ADVICE FOR MANUFACTURERS

ADVICE FROM EXPERIENCED MANUFACTURERS TO ASPIRING MANUFACTURERS

Part of the second goal of the project was to develop information that could help organizations hoping to develop and commercialize medical devices to understand the managed care market environment and to prepare accordingly. We asked interview respondents representing manufacturers to offer advice for such organizations. Interview respondents generally offered extensive and thoughtful answers to this query. While emphases differed across interviews, some consistent messages emerged. We first summarize advice that was offered—in one form or another—in most (and in some cases, virtually all) of our interviews with manufacturers. We then briefly relate advice that was offered by a minority of the respondents.

Almost all of the interview respondents emphasized early development of commercialization strategies and planning of commercialization efforts. One especially experienced respondent emphasized that a strategy should be developed when the “product is just an idea”—that it was not good business practice to put effort into developing a new device unless there was reason to believe that a viable commercialization strategy could be developed and implemented.1

1In contrast, a participant in the October 7 meeting took exception to this advice, saying, “If the technology is good enough, you have to throw your heart in before your head.”
Despite lack of agreement about precisely when companies should begin to prepare for commercialization, virtually all manufacturers emphasized that companies should analyze several issues well before a product is ready for FDA review, including the following:

- **Prevalence, incidence, and patient demographics of the disease or medical condition at which the product is aimed.** Such information is critical to understanding the potential size of the market and who the key payers will be.

- **Effectiveness, safety, and costs of existing alternatives to the product.** These factors determine the nature of the competition that the new product will face. To be successful in the marketplace, a new product generally will need to demonstrate superiority to alternatives on at least one of these dimensions.

- **Availability and levels of reimbursement for similar devices.** The current reimbursement environment for devices similar to the one under development can provide the best guide to the situation the new device will face. Several respondents cautioned that it is very difficult to command a premium price in today’s marketplace—even if a device has superior performance—and that the current reimbursement situation might reasonably be interpreted as a realistic or even optimistic projection of what the future will hold.\(^2,3\)

- **Reimbursement codes and reimbursement levels for professional and institutional services associated with the device.** Several respondents emphasized that these factors can be critical, for example, to the enthusiasm of physicians and hospitals for performing or scheduling procedures that use the device.

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\(^2\)At least one participant at the October 7 meeting expressed the opinion that many manufacturers lack a fundamental understanding of the payment system, including coding issues and who is at risk for what dollars.

\(^3\)When we asked how companies might project potential reimbursement levels for devices with no similar predecessors, a few respondents suggested that reimbursement levels would have to reflect demonstrated product value. Others merely indicated that projecting is much harder in that situation. These rather unspecific comments may, in fact, be the most useful general advice that can be offered, because it seems likely that the best approaches to projecting reimbursement for very innovative devices will typically be context-specific.
• Importance of Medicare coverage. Depending on patient demographics, use of the product by or on behalf of Medicare patients can be crucial to commercial success. If so, it is critical to understand the procedures for seeking national Medicare coverage from the HCFA. And, because national coverage decisions are made fairly infrequently, it is perhaps more important to understand the coverage policies of the numerous Medicare contractors that process claims for the HCFA.4

Almost all interview respondents emphasized early planning of clinical and economic studies. In this regard, respondents suggested the following:

• When planning studies, ask payers what kind of information they would find useful in making coverage and medical-necessity decisions. Several interview respondents indicated that, in their experience, payers are willing to play this role.

• Develop clear, evidence-based guidelines for appropriate use. This information can be critical in determining FDA-approved indications, which determine the claims that companies may make in marketing. Moreover, this information can be very helpful to MCOs in developing patient-selection criteria for medical-necessity determinations and can help allay concerns about inappropriate use and rapidly expanding costs.

• Design studies to do more than is typically required for FDA approval. Specifically, compare the new device to alternatives in terms of safety, efficacy, and cost. One interview respondent emphasized that, because a new technology must compete with the standard of care, companies should develop evidence about its technology relative to the current standard of care, as well as to other approaches that could become the standard by the time the new device is ready for market.

• Work with centers of excellence in designing and executing studies. High-quality studies published in highly respected,

4Such as local “fiscal intermediaries” and “carriers,” and regional “durable medical equipment carriers” (National Health Policy Forum, 1998, pp. 3–4).
peer-reviewed journals can be enormously valuable in commercialization efforts.

- Involve potential physician champions—national or regional opinion leaders—in studies. Physician champions can be very helpful in influencing other physicians, in easing access to medical directors, and in making a case to medical societies.

- Make sure, however, that any studies that are undertaken are good investments. Studies cost money, and they take time. Extra time spent doing studies can delay product introduction and the generation of revenue, thereby threatening the financial viability of the product.

Finally, one or two interview respondents offered the following pieces of advice that seem well worth considering: (1) try to work within the existing coding system; (2) ground your marketing program on evidence that you expect to be able to develop; (3) earn the trust of medical directors; (4) plan to build momentum and involve specialty societies; and (5) create an in-house team to support early adopters.

**ADVICE FROM MCOs TO MANUFACTURERS**

Almost all of the MCO medical directors emphasized that manufacturers should make their clinical studies as rigorous as possible and accept that FDA approval is not sufficient to warrant coverage of a device. MCO respondents warn manufacturers not to push products that lack substantial clinical evidence, because they will not receive approval and will create suspicion about the manufacturer in its future dealings with the MCO.

MCOs also offered advice about marketing strategies and tactics. Because most of the MCO contracts with payers are annual or multi-year contracts, it can be very difficult for MCOs to accommodate expensive devices without warning. Medical directors recommend strongly that manufacturers not “drop devices on the market” without prior information-sharing with MCOs. The creation of an “early-warning system” was desired. The MCO medical directors were unanimous in expressing irritation about direct marketing of devices to patients and physicians. While they acknowledge that MCOs do
respond to patient and physician demand, they also point out that floods of requests may cause heightened concern about inappropriate use. Specifically, MCOs need time to complete their technology-assessment processes, and high demand arising over a short time period tends to short-circuit that process. MCOs also suggest the development and implementation of a standard format for manufacturers to present information to MCOs, including the specification of medical-evidence selection criteria (such as Medline search terms).

In general, the MCOs were not entirely satisfied with the current processes of technology adoption, but there was no consensus on strategies that might be employed by MCOs and manufacturers to improve these processes. MCO medical directors differed widely in their enthusiasm for engaging in joint efforts with manufacturers.

At least one MCO medical director offered each of the following suggestions, although none was endorsed by all:

- Manufacturers should help MCOs anticipate what is “in the pipeline” and the potential costs for new technologies.
- Manufacturers should share information on experience with medical devices across MCOs and providers.
- Manufacturers and MCOs should foster cooperative clinical research—for example, manufacturers would supply the devices at a reduced cost to give the MCO and its providers some experience with the device in routine clinical settings.
- Manufacturers and MCOs should facilitate cooperative provider education—for example, by creating programs for training surgeons in the implantation of devices—in order to reduce complications and improve quality of care.
- Manufacturers and MCOs should create purchasing contracts that enable MCOs to obtain upgraded versions of expensive, multi-use devices—for example, new diagnostic imaging equipment—at reduced cost as improvements are made.
- MCOs should allow manufacturers to participate in an open technology-assessment process or to recommend physicians who are experienced with their devices.
A general lesson from the interviews is that the issue of technology adoption is a much higher priority for the manufacturers than for medical directors of California MCOs, and a much higher priority for some MCOs than for others. It is hardly surprising that MCO medical directors are not as focused on technology adoption as are manufacturers: New technologies are the lifeblood of the manufacturers we interviewed. It is unclear whether MCO personnel other than medical directors, such as those involved in marketing or in contracting with payers, are more focused on technology-adoption issues than are medical directors.