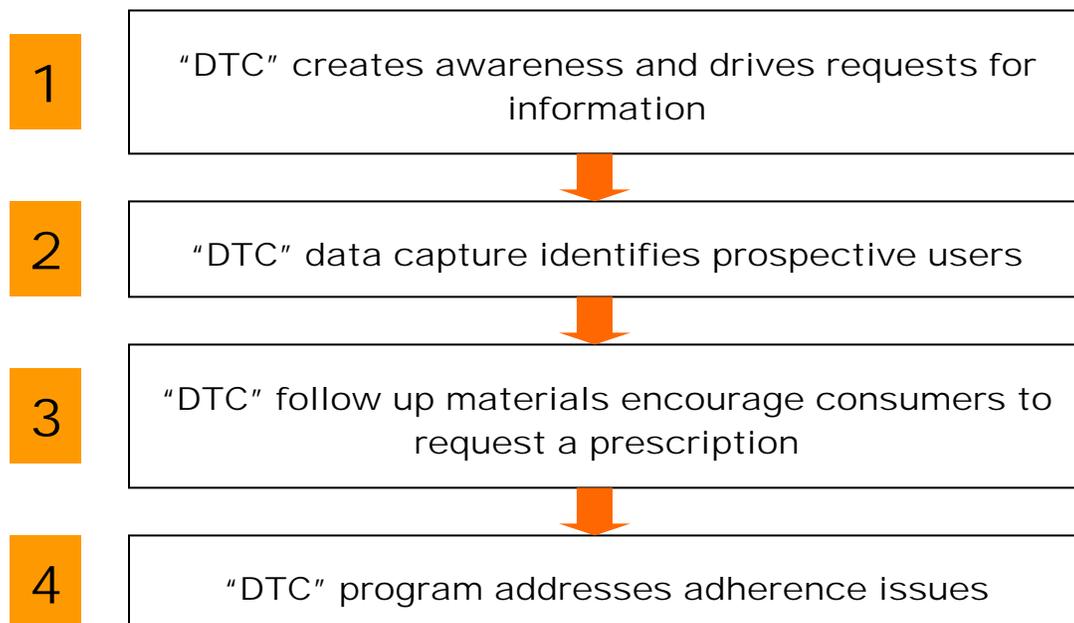


ONLINE DOCKET 2005N-0354
CONSUMER-DIRECTED PROMOTION OF REGULATED MEDICAL PRODUCTS
Submitted February, 2006

Perspective provided by Patient Marketing Group, Inc., a marketing services company engaged in providing relationship marketing programs for patients on behalf of its pharmaceutical clients for the past 15 years.

Medicine is a fundamentally human endeavor. Any communication to people about illness and its treatment is therefore a fundamentally human interaction – and regulations that govern these communications must take into account the way that such information is processed. While these communications may be promotional in intent, they also must recognize the full responsibility they bear as a perceived authoritative source of information, encouragement, and education for consumers. It is our viewpoint that consumer-directed prescription marketing requires greater expertise in behavioral science than we have seen evidenced in DTC communications and the follow-up information sent as a result of consumer requests for more information.

Effectively interpreting and improving consumer-directed prescription marketing requires expanding it's definition to include the communications that occur after a consumer has expressed interest in a product. We suggest that taking a consumer-centric perspective will best serve the public interest. From a consumer perspective, any communication intended for patients or prospective users of medical products is considered "DTC." DTC can best be viewed as a **process of engagement** with consumers/patients. Each step in the process presents opportunities to provide meaningful information and education:



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Enhanced guidelines should be considered for each stage of this expanded view of DTC as a communication process. Guidance is needed on what kinds of communications will best serve the public at each stage, and what considerations must be taken into account as these communications are developed and disseminated. The suggestions below are intended as enhancements to existing related guidelines.

- **All DTC communications should be respectful in tone and educational in design.** Pharmaceutical marketers have been working toward this since 1997, and there are now benchmarks in the industry for this standard (PMG results from ConsumeRxperience tracking study on file, 2006).
- **Any product whose labeling includes efficacy based on additional support** (such as “with diet and exercise,” or “with behavioral support”) **should be tested with this support in place in Phase III trials, and marketed with such support made available to consumers in conjunction with the launch of the product.**
- **DTC communications should include disease-specific tools that are usable by consumers in their daily lives and that assist in disease self-management where appropriate.**
- **Comprehensive DTC program materials should be included in product promotion to health care practitioners** (whether provided directly or through pharmaceutical sales representatives), so that providers are aware of the educational resources available for their patients, and are better equipped to address questions their patients raise.
- **Adequate consumer materials should be available** to all interested consumers through multiple channels and in multiple formats so that information and education is accessible to all.
- **The provider-patient relationship** should be supported with communications that are developed by experts who have clinical and practical experience in developing patient programs. These communications can be tailored to the individual patient, and enhanced with well-conceived education content. Ideally, such resources serve as an extension of the physician’s provision of care and guidance, thus ensuring that the physician-patient dialogue in the office is productive, efficient, and mutually beneficial.

More specifically....

1

Disease awareness communications to consumers should:

- Reflect consumers' current understanding of the disease;
- Provide respectful education about the consumer's role in treatment, including associated lifestyle management; and
- Address specific needs of important subgroups of the at-risk or affected population

2

Identifying prospective users should be an educational initiative as well as a marketing tactic:

Currently, as consumers become aware of a medical product, they express initial interest and then are often asked a set of questions to aid the marketer in determining whether they are in a selected target market segment. This "survey" could be used more effectively as the beginning of a dialogue with the consumer, and serve as the foundation for effective educational messages (and in many cases could drive more meaningful individualized communications).

3

Risk and benefit communications should:

- Incorporate tailored messages to highest risk sub-populations, so that risk information is highlighted and perceived as personally relevant;
- Couple promotional efforts with follow-up communications that are designed to inform consumers as their needs change over time (e.g. awareness, trial, side effect experience, therapeutic benefit experience, maintenance of therapy);
- More fully recognize the limitations of broadcast media and provide multi-channel communications for reaching diverse populations with divergent informational needs;
- Complement promotional efforts with application of behavior change principles and dynamic disease education;
- Capitalize on emerging communications technologies to employ these strategies efficiently, thus addressing consumers' true individual information needs.