DIRECT-TO-CONSUMER (DTC) ADVERTISING OF PRESCRIPTION MEDICATIONS has rapidly become one of the most contentious issues facing the medical profession in the United States. Prior to the early 1980s, pharmaceutical companies promoted their prescription products exclusively to physicians, who were expected to act as “learned intermediaries” interpreting drug information for the general public.1 During the past 2 decades, however, changes in the political and regulatory climate, cultural shifts emphasizing the patient’s role in making medical decisions, and expanding profits from drug sales have encouraged the industry to pursue more direct marketing strategies.2

Today, advertisements for prescription drugs dot the pages of popular magazines and punctuate television programs. A survey of 18 diverse lay magazines from 1989 to 1998 revealed a total of 320 distinct DTC ads, representing 101 brands and 14 categories of medical conditions.3 This year, pharmaceutical companies will spend more than a billion dollars marketing their drug products directly to consumers, compared to only $55 million in 1991.4 According to a recent survey, more than one third of patients have asked their physicians for information on drugs they have seen in a DTC ad, and nearly one fourth have asked for the drug itself.5 Perhaps more significantly, three quarters of the patients requesting drug prescriptions received them from their physicians.

Proponents argue that DTC promotion provides a service by increasing public awareness of medical conditions and encouraging informed communication between patients and providers. Furthermore, DTC ads encourage consumers to act as autonomous decision-makers, able to weigh the benefits and risks of their health choices.6 At the same time, critics fear that drug companies will trade on the public’s lack of medical knowledge to obscure products’ risks and adverse effects. Physicians complain that they must devote increasing amounts of scarce time to dissuading patients from taking drugs that advertising has led them to believe are unproblematic.

This month, MSJAMA explores some of the issues raised by the growth of DTC advertising of pharmaceutical products in the United States. How does DTC marketing affect the relationship between patients and physicians? What is the role of the government in ensuring that DTC advertisements are accurate and complete? Should the rise of DTC advertising change physicians’ liability in suits brought by drug consumers? How does the rise of DTC advertising change our perspective on drug companies’ traditional practice of marketing drugs to physicians?

REFERENCES
Rethinking the Role of the Learned Intermediary: The Effect of Direct-to-Consumer Advertising on Litigation

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In a 5-2 decision issued in August 1999, which reversed the rulings of 2 lower courts, the New Jersey Supreme Court took a controversial stand challenging the foundation of pharmaceutical liability litigation. In Perez v Wyeth Laboratories Inc, the court argued that the “learned intermediary doctrine,” which has historically shielded pharmaceutical companies from any obligation to warn patients directly about their prescription products, does not apply when companies engage in direct-to-consumer (DTC) advertising.

The term “learned intermediary” originated in a 1966 liability suit brought against the producer of chloroquine phosphate for failing to warn physicians of its potential to cause irreversible retinopathy. The federal court in this case established a hierarchy of responsibility in which pharmaceutical companies have a duty to warn physicians directly about potential adverse effects caused by their products, while physicians must serve as “learned intermediaries” who interpret this information and advise patients appropriately. Under this rule, drug manufacturers have no legal obligation to ensure that warning information reaches the final consumer.

For more than 30 years, courts as well as legislative bodies have relied on this doctrine to define the legal boundaries of “failure to warn” suits brought against pharmaceutical manufacturers. As early as 1968, however, some legal exceptions to the learned intermediary doctrine were arising. In Davis v Wyeth Laboratories Inc, for example, it was determined that vaccine manufacturers had a specific duty to warn consumers directly of the dangers of immunizations, since they are often administered in a setting “without an individualized balancing by a physician of the risks involved.” In 1985, the Massachusetts Supreme Court decided in MacDonald v Ortho Pharmaceutical Corp that in the case of oral contraceptive prescriptions, physicians are often “relegated to a relatively passive role,” while the “young consumer of oral contraceptives is usually actively involved in the decision to use ‘the pill’”—thus putting the burden to warn the consumer directly upon the oral contraceptive producers.

The Perez decision represents the first challenge to the applicability of the doctrine in the context of DTC advertising. Five New Jersey women (chosen to represent a larger group of similar plaintiffs) claimed that Wyeth Laboratories failed to provide adequate warnings about the adverse effects and surgical complications they later suffered using the heavily advertised Norplant contraceptive system. Both the trial court and New Jersey Appellate Division summarily dismissed the case in favor of Wyeth on the basis of the learned intermediary rule. Upon further appeal, however, the New Jersey Supreme Court agreed to hear this case as an opportunity “to resolve the threshold issue of whether the learned intermediary doctrine applies in the case of direct-to-consumer marketing of pharmaceutical goods.”

In its majority opinion, the court reevaluated the learned intermediary doctrine in terms of its historical context. It determined that the doctrine depended heavily on the premise that the patient-physician relationship is the focal point for all medical care, and that pharmaceutical companies are unable to communicate information about products directly to patients. In the current era of time-limited medical visits, appealing new “lifestyle” prescription drugs (for hair loss, impotence, etc), and widespread advertising opportunities, a physician’s ability to influence the “preconceived expectations about treatment” was found to be significantly diminished.

Arguing that these developments compromised the role of the learned intermediary, the court found that companies engaging in DTC marketing were legally responsible for providing adequate warnings to consumers about the potential dangers of their products.

Seemingly at odds with this decision, the facts presented in Perez actually contained no evidence that DTC advertising had influenced the plaintiffs. The dissenting justices contended that this decision did not address the particular case, but was intended purely to establish a legal precedent to be applied to all pharmaceutical products for which DTC advertising is used. Final judgment on whether Wyeth truly failed to warn the plaintiffs remains to be determined.

By creating a potentially explosive new basis for litigation against pharmaceutical companies, Perez raises important questions about the complex changes affecting our health care system. In addition to making pharmaceutical companies more accountable for the ways that they market products to consumers, the court’s ruling also provides a reminder of the growing limitations physicians may face in informing the medical decisions of their patients. Although physicians may be elated at the prospect of sharing some of the legal burdens placed upon them, this landmark decision reflects the growing inability of physicians to serve as effective learned intermediaries in a health care system in which this function may be more necessary than ever.

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Challenges in Regulating Direct-to-Consumer Advertising

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FOR THE FOOD AND DRUG ADMINISTRATION (FDA), THERE HAS ALWAYS BEEN 1 CENTRAL QUESTION SURROUNDING DIRECT-TO-CONSUMER (DTC) ADVERTISEMENTS OF PRESCRIPTION MEDICATIONS: DO THESE ADVERTISEMENTS PROVIDE CONSUMERS WITH INFORMATION THAT EMPowers THEM TO CARE FOR THEIR HEALTH, OR ARE THEY MISLEADING IN A WAY THAT PRESENTS A PUBLIC HEALTH HAZARD?

To ensure that advertisements for medications provide public health benefits without creating health risks, the FDA determined more than 30 years ago that under the 1962 Kefauver-Harris Amendments to the Federal Food, Drug, and Cosmetic Act, advertisements must have 4 basic attributes: (1) they cannot be false or misleading; (2) they must present a “fair balance” of information about the risks and benefits of using the drug; (3) they must contain “facts” that are “material” to the product’s advertised uses; and (4) in general, the advertisement’s “brief summary” of the drug must include every risk from the product’s approved labeling.1

For many years, pharmaceutical promotion was directed exclusively at health care professionals. After the first DTC prescription drug advertisements appeared in the early 1980s, however, researchers began to question whether pharmaceutical advertisements could “serve two masters: the promotional interest of the pharmaceutical industry and the public’s health needs.”2 In response to calls from both the public and manufacturers, the FDA requested that companies suspend their DTC promotion while it conducted a study of its effect on consumers.3

The results of the study satisfied most FDA concerns about the new wave of DTC promotion. Among other insights, the study showed that such advertisements can successfully communicate a large amount of information about the potential risks of taking prescription medications. Sixty-six percent of the 1500 survey respondents regarded DTC promotion as useful, and 74% of them strongly supported their physician as the decision-maker in the prescription of drugs. Based on these findings and consultations with consumers, the FDA lifted the DTC moratorium in 1985 and announced that the existing regulations were “sufficient . . . to protect consumers.”4

Promotion of prescription medications by television and radio—media with severe time constraints—has presented a special regulatory challenge. For many years, pharmaceutical companies avoided the requirement for lengthy risk disclosure by airing vague “reminder” messages. Critics charged, however, that the commercial spots were often confusing and provided little information that consumers could use to improve their health care.5

By the mid-1990s, public input and the FDA’s own experience with DTC promotion prompted the agency to publish a draft guidance designed to encourage more informative commercials. The document stated that broadcast commercials could meet FDA requirements for risk disclosure if they list the product’s major risks and provide the audience with instructions for obtaining the full product labeling.6 The guidance, which was finalized last year, also announced that the FDA would assess its impact and that of DTC promotion in general, a process that is still under way.

Although pharmaceutical companies are not required to submit the content of their DTC promotional materials to the FDA for prior clearance, the agency routinely examines commercials and published DTC drug ads after they become available to the public. In the last 3 years, the FDA has sent about 70 notices to sponsors that their promotion violated regulations, usually by presenting insufficient or understated risk information, and in some cases by overstating the product’s effectiveness or the extent of its approved use. Companies have historically complied with the FDA’s requests, and the number of broadcast violations has declined.

A consumer survey conducted by the FDA in 1999 suggested that DTC prescription drug promotion offers public health benefits that may outweigh the potential costs.7 For example, patients report that DTC advertisements remind them to get their medicines refilled and help them adhere to their regimens; advertisements also prompt patients to ask their physicians about new medical conditions.

But while 62% of respondents said that DTC advertisements helped them discuss their health with physicians, not all the responses were favorable. Fifty-eight percent said that the advertisements “make the drugs seem better than they are.” Other research suggests that DTC promotion causes tension between patients and their physicians, and that physicians are less positive about DTC ads than most consumers.8 There are also questions as to whether the multiple-page long lists of risks required for printed advertisements—which may be ignored by 33% of patients—are optimal.

After more research, the FDA will carefully evaluate DTC drug promotion and take any additional measures needed to protect the public’s health.

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Gifts to Physicians in the Consumer Marketing Era

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Many physicians are concerned about the rise of direct-to-consumer (DTC) advertising of prescription medications. However, with an annual budget of more than $5 billion supporting 59 million sales representative visits to physicians and hospitals, drug detailing remains a cornerstone of the pharmaceutical industry’s marketing strategy.1,2 Although often viewed as different issues, concerns about consumer-directed marketing may also apply to physician-directed marketing—in particular, gifts to physicians from the pharmaceutical industry.

A majority of physicians believe that DTC advertising can have an inappropriate effect on prescribing.3 This contrasts with physicians’ mixed feelings about the effect of gifts from the industry. Studies show that most physicians believe that gifts do not influence their prescribing; however, the same physicians often believe that gifts influence their colleagues.4,5 Limited data suggest that these concerns may be well founded. One study of faculty physicians found that accepting a free meal was independently associated with self-reported change in their prescribing practices.6 Another study found that physicians who requested that drugs be added to a hospital formulary were more than 10 times as likely as their colleagues to have received financial support from the companies that manufacture those drugs.7

Other physicians worry that DTC advertisements erode public trust in physicians. Patients may lose faith in their physicians when advertising messages conflict with professional advice.3 However, gifts to physicians may also undermine patient confidence in the profession. Surveys show that as many as 70% of patients believe these gifts significantly impact prescribing, and as many as two thirds believe they increase the overall cost of medications for the public.8 Furthermore, 24% of patients reported that their perception of the medical profession changed after learning about drug company gifts to physicians.9

Another concern about DTC advertisements is that patients lack the sophistication to properly interpret companies’ DTC marketing claims. However, physicians who view pharmaceutical representatives as a useful source of information may face similar challenges.10,11 Studies suggest that the information provided by representatives can be biased or even incorrect, and that physicians often cannot distinguish true statements from false ones.11 Moreover, many physicians appear unaware of the extent to which commercial sources of information shape their prescribing practices.12

Physicians’ awareness of the consequences of gift-giving may be limited by the lack of policies and educational programs that address this topic.3,10 Many residency training programs have no policy regulating interactions with pharmaceutical representatives.13 Policies that do exist are poorly publicized and largely unknown to residents.14 As many as 90% of physicians feel they received insufficient training about how to interact with industry representatives,15 and guidelines from organizations such as the American Medical Association are not widely known. Perhaps more importantly, drug company gifts are an accepted social norm,4,9 and colleagues may be unsupportive of physicians and medical students who challenge these practices.

Despite their concerns about the marketing of drugs to consumers, physicians are not exempt from the ethical issues raised by pharmaceutical marketing. Issues of influence, patient-physician distrust, and a susceptibility to marketing ploys apply to caregivers as well as to patients. By highlighting these parallels, the debate over DTC advertising may be a useful way for the medical profession to reflect on its own relationship with the pharmaceutical industry.

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ANYONE WHO SWITCHES ON A TELEVISION OR READS A NEWSPAPER cannot help but notice the dramatic upsurge in the number of prescription drug advertisements. The benefits and costs of this practice have been intensely debated. A major concern is the effect of DTC advertising on the patient-physician relationship.

One factor contributing to the rise of DTC advertising is the erosion of physicians’ authority to prescribe specific drugs. Recent years have seen the proliferation of drug formularies, utilization review systems, and pharmaceutical risk-sharing agreements. As a result, it is more difficult for pharmaceutical companies to transform the goodwill generated from company-sponsored “educational” dinners into actual prescriptions. Critics of DTC advertising argue that pharmaceutical companies have simply found a new way to push physicians—in the face of resistance from group medical directors and chairs of formulary committees to prescribe the brand name drug over the generic, the new drug over the old, and the profitable drug over the unprofitable. And who better to provide the pushing than the patient, now an enlightened “health care consumer” armed with information from DTC ads?

Studies suggest that while patients are in favor of these ads, their physicians are not. A survey conducted in the early 1990s, for example, found that consumers were open to the idea of using DTC ads as a source of information about drugs to supplement advice from physicians. A 1997 study of US family physicians, however, found that four fifths believed that DTC advertising was “not a good idea” because they increase costs and promote “misleading, biased views” of drugs.

Recent studies have shown beyond a doubt that DTC advertising motivates discussions between patients and their physicians about pharmaceutical products. What could be wrong with that? Nothing, if the discussions focus on the patient’s presenting complaints, their diagnostic implications, the meaning of the diagnosis in the context of the patient’s life, and the full range of treatment options available. However, if discussions focus on specific brand-name drugs, trivial complaints, or procurement issues, they could detract from more meaningful discussions about health.

One concern is that DTC advertising rarely mentions lifestyle changes or other nonpharmacological interventions, which are often as important as drug therapy in improving outcomes. Patients may become angry when their physician insists on discussing a low-fat diet, stress management, or allergen avoidance rather than writing a prescription. Indeed, 1 study found that as many as half of patients would register disappointment, and 15% would consider switching physicians, if their physician refused a request for an advertised prescription medication.

The complicated issues raised by DTC advertising can be illustrated by 2 examples. Imagine a patient who sees a magazine advertisement for an antidepressant and decides that her symptoms are suggestive of major depression. She reveals her symptoms to a physician, who performs a careful history and physical exam and decides that hypothyroidism could be responsible. After testing confirms the diagnosis, the patient is successfully treated with thyroid hormone replacement therapy. In a different scenario, the patient waves the same ad in front of another physician and demands the drug. After taking a cursory history that suggests depressive symptoms, the second physician writes the prescription. Six months later the patient is hospitalized for severe hypothyroidism.

In the first example, the DTC advertisement serves as a springboard for a thorough investigation of the patient’s symptoms, development of a reasonable differential diagnosis, and prescription of appropriate therapy. The first physician remembers her professional responsibility to evaluate not just the patient’s request but also the patient’s problem. In the second scenario, however, the physician carries the ethos of customer satisfaction to an unsafe extreme.

What should physicians do with patients who make ad-induced requests? A responsible strategy is to direct the conversation back to symptoms and concerns, from which a differential diagnosis can emerge and appropriate therapy follow. Requests are often best met by more questions, asked in a neutral way: “Where did you hear about the drug? What did the ad say? How were you hoping it would help? What do you know of the drug’s benefits and side effects? Tell me more about your symptoms. Would you like to hear more about this drug and its alternatives?”

By asking sincere and open questions, the physician begins to understand the context of the patient’s request and makes his or her concern for the patient more palpable. This opens the way to a more productive clinical dialogue that is uninhibited by patient anxiety and physician defensiveness.

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it was too soon when I went down
it was too soon when I went down
with pain my only midwife
but still she came
bound up in blood thick rope
that neither her weight or mine could break she,
  a stranger
and me, a thin black girl
worn out
giving birth to a woman

Grandpa

Grandpa, the mushrooms are moving
Up through leaves and twigs
Up past the worms curled,
Crickets perched
Up to the wet rain
That licks the whole woods
Into a glazed song
Slick and sweet
As your morning donut
waiting Grandpa, the salamanders are moving
Up through the mud
In slow crawls
From under mossy boards and
Edges of wet lipped ponds
Passing through leaves
Sliding past corners of the house
Out to the air that is thick and wet
As the space over your cold coffee
waiting Grandpa, the black birds are moving
Hundreds of them
Filling the thin spring trees
Till the tree is solid bird
Branches and ground covered with white droppings
Bowing limbs from the weight of bird
We try to save the trees by throwing rocks
But the swarm only lifts momentarily
Then settles like a black sky collapsing
Like dark dust in your house, collecting on your piano
waiting waiting
They say the wait is over
That your lungs stopped moving
That it was quick, little pain
But these are things that are said
Without realizing
The woods wait
For your boots to sink a trail
For your hands to plant your ginseng
On the ridge above the sycamore
There is waiting
That won’t go away

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