

**"[S]OME [A]CCURATE [I]NFORMATION IS [B]ETTER THAN [N]O [I]NFORMATION
[[A]T [A]LL": [FNd1] ARGUMENTS AGAINST AN EXCEPTION TO THE LEARNED
INTERMEDIARY DOCTRINE BASED ON DIRECT-TO-CONSUMER ADVERTISING**

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It is hard to flip through a magazine these days without being confronted by at least a few advertisements for prescription medications. Turn on the television and you will likely see several more. In a world where Rogaine [FN1] and Claritin have become household words and stories on Viagra get top billing in most newspapers, it is hardly surprising to learn that since 1994 spending on prescription drug marketing has increased by over four-hundred percent. [FN2] No doubt the direct-to-consumer (DTC) marketing has been a boon for pharmaceutical manufacturers, but many critics of the practice feel the time has come to reevaluate the perception of the role that manufacturer- provided information plays in the lives of consumers. In their opinion, the days of the learned intermediary doctrine have come to a close, and it is now time to impose on the manufacturer a duty to warn patients directly of the hazards that inhere in a particular medication. These critics cite to changes in the traditional physician-patient relationship as meriting the suspension of the learned intermediary doctrine, as well as a variety of other justifications. Yet, as discussed in this Article, all these justifications are flawed in several respects.

This Article argues that although DTC advertising has numerous advantages, its recent evolution does not justify abandoning the learned intermediary doctrine. For example, DTC advertising increases consumer awareness of illnesses and their symptoms, empowers consumers to take charge of their healthcare decisions, and enhances the quality of the dialogue between physicians and patients. Yet, the learned intermediary model retains its relevance even in today's changing health care environment, because the traditional relationship between physicians and their patients remains fundamentally unchanged. Moreover, the effects of suspending the learned intermediary doctrine would be disastrous. The Food and Drug Administration (FDA) already regulates the content of DTC advertisements, and to otherwise impose on manufacturers a duty to warn patients would interfere *607 with the First Amendment rights of the manufacturers. The answer, therefore, is to continue to respect the wisdom of the learned intermediary and to leave the manufacturer out of the equation.

Part I of this Article discusses the recent debate surrounding the Restatement (Third) of Torts and the omission of a manufacturer's duty to warn based on DTC advertising. Part II details the history of the learned intermediary doctrine, highlighting cases in which it was implemented to absolve manufacturers from liability. Cases refusing to recognize an exception to the learned intermediary doctrine based on DTC advertising are also briefly discussed. Part III highlights the most common arguments of those critics who favor carving out a new exception, including the often asserted notion that the physician-patient relationship has fundamentally changed. Part IV details the numerous arguments against an additional exception, noting the various difficulties, both constitutional and financial, that will attend such an implementation. Finally, this Article reiterates the importance of the learned intermediary doctrine and the need for its continued application.

I The Restatement (Third) of Torts

The Restatement of Law is a series of volumes containing leading legal scholars' insights into the current landscape of a given area of law and how the law should be changed to meet the needs of an evolving society. [FN3] Authorities within the legal community comprise the American Law Institute (ALI), which is responsible for updating the Restatements. [FN4] In 1997, the Restatement (Third) of Torts was finally accepted by the ALI. [FN5] Although this Restatement is not an actual code and it is not mandatory that the courts follow it, it will prove to be extremely influential in American law. [FN6]

The drafts leading up to the final version of the Restatement (Third) of Torts dealt with DTC advertising very differently. *608 Professor Lars Noah has extensively chronicled the additions and deletions of provisions regarding the manufacturer's duty when advertising directly. [FN7]

In early drafts, the authors included a "caveat" asserting that the ALI recognized the possibility that the manufacturer had a duty to warn patients directly, but declined to take a definite position. [FN8] This seemed to contradict other sections of the Restatement that stated that the manufacturer was not liable for warning the patient directly unless its warnings to the intermediate medical provider were insufficient. [FN9]

This caveat was replaced in a later draft with a specific provision within the black letter rule that included three exceptions to the learned intermediary doctrine. [FN10] The manufacturer had a duty to warn the patient directly if: (1) the manufacturer knew or should have known that it was a mass immunization situation where no healthcare professional would be available to warn the patient; (2) the FDA required direct warnings; or (3) the manufacturer participated in DTC advertising. [FN11]

The third exception of DTC advertising was deleted within a few months because the ALI council was hesitant to create the exception on its own. [FN12] Instead, the ALI council believed that the courts should decide the issue. In addition, the ALI council attempted to incorporate the DTC exception into the second exception, as is demonstrated in the preface of the new draft: "We have removed from the black letter a special exception to the learned intermediary rule for direct advertising to patients. Instead we have amended comment e to indicate that, where government agencies mandate that advertisements carry warnings to patients, the learned intermediary rule does not apply." [FN13]

Eventually, even the FDA exception was deleted because the ALI feared taking the initiative in a matter that courts are just ***609** beginning to address. [FN14] Although the mass immunization exception survived, the ALI explained that DTC advertising is just too new a controversy for it to take a position. Therefore, the area is left open. [FN15]

II Case History

With the lack of any Restatement guidance, courts are struggling through DTC advertising cases. The learned intermediary doctrine is widely accepted, as are exceptions to it. DTC advertising, however, presents itself as a relatively new area that repeatedly causes confusion for courts and among scholars.

A. The Learned Intermediary Doctrine

Courts in the United States have long recognized that if pharmaceutical manufacturers warn the physician of any risk involved with taking a prescribed drug the duty to warn the patient is thereby relinquished. [FN16] This concept was introduced as early as 1948 when a New York court found that a manufacturer was not directly liable because it had neither held itself or its product out to the patient. [FN17] The court's rationale was that the physician could make an informed decision by assessing the risks involved with taking the drug in relation to the medical history of the individual patient. [FN18] Therefore, the manufacturer had a duty only to warn the physician. [FN19]

This line of reasoning was finally given a name in 1966. [FN20] The Court of Appeals for the Eighth Circuit referred to the physician as the "learned intermediary" when it held that the manufacturer had a duty to warn the physician, or the learned intermediary, ***610** who in turn was responsible for warning the patient. [FN21] The doctrine has since been infused into modern tort law. [FN22]

B. Exceptions to the Learned Intermediary Doctrine

1. Mass Vaccinations

Although the learned intermediary doctrine is widely accepted, shortly after its christening exceptions to the defense began to emerge. In the late 1960s, oral polio vaccines were commonplace [FN23] as were lawsuits against drug manufacturers. [FN24] Courts found that in mass immunization cases, a physician making individualized assessments was often unavailable. [FN25] With the lack of an informed decision made by the learned intermediary, the manufacturer was held to be responsible for informing the patient of all risks associated with the prescribed medication, [FN26] and the learned intermediary doctrine was set aside. [FN27] This exception has persisted to the present day.

2. Birth Control Pills, Intrauterine Devices, and Nicotine Patches

In addition to mass immunizations, a limited number of states have developed exceptions to the learned intermediary doctrine *611 for oral contraceptives, [FN28] intrauterine devices ("IUDs"), [FN29] and nicotine patches. [FN30] In those jurisdictions, the manufacturer's duty to warn the patient is restored for several reasons: the products are not therapeutic drugs, [FN31] the FDA requires direct warning, [FN32] the drugs are typically prescribed on patient initiative, [FN33] and there is often a lack of continued treatment by the physician. [FN34]

3. What to do with Direct Advertising

Prescription drug manufacturers' new marketing strategies are causing confusion in the courts and generating much debate among academics. Plaintiffs argue for an exception to the learned intermediary doctrine if the pharmaceutical company directly advertised to the patient via brochures, pamphlets, television, newspapers, or magazines. Alternatively, manufacturers argue that courts should hold fast to the well-established learned intermediary doctrine.

4. Courts Inclined to Grant an Exception

Oddly enough, until very recently, the only courts giving hope to plaintiffs arguing for an exception to the learned intermediary doctrine were in cases where the court was not directly deciding the issue. [FN35] Instead, in dicta, courts have commented that a possible exception to the doctrine exists where the manufacturer engages in DTC advertising. For example, a Massachusetts district court, in a footnote stated: "In an appropriate case, the advertising *612 of a prescription drug to the consuming public may constitute a third exception to the learned intermediary rule. By advertising directly to the consuming public, the manufacturer bypasses the traditional patient-physician relationship, thus lessening the role of the 'learned intermediary.'" [FN36] Until a recent decision by the Supreme Court of New Jersey, [FN37] however, there had been no binding precedent in any jurisdiction recognizing the existence of an exception to the doctrine where a manufacturer directly advertises.

In *Perez v. Wyeth Laboratories, Inc.*, plaintiffs who suffered from the side effects of Norplant, a birth control mechanism, argued that an exception to the learned intermediary doctrine should be recognized because Norplant was not a therapeutic drug and the manufacturer had directly advertised its product to consumers. [FN38] Relying on the New Jersey legislature's inaction on a law revitalizing the duty to warn the consumer, the New Jersey Appellate Division rejected plaintiffs' argument that direct advertising created an exception to the learned intermediary doctrine and affirmed the trial court's grant of summary judgment to the manufacturer based on an application of the learned intermediary doctrine. [FN39]

The New Jersey Supreme Court reversed the decision of the lower courts' holding that "[p]rescription drug manufacturers that market their products directly to consumers should be subject to claims by consumers if their advertising fails to provide an adequate warning of the product's dangerous propensities." [FN40] The court further explained that a rebuttable presumption exists where the warning supplied by the manufacturer to the consumer complies with FDA regulations, stating:

We believe that in the area of direct-to-consumer advertising of pharmaceuticals, the same rebuttable presumption should apply when a manufacturer complies with FDA advertising, labeling and warning requirements. That approach harmonizes the manufacturer's duty to doctors and to the public when it chooses to directly advertise its products, and simultaneously recognizes the public interest in informing patients about new pharmaceutical developments. Moreover, a rebuttable presumption that the duty to consumers is met by compliance *613 with FDA regulations helps to ensure that manufacturers are not made guarantors against remotely possible, but not scientifically-verifiable, side-effects of prescription drugs, a result that could have a "significant anti-utilitarian effect." [FN41]

In determining the role of the physician in the causative chain in a situation where DTC advertising exists, the court held that the intervention of the physician did not necessarily break the chain of causation flowing from the manufacturer to the consumer. [FN42] The court explained this holding as follows: "In the case of direct marketing of drugs, we believe that neither the physician nor the manufacturer should be entirely relieved of their respective duties to warn. Pharmaceutical manufacturers may seek contribution, indemnity or exoneration because of the physician's deficient role in prescribing that drug." [FN43]

To date, no other courts have followed the decision set forth in *Perez*. Over time, however, *Perez* may signal a sea change in the application of the learned intermediary doctrine where DTC advertising is present. From a policy

standpoint, the court's analysis in *Perez* creates a potential adversary relationship between both pharmaceutical manufacturers and consumers and the manufacturers and physicians, a situation that threatens the traditional trusting relationship between manufacturers and physicians and physicians and their patients.

5. Cases Denying an Exception

Alternatively, virtually every court forced to decide the issue directly has held that no exception exists. In the following cases, courts explicitly refused to recognize such an exception to the learned intermediary doctrine and found that the manufacturer is still protected from any liability under the doctrine.

a. *Polley v. Ciba-Geigy Corp.* [FN44]

In *Polley*, the plaintiff argued that an exception to the learned intermediary doctrine should be established because the pharmaceutical company made patient brochures available. [FN45] The court, however, determined that the brochures did not establish an exception *614 to the doctrine, and therefore the manufacturer had no duty to warn patients of the risk within the pamphlets. [FN46]

b. *Mikell v. Hoffman-Laroche, Inc.* [FN47]

After receiving a pamphlet on Accutane, an acne medication, the plaintiff in *Mikell* began taking the medication and allegedly suffered from inflammatory bowel disease as a result. [FN48] Relying on the fact that the prescribing physician was aware of the risks involved with ingesting the drug, the court applied the learned intermediary doctrine. [FN49] Because the manufacturer had informed the physician of the risk, it was not liable to the patient.

c. *Presto v. Sandoz Pharmaceuticals Corp.* [FN50]

In *Presto*, parents sued on behalf of their deceased son who committed suicide after discontinuing use of his prescription Clozaril, an anti-psychotic medication. [FN51] The drug manufacturer had provided a brochure to the deceased's family. The parents claimed this pamphlet restored the manufacturer's duty to warn the patient of the risks, especially those associated with discontinuance. The court rejected the plaintiff's argument, however, because the manufacturer never purported to be informing of all the dangers. To the contrary, the manufacturer advised consultation with a physician.

III Arguments in Favor of an Exception to the Learned Intermediary Doctrine: The Erosion of the Physician-Patient Relationship and the Inefficacy of the Learned Intermediary

Although few courts have recognized an exception to the learned intermediary doctrine based on DTC advertising, supporters of such an exception are resolute in their view that health care in this country has changed, and with those changes has gone the individual patient attention that physicians once provided. *615 The primary rationales advanced in support of this argument are that: (1) the physician-patient relationship has been altered by both patient initiative and health maintenance organizations; and (2) the learned intermediary doctrine is an inherently unworkable and faulty doctrine that does not reflect the medical reality of today. Each argument is briefly presented below.

A. Changes in the Physician-Patient Relationship

Of all the rationales offered in favor of another exception to the learned intermediary doctrine, perhaps the most common is the changing nature of the physician-patient relationship. [FN52] Both judges and scholars alike [FN53] are quick to point out that given the abundance of consumer advertising, patients are the ones who initiate the prescription of certain well-advertised drugs. [FN54] In combination with the effect of the modern health maintenance organization ("HMO") structure and the inadequacies of the learned intermediary doctrine in general, [FN55] these changes in the physician-patient relationship, according to the supporters, merit the suspension of the learned intermediary doctrine in the prescription drug context. [FN56]

*616 1. Patient-Initiated Choice

Supporters of an exception to the learned intermediary doctrine based on DTC advertising are quick to focus on the fact that today patients often take it upon themselves to suggest a particular kind or brand of medication to their

physicians. [FN57] A recent study by IMS Health, a medical research firm, found that sixty-five percent of physicians noted more patients asking for drugs by name, [FN58] and a 1995 study of four-thousand physicians found that ninety-nine percent had prescribed, or would consider prescribing, a drug suggested by a patient. [FN59] This is hardly surprising, given that pharmaceutical companies are expected to spend at least 1.3 billion dollars in 1998 to advertise their products. [FN60] Sixty percent of those advertising dollars will be directed at television ads, up from just eleven percent in 1996, and forty percent will go toward magazine and print ads. [FN61] The motivation behind DTC advertising is no secret: drug companies hope to convince consumers to visit the physicians and request specific drugs for their medical conditions, to encourage them to request new drugs more rapidly than their physicians might otherwise decide, and to create brand loyalty such that the consumer resists the physician's efforts to change prescriptions. [FN62] In the supporters' view, this patient initiative merits more aggressive policing of prescription drug advertising and more willingness to hold drug *617 manufacturers liable for patient injuries caused by their medications.

a. The Impact of the HMO

New to the discussions surrounding the carving out of another exception to the learned intermediary doctrine is the impact of the HMO, and other managed care arrangements, on the physician-patient relationship. It is estimated that more than fifty million people are currently served by HMOs, [FN63] with millions of others in some other kind of managed care program. [FN64] According to at least one scholar in this area:

The traditional situation in which the patient establishes a long-term relationship with a particular physician best suited to his needs is becoming less common. A patient's choice of physician is now often constrained by the patient's third party payor. Patients enrolled in managed care organizations (MCOs) may be less likely to develop a long-term relationship with a single physician. Because of increasing cost pressures, patients are likely to spend less time with physicians and receive more and more care from health care professionals who are not doctors. [FN65]

In addition to the lack of physician choice under HMO systems, supporters of a new exception also point to the fact that many such organizations use arguably dubious techniques to influence prescription decisions. [FN66] In addition to requiring the patient to accept generic drugs as substitutes for name-brand medication [FN67] and/or offering cash incentives to physicians who prescribe particular drugs, [FN68] managed care plans are now also contracting with pharmacy benefit managers ("PBMs") to provide*618 prescription drugs to members. [FN69] These PBMs often negotiate with pharmaceutical manufacturers in developing a prescription drug formulary, a list of medication preferred for a variety of medical conditions. [FN70] Pharmaceutical manufacturers have increasingly purchased these PBMs or entered into contracts with them to ensure that the manufacturer's product will be included on the formulary. [FN71] The result is little patient or physician choice as to which prescription drug to use.

In this climate, supporters argue, it is fantasy to suggest that physicians are driving the prescription decision. Rather, the "'dialogue' between manufacturers and physicians about a particular prescription drug has become a group session, with each communicator driven by its own motive." [FN72] Thus, the argument goes, it is incumbent upon manufacturers to take responsibility for informing the patient-consumer.

B. Inherent Difficulties in the Learned Intermediary Model

In the years since courts began adopting the learned intermediary rationale, the resilience of the doctrine has been tested time and again. In particular, courts have grappled with the problem of just who is a "learned intermediary." Although it is clear that a patient's physician qualifies, does a school nurse? [FN73] A pharmacist? [FN74] A physician's assistant? A clinician? Because *619 of the changing nature of the physician-patient relationship all of these individuals have the potential to impact a patient's health care decisions. And because the courts have yet to determine precisely who is or is not a learned intermediary in every situation, supporters of the exception feel that the learned intermediary doctrine simply does not offer enough protection. In their view, the learned intermediary is, again, mostly a fiction in the medical reality of today. If we cannot be sure that a physician will be there to educate the patient as to risks and side effects of a particular medication, the argument goes, then we must impose a duty on someone else: the manufacturer.

IV The Argument Against Another Exception

The supporters' arguments notwithstanding, it is clear that further whittling away of the learned intermediary

doctrine is not the answer. Whatever changes are occurring in the physician-patient relationship, it is nevertheless true that DTC advertising provides real benefits, and imposing a duty to warn on drug manufacturers would have serious, and perhaps even tragic, results. [FN75] Five arguments against an exception to the learned intermediary doctrine are presented here: (1) the physician-patient relationship is fundamentally unchanged, and the physician still retains control over the prescription-writing process; (2) the carving out of yet another exception based on DTC advertising will have disastrous effects, both in terms of technological advancements and litigation costs; (3) adequate warnings will be especially hard to convey to each and every consumer of a particular product; (4) the FDA already has a heavy presence in the drug marketing arena and the existing regulations already restrict what advertisement can and cannot say; and (5) imposing a duty to warn on manufacturers will impermissibly interfere with their First Amendment commercial speech rights.

A. The Physician is Still the Gatekeeper

The rationale behind the learned intermediary exception is clear: not only is the manufacturer not equipped to communicate ***620** warnings to patients, but courts do not wish to interfere with the physician-patient relationship. [FN76] For a variety of reasons, courts have recognized that the physician is the appropriate communicator of warning information to the patient. First, courts are reluctant to create an atmosphere that provides patients with conflicting warnings, one from their physician, and another from the manufacturer. [FN77] Second, physicians are thought to be in a better position to convey information to patients and to quantify the risks involved with certain medication. [FN78] Third, drug manufacturers do not necessarily have the means to communicate with each and every consumer the same way a physician can communicate. [FN79] For all these reasons, courts have consistently reiterated the principle that the physician, not the manufacturer, is in the best position to warn patients of the risks involved with certain medications.

1. The Physician Retains Control Over Prescriptions

While supporters are correct, to some extent, in noting that the physician-patient relationship is undergoing changes, it is also true that the fundamental nature of the relationship has remained the same. In particular, it remains true that in all instances in which patients request a particular brand of medicine, the physician is the one who ultimately writes the prescription. [FN80] ***621** Given the strict ethical duty imposed on physicians, not to mention the threat of malpractice suits that no doubt linger in a physician's mind, physicians must assimilate all relevant information about the patient and choose the best medicine for that individual. [FN81] It is simply not the case that physicians are merely "signing off" on patient suggestions. Although surveys have indicated that physicians have prescribed, or are willing to prescribe, medicines suggested by patients, [FN82] this does not necessarily mean that physicians are blindly following those suggestions.

The fact that patients are more familiar with certain well-advertised drugs, and that they are more willing to suggest those drugs to their physicians, does not merit much concern for another reason: Physicians themselves have been bombarded by pharmaceutical advertising for years. [FN83] If physicians have been able to filter this direct marketing information from drug companies, [FN84] then it follows that they can do the same when confronted by a patient's suggestion. Arguably, a patient's suggestion is less convincing and less forceful. Since 1962, the FDA has had in place regulations that mandate the content of prescription drug advertisements to physicians, [FN85] and in August 1997, the FDA ***622** promulgated specific guidelines for DTC advertisements. [FN86] Given a physician's education, experience, and ability to filter these already-regulated ads, there is no real threat to the traditional physician-patient relationship.

2. Continued Monitoring of the Physician-Patient Relationship

In addition to the fact that the fundamental nature of the physician-patient relationship has not significantly changed, it is also true that the relationship has been, and continues to be, subject to monitoring from courts and regulatory agencies. [FN87] Such scrutiny of that relationship is meant to "ensure that the physician receives and relies upon clear, unbiased, accurate information." [FN88] And courts have been willing to impose liability on the pharmaceutical manufacturer when this relationship has been interfered with. Both the California Supreme Court [FN89] and the North Carolina Court of Appeals [FN90] have done just that in cases where manufacturers ***623** have over-promoted their products. Given this close scrutiny, it is unnecessary to add another layer of regulation. The physician-patient relationship is closely guarded as it is, and physicians are qualified to thwart the unlearned recommendations of their patients. [FN91] Simply put, the rationale put forth for creating the learned intermediary doctrine in the first place continues to hold true, regardless of the increase in DTC advertising.

B. Effects on Litigation

If courts begin to allow an exception to the learned intermediary doctrine in DTC advertising cases, not only will the pharmaceutical companies suffer, society as a whole will pay the consequences. In an attempt to avoid future litigation manufacturers may stop advertising if they believe litigation costs will outweigh the sales expected from marketing their products. Courts, however, disfavor keeping consumers in the dark because informed consumers are reflective of an informed citizenry. [FN92] In addition, if manufacturers do stop advertising, future plaintiffs will continue to point to old brochures and advertising even if there was no influence on that particular individual's decision to take the medicine. Courts will have a difficult time designating dates for the statute of limitations without appearing arbitrary.

Not only will the possibility of litigation have a chilling effect on speech, it will further affect the amount of money spent on research of new medications. [FN93] Large verdicts against the manufacturers will affect the allocation of funds throughout the company. Because manufacturers are bound by the law to pay the *624 damages, medical research also will suffer. [FN94]

In the past, [FN95] the ALI has attempted to deal with such a concern in comment k to section 402A of the Restatement (Second) of Torts, addressing the unavoidably unsafe product. [FN96] Comment k states that while some products such as drugs are inherently unsafe, their value to society is too great to be held to a strict liability standard. The Supreme Court of Arkansas stated that comment k "reflects the concern . . . that large monetary judgments would deter drug manufacturers from undertaking research programs to develop socially beneficial pharmaceuticals." [FN97] Thus, both scholars in the field and the courts have recognized *625 the disastrous effects litigation will have on the development of new medication.

C. Adequacy of Warnings: Is Too Much Ever Enough?

Perhaps the most perplexing difficulty that attends the implementation of yet another exception is the imprecise and nebulous nature of the warning to be given. Whereas physicians can tailor the warning to the individual patient, the manufacturer would be required to develop one universal warning for every consumer of the medication. As it is right now, the warning that manufacturers must convey to physicians is governed by a reasonableness standard: An adequate warning is one that is "given in a form that could reasonably be expected to catch the attention of a reasonably prudent physician." [FN98] This reasonableness standard is sufficient, in part, given the extensive education and expertise of most physicians. Yet in dealing with patients, from all walks of life and of varying intelligence and educational levels, it would be dangerous for the manufacturer to assume that one warning could adequately convey the risks and side effects of a particular drug. This unusually burdensome standard has already led to an increase in liability in those contexts in which exceptions to the learned intermediary doctrine exist, namely, birth control pills, IUDs, and mass vaccinations. This would likely have a similar effect in the DTC marketing arena.

1. Increased Liability for Inadequate Warnings

In *MacDonald v. Ortho Pharmaceutical Corp.*, [FN99] a patient sued a manufacturer of a birth control pill claiming that the warning accompanying her medication was insufficient. [FN100] Despite a package insert which stated that "[t]he most serious known side effect is abnormal blood clotting which can be fatal," and "blood clots occasionally form in the blood vessels of the legs and the pelvis of apparently healthy people and may threaten life if the clots break loose and then lodge in the lung or if they form in other vital organs, such as the brain," [FN101] the patient argued that she was not adequately warned that she might suffer from a *626 stroke. [FN102] The court agreed, finding the learned intermediary doctrine inapplicable, and holding the drug manufacturer liable for inadequately warning the patient. [FN103]

In *Allison v. Merck & Co.*, [FN104] the manufacturer of a measles, mumps and rubella ("MMR") vaccine included a warning that indicated the possibility of adverse reactions. According to the information distributed to the mother of the injured child, children who develop measles can get "an inflammation of the brain (encephalitis), which can lead to convulsions, deafness, or mental retardation." [FN105] The child in that case developed measles soon after receiving the MMR vaccine and contracted encephalitis soon after. [FN106] As a consequence of the encephalitis, the child suffered from "blindness, deafness, mental retardation and spastic contractures." [FN107] Holding that the drug manufacturer failed to sufficiently warn the parents of these risks, the court explained that the

mother was not properly warned that the vaccine might cause "permanent brain damage . . . inflammation of the brain, yes; but permanent blindness, deafness, and mental retardation, no." [FN108] The manufacturer was thus held liable for the child's injuries.

2. The Lesson to be Drawn: No Warning is Ever Enough

The lesson to be drawn from the above cases is simply that no warning may ever be enough. While manufacturers may be careful to highlight the general side effects that may occur as a result of taking certain medications, it seems that courts rather expect an unrealistic amount of prescience in predicting what may befall a particular patient. Minor mistakes can lead to thousands, even millions of dollars in liability. [FN109] And even assuming that manufacturers are able to draft a warning that outlines every possible risk involved with their products, difficulties in quantifying those *627 risks will persist: How is the manufacturer to make the consumer (indeed, every consumer) understand what the chances of developing a certain side-effect are? [FN110] Without being able to communicate these odds in understandable lay terms and instead merely outlining a laundry list of possible side effects, the consumer may be overwhelmed by the apparent risks involved and may elect simply to not take the medication, rather than risk a perceived host of unpleasant or deadly effects. [FN111] Yet attempting to detail the actual percentage chance of developing each and every possible *628 side effect may leave consumers frustrated and confused. [FN112] And the risk of overinforming consumers is undeniably large. [FN113] Consumers simply are not equipped with the necessary medical training and expertise to be able to evaluate the hazards of a particular medication; only the physician is so qualified.

Beyond difficulties in drafting the substance of warnings, problems also surround the placement of warnings. That is, manufacturers must also ensure that patients actually receive the warning, not just that the warning is adequately drafted. This requirement has proven especially difficult in cases involving vaccinations and other such medical procedures where the patient does not actually see the medicine's original container. [FN114] The *629 result, again, will be an increase in manufacturer liability. Pills that are sold to patients without their original containers and samples distributed by physicians and hospital emergency rooms are just two examples of situations in which manufacturers could increasingly face liability. [FN115] The situation becomes arguably more complicated when illiterate patients or foreign-speaking patients *630 are thrown into the mix: In such situations, the problem is much greater than just the placement of the warning. [FN116]

Given the difficulties that inhere in a manufacturer-controlled warning scheme, the better argument, therefore, is to let the physician continue to oversee patient information. Manufacturers are ill-equipped to handle this task, and to impose such a burden notwithstanding these difficulties may have disastrous effects. [FN117] A system that puts the onus on manufacturers to communicate with each and every consumer of their product, and to tailor that communication in such a way that each consumer is fully informed of the risks that inhere in a particular product, is problematic and ineffective at best. The fact is simply that the physician remains the best communicator of this information.

D. The Already-Heavy Presence of the FDA

Another argument in favor of the survival of the learned intermediary doctrine stems from the pre-existing FDA regulations regarding the policing of warnings in DTC advertising. It must not be forgotten that our legal system is built on consistency. Therefore, there is no need to disregard precedent by allowing an exception to the learned intermediary doctrine when existing regulatory mechanisms presently provide enough warning. While plaintiffs claim that patient protection is needed, the FDA is already providing this protection.

The FDA was given control to regulate pharmaceutical advertisements*631 in 1962. [FN118] However, the manufacturers' ads were directed to persons within the medical field. At that time, as the drug manufacturers expanded their marketing techniques into the realm of DTC ads, the FDA also expanded its role as protector of consumers. In the past, the marketers of prescribed drugs were generally allowed to mention either the name of the drug or the ailment it treats. [FN119] Both could be mentioned only if the manufacturer also included a "brief summary" regarding the side effects, contraindications, and effectiveness of a product. [FN120] What specifically had to be included varied according to the type of advertisement; none, however, truly were as brief as the name implies. [FN121] The FDA was attempting to create ads that portrayed a balance between both the positive result of the medication and the risks associated with it. If this balance occurred, then the consumer would not be misled into a false belief that a miracle drug was on the market. As a result, pharmaceutical companies generally only did "reminder ads" to the public naming either the product or the ailment, but not both. [FN122]

In August of 1997, the FDA changed its policy [FN123] and is presently allowing drug manufacturers to name both the prescription drug and the condition it treats within the same broadcast without requiring a brief summary. [FN124] Instead, in advertisements broadcast through the media, the FDA requires the manufacturer to disclose the drug's major risks in what has become *632 known as the "major statement." [FN125]

In addition, the manufacturers in DTC media advertising are required to include an "adequate provision." [FN126] The FDA has recently published a guidance draft to clarify what this "adequate provision" requirement in DTC broadcast advertising should contain. [FN127] Working under the presumption that the ad will contain a "major statement" disclosing all risk information in an easily understandable manner, the FDA also wants the audience to have access to the drug's full prescribing information. [FN128] Suggestions for making this information available include a toll-free number which will allow consumers to request the label information, an address to send for information, Internet addresses, brochures available in a variety of publicly accessible locations, [FN129] and/or a statement declaring that pharmacists and/or physicians may provide more information. [FN130] The FDA, while requiring the approved package labeling be provided, is also asking manufacturers to provide non-promotional, consumer-friendly product information. [FN131]

The FDA is taking these regulations very seriously. In the first three months after the publication of the guidance statement, the FDA pulled four television and radio ads that it found to be misleading and not in concert with the FDA regulations. [FN132] The ads were problematic either because they failed to provide enough information regarding the risks or the information regarding the risks was not prominent enough under FDA guidelines. In addition, most ads failed to inform the consumer of how to receive a product insert. Norman Drezin, deputy director of the FDA's *633 division of drug marketing, commented on Zeneca's Accolate ads, which were deemed misleading by the FDA:

Accolate is a product used for the prevention and chronic treatment of asthma, . . . but there is a special type of asthma - exercise-induced asthma - for which this product is not intended.

Zeneca's commercial had the theme, 'I will accept no limitations,' and portrayed a cross county runner, mountain biker, competitive swimmer and rock climber We were concerned because this was not an approved use, and anyone who had the drug already might go out and do things they wouldn't ordinarily do because they would think they were protected [by the drug]. [FN133]

The FDA sees no reason why its success in monitoring prescription ads would not continue and is confident that its strict enforcement of regulations will also continue. [FN134]

E. First Amendment Concerns

While imposing a duty to warn on manufacturers may have potentially disastrous financial effects, it is also true that such a duty may unconstitutionally interfere with drug manufacturers' First Amendment rights. The advertising of prescription drugs is, after all, commercial speech, and the Supreme Court has long held that commercial speech merits First Amendment protection if it is truthful. [FN135] This recognition of the value of commercial speech is based in large part on the fact that consumers need the information that product manufacturers have to offer:

[S]ignificant societal interests are served by such speech. Advertising, though entirely commercial, may often carry information of import to significant issues of the day. And commercial speech serves to inform the public of the availability, *634 nature, and prices of products and services, and thus performs an indispensable role in the allocation of resources in a free enterprise system. [FN136]

Advertising thus plays a crucial role in the dissemination of information and interference with the content of such advertising is regarded with suspicion by the Supreme Court. [FN137]

1. Constitutional Analysis of Coerced Speech

Obviously, an outright ban on the advertising of prescription drugs, or restrictions on the amount of such advertising, would be more constitutionally problematic than regulations of the content of that advertising. [FN138] In a long line of cases, the Supreme Court has, relying on the above rationale, struck down state and federal legislation designed to outright prohibit certain forms of commercial speech. [FN139] But regulation of the content

of commercial speech can also be problematic. Both outright bans on speech and coerced speech [FN140] are analyzed under the same constitutional test: [FN141] (1) is the speech at issue protected by the First *635 Amendment? [FN142] (2) is the asserted governmental interest substantial? (3) does the regulation advance the governmental interest? and (4) is the regulation more extensive than necessary to serve that interest? Thus, in some contexts, even coerced speech can be unconstitutional. [FN143]

Though the Supreme Court has in the past sanctioned the use of warning labels on products, [FN144] it is nevertheless true that regulations mandating such labels must still pass muster under the Court's four-prong analysis. [FN145] Imposing a duty on the manufacturer to warn consumers of dangers associated with their prescription *636 drugs will not, however, survive the Court's constitutional analysis. First, the speech at issue is protected by the First Amendment. It is speech concerning a lawful activity and, in all but the most exceptional cases, is truthful. Given the Court's past endorsement that "some accurate information is better than no accurate information at all," [FN146] it is beyond cavil that courts will recognize prescription advertising as deserving of First Amendment protection.

Second, although the asserted governmental interest, protection of consumers' health, is substantial, any such regulation will still fail to pass muster under the third and fourth prongs. While an argument can be advanced that a manufacturer's duty to warn does advance the government's interest in protecting patients, this argument is nevertheless flawed in two respects. First, restricting what information can be made available to consumers will only result in a poverty of consumer information; quite the contrary to what the Supreme Court has sought in protecting commercial speech. [FN147] Second, coercing manufacturers to communicate to consumers every possible adverse effect of a certain medication may ultimately so confuse or overwhelm consumers as to convince them to forego medication altogether. [FN148] In that sense, manufacturer-provided warnings may actually be counterproductive to patient safety.

Finally, the regulation would almost certainly be more extensive than necessary to serve the governmental interest, given that the status quo is perfectly able to protect patients. Of course, one has to accept the status quo as sufficient in order to understand manufacturer-provided warnings as completely superfluous and overly extensive (while at the same time interfering with First Amendment rights); but even assuming that the status quo is not sufficient, there is still an argument to be made that manufacturer-provided warnings are more extensive than necessary. Simply put, imposing such a duty will impermissibly chill manufacturers' *637 speech, and alternative means of achieving the goal of patient protection already exist.

2. The Chilling Effect of Coerced Speech

Imposing a duty on drug manufacturers to warn patients will have a chilling effect. Complying with regulatory requirements may become so burdensome and expensive that manufacturers are driven from the advertising arena. Also, the potential liabilities that will attend consumer directed advertising may become so great that manufacturers will be, for all practical purposes, forced to abandon such efforts. These types of chilling effects are constitutionally impermissible, and thus any regulation imposing a duty on manufacturers to warn patients directly fails to pass muster under the fourth prong of the Supreme Court's commercial speech jurisprudence.

A common argument has been advanced that regulations aimed at commercial speech cannot actually have a chilling effect. [FN149] The argument is based on the notion that those who speak commercially are driven by a "profit motive," [FN150] and that regulations that would otherwise interfere with commercial speech therefore have only a negligible impact on the speakers. According to the plurality in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, "the greater objectivity and hardiness of commercial speech . . . may make it less necessary to tolerate inaccurate statements for fear of silencing the speaker." [FN151] This objectivity and hardiness, it is argued, insulate the commercial speaker from the deterrent effects of such regulations.

Yet what proponents of this argument fail to realize, and what the Supreme Court was not considering when it spoke of the "hardiness" of commercial speech, is that the calculus is markedly different when dealing with pharmaceutical manufacturers. Simply put, imposing a regulation on attorneys to disclose their fee arrangements in their advertisements [FN152] and imposing on *638 pharmaceutical manufacturers a duty to warn consumers of the hazards involved with medication are not the same. In the first instance, the attorney fee is not "unavoidably unsafe," and the attorney does not have to contend with communicating sensitive and technical information to consumers who are not likely to understand a great deal of it. In the second instance, however, we would be asking a manufacturer of a medication that is unavoidably unsafe to communicate with thousands of consumers about

highly technical and unfamiliar information, and, in the event the manufacturer was not able to convey such information sufficiently enough, would be holding that manufacturer liable for whatever befalls the consumer. [FN153]

The consequences of not being able to meet the duty, therefore, are not at all similar. The omnipresent threat of being held liable for the death or injury of consumers is certainly enough to deter a pharmaceutical manufacturer from speaking. It is simply not the case that a "profit motive" would overcome this threat. Rather, in the face of potentially limitless liability, a profit motive would militate in favor of not advertising, not taking on the risk of liability. Thus, the financial drain that will come from complying with disclosure requirements and the overwhelming, and very real, threat of liability that will come with disclosure requirements will in fact have a chilling effect on manufacturers. To argue otherwise is to completely misunderstand the effect of imposing a duty to warn on the manufacturer. In sum, the better argument is to continue to respect the role of the learned intermediary.

Conclusion

In spite of the perceived changes in modern health care, the learned intermediary continues to play a crucial role in the health care decisions of patients. While HMOs and patients themselves now exert some influence over the prescription-writing process, this influence remains limited and is ultimately secondary to the physician's own knowledge and expertise. The advent of DTC ***639** advertising does not, therefore, merit the imposition of a duty to warn on the manufacturer. Rather, DTC marketing should be encouraged for the benefits that it provides to both physicians and patients. Imposing a duty on the manufacturer, however, will only provide disincentives. Those who argue for the suspension of the learned intermediary doctrine fail to fully comprehend the implications of a manufacturer-provided warning and, as such, present a myopic view of the debate. The better approach is to recognize the benefits of DTC advertising, to encourage its emergence in the marketplace, and to leave the task of informing patients to the learned intermediary.

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[FNd1]. *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557, 562 (1980).

[FN1]. Upjohn Pharmaceutical Company's successful marketing of Rogaine, a baldness treatment for men, sparked the interest in direct-to-consumer advertising. See Mark Peyrot et al., *Direct-to-Consumer Ads Can Influence Behavior, Marketing Health Services*, Summer 1998, at 27.

[FN2]. See Peyrot et al., *supra* note 1, at 27.

[FN3]. See *Black's Law Dictionary* 1313 (6th ed. 1990).

[FN4]. See *id.* at 82.

[FN5]. See *Restatement (Third) of Torts: Products Liability (Proposed Final Draft 1997)*.

[FN6]. See Lars Noah, *Advertising Prescription Drugs To Consumers: Assessing the Regulatory and Liability Issues*, 32 *Ga. L. Rev.* 141, 143, 161 (1997).

[FN7]. See *id.* at 163-64.

[FN8]. See *id.* at 162 (citing *Restatement (Third) of Torts: Products Liability* § 103, at 108 (Preliminary Draft No.

1, 1993)).

[FN9]. See *id.*

[FN10]. See *infra* Part II.

[FN11]. See Noah, *supra* note 6, at 163 (citing Restatement (Third) of Torts: Products Liability § 103(a)(3) (Council Draft No. 1, 1993)).

[FN12]. See *id.* at 164 (citing Restatement (Third) of Torts: Products Liability § 4(b)(3), at 66 (Council Draft No. 1A, 1994)).

[FN13]. See *id.* at 164 n.91.

[FN14]. See *id.* at 166 (citing Restatement (Third) of Torts: Products Liability § 4(b)(3) & cmt. e, at 93-94 (Tentative Draft No. 1, 1994)).

[FN15]. See *id.*

[FN16]. See, e.g., *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82 (8th Cir. 1966); *Marcus v. Specific Pharm., Inc.*, 77 N.Y.S.2d 508 (App. Div. 1948).

[FN17]. See *Marcus*, 77 N.Y.S.2d at 509-10 (granting motion to dismiss because a child died when prescribed the adult dosage for a suppository and defendants had advertised only through medical journals).

[FN18]. See *id.*; see also *Bean v. Baxter Healthcare Corp.*, 965 S.W.2d 656, 662 (Tex. Ct. App. 1998, no writ).

[FN19]. See *Marcus*, 77 N.Y.S.2d at 509-10.

[FN20]. See *Sterling Drug*, 370 F.2d at 82 (plaintiff developed an eye disease after taking an arthritis prescription).

[FN21]. *Id.* at 85.

[FN22]. See, e.g., *Richards v. Upjohn Co.*, 625 P.2d 1192 (N.M. Ct. App. 1980); *Pittman v. Upjohn Co.*, 890 S.W.2d 425 (Tenn. 1994); Restatement (Second) of Torts § 402A cmt. K (1965).

[FN23]. See Dennis A. Conrad, *New Recommendations for Poliovirus Vaccination*, *Post Graduate Med.*, Nov. 1997, at 45 (noting that when the oral polio vaccine is administered, there is a slight risk that instead of protecting against future possibilities of contracting the disease, the vaccine may immediately infect the patient. However, the vaccine continued to be used because it was "inexpensive, easy to administer, and highly effective.").

[FN24]. See, e.g., *Reyes v. Wyeth Lab.*, 498 F.2d 1264 (5th Cir. 1974); *Davis v. Wyeth Lab., Inc.*, 399 F.2d 121 (9th Cir. 1968) (imposing on the manufacturer a duty to warn in polio vaccine cases).

[FN25]. With the loss of the trained physician's input, it has been argued that mass immunization is similar to over-the-counter sales of medicine. See *Davis*, 399 F.2d at 130-31.

[FN26]. See *id.* at 131 (explaining manufacturer has a duty to warn in polio vaccines); see also *Mazur v. Marck & Co.*, 964 F.2d 1348 (3d Cir. 1992); *Reyes*, 498 F.2d at 1279. This has been rejected in various jurisdictions. See, e.g., *Walker v. Merck & Co.*, 648 F. Supp. 931 (M.D. Ga. 1986), *aff'd*, 831 F.2d 1069 (11th Cir. 1987).

[FN27]. Therefore, the manufacturer, who was assumed to be knowledgeable about its distribution system "was required to warn foreseeable users." *Mazur*, 964 F.2d at 1362 (quoting *Reyes*, 498 F.2d at 1277).

[FN28]. See, e.g., *Odgers v. Ortho Pharm. Corp.*, 609 F. Supp. 867 (E.D. Mich. 1985); *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65 (Mass. 1985).

[FN29]. See, e.g., *Hill v. Searle Lab.*, 884 F.2d 1064 (8th Cir. 1989).

[FN30]. See, e.g., *Edwards v. Basel Pharm.*, 933 P.2d 298 (Okla. 1997).

[FN31]. Because these drugs tend not to cure a traditional illness, they are sometimes considered nontherapeutic. Plaintiffs argue that the learned intermediary doctrine should not apply in such cases.

[FN32]. See *Spychala v. G.D. Searle & Co.*, 705 F. Supp. 1024 (D.N.J. 1988); *Edwards*, 933 P.2d at 298; *infra* Part IV.D.

[FN33]. Patients often visit the physician for the specific purpose of obtaining a nicotine patch, oral contraceptives, or IUDs. See *Hill*, 884 F.2d at 1064.

[FN34]. After the patient has received the prescription, there is often no further need to see that specific physician again. See *Odgers v. Ortho Pharm. Corp.*, 609 F. Supp. 867 (E.D. Mich. 1985); *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65 (Mass. 1985).

[FN35]. See, e.g., *In re Norplant Contraceptive Prods. Liab. Litig.*, 955 F. Supp. 700 (E.D. Tex. 1997); *Garside v. Osco Drug, Inc.*, 764 F. Supp. 208 (D. Mass. 1991), *rev'd on other grounds*, 976 F.2d 77 (1st Cir. 1992); *Shanks v. Upjohn Co.*, 835 P.2d 1189 (Alaska 1992).

[FN36]. *Garside*, 764 F. Supp. at 211 n.4 (emphasis added).

[FN37]. See *Perez v. Wyeth Lab., Inc.*, 734 A.2d 1245 (N.J. 1999).

[FN38]. *Id.* at 1246.

[FN39]. *Id.* at 1249-50.

[FN40]. *Id.* at 1257.

[FN41]. *Id.* at 1259.

[FN42]. *Id.* at 1260-62.

[FN43]. *Id.* at 1262-63.

[FN44]. 658 F. Supp. 420 (D. Alaska 1987).

[FN45]. *Id.* at 422.

[FN46]. *Id.* at 423.

[FN47]. 649 So.2d 75 (La. Ct. App. 1994).

[FN48]. *Id.* at 76.

[FN49]. *Id.* at 79.

[FN50]. 487 S.E.2d 70 (Ga. Ct. App. 1997).

[FN51]. *Id.* at 72.

[FN52]. See, e.g., Susan A. Casey, *Laying an Old Doctrine to Rest: Challenging the Wisdom of the Learned Intermediary Doctrine*, 19 Wm. Mitchell L. Rev. 931, 949-58 (1993); Nancy K. Plant, *The Learned Intermediary Doctrine: Some New Medicine for an Old Ailment*, 81 Iowa L. Rev. 1007, 1024 (1996) ("The traditional situation in which the patient establishes a long-term relationship with a particular physician best suited to his needs is becoming less common.").

[FN53]. See, e.g., *Hill v. Searle Lab.*, 884 F.2d 1064, 1071 (8th Cir. 1989) (noting that the decision to use birth control medication often involves increased patient input); Teresa Moran Schwartz, Esq., *Consumer-Directed Prescription Drug Advertising and the Learned Intermediary Rule*, 46 *Food Drug Cosm. L.J.* 829 (1991) (suggesting that DTC advertising may alter the relationship between physician and patient).

[FN54]. See, e.g., *Casey*, supra note 52, at 931 (noting that one of the chief rationales offered in favor of another exception is that patients are now active participants in their health care decisions); Schwartz, supra, note 53, at 829.

[FN55]. See *infra* Part III.B. The argument is that the learned intermediary has not been identified in every conceivable situation.

[FN56]. Some critics have even called for the "death" of the learned intermediary doctrine altogether. See, e.g., *Casey*, supra note 52, at 957:

Even if the courts were to recognize an advertising exception, the learned intermediary doctrine, contrary as it is to both the modern realities of medical practice and to contemporary public policy, is a concept that has outlived its erstwhile value. Principal among its shortcomings is the fact that the doctrine substantially overstates the ability and willingness of the medical community to act as a learned intermediary, contradicts the concept of informed consent and a patient's right to self-determination, and ignores the substantial benefits of an informed patientry.

[FN57]. See, e.g., *Casey*, supra note 52; Schwartz, supra note 53.

[FN58]. See *Peyrot et al.*, supra note 1, at 7. The study also found that females and higher-educated people were more likely to request specific prescription drugs. See *id.* The study's authors attributed this to the fact that pharmaceutical manufacturers direct their ads at women, and to the fact that higher-educated people may be more likely to approach their physicians with information. See *id.*

[FN59]. See *id.* at 4.

[FN60]. This figure is up 50% from the amount spent on advertising in 1997. See *Study: Spending on TV, Magazine Drug Ads Up by 50 Percent in 1998*, Associated Press, July 9, 1998 [hereinafter *Spending on TV*].

[FN61]. See *id.*

[FN62]. See *Noah*, supra note 6, at 150; see also Philip R. Alper, *Who to Trust: Drug Companies or Your Doctor?*, *Wall St. J.*, Dec. 4, 1996, at A18 ("The aim is to create consumer demand even before the doctor would be willing to use the drug spontaneously. Call it an end-run around the doctor."). This strategy appears to be working: By at least one account, "[s]ales gains for several of the companies' prescription drugs were spurred by consumer advertising, following the recent loosening of federal rules governing television and print advertising." Robert Langreth, *Three Drug Makers, Helped by Ads, Post Higher Profits*, *Wall St. J.*, Oct. 22, 1997, at B6.

[FN63]. This is roughly one-fifth of the U.S. population. See Erik Eckholm, *While Congress Remains Silent, Health Care Transforms Itself*, *N.Y. Times*, Dec. 18, 1994, at A1.

[FN64]. See *Plant*, supra note 52, at 1024 n.81.

[FN65]. *Id.* at 1024-25 (citations omitted). As of 1994, "[a] majority of privately insured Americans were insured in managed-care plans that limit choice of doctors and treatments. Sixty-five percent of workers at medium and large companies were in such plans by 1994." Eckholm, supra note 63, at A1, quoted in *Plant*, supra note 52, at 1024.

[FN66]. See *Plant*, supra note 52, at 1026 (noting that in some cases a physician must be authorized by an HMO before prescribing certain drugs).

[FN67]. See, e.g., Donna A. Boswell, *Recent Developments in Outpatient Prescription Drug Payment*, in 1992 *Health Law Handbook* 205 (Alice G. Gosfield ed., 1992); *Plant*, supra note 52, at 1026.

[FN68]. See *Plant*, supra note 52, at 1026-27 (noting that third party payors may provide monetary incentives to physicians who prescribe certain, less expensive drugs).

[FN69]. See *id.* at 1027 ("Increasingly, MCOs, large employers, and other third party payors ... are contracting with ... [PBMs] to obtain and provide prescription drug services for the plan.").

[FN70]. See *id.* at 1028.

[FN71]. See *id.* at 1029 n.108 (outlining the various purchases of PBMs by drug manufacturers since 1993).

[FN72]. See *id.* at 1031-32. The author believes that the "motives" in question are largely economic in nature, and that somewhere in this "dialogue" concern for what is in the patient's best interest gets lost. *Id.*; see also Barbara A. Noah, *The Managed Care Dilemma: Can Theories of Tort Liability Adapt to the Realities of Cost Containment*, 48 *Mercer L. Rev.* 1219, 1225-27, 1227 n.38 (1997) (outlining various strategies for cost containment, including restricting drug prescriptions).

[FN73]. See *Walker v. Merck & Co.*, 648 F. Supp. 931 (M.D. Ga. 1986) (dealing with a measles, mumps and rubella (MMR) vaccine given by a school nurse), *aff'd*, 831 F.2d 1069 (11th Cir. 1987); *Holley v. Burroughs Wellcome Co.*, 330 S.E.2d 228 (N.C. Ct. App. 1985) (holding that the learned intermediary doctrine can be applied to a nurse anesthesiologist), *aff'd*, 348 S.E.2d 772 (N.C. 1986).

[FN74]. See Brenda Raffath, *Does the Pharmacist Have a Duty to Warn Patients of a Prescription Medication's Potential Risks or Dangers?*, 1 *J. Pharmacy & L.* 61 (1991-1992) (discussing the potential for liability to be imposed on pharmacists in the near future for failing to fully inform patients of the benefits and risks of a particular drug).

[FN75]. Briefly, the argument is that if patients are confronted with an overwhelming amount of information detailing all possible side effects and risks that inhere in taking a certain form of medication, they will choose instead to forego the medicine, thereby jeopardizing their health. See *infra* note 96 and accompanying text.

[FN76]. See Noah, *supra* note 6, at 157 (explaining that courts do not want to interfere with the physician-patient relationship).

[FN77]. See *Swayze v. McNeil Lab., Inc.*, 807 F.2d 464, 471 (5th Cir. 1987) ("In all likelihood, such warnings would only lead to confusion, and perhaps undermine the physician-patient relationship."); *Dunkin v. Syntex Lab., Inc.*, 443 F. Supp. 121, 123 (W.D. Tenn. 1977) ("[A]ttempts to give detailed warnings to patients could mislead patients and might also tend to interfere with the physician/patient relationship.").

[FN78]. See *Martin v. Ortho Pharm. Corp.*, 661 N.E.2d 352, 357 (Ill. 1996) ("[P]rescribing physicians, and not pharmaceutical manufacturers, are in the best position to provide direct warnings to patients concerning the dangers associated with prescription drugs."); *Terhune v. A.H. Robins Co.*, 577 P.2d 975, 978 (Wash. 1978) (noting that "[t]he physician decides what facts should be told to the patient").

[FN79]. The argument here is that although some prescription drugs, e.g., birth control pills and asthma inhalers, are delivered to the patient in original packaging and thus could contain a patient insert detailing warnings, most prescription drugs dispensed by pharmacists are in pill form. See Noah, *supra* note 6, at 158 ("Unlike OTC products, pharmacists usually dispense prescription drugs from bulk containers rather than as unit-of-use packages in which the manufacturer may have enclosed labeling.").

[FN80]. See, e.g., *West v. Searle & Co.*, 806 S.W.2d 608, 614 (Ark. 1991). In *West*, the Supreme Court of Arkansas refused to recognize an exception to the learned intermediary doctrine in the birth control pill context. The court reasoned that:

[T]he patient would normally make the initial choice about birth control but, after that, the physician would exercise his medical judgment concerning the best method of contraception for his patient. In this case, for instance, the physician chose an oral contraceptive, Ovulen-28, because it contained the proper estrogen dosage for appellee The doctor was fully aware of the risks associated with the drug and considered those risks in periodically renewing the prescription for her.

Id.; see also Noah, *supra* note 6, at 173 ("[P]atients cannot lawfully purchase a prescription drug without receiving authorization from a physician.").

[FN81]. See Noah, *supra* note 6, at 171-72 ("Advertising has played some role ... in equipping patients with additional knowledge about their treatment options; however, it does not follow that physicians must be concomitantly less active in the decisionmaking process.").

[FN82]. See *supra* note 1 and accompanying text.

[FN83]. Although DTC advertising is a relatively recent phenomenon, advertising to physicians and medical professionals has been the norm for many years. See Peyrot et al., *supra* note 1, at 27 ("Historically, most prescription pharmaceutical product advertising was targeted at physicians through professional medical journals."); see also Yumiko Ono, *Fine Print in Drug Ads Sparks a Debate*, *Wall St. J.*, Apr. 1, 1997, at B1 ("Before [the 1980s], drug companies advertised chiefly in medical publications, targeting physicians who could easily understand the fine print"), quoted in Noah, *supra* note 6, 141.

[FN84]. In rare cases, it has happened that a drug manufacturer has been held liable for over-promoting its product and thereby over-influencing the physician's prescribing decision. See *supra* notes 37-38 and accompanying text. In any case, courts are perfectly capable of dealing with these rare instances.

[FN85]. Prescription drug advertisements must contain the established name, list of ingredients, a brief summary of side effects, and any other required information. See 21 U.S.C. § 352(n) (1994) (providing that a prescription drug shall be deemed misbranded "unless the manufacturer, packer, or distributor thereof includes in all advertisements ... such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations"); Noah, *supra* note 6, at 145 (detailing the regulations promulgated by the FDA).

[FN86]. See Draft Guidance for Industry, *Consumer-Directed Broadcast Advertisements; Availability*, 62 Fed. Reg. 43,171, 43,172 (1997) ("This draft guidance is intended to provide consumers with adequate communication of required risk information, while facilitating the process used by sponsors to advertise their products to consumers."); Center for Drug Evaluation & Research, FDA, *Consumer-Directed Broadcast Advertisements* (last modified Feb. 17, 2000) <<http://www.fda.gov/cder/guidance/index.htm>>; see also *supra* Part III.

[FN87]. See Michael C. Allen, *Comment, Medicine Goes Madison Avenue: An Evaluation of the Effect of Direct-to-Consumer Pharmaceutical Advertising on the Learned Intermediary Doctrine*, 20 *Campbell L. Rev.* 113, 125 (1997) ("The patient-physician relationship has historically been granted special protection under the law."); see also *Department of Air Force v. Rose*, 425 U.S. 352 (1976); *Stevens v. Parke, Davis & Co.*, 507 P.2d 653 (Cal. 1973); *Whitley v. Cubberly*, 210 S.E.2d 289 (N.C. 1974). A consistent theme running throughout these opinions is that manufacturers must preserve the physician's impartiality and not, by inundating him or her with advertisements, so cloud their judgment as to influence their prescribing decisions. Obviously, then, these cases provide more support for the argument that yet another exception to the learned intermediary doctrine is unnecessary: Judicial controls are in place to sanction those who "over-promote" products and thereby interfere with the normal functioning of the physician-patient relationship.

[FN88]. Allen, *supra* note 87, at 127.

[FN89]. See Stevens, 507 P.2d at 662 ("[E]vidence in the record ... support[s] the implied finding that [the manufacturer] negligently failed to provide an adequate warning as to the dangers of [the antibiotic] by so 'watering down' its warnings and so over-promoting such drug that ... the medical profession ... were caused to prescribe it when it was not justified.").

[FN90]. See Whitley, 210 S.E.2d at 292 ("That [defendant] ... fully complied with ... Federal laws in its marketing and labeling ... would not in itself free it of liability for harm caused by use of the drug if it were shown that such use and resulting harm was caused by the Company's negligent acts in overpromoting the drug.").

[FN91]. It is worthwhile to note that, in the days prior to DTC advertising, most patients received prescription drug suggestions from friends and relatives. See Spending on TV, *supra* note 60. ("Advertisements have replaced advice from friends and relatives as those patients' primary source of information"). Thus, physicians have always had to combat some kind of external influence. One might argue that the well-meaning suggestions of friends and relatives, presumably based on personal history, carry more weight with patients than the average television spot created by a pharmaceutical company.

[FN92]. For further discussion, see *infra* Part IV.E.

[FN93]. See Steven Garber, *Inst. For Civil Justice, Product Liability and the Economics of Pharmaceuticals and Medical Devices* 36 (1993) (noting that lawsuits have already negatively affected progress on vaccines, contraceptives, and orphan drugs, emphasizing the AIDS vaccine specifically).

[FN94]. See Harvey L. Kaplan et al., *Third Restatement: New Prescription for Makers of Drugs and Medical Devices*, 61 *Def. Couns. J.* 64, 74 (1994) (asserting that huge verdicts will make drugs unavailable and unaffordable).

[FN95]. The learned intermediary doctrine is addressed in the Restatement (Third) of Torts: Products Liability. See *supra* Part I.

[FN96]. See Restatement (Second) of Torts § 402A cmt. k (1965):

Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

[FN97]. *West v. Searle & Co.*, 806 S.W.2d 608, 612 (Ark. 1991). See also Jeffrey D. Winchester, *Section 8(c) of the Proposed Restatement (Third) of Torts: Is It Really What the Doctor Ordered?*, 82 *Cornell L. Rev.* 644, 646 (1997), stating that:

The rationale for the judicial system's reticence to apply design liability for drug-induced injury boils down to a common-sense trade-off--many, if not most, drugs cannot be made completely safe. If courts hold drug companies liable for every injury their products cause, they will be disinclined to market their product, and as a result society will suffer.

[FN98]. See *Bean v. Baxter Healthcare Corp.*, 965 S.W.2d 656 (Tex. App. 1998) (dealing with the learned intermediary doctrine in the context of breast implants).

[FN99]. 475 N.E.2d 65 (Mass. 1985).

[FN100]. *Id.* at 67.

[FN101]. *Id.* at 67 nn.3-4.

[FN102]. *Id.* at 67.

[FN103]. *Id.* at 71-72.

[FN104]. 878 P.2d 948 (Nev. 1994).

[FN105]. *Id.* at 964.

[FN106]. *Id.* at 951.

[FN107]. *Id.*

[FN108]. *Id.* at 957.

[FN109]. See, e.g., Michael S. Jacobs, *Toward a Process-Based Approach to Failure-to-Warn Law*, 71 N.C. L. Rev. 121, 149 (1992) ("[B]y permitting outcomes to hinge on the presence or absence of one or two seemingly innocuous words, courts impose upon manufacturers a duty of virtual perfection, easily breached, and satisfied only by chance.").

[FN110]. See, e.g., Allen, *supra* note 87, at 130 ("[S]erious difficulties are present in attempting to translate the complexities and subtleties of medical terminology into consumer useable information."); see also Howard Latin, "Good" Warnings, Bad Products, and Cognitive Limitations, 41 UCLA L. Rev. 1193 (1994). Latin provides a comprehensive explanation of why, in his opinion, warnings are almost never adequate: (1) consumers are "functionally illiterate" and simply do not read warnings; (2) consumers are "inattentive, unable or unwilling to devote the time and effort needed to read detailed warnings"; (3) consumers do not pay attention to warning labels because they rely on learned intermediaries to communicate vital information; (4) warning labels are often misplaced; (5) consumers tend to rely on their own experience with medications rather than heeding cautionary statements; and (6) consumers are bombarded with so much medical information that they ultimately suffer from "information overload" and no longer pay attention to warning labels. *Id.* at 1207-11. For further discussion of information overload, see Mark R. Lehto & James M. Miller, *The Effectiveness of Warning Labels*, 11 J. Prod. Liab. 225, 225 (1988). Lars Noah, in his article, *The Imperative to Warn: Disentangling the "Right to Know" from the "Need to Know" about Consumer Product Hazards*, 11 Yale J. on Reg. 293, 374-75 (1994), makes an excellent argument about the effectiveness of warnings: "Even if it were possible to include cautionary information about every potential hazard in product labeling, it would be undesirable to do so for a number of reasons. The proliferation of warnings may dilute the impact of truly important cautionary information." By the same token, it may cause consumers to overreact to information about relatively inconsequential risks. This last point provides support for *supra* note 94.

[FN111]. In a statement before the House Subcommittee on Health and the Environment in 1978 (studying the proposed, but never enacted, Drug Regulation Reform Act, which would have required labeling of prescription drugs), the National Association of Chain Drug Stores stated:

[B]ecause [patient package inserts currently required by the FDA for some medications] is so flagrantly slanted toward the undesirable aspects of therapy, it is our firm belief that under a comprehensive package insert program, a vast number of patients who receive this alarming kind of information will be frightened from taking their medications [I]f patient noncompliance increases, greater numbers of individuals might develop more serious illnesses, which could lead to higher health care costs

Drug Regulation Reform Act of 1978: Hearings on H.R. 11611 Before the Subcomm. on Health and the Environment of the House Comm. on Interstate and Foreign Commerce, 95th Cong., 2d Sess. 2665 (1978) (statement of Sheldon W. Fantle, Director, National Ass'n of Chain Drug Stores); see also Allen, *supra* note 87, at 130 ("Consumers, lacking the training and understanding to properly evaluate risks of treatment as opposed to risks associated with failure to treat, may needlessly discontinue or fail to initiate necessary treatment.").

Lars Noah comprehensively discusses the difficulties surrounding product warning labels including, *inter alia*, the risk that consumers will be bombarded by too much information:

Although ... warning labels should provide accurate and detailed risk information, there is a countervailing need to guard against overwhelming consumers with too much information. Because risk messages "cannot include all the details known to science and still be read and understood by nonexperts," persons who design such messages must "omit some information and highlight other information."

Noah, *supra* note 110, at 369.

[FN112]. It is worth mentioning that the FDA currently prohibits drug manufacturers from including differences of opinion in their warning labels. See 21 C.F.R. § 1.21(c)(1) (1999) (prohibiting "a statement of difference of opinion with respect to warnings"). That is, a manufacturer, in attempting to quantify the risk estimates of a particular drug, cannot say that a certain percentage of physicians or medical studies found no incidents of a certain side effect, for example, headaches, while certain other physicians or studies found a few such incidents. Thus manufacturers are at an even greater disadvantage than is at first apparent when forced to communicate with the patient directly. The FDA's rationale for this prohibition is apparently that such warnings end up confusing the consumer. See Drug Labeling, 40 Fed. Reg. 28,582, 28,583 (1975) ("[W]here warnings are required, disclamatory opinions necessarily detract from the warning in such a manner as to be confusing and misleading."). But the obvious argument to the contrary is that warnings which do not attempt to put the various hazards into perspective end up leaving the

consumer even more confused than they would otherwise be.

[FN113]. See Noah, *supra* note 110, at 374-85 (detailing the causes and effects of overwarning consumers).

[FN114]. See, e.g., *Davis v. Wyeth Lab., Inc.*, 399 F.2d 121, 131 (9th Cir. 1968) (requiring manufacturer of vaccine to implement new way of warning patients, such as advertisements, posters, releases to be read and signed by vaccine recipients, or oral warnings). It is also important to note that, in several cases, the courts have imposed a burden on manufacturers to know how their medications are being distributed. In *Givens v. Lederle*, 556 F.2d 1341 (5th Cir. 1977), for example, the manufacturer supplied vaccinations to a physician for use on his patients. Noting that the physician's dissemination of vaccines was more akin to a small health clinic than it was a personal physician-patient transaction, the court refused to apply the learned intermediary doctrine. Rather, the court reasoned that because the vaccine was being distributed en masse, the duty shifted back to the manufacturer to warn the patient--even though the manufacturer may not have been aware of the shift. It would seem that manufacturers are thus being forced to take into account every possible contingency when distributing their products, a standard dangerously close to one of strict liability.

[FN115]. One other extremely problematic situation is where someone other than the manufacturer is doing the advertising. This situation arose, for example with the anti-impotence drug Viagra. Before the manufacturer of the drug, Pfizer, Inc., began marketing the medication to consumers, a group of physicians in Kansas got together and placed an ad in a newspaper that read: "Appointment Today, Viagra Tonight." According to the physicians, calls to the clinic nearly tripled in the days following the placement of the ad. See Scott Farmelant, *Viagra Ads Spur Boom Business--and Criticism*, Boston Herald, July 12, 1998, at 001. The ad, however, contained no warnings and no enumeration of side effects.

In Milwaukee, Wisconsin, a physician offered prescriptions for Viagra via the Internet just a day after the FDA approved the drug. See *id.* The Wisconsin licensing officials shut his website down, but others like it continue to proliferate. See *id.* The obvious problem, then, would be imposing liability on the manufacturer for these physician-created advertisements. Yet under a system requiring a manufacturer to provide warnings to all of its consumers, such would be the case. Again, this would require an amazing amount of foresight on the manufacturers' part.

Turning to the Internet more generally, a host of problems would attend manufacturer liability for failure to warn. Increasingly, more and more companies are using the Internet as a vehicle for large-scale dissemination of information. At least 18 pharmaceutical companies currently sponsor websites. Pharmaceutical companies, in particular, often post web pages that contain information relating to the company, press releases, information about employment opportunities, and financial information. See Nancy K. Plant, *Prescription Drug Promotion on the Internet: Tool for the Inquisitive or Trap for the Unwary*, 42 St. Louis U. L.J. 89, 104-05 (1998). Often these sites also contain product information as well. The problem, therefore, is how to deal with warnings in the Internet context. If the Internet site was created for physicians, but lay consumers access the site, can the manufacturer be held liable for not providing patient-directed warnings? Information on the web is, after all, universally available. See Marc J. Scheineson, *Legal Overview of Likely FDA Regulation of Internet Promotion*, 51 Food Drug L.J. 697, 704 (1996) ("[M]ust a sponsor comply with the direct-to-consumer rules for all information segments even if the information is intended for investors, physicians, insurers, or other audiences?"). But even the FDA has recognized that most information on-line is directed at physicians and not consumers. See *Meeting Notice*, 61 Fed. Reg. 48,707, 48,709 (1996); Plant, *supra*, at 113. Or if the website contains a link to some other informational website, can the manufacturer be held liable for the contents of that second website? For a thorough treatment of Internet-related liability issues and the FDA's attempts at dealing with these problems, see Plant, *supra* and Scheineson, *supra*.

[FN116]. See, e.g., R. Geoffrey Dillard, *Multilingual Warning Labels: Product Liability, "Official English," and Consumer Safety*, 29 Ga. L. Rev. 197, 207 (1994) ("A label printed only in English lacks the chief component of adequacy--ability to communicate the risk--when read by a non-English speaker."). Dillard notes that drafting warnings that communicate information to the "average consumer" of a product are no longer sufficient, given the ever-increasing diversity of the nation's cities. *Id.* at 212. For example, according to the 1990 census, 27% of Los Angeles' population was born in another country, and 35.2% speak a language other than English at home. In the Miami-Ft. Lauderdale area, 33.6% of residents were born in another country, while 38.8% speak a language other than English in their homes. *Id.* at 212 n.65 (citing Bureau of the Census, 1990 Census of Population and Housing, Summary: Social, Economic, and Housing Characteristics 1990 CPH-5-1, Table 1 (1992)). The great number of non-English speaking residents provides difficulties for manufacturers of even over-the-counter drugs--drugs that are arguably "safer" than most prescription drugs.

[FN117]. For example, increased manufacturer liability may lead to a drastic increase in litigation costs and a concomitant increase in prescription drug prices. For a more thorough discussion of this potential effect and others, see *supra* Part III.B.

[FN118]. Congress enacted the Drug Amendments in scattered sections throughout 21 U.S.C.

[FN119]. See U.S. FDA Clears Indication Television Advertising Hoechst Marion Roussel's Allegra(R) To Debut New Commercial, PR Newswire, Aug. 8, 1997, available in LEXIS, News Library, Wires File [hereinafter U.S. FDA].

[FN120]. 21 U.S.C. § 352(n) (1994). The statute states that a prescription drug being advertised is misbranded if it does not include the proper "established name; quantitative formula; side effects, contraindications, and effectiveness." *Id.*

[FN121]. The FDA regulates minute detail such as the order of the listing of the ingredients, 21 C.F.R. § 202.1(a)(2) (1999), and the letter size of the prescription name, 21 C.F.R. § 202.1(b)(2).

[FN122]. Lisa I. Fried, Chain Pharmacy: RX Ads on TV: Enhancing Information or Promoting A Demand-Driven Market? The FDA Has Pulled Four Ads Off The Air, and the Debate Continues, *Drug Store News*, Feb. 16, 1998, at CPI.

[FN123]. Although no new regulations were enacted, the FDA published a guideline showing how drug manufacturers could stay within the existing law. See U.S. FDA, *supra* note 119.

[FN124]. See *id.* An advertisement for the allergy drug, Allegra, was the first television ad cleared under the new FDA guidelines. See *id.*

[FN125]. Media broadcasts need to include the major side effects of the advertised drug in either the audio or audio and visual parts of the ad. See 21 C.F.R. § 202.1(e)(1).

[FN126]. See *id.*

[FN127]. The adequate provision statement already existed, but manufacturers were uncertain what it required. They interpreted it as more restrictive and, therefore, continued to limit their DTC ads to reminder ads.

[FN128]. See 21 C.F.R. § 202.1(e)(1).

[FN129]. For example, pharmacies, physicians' offices, grocery stores, and public libraries. See *id.* § 202.1(e)(3).

[FN130]. *Id.* § 202.1.

[FN131]. See *id.*

[FN132]. Television advertisements pulled from the air include: Schering- Plough's Claritin, Merck & Co.'s Zocor, and Zeneca Pharmaceutical's Accolate, and G.D. Searle pulled its radio advertisement for Covera-HS, as well. See Chain Pharmacy: RX Ads on TV: Enhancing Information or Promoting a Demand- Driven Market? The FDA Has Pulled Ads Off the Air and the Debate Continues, *Drug Store News*, Feb. 16, 1998, at A11.

[FN133]. *Id.* (alteration in original).

[FN134]. See *id.*

[FN135]. Since the mid-1970s, the Supreme Court has recognized that advertising is protected by the First Amendment. In *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748 (1976), the Court held that prescription drug prices could be advertised and that a state ban to the contrary was unconstitutional. The Court based its holding, in part, on the belief that commercial speech is often more important to consumers than political speech and is thus deserving of First Amendment protection. *Id.* at 763

("When drug prices vary as strikingly as they do, information as to who is charging what becomes more than a convenience. It could mean the alleviation of physical pain or the enjoyment of basic necessities."). See generally Lars Noah & Barbara A. Noah, *Liberating Commercial Speech: Product Labeling Controls and the First Amendment*, 47 Fla. L. Rev. 63 (1995).

[FN136]. *Bates v. State Bar*, 433 U.S. 350, 364 (1977) (citations omitted) (invalidating a state law that prohibited attorney solicitation). This same reasoning was later reiterated by the Supreme Court in *Central Hudson Gas & Electric Corp. v. Public Services Commission*, 447 U.S. 557, 561 (1980) (emphasis added):

Commercial expression not only serves the economic interest of the speaker, but also assists consumers and furthers the societal interest in the fullest possible dissemination of information Even when advertising communicates only an incomplete version of the relevant facts, the First Amendment presumes that some accurate information is better than no information at all The First Amendment's concern for commercial speech is based on the informational function of advertising.

[FN137]. The level of scrutiny for commercial speech regulation is something akin to strict scrutiny. See Scheineson, *supra* note 115, at 700 ("Strict scrutiny of the government's reasons for abridging these rights will be applied."); *supra* note 67 and accompanying text.

[FN138]. The Supreme Court itself has expressed that there are "material differences between disclosure requirements and outright prohibitions on speech." *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 650 (1985).

[FN139]. After *Virginia State Board of Pharmacy*, 425 U.S. at 748, the Court dealt with several cases in the commercial speech context. For a thorough treatment of these cases, see Noah & Noah, *supra* note 135, at 72-76. Generally speaking, the Court invalidated bans on attorney solicitation, public utility advertising for services, pharmaceutical solicitation, solicitation by realtors, and solicitation by accountants.

[FN140]. Mandating that manufacturers warn a consumer directly would be a type of coerced speech.

[FN141]. This four-prong analysis comes from *Central Hudson*, 447 U.S. at 557, and has been used throughout the Court's commercial speech jurisprudence to evaluate restrictions on advertising. Though the Court has modified the analysis in certain cases, or has emphasized different prongs in certain cases, the test has remained fundamentally unchanged. See generally Noah & Noah, *supra* note 135, at 76-82 (noting the various cases in which the analysis has been applied and how it has been applied, and ultimately concluding that the Court will focus on different prongs in different cases, but that this has little substantive effect on the outcomes). See also *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996); *United States v. Edge Broad. Co.*, 509 U.S. 418 (1993); *Edenfield v. Fane*, 507 U.S. 761 (1993); *Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410 (1993); *Posadas de Puerto Rico Assocs. v. Tourism Co.*, 478 U.S. 328 (1986); *Zauderer*, 471 U.S. at 626; *In re R.M.J.*, 455 U.S. 191 (1982); *Central Hudson*, 447 U.S. at 566.

[FN142]. For commercial speech to be protected by the First Amendment, it at least must concern lawful activity and not be misleading. See Noah & Noah, *supra* note 135, at 76.

[FN143]. To date, three federal courts have found commercial disclosure requirements to be unconstitutional. See *International Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67 (2d Cir. 1996); *Schwartz v. Welch*, 890 F. Supp. 565 (S.D. Miss. 1995); *Texans Against Censorship, Inc. v. State Bar*, 888 F. Supp. 1328, 1357-59 (E.D. Tex. 1995), *aff'd*, 100 F.3d 953 (5th Cir. 1996). The latest decision, *International Dairy Foods*, invalidated a Vermont law that forced dairy farmers to label dairy products containing a synthetic growth hormone for cows. Because this was a decision by the Second Circuit Court of Appeals (and the other cases were merely district court cases), it is receiving much attention by those who argue for the eradication of the distinction between commercial and political speech. See, e.g., Caren Schmulen Sweetland, *The Demise of a Workable Commercial Speech Doctrine: Dangers of Extending First Amendment Protection to Commercial Disclosure Requirements*, 76 Tex. L. Rev. 471, 476 (1997) (arguing for continuing distinction between commercial and political speech).

[FN144]. See, e.g., *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748, 772 n. 24 (1976) (noting that it might be appropriate to compel a manufacturer to include "such additional information warnings, and disclaimers, as are necessary to prevent its being deceptive"). Note, however, that the concern here was for deceptive or misleading warnings. The DTC advertising that is the subject of this Article, already regulated

by the FDA's "fair balance" requirements, is not necessarily deceptive. For further discussion of the already-existing content requirements mandated by the FDA, see *supra* Part IV.D.

[FN145]. The Central Hudson analysis has subsequently been applied to all commercial speech cases, not just those dealing with outright bans on commercial speech. See, e.g., Sweetland, *supra* note 143, at 491 ("The Supreme Court has applied the [Central Hudson] test to all but one of the commercial speech cases it has heard since 1980."). According to Sweetland, who takes issue with an across-the-board application of the Central Hudson test to all commercial speech cases, the Central Hudson bar is so high that only five cases have survived its scrutiny. Sweetland, *supra* note 143, at 492 n.124 (citing the cases that have survived Central Hudson scrutiny).

[FN146]. Central Hudson, 447 U.S. at 557.

[FN147]. The authors assume that any regulation designed to coerce manufacturers to communicate with patients directly will concomitantly place restrictions on what the manufacture can say in its advertising. Such regulations, to some extent, are already in place. See *supra* Part IV.D.

[FN148]. This argument is explored in more detail at *supra* notes 55-56 and accompanying text.

[FN149]. This argument was first suggested by the Supreme Court itself in *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996). According to Justices Stevens, Kennedy, Souter, and Ginsburg, commercial speech is more "hardy" than regular speech and, given the profit motive that is driving manufacturers, less likely to be deterred by regulations that otherwise impinge on the ability to speak commercially.

[FN150]. *44 Liquormart*, 517 U.S. at 498.

[FN151]. 425 U.S. 748, 772 (1976).

[FN152]. This is what the regulation at issue in *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985) mandated: that attorneys disclose their fee arrangements in advance to prevent unwitting clients from being misled. The Supreme Court upheld this regulation under a Central Hudson analysis.

[FN153]. As was noted in *supra* Part IV.C., the situations in which manufacturers could be expected to provide warnings are too numerous to imagine, particularly when one considers that vast reaches of the Internet. In fact, nearly 25% of all Internet traffic is health related. See Scheineson, *supra* note 115, at 697.