By Robert J. Morais and Robert C. Brandt

Once an experiment, direct-to-consumer (DTC) activities are rapidly entering the mainstream of pharmaceutical promotion. This wasn’t by chance; it is the result of a number of successful experiences. Yet, the stakes are high. This article will briefly review the status of DTC advertising as it exists today, and provide guidelines for marketers who wish to consider DTC as an adjunct to their product promotion programs.

FIVE YEARS OF EXPLOSIVE GROWTH

The growth of DTC advertising witnessed over the past five years has established this form of promotion as a mainstream element that must be considered for many of today’s pharmaceuticals. For the purposes of this article, DTC advertising is defined as exposure in the major media that is audited by the leading reporters of consumer advertising expenditures.

In 1990, only seven manufacturers were experimenting with this new and relatively unproven form of communication. Total branded DTC expenditures for the year were only $70 million, approximately half of which was spent for promotion of one brand, Rogaine. By 1992, investment in branded DTC programs had increased to $155 million, more than half of which was expended on the short-lived promotion of antismoking nicotine patches.

In spite of the withdrawal of all consumer media spending for antismoking patches, spending for other DTC campaigns grew to $163 million in 1993 and nearly reached one-quarter of a billion dollars in 1994. In that same year, 26 brands invested an average of $9.1 million in DTC advertising. The five brands which spent most heavily in 1994 were Rogaine (Upjohn), Proscar (Merck), Hytrin (Abbott), Mevacor (Merck, which only began to advertise during the third-quarter), and Claritin (Schering-Plough). These five brands accounted for 50% of reported spending, each investing in excess of $17 million.

New categories that have fueled the rapid growth of DTC campaigns over the past two years include prostate therapies, contraceptive implants, antiarthritics, and agents to combat cholesterol and migraine. Categories which have seen intensive DTC activity for a longer period include estrogen replacements, antihistamines, and hair growth stimulants.

It can be seen that DTC activity is not just the province of a narrow group of manufacturers. In all, 18 major pharmaceutical companies have employed DTC promotion since 1990, including 13 of the top 20 manufacturers. Fifteen companies were active in 1994; the 23 products supported with DTC promotion during the past year is the highest number ever.

In addition to branded DTC activity, pharmaceu-
Rogaine, a pioneer in DTC, has invested heavily against the consumer since 1988.

Medical studies reveal...

The earlier you use Rogaine, the better your chances of growing hair.

PATIENT AND PHYSICIAN RESPONSE

Advertisers are not the only ones to demonstrate an appreciation of the potential value of DTC; patients are favorable to the concept, too. The July/August 1994 issue of the Journal of Advertising Research cited a study in which 69% of 400 consumers surveyed said that they felt prescription drug advertising served to educate them whereas only 28% said they felt it would confuse them. These findings are entirely consistent with the trend of patients becoming increasingly comfortable with playing a decision making role in the management of their own health care. Our experience with DTC copy shows it to be extremely well received by consumers, regularly and substantially outperforming the statistical norms for OTC/packaged goods in quantitative testing, and observationally outperforming it in qualitative research.

Physicians, for the most part, are not necessarily in favor of DTC advertising, but have essentially made their peace with it and accept patients' exposure to DTC. Scott-Levin Associates, Newtown, Pennsylvania, has studied the increases in patients' use of the information presented in DTC advertising, as reported by their physicians. By 1992, 88% of
tical companies spent an additional $170 million between 1990 and 1994 on “general promotion.” Much of this activity is DTC advertising that encourages the consumer to consult a physician on a given topic, but which carries the signature of a corporation rather than a specific brand. It is estimated that approximately 75% of what has been considered general promotion is, in fact, unbranded DTC advertising (LNA/MediaWatch 1990-1994).

These statistics are drawn from the principal sources of consumer spending that measure the major media. There are other companies and brands engaging in advertising and education programs that interface directly with the consumer that are not measured by these sources. Examples of such activity include the placement of advertising in specialized, small-circulation magazines; direct mail; expenditures by companies that employ public relations and publicity campaigns; and/or programs designed to reach patients in the physician’s waiting room, the hospital, the pharmacy, and various types of clubs and activity centers.

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physicians stated that they had experienced patients requesting a drug by its brand name and 84% said they would consider prescribing a drug that their patient mentioned. Additionally, 44% acknowledged that patients had brought copies of DTC advertisements to their office to discuss with the physician. These findings represent significant increases from a similar survey conducted only two and a half years earlier. Perhaps most importantly, whereas 56% of doctors participating in the survey indicated that they opposed DTC advertising, the majority expressed the belief that patients who receive a drug they have requested would be more likely to comply with the correct regimen.

**HOW DTC WORKS**

A well-crafted DTC program can work on a number of levels to achieve the advertiser’s objectives. First, and very obviously, it can influence the behavior of the individual consumer/patient who is exposed to it. Second, it can reach the physician who, after all, is also a consumer during his or her off-duty hours. If the physician is accepting the advertiser’s message, he or she may be positively influenced without any patient intervention.

Third, DTC advertising causes the patient to “detail” the physician. If the drug or therapy is appropriate and the doctor accedes to his patients’ requests, the result is that he conducts a mini-trial that can alter his prescribing pattern for all of his patients. Many DTC advertisers have elected to spend heavily over a relatively short duration of time because their real objective is to change physician behavior—not patient behavior. Once DTC has accomplished this, there is no longer a need to spend heavily to reach the consumer.

Lastly, physicians must assume that patients are aware of major DTC campaigns relevant to their conditions, regardless of whether or not those patients initiate a conversation on the subject. Direct influence on individual consumers is just one of several ways that a DTC program can benefit a pharmaceutical company, but only if the message is compatible with physicians’ perceptions of sound medicine.

**IS DTC RIGHT FOR YOUR BRAND?**

Although product managers are encouraged to include DTC in their review of tactical alternatives, there is a limit to the number of brands that will profit from the substantial investment this approach requires. The most obvious candidates for DTC are products that offer distinctive, if not proprietary benefits for patients with chronic conditions. The ideal situation is to be the sole or obvious drug of choice for a condition which is largely underdiagnosed. Generally, products that treat an acute condition, unless it is a condition in which repeated flare-ups occur, are not candidates for DTC promotion. It usually takes a reasonably extended period of therapy to generate profit from DTC programs.

Incidence of the condition for which a drug is indicated is another consideration, but this can be overemphasized. Obviously, DTC is not intended for orphan drugs that treat rare diseases, except perhaps as public service. The three equally critical determining factors are: (1) the size of the population that is available for conversion, (2) the share of new prescriptions that can be anticipated within that population, and (3) the profit value of each conversion accomplished. If these three factors can be quantified through data and affordable research, then the potential effects of a DTC campaign can be assessed.

Another variable is the expected duration of the course of therapy on a given drug. If a two-year, $20 million DTC campaign will return increased business for 10 years, that is far more promising than a situation where competition will cause substantial erosion shortly after inception of a program.

Ultimately, companies considering prescription drug advertising must ask themselves some specific questions regarding the appropriateness of DTC: Does DTC make bottom line sense? Will the investment yield an acceptable return? To answer these
Mevacor invested $20 million during the second half of 1994.

If questions, pharmaceutical companies and their agencies should work together on a pay-out model that:

- Defines the source of DTC-generated business
- Reflects the reach and frequency of a proposed media plan
- Assumes a conservative level of persuasion for the advertising
- Considers the percentage of physicians who will prescribe the drug on being queried by the patient
- Weighs the total number of incremental sales against the DTC expenditure

Such a model is a test of reasonableness; it is not precise enough to predict actual success or failure. If the projected return on investment meets corporate objectives, the plan should be pursued to the next phase. If not, the assumptions should be reconsidered or DTC should be abandoned.

If the pay-out model holds promise, the next step is to assess how consumers will respond to advertising. This phase must begin with a comprehensive look at the consumer's illness from a patient's perspective, which can be quite different from the physician's perspective. Such data can be derived from existing research and qualitative inquiries such as one-on-one interviews or focus groups. Once an understanding is obtained, another round of interviews should be scheduled, this time exposing consumers to concepts that represent various strategic approaches to the DTC opportunity. If time allows, the most promising strategic options should be assessed quantitatively.

Once the strategic direction is set, the agency can then create the advertising. When several executions have been chosen and approved through the corporate regulatory process and by the FDA, inexpensive, rough versions of the advertising should be assessed. After a winning execution has been determined, a test market can be implemented. Markets should be selected based on their representativeness of both the consumer and the physician setting. Corporate marketing, sales, and agency personnel should work closely to design, implement, and track the in-market test. With a well-conducted market assessment in hand, a decision can be made.

**THE FDA INTERFACE**

Assuming DTC advertising has potential for a brand, a critical component of the development process is working with the FDA to field clear, balanced, and effective advertising. The FDA has authority over all prescription drug activities that are subsumed within labeling and advertising. This authority extends, in effect, to virtually all drug communications emanating from a pharmaceutical company. Currently, formal FDA regulations do not distinguish between DTC advertising and promotions targeted to professional audiences. However, the FDA does interpret these regulations differently given the more limited medical knowledge of consumers versus professionals. Additional or different types of information may be required for a DTC advertisement to ensure that the consumer fully comprehends product benefits and risks.

The FDA's guidelines do not cover every possible DTC advertising approach and, as a result, there are some gray areas. In conversations with the FDA, it was disclosed that DTC advertisements are evaluated on a case-by-case basis. The best procedure is to discuss approaches initially with the FDA and submit a concept board for their review. This is the quickest and most cost efficient way to assess their reaction. It also allows for both client and agency to work jointly with the FDA to create an advertisement that is both acceptable and effective.

In recognition of the need for more user friendly DTC guidelines, the FDA's Division of Drug Marketing, Advertising, and Communications has recently made development of specific written requirements for DTC a priority. Within several months, according to our source, public feedback will be invited on this much needed and long awaited document.

**OTHER DTC CLEARANCES**

Consumer magazines do not have a uniform review procedure for DTC advertisements. Most will assume that submitted advertising meets FDA requirements. The television networks normally follow the FDA's lead in their acceptance of DTC. Our experience is
that the networks want to know what the FDA thinks before approving DTC commercials. Syndicated, cable, and local television do not have formal review procedures; however, the advertiser should have the FDA agreement in hand before submission.

The American Medical Association (AMA), although not having legal authority over medical promotion, does influence the medical community. Consequently, pharmaceutical companies must be cognizant of the AMA's views concerning DTC advertising. Fortunately for DTC advertisers, the AMA recently reversed its position that DTC is inappropriate and now accepts DTC advertising that is educational and conforms to FDA guidelines. The new policy is more likely a recognition that the DTC floodgates are open than a deeply felt philosophical shift. Nonetheless, the fact that the AMA no longer rejects the concept of DTC outright is one less barrier for DTC advertisers to overcome.

**CHARACTERISTICS OF DTC ADVERTISING**

Once a decision is made to pursue DTC and the FDA's guidelines are understood, another factor must be considered by the pharmaceutical marketing professional: What defines DTC as a distinct class of advertising?

Executionally, DTC advertising exhibits both commonalities with and differences from most consumer packaged goods advertising. In both cases, the first task of the advertising is to break through and capture the reader's attention. This is best accomplished in DTC by a technique called "target sorting," which can also be highly effective in traditional consumer advertising. Target sorting consists of making the first communication the identification of exactly whom the copy is addressed. The extraordinary interest that most sufferers of chronic health problems have with their conditions virtually guarantees attentiveness to advertising that readily makes it apparent that the subject is their condition.

Direct-to-consumer advertising also enjoys an advantage in the depth of sale that can be achieved. The readers (or viewers) of DTC advertising are hungry for knowledge about their conditions, and will respond best to copy that promises to educate them. Thus, DTC advertising will benefit from an execution that appears clinical and informative, and generally has the opportunity to present far more copy than would be tolerated by consumers in almost all other categories of advertising.

There are other reasons for the clinical appearance of DTC advertising, and most of them are valid. First, many brands' DTC advertising has been executed by

their medical agencies and are adaptations of their professional campaigns. Although this is not a tactic to follow blindly, it is not illogical. Physicians are exposed to consumer advertising and one should not present one's product in a way that would trivialize it in the eyes of its professional audience or contradict the message they are accustomed to receiving. Whether it is an adapted medical program or a standalone consumer campaign, DTC advertising must be developed with the same degree of experience and expertise that is required to create a new physician program.

**THE PROFESSIONAL COMPONENT**

When a DTC program is a chosen vehicle, it is imperative to bear in mind its primary limitation: consumers can request a drug but they cannot buy it directly. The gatekeeper, their physician, must be reached and motivated to support their request. Professionals must be made aware that a DTC effort is about to be launched. In our experience, the most efficient and effective means to inform the physician of a DTC program is through a one-time mailing of a letter with a reprint of the consumer advertisement and/or promotion (i.e., coupon). Other professionals—pharmacists, nurses, etc.—should also be informed of the DTC effort. In addition to direct communication with professionals through mailings, the corporate sales force must be well informed concerning the DTC program.

The approach is simple, yet it demonstrates corporate sensitivity to the professional's need to be knowledgeable about communications relevant to the treatment of his or her patients.
TABLE: OPTIMAL DTC TIMETABLE

<table>
<thead>
<tr>
<th>Event</th>
<th>Approximate Net Cost</th>
<th>Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prepare concepts</td>
<td>$2,000</td>
<td>2 Weeks</td>
</tr>
<tr>
<td>FDA discussion/review</td>
<td>N/C</td>
<td>4 Weeks</td>
</tr>
<tr>
<td>Focus groups and analysis</td>
<td>$20,000</td>
<td>3 Weeks</td>
</tr>
<tr>
<td>Prepare creative</td>
<td>N/A</td>
<td>4 Weeks</td>
</tr>
<tr>
<td>Prepare media plan</td>
<td>Variable</td>
<td>4 Weeks</td>
</tr>
<tr>
<td>FDA approval of advertising</td>
<td>N/A</td>
<td>4 Weeks</td>
</tr>
<tr>
<td>Prepare test advertising</td>
<td>$8,000 per</td>
<td>3 Weeks</td>
</tr>
<tr>
<td>Copy test results</td>
<td>$10,000 per</td>
<td>4 Weeks</td>
</tr>
<tr>
<td>Produce winning execution</td>
<td>$50,000 Print</td>
<td>6 Weeks</td>
</tr>
<tr>
<td></td>
<td>$200,000 TV</td>
<td></td>
</tr>
</tbody>
</table>

OTHER CONSIDERATIONS WITH DTC ADVERTISING

Timing and Cost of DTC Programs. DTC, like any marketing tactic, varies highly in its timeframe and commitment of resources. The Table summarizes timing and cost for a typical DTC effort, excluding media. Of course, the key to setting and meeting any timetable is communication. In this respect, managing a DTC program is no different than managing any other project.

Choosing an Agency. Selection of an agency for a DTC program should adhere to the same principles as those for selecting a professional agency. The particulars will center on an agency's experience in and talent for DTC. Actual DTC experience is preferable because the agency will know the rules of the game. The agency should have other consumer advertising experience as well, particularly in the OTC domain. Over-the-counter experience is relevant because DTC advertising requires an understanding of how to best communicate health benefits to the consumer, and know-how in selecting the best media to reach the OTC target. In this sense, OTC brands are a close cousin to DTC brands. An agency with success in OTC advertising will bring insight and expertise to DTC ventures.

A DTC agency must appreciate the medical underpinnings of a DTC brand. It should understand the medicine itself; the professional's attitude toward the medicine, the brand, and the manufacturer; and the roles of the professional promotion program and sales force. Ideally, the DTC agency will have both consumer and professional divisions that are comfortable working together. The advantages of an "under one roof" DTC/professional agency operation in terms of cooperation and synergy can't be overstated. Most consumer advertising agencies are compensated on a commission basis; most professional agencies receive a fee for hours or services. Our recommendation is that DTC agencies receive a monthly fee for services until the DTC program is fielded nationally. At that time, fees can be converted to a commission agreed upon by both parties. Fees accrued during the development period would then be credited to the advertiser. This arrangement protects the agency's initial time against the project and then allows a reasonable and industry-accepted compensation framework for national expansion.

Convincing Management. Management within pharmaceutical manufacturers is at once intrigued and cautious about DTC. They witness successful DTC programs yet are concerned about the comparatively heavy media investment. A well formulated pay-out model is the best way to assuage initial apprehension. Solid, up-front consumer research is another. The goal must be for management to be convinced that DTC will return its investment and more. If the project is approached with the steps discussed in this article, management should at least be receptive to the idea.

MOVING AHEAD

The rapid growth of DTC media spending in recent years, in receptivity by professionals, and in patient responsiveness, suggests a promising future for DTC advertising. If, based on the kind of preliminary assessments outlined here, your brand qualifies, there is no reason to delay an exploratory program. The dividend in near-term profit and long-term brand protection is well worth the effort.

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other project.