Contemporary Issues

Patient Autonomy and the Regulation of Direct-to-Consumer Advertising

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ABSTRACT

Background: The current direction of the US Food and Drug Administration (FDA) policy on direct-to-consumer advertising (DTCA) of pharmaceuticals is a subject of debate. The literature addresses the benefits and drawbacks of DTCA, but the foundations for such policies have not been investigated in detail.

Objective: This paper explores the most recent FDA guidance on broadcast DTCA based on a critical examination of the principle of autonomy.

Conclusions: Autonomy is determined not by the ability to choose a therapy, but by the ability to actively participate in choices about health care. DTCA can be an effective tool to increase patient awareness of their therapeutic choices, encourage patients to seek more information, and help them draw closer to autonomous choices, but only if the presentations provide fair and balanced information on the benefits and risks of therapy.

Key words: autonomy, direct-to-consumer advertising, consumer-directed promotion, paternalism. (Clin Ther. 2001;23:2024–2037)

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INTRODUCTION

With the release of the August 1997 Draft Guidance for Industry: Consumer-Directed Broadcast Advertisements, the US Food and Drug Administration (FDA) took a dramatic step in redefining the regulatory framework of broadcast prescription drug advertising. Motivated by a need to decrease advertisements that were not sufficiently informative, the FDA issued guidance that clarified the requirements for broadcasting product-specific prescription drug advertisements. Since the release of the guidance, there has been a marked proliferation of broadcast direct-to-consumer advertisements (DTCAs), much to the disappointment of many in the health care community. In fact, some have wondered why the FDA appeared to ease restrictions on broadcast prescription drug advertisements.

Before August 1997, prescription drug advertisements had to satisfy the same basic regulations as they do today. Specifically, broadcast prescription drug advertisements must provide “information in brief summary relating to side effects, contraindications and effectiveness” unless a statement of the product’s major risks is provided and an adequate provision is made for the attainment of the approved package labeling. However, the interpretation of the adequate-provision requirement before August 1997 was much different from what it is today.

Currently, broadcast advertisements must provide the following to satisfy the adequate-provision requirement: (1) a toll-free number for consumers to call for approved package labeling, (2) a reference in the advertisement from which consumers of limited technical sophistication can obtain approved package labeling, (3) an Internet Web site address that provides the approved package labeling, and (4) disclosure that pharmacists, physicians, veterinarians, or other health care professionals may provide additional product information.

Before the draft guidance, advertisements targeted at health care professionals satisfied the adequate-provision requirement by providing either the full package labeling or the page number in the Physicians’ Desk Reference® (PDR) on which the labeling information could be found and a toll-free telephone number for package insert requests. However, it was assumed that adequate provision could not be applied to broadcast advertisements directed at consumers, as it was believed that most consumers would not have ready access to a PDR. Furthermore, many questioned whether consumers could interpret such information (for a thorough discussion of the history of DTCA, see Pines, 1999). The FDA’s interpretation of the adequate provision of information to consumers essentially made it impossible to broadcast prescription drug advertisements. Arguably, the FDA acted to protect the consumer, based in part on its interpretation of the consumer’s level of autonomy. Physicians were assumed to be able to access and process the information and hence were responsible for their own information evaluations, whereas the same could not be said for consumers. Historically, the medical profession has endorsed this type of paternalism. This is still a common practice today and is considered ethically suspect.

Was it ethical for the FDA, by its interpretations of adequate provision, to impede the flow of information to consumers? Is it possible to achieve patient autonomy with broadcast advertisements,
and if so, is this purpose better served by a less stringent regulatory guidance? These are important questions as many wonder whether the FDA should adopt DTCA restrictions that favor paternalism over autonomy.

**AUTONOMY**

The word *autonomy* springs from the Greek *autos nomos*, or roughly, "self-rule." It was first used to describe the style of government of early Hellenic states. Modern reflection has extended the concept of autonomy to self-governance in describing issues related to freedom, privacy, liberty, and decision making. The 2 conditions that virtually every theory of autonomy deems essential are liberty— independence from controlling influences—and agency—the capacity for understanding and intentional action.

An individual's liberty is violated when a person is not free to act because of coercion or undue influence. Typically, one envisions a violation of liberty as limited to instances where an individual is coerced to act in a prescribed manner under the threat of social and/or economic punishment. The punishments can include social isolation, physical harm, or disqualification for the receipt of monetary rewards. Although not as dramatic as blackmail, violations of liberty because of undue influence are also common. For example, smoking is widely considered an addiction, which implies a lack of ability to make rational decisions about smoking free from the undue influence of the cigarette. More subtle violations by undue influence can also include the use of biased, misleading, or erroneous information to convince a person to act in a certain manner.

An individual does not possess agency unless he or she can understand the information needed to make a choice and then execute an intentional action based on that understanding. Defining what constitutes understanding is difficult. Provided that one is never truly *fully* informed (i.e., possession of infinite knowledge is not possible), it is arguable that one never possesses *full* understanding. The task of determining agency then rests on the degree to which a person is provided with information *relevant* to a decision, and to what degree a person comprehends the relevant information.

For this discussion, autonomy can be truly served only if a person possesses both liberty and agency, that is, the capacity to inform oneself, reason, understand, and execute a choice satisfactorily free from controlling influence. However, autonomy is a continuum rather than a dichotomy. To the degree that liberty and agency are not possible, a corresponding level of paternalism may be justified. Therefore, we must ask if and to what extent these capacities are possible and/or served in consumers' viewing prescription drug advertisements.

**Provision of Information**

The ability to be autonomous and making an autonomous choice are not synonymous. That a person has the capacity for autonomy does not mean he or she will execute it. An autonomous person may sign a surgical release form, but the act of not reading the form has undermined the autonomous choice to provide informed consent. The person was not fully aware of the benefits and risks of the procedure and therefore could not possibly have proceeded to a choice indepen-
dent of ignorance. The simple act of not informing oneself prohibits the weighing of the choices based on the appropriate information.

Similarly, consumers must have information to make autonomous choices about their drug therapy. This process may begin with an advertisement intended to sell a product rather than to inform. Arguably, the process of autonomy has a higher chance of success if the consumer has unbiased information made available along with the promotional message. However, even if unbiased information is presented, consumers might not choose to read it. One national survey in the United States\textsuperscript{12} found that 54\% of readers remembered seeing the brief summary of product information in print advertisements. Of those respondents, 12\% read this information thoroughly, and another 12\% read the information for important points.\textsuperscript{12} A survey by the American Association of Retired Persons found that approximately one third of respondents reported that they rarely or never pay attention to the “small print” in an advertisement.\textsuperscript{13}

Even if patients obtain the facts, the data may not provide complete information with which to make an autonomous decision. The FDA does not require the brief summary to contain contextual and background information, such as disease incidence and prevalence, cure rate, and drug performance in specific populations. Also, advertisements do not have to contain information about competing products for the same condition. In their assessments of prescription drug print advertising, Wilkes et al\textsuperscript{8,14} found that 29\% of the advertisements acknowledged a competing product, 24\% suggested concordant lifestyle changes, and only 9\% provided an estimate of the drug success rate. Furthermore, as an advertisement-content analysis by Bell et al\textsuperscript{15} revealed, many advertisements use appeals that imply a consumer advantage. The most common appeals used were efficacy (57\%), innovation (41\%), prevention of disease/condition (16\%), power/strength (9\%), and reduced mortality (7\%). Appeals to the cost savings associated with a medication were found in only 1 of every 20 advertisements.\textsuperscript{15}

From these arguments alone, many may believe that DTCA should be restricted. Indeed, it is easy to feel that the pre-1997 concerns with adequate provision of appropriate information to consumers were justified. Admittedly, non-health care professionals may not have reasonable access to drug-related information. Unfortunately, in the absence of any information, consumers are still forced to make decisions about whether to seek physician care, purchase a prescribed medication, take their current prescription medicine as directed, or self-medicate with over-the-counter products. Decision theory research suggests that these choices are sensitive to many factors related to the context and task.\textsuperscript{16,17} Social learning theories further suggest that consumers’ actions are contingent on their belief that an outcome is possible and on their ability to perform behaviors leading to that outcome.\textsuperscript{18} Some suggest that in the absence of DTCA, patients will be forced to seek information from unbiased sources (eg, physicians, pharmacists, or nurses) to formulate health-related beliefs and make choices concerning their care.\textsuperscript{7,8} Unfortunately, this will not help patients who are unaware that they should seek care or ask questions, or that information is available about different treatments.
Advertising appears to be effective in generating awareness of treatment options. A 1999 telephone survey conducted by the FDA found that 75% of the respondents had seen at least 1 drug advertisement within the last 3 months, and 85% stated that the advertisements made them more aware of new drugs. A recent national survey in the United States indicated that 91% of the population had seen a DTCA, 34% had seen an informational advertisement devoid of a promotional message, and 22% felt that they were more likely to take their current medication as a result of the advertisement.

In a previous survey by the same researchers, 33% of those who viewed a DTCA were reminded by the advertisement to refill their prescription. Furthermore, many consumers who saw an advertisement for products such as Claritin® (71%), Lipitor® (45%), Premarin® (68%), Glucophage® (56%), and BuSpar® (44%) could correctly identify that product's indication. DTCAs can achieve considerable public awareness. For example, in 1992, a DTCA aired during the Super Bowl, informing consumers of the availability of a nicotine patch. Public response to this advertisement was so great that inventories could not keep up with the demand. Although the product had been available for many months before the airing of the DTCA, many consumers were simply not aware that a product was available to aid in smoking cessation.

The awareness generated by pharmaceutical promotions, however, does not guarantee that adequate information will be provided to consumers. The information in broadcast advertisements provides a drug name, a major indication, a brief description of the product benefits, a major statement of the risks involved in taking the product, and sources of additional information (eg, physicians, printed information, toll-free number). However, only a moderate percentage of consumers feel that the information on risks and benefits is the kind they need to be able to ask their physician about a medication. Thus, the consumer is left with the responsibility of seeking more information beyond what was provided in the broadcast advertisement. Moreover, there is no guarantee that consumers will try to obtain any information beyond that presented in a DTCA in formulating their beliefs about a product's attributes. Early research has suggested that this limited information could lead to misconceptions about a product's attributes possibly associated with the nonverbal promotional cues in the DTCA.

Commonly, drug information is limited to that which the physician has chosen for the patient. Even then, only 54% of consumers report that their doctors "usually" talk to them about the risks and potential effects of medications prescribed. Alternative medication options are not discussed unless the patient is aware of other treatments. In this manner, informed consent is applied only to situations in which the perceived risk to the patient's health is great. Why has informed consent been used so sparingly? If informed consent

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*Trademark: Claritin® (Schering-Plough, Kenilworth, New Jersey).
Trademark: Glucophage® (Bristol-Myers Squibb Company, Princeton, New Jersey).
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was used to enable the patient to make an autonomous choice, a broader standard would develop. Patients would be consulted and subsequently educated more often as a result. However, the use of informed consent has largely been relegated to legal and liability-related issues. In a sense, informing the patient is necessary only when "important" decisions need to be made. This would excuse the practitioner from liability stemming from negative consequences, since the patient had been given the opportunity to provide autonomous consent. If autonomy is considered the guiding principle for informed consent, rather than a protection from liability, the provision of information to the consumer must be reconsidered. Ideally, consent should involve a series of educational exchanges between the health care practitioner and the patient, rather than a single event of only legal significance.

The consumer should be able to seek, without encumbrance, information that will allow him or her to discuss treatment options with those more knowledgeable so that decisions about the consent of care are exercised with a satisfactory degree of autonomy. In fact, it should be a duty of practitioners to promote discussion of treatments, because having the information necessary to make a well-informed choice is integral to this process. In so doing, physicians actually release themselves from considerable legal liability by ensuring that the patient is sufficiently informed to meet the legal burden of consent. In this manner, it becomes the responsibility of patients to take advantage of the resources of information to promote their own welfare. With cues to action from media sources, consumers now have the opportunity to gather more information to continue the process of reasoning, questioning, understanding, and subsequently executing an independent choice to agree or not agree with their care. Patients often demonstrate disagreement with their care in the form of non-compliance with what they do not understand. Hampering the dissemination of FDA-approved information (ie, the package insert) to the consumer only short-circuits the process of questioning and understanding, denying the consumer the opportunity to make truly autonomous choices. It must be emphasized that patients are being empowered with information to discuss their health care, not with the authority to prescribe.

Reasoning and Questioning Free from Controlling Influence

Unimpeded access to information and a high level of consumer attention to that information do not ensure autonomous choices. Patients must be able to process the information independent of controlling influences. Deceptive practices by pharmaceutical advertisers can be considered one such controlling influence. A pharmaceutical manufacturer's primary responsibility is that of a business: to guarantee adequate return on investment to shareholders. In the process of ensuring an adequate return on investment, a manufacturer will have predilections for promoting a product's positive aspects and downplaying its negative aspects. Furthermore, companies will be inclined to downplay therapeutic alternatives they perceive as competition. Consumers might not be able to defend themselves against these practices, as most consumers may not know if they are being misled by an advertisement. Research has found that vari-
ations in the level of risk and benefit information and even the mode of integration of risk into the pharmaceutical advertisement were related to consumer perceptions, beliefs, awareness, and learning.26-28 Based on these findings, it appears that patients could be easily influenced by a "slick" product advertising presentation. However, the risk of undue influence or misleading statements in pharmaceutical advertisements may not be as great as in other less regulated advertisements.

The FDA has continually demanded fair and balanced content in advertisements throughout the history of DTCA regulation. The new guidance reaffirmed this, broadly stating that broadcast advertisements may not be "false or misleading in any respect" and must "present a fair balance between information about effectiveness... and risk."11 This broad language is dynamically defined to protect consumers from undue influence by allowing the FDA to rigorously prosecute any practice deemed to violate the spirit of fair and balanced content. In so doing, the FDA actually has promoted the consumer's autonomy by ensuring that the processing of information is relatively free from the majority of erroneous and misleading influences. Admittedly, more subtle factors still may play a role as a controlling influence in the patient's reasoning process. It is these more subtle advertising messages that should cause public concern.

The subtle influences in advertisements may include proven marketing strategies such as appeals to authority, "bandwagoning," and red herrings. Advertisements that feature celebrities, or even the visual cues engendered by a white-coated professional, can appeal to our sense of trust of people who obviously "know" what they are talking about. For example, judging by his health, who would deny that the professional baseball player Mike Piazza is not a good spokesperson for Claritin? Advertisements can also entice by suggesting that the consumer is the only person who has yet to join the crowd of people taking the drug. These advertisements appeal to the consumer's need for association with what "most" people agree is the best treatment available. Bandwagoning techniques have been used for years in advertisements of nonsteroidal anti-inflammatory drugs. Finally, an advertisement can provide useless information (ie, red herrings) that makes a drug appear to have an advantage that is illusory (eg, phrases such as "the purple pill" or "the first of its kind"). A certain percentage of people will tie innovation to improvement and ignore mature products that may be therapeutically as good as or better than what is advertised.29

These marketing practices, although troubling, are still not as influential as the misleading presentation of scientific data. Although all drug promotions are a representation of the information contained in the package insert, a DTCA is in no way a substitute. In the words of former commissioner of the FDA Dr. David Kessler, "The FDA commits an enormous amount of time and resources to the development of a package insert that will fully inform the practicing physician about the risks, limitations and benefits related to a product's use."6 Unfortunately, some in the pharmaceutical industry have used subtle techniques to distort information in physician-directed advertising, such as making claims of "no difference" based on stud-
ies with low statistical power. Reviews of drug advertising in medical journals have derided some presentations as misleading, incomplete, and noncompliant with FDA standards. Studies have found that 30% of the advertisements communicated statistics that were based on inadequate interpretation of data, and the majority did not cite peer-reviewed evidence. Also, pharmaceutical promotional materials commonly use relative risk reduction estimates to make risk reduction appear dramatic. Few if any of these advertisements provide information needed to gauge the effect, such as the absolute risk reduction and the number needed to treat before a benefit is realized.

The misleading presentation of data may have a significant impact on physicians who feel they do not have the time to review original research. Clinicians with a less discriminating eye can easily be lulled into trusting the data presented in promotional materials, blurring the line between science and promotion. An early study by Avorn et al showed that physicians were generally unaware that they held non-scientific beliefs portrayed by advertising. Further research has supported the idea that pharmaceutical representatives and company literature play important roles in translating these beliefs into the use of the advertised product. Chren and Landefeld found that the level of contact a physician had with drug companies was positively correlated with requests that the companies' products be added to formularies. Other research has found significant omissions and inaccuracies professed by pharmaceutical representatives in the interests of promotion. Particularly troubling is that throughout the history of health care, consumers have been discouraged from questioning treatment plans that may have been heavily influenced by inaccuracies and puffery.

Consumers' advertising-induced misconceptions, both from DTCA and indirectly through a physician, are only strengthened in the absence of more complete information. The only way these controlling influences can be countered is through better information that is easily accessible to the consumer. In this respect, the existing regulations and current guidance promote fair and balanced information while encouraging a greater transfer of unbiased information (ie, package insert) needed to promote the patient's autonomous behavior. Without this information, the consumer must rely solely on the judgment of the physician, which might be colored by the same influences from which we seek to protect the consumer. This effectively denies the consumer the opportunity to question based on unbiased information, in favor of a paternalism that may or may not be based on the best available evidence.

Admittedly, the fair balance requirement does not provide the consumer with all the necessary elements needed to weigh the risks and benefits. Although consumers are likely to retain and process only limited amounts of information about 1 drug, clinicians have the contextual knowledge and experience necessary to weigh the benefits of several treatment options. Some believe that a lack of functional medical knowledge diminishes the consumer's ability to process information appropriately, and justifies the need for paternalism. This perceived need to protect the consumer can easily be translated into the pre-1997 strict interpretation of prescription drug advertising regulations. This is particularly true when it
is perceived, as it was before the 1997 guidance, that a patient does not have reasonable access to the unbiased information needed to combat undue influences and misconceptions.

Although competent patients may not have the capability to make medical decisions independently, they do retain the independent ability to reason in providing consent to be treated. Based on the concept of informed consent, the duty of the practitioner is to help patients understand their treatment choices. When health care professionals have provided the consumer with all the necessary information in understandable language, the consumer may then possess the liberty and agency to take the autonomous action of accepting the medical recommendation of a practitioner or seeking more information elsewhere. Research has shown that patients who are more involved with their care tend to have better outcomes.38-40 Instead of promoting actions of disconnection from the care process, the actions of autonomy are promoted. Ultimately, the consumer never gains medical authority but does retain self-determination.

Understanding and Executing an Independent Choice

Traditionally, the physician has functioned as the patients’ main advocate in informing them about therapies and other health-related behaviors. In fact, physicians were found to be legally responsible for providing adequate warnings to patients via the learned intermediary doctrine.41 Under this doctrine, the physician’s knowledge of the patient’s needs and the medications available to the patient identifies the physician as the logical intermediary between the drug manufacturer and patient. Furthermore, the physician has access to literature and knowledge not generally available to the layperson. As the learned intermediary, the physician then has the duty to provide warnings of the potential risks of a product and to stay well informed to function appropriately in this and other roles. The doctrine has face validity in the context of supporting patient autonomy. Historically, the consumer could make autonomous choices only when he or she was informed, in understandable language, by an unbiased intermediary. The manufacturer was not in a position to provide or explain the medical information to the consumer.

Today, health-related information, even to those of limited technical sophistication, is much more accessible and easier to obtain outside the domain of the typical learned intermediary. It is estimated that nearly one fourth of the Internet is devoted to health care-related information.42 Consumers are increasingly using drug references and drug manufacturer data made more accessible by the improvements in the communications infrastructure. As a result, consumers often have access to the opinions of nontraditional intermediaries.

A recent survey reports that the majority of consumers want information about medications and typically seek a pharmacist or physician for answers. However, the number of people who want specific information from physicians or pharmacists is higher than the number who actually receive it.20 This suggests that patients must seek information from several other sources. According to the FDA, approximately half of consumers exposed to DTCA seek more information,19 most commonly from a physician (80%), a pharmacist (50%), a nurse (32%), and a friend, relative, or neighbor (30%).
The most common nonhuman sources of information for those visiting a physician in the last 3 months included reference books (36%), the Internet (18%), and the toll-free number provided in a drug advertisement (18%). Furthermore, 26% of those seeking information reported that they made an appointment with a physician to obtain it.\textsuperscript{19}

The increased risk that a patient can and will process information to some extent outside a physician's office has not been ignored by the courts. Although courts appear to be reluctant to excuse the physician from the role of learned intermediary, they have found other health care professions at least partially responsible for a duty to inform. Furthermore, manufacturers who attempt to inform the public through DTCA also share more responsibility for the patient's autonomy. The responsibility of manufacturers to provide accurate information and hence promote a decision free from controlling influences was demonstrated in a recent court case. In \textit{Perez v Wyeth Laboratories, Inc.},\textsuperscript{43} the court found that since the company took part in DTCA, Wyeth was legally responsible for providing adequate information about its products. Also, several consumer groups filed a lawsuit against makers of Claritin, alleging that advertisements for the drug made claims of relief that were not true.\textsuperscript{44} Legal opinion further suggests that courts are recognizing that the physician is not the only source of pharmaceutical risk information, decreasing physician liability under the learned intermediary doctrine for misconceptions drawn from advertising messages.\textsuperscript{23,45} Now that consumers are increasingly likely to attempt to inform themselves, manufacturers and health care professionals alike are responsible for promoting consumer understanding. This responsibility involves ensuring the quality and clarity of the information conveyed to promote the consumer's questioning and understanding. The end purpose is to allow consumers to make informed, reasoned, and independent choices of consent to care.

**CONCLUSIONS**

Autonomy is determined not by the ability to \textit{choose} a therapy, but by the ability to actively \textit{participate} in choices about health care. This active participation ultimately leads to a greater degree of autonomy in decisions of informed consent, and thus better outcomes.\textsuperscript{40} Without DTCA, an effective tool to begin the process of an autonomous choice is lost. With DTCA, there is a dangerous risk of misleading or influencing patients into false beliefs, which can damage patient autonomy. Therefore, the challenge is to enable DTCA to make patients more aware of treatment options, and thus stimulate more information seeking, but only if it does not mislead. Furthermore, DTCA must provide unbiased information while motivating patients to seek direction from those more knowledgeable (eg, physicians, pharmacists, nurses) and from nonindustry sources of information (eg, references, Internet health care sites, support groups) that can dispel flawed conclusions. The goal is to strike an ethically justifiable balance between a moratorium and a laissez-faire approach to DTCA regulation. The current FDA guidance regarding DTCA has attempted to achieve this much more than the old. The new guidance remains consistent in its demands for fair and balanced information while requiring patients to be informed of...
the provider's role in helping them process the information. The FDA does not review advertisements before they are released; however, it does reserve the right to hold the manufacturer legally accountable to strict advertising regulations. The guidance prudently accepts the need to promote the transfer of information while cautiously guarding the consumer from some adverse controlling influences. It also promotes greater consumer involvement in care to ensure that the proper choices are being made. Furthermore, the current regulations and the courts are holding the manufacturer responsible for its duty to inform and not mislead.

Professionals must also recognize their role in promoting patient autonomy. In their official position concerning DTCA, the American Public Health Association (APHA) recognized that "DTCA may have value in increasing health and disease awareness," but also recognized the potential for DTCA to be "detrimental to public health."46 Among other things, the APHA urged health care professionals to support the FDA in finding misleading DTCAs and helping patients obtain unbiased sources of information and distinguish promotional messages from educational messages.46 Furthermore, the APHA urged professionals to strengthen their responsibilities to choose and monitor medications based on optimum effectiveness. The importance of this statement was that the APHA officially supported positions that appeared to recognize the worth of an informed consumer participating in care while strongly supporting the role of the health care professional to protect the patient's interests. In this manner, the APHA acknowledged the importance of well-informed consumers, but also recognized the ultimate responsibility of professionals to provide appropriate communication and prescriptions.

In the foreseeable future, the prescription medication needs of a patient will continue to be controlled by the clinician. However, control over self-determination is strictly the domain of patients able to demonstrate liberty and agency. Some may argue that DTCA has eroded the physician's control over therapeutic decisions, but only if the physician does not act in the best interest of the patient. In remembering their professional responsibility, clinicians should not only evaluate patients' requests but also their problems and therapeutic needs.47 Clinicians should use these opportunities to talk with their patients, inform and promote understanding of their therapy, and promote patient health and personal responsibility for that health. It is also an opportunity to receive feedback from patients concerned about their care and to promote the reevaluation of the messages physicians and their patients receive from pharmaceutical manufacturers.

Autonomy is a powerful principle of ethics that cannot be ignored. In our efforts to promote good and prevent harm, we must always recognize the dignity of the patient. Policies that are predicated on a respect for patient autonomy must be promoted. However, these policies must be continually evaluated to ensure that patient health is promoted rather than commercial interests, and that commercial entities are held accountable for their conduct.

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