software has been verified. The reader may not be aware that the history of such approval in radiation oncology goes back more than 35 years ago, when a patient with breast cancer was crushed to death, because of a lack of a fail-safe feature on the radiation treatment couch.

I doubt that patients would literally demand these technologies (as they sometimes do today) if they were honestly informed about predictable risks, about the lack of long-term data, and about the limited experience in some of the community centers that are attempting to compete with major medical centers. There are still some institutions and some physicians who are waiting on the sidelines for some formal and disciplined evaluation process for such treatment, to determine whether there truly is objective improvement to be obtained. The pressures on the community practitioners and hospitals that are trying to hold off and await true outcome results of these new technologies must be enormous. Unfortunately, the almost ridiculous plethora of gamma knives presently in the United States suggests a pattern of medical decision-making driven by a quest for “market share.”

There may be a role for IMRT or other new technologies in the treatment of some cancers. However, this remains to be proven. Lacking long-term data, current cheerleaders for IMRT risk damaging the credibility of the medical profession with a premature rush to claim major advances, which cannot meet unrealistic expectations created by excessive hyperbole.

Perhaps patients’ enthusiasm for a new treatment that they do not understand would diminish if the risks of secondary-induced cancers were honestly explained to them. Perhaps patients would balk if they knew they were part of dose escalation treatments for which long-term follow-up data do not exist.

In the nineteenth century, snake oil salesmen did the selling directly to the public from the back of wagons. Today, it’s smoothly pitched over mass media, as the twenty-first century threatens to become the century of hucksters. Marshall McLuhan is alive and well!

REFERENCE