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# Contact Lens (Mis)Labeling as Misbranding and Overwarning

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## I. Introduction

One of the most important functions of the Food and Drug Administration (FDA) is the administration of labeling requirements promulgated pursuant to the Federal Food, Drug, and Cosmetic Act (FDCA).<sup>1</sup> This function is especially important in the area of medical devices. Although consumers may use such devices on a routine basis, most lack both the scientific knowledge to adequately inform themselves of the risks of device usage and the resources to keep abreast of developments in the device field. But protecting consumers involves more than merely informing them of risks. The FDA has also sought to restrain its regulatory power in this area in order to provide device manufacturers with the flexibility needed to innovate and to ensure widespread device distribution.<sup>2</sup> Any FDA decision in the device labeling context, therefore, inevitably involves the weighing of these two often contradictory goals.

The FDA has recently brought this weighing test to bear on the issue of new labeling practices adopted by certain members of the contact lens manufacturing industry. These practices essentially involve specialized brand naming, under which identical varieties of contact lenses and lens solutions are labeled as use specific products. Although these practices have led to consumer complaints – most notably regarding the differential pricing of identical products – the FDA has refused to take action. Unfortunately, the agency’s decision is based on two incorrect premises. The first of these is that the issue is merely one of pricing, and is therefore more appropriately addressed by consumer protection institutions other than the FDA. This

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<sup>1</sup>See Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 343 (misbranding of food), 352 (misbranding of drugs and devices), and 362 (misbranding of cosmetics) (1988).

<sup>2</sup>See Peter Barton Hutt, *A History of Government Regulation of Adulteration and Misbranding of Medical Devices*, 44 FOOD DRUG COSM. L.J. 99, 117 (1989). (“Congress sought to balance the need to protect the public from adulteration and misbranding of medical devices against the need to foster the development of innovative new lifesaving medical devices. The FDA, in turn, has sought to achieve the same balance.”)

assertion is refuted by current interpretations of the FDCA – a statute that the FDA is charged to enforce – which clearly identify the disputed labeling practices as misbranding. The second is that these practices are merely an additional means of preventing the misuse of lenses and lens solutions, and therefore increase consumer safety. This assertion is refuted by the current literature on the hazards of overwarning, which suggests that such practices actually increase the risk to public health.

## II. The Contact Lens Controversy

The labeling practices of contact lens manufacturers have recently come under the scrutiny of journalists and consumer advocates, with the practices of optometrical giant Bausch & Lomb causing the most concern. The company currently manufactures a lens which accommodates a variety of wearer needs. The versatility of this product, however, is masked by the fact that Bausch & Lomb labels the identical lens as four distinct and different products. Although the constituent materials and production process for the lenses are the same, each product bears its own brand name, separate wearing instructions, and an individualized price.<sup>3</sup> It is this final factor – differential pricing for identical products – which has raised the ire of consumer advocates. The price differentials for Bausch & Lomb's contact lenses are significant. The least expensive brand, Occasions, cost about \$3 a pair, and contain instructions recommending that they be used for only a single day, while the most expensive brand, Optima F.W., cost about \$70 a pair, and contain instructions stating that they may be used for a year or more.<sup>4</sup> Two intermediate brands – Medalist, which cost \$15 a pair and are marketed as requiring monthly replacement, and SeeQuence 2, which cost \$8 a pair and are marketed as requiring weekly replacement – fill out the product line-up with smaller, but no less merited,

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<sup>3</sup> *Contact-lens Prices Change in the Blink of an Eye*, CONSUMER REPORTS, Aug. 1994, at 490.

<sup>4</sup> Jane Bennett Clark and Christopher Phillips, *Bausch & Lomb: Pulling the Wool Over Its Customers Eyes?* KIPLINGER'S PERSONAL FINANCE MAGAZINE. Mar. 1994, at 152.

price differentials.<sup>5</sup>

In response to complaints, Bausch & Lomb has put forth two separate justifications for its labeling practices. The first is that it is simply providing its customers with a volume discount.<sup>6</sup> Consumers whose doctors recommend that they replace their contact lenses more frequently, for whatever reason, constitute an important part of the lens buying market with which Bausch & Lomb wishes to curry favor by providing special discounts. This justification, however, fails to explain the need for separate brand names. A lens manufacturer could just as easily provide volume discounts by offering different numbers of lenses at different prices, with full disclosure that all lenses are identical. The second justification is, ironically, the desire to prevent confusion which could lead to health problems.<sup>7</sup> Bausch & Lomb essentially argues that labeling the same lens as different products reinforces the notion that, even when a large number of people are using an identical medical device, what constitutes safe usage of the device is still very much an individualized determination. Although a daily wear lens may be exactly the same as an extended wear lens, an individual could suffer significant harm by using the lens in one manner instead of the other. Labeling the lens with a brand name intended *only* for daily wear or *only* for extended wear, Bausch & Lomb argues, limits the confusion or misuse which could lead to this type of harm. This explanation, however, fails to account for the fact that contact lenses are a *restricted* medical device for which an doctor must provide a prescription. Thus, any confusion an individual might have regarding the proper usage of contact lenses may be more appropriately dealt with by his or her doctor or pharmacist. Bausch & Lomb's position is akin to arguing that manufacturers should be given free reign to market identical prescription medications under as many different brand names and at as many different prices as they wish simply because different doses may have different effects on individual consumers.

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<sup>5</sup>Id.

<sup>6</sup>*Digest*, WASH POST, Nov. 3, 1994, at B11.

<sup>7</sup>*Dateline NBC: Optical Illusions?* (NBC television broadcast, Nov. 14, 1995) (transcript available from Burrelle's Information Services) at 15.

Bausch & Lomb has extended these questionable labeling practices into other areas as well. Rather than limiting the practice of marketing identical products under different brand names to the contact lenses themselves, Bausch & Lomb has also applied this tactic to products for the care of contact lenses. Currently, the company markets contact rinsing solution at about \$0.23 an ounce.<sup>8</sup> This solution is intended for use in both cleaning the lens after removal from the eye and in storing the lens overnight or for other extended periods. It also markets rewetting drops at a cost of \$4.49 an ounce.<sup>9</sup> These drops are intended for lubrication of the lens while it remains in the eye. In spite of the fact that one product costs the consumer twenty times as much as the other, there is no difference whatsoever. Both the rinsing solution and the rewetting drops are composed of the same sterile isotonic buffered solution.<sup>10</sup>

Rather than relying on claims of volume discounts or the need to prevent consumer confusion, Bausch & Lomb justifies the labeling of its contact lens solutions as based on safety requirements imposed by the FDA. Because the FDA wishes to prevent potential injuries resulting from consumer attempts to squirt lens solution directly into the eye using the larger bottle in which rinsing solution is packaged, it requires the eye dropper bottle packaging used for rewetting drops.<sup>11</sup> Bausch & Lomb thus contends that it is this mandatory packaging which accounts for the price differential between the two identical products. Once again, however, this justification fails to explain the need for separate brand names. With disclosure of the fact that the two products were, in fact, identical, consumers would be able to make more cost effective decisions without any increase in the risk to their safety. Armed with the knowledge that the eye dropper packaging accounts for much of the product's cost, for example, consumers could purchase the product in this form only once, thereafter purchasing lens solution in the less expensive packaging and refilling the eye dropper container for

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<sup>8</sup>*Id.* at 17.

<sup>9</sup>*Id.*

<sup>10</sup>*Id.*

<sup>11</sup>*Id.* (The FDA contends that the eye dropper bottle provides a more sanitary method of delivering lens solution directly into the eye.)

reuse.<sup>12</sup>

Although examination of the ingredients printed on the product's label reveals that both the different brands of lenses and the different brands of lens solution are identical, this has not served to limit consumer confusion. In the case of lenses for example, 65% of lens wearers continue to purchase the most expensive variety; those labeled as requiring replacement only after a year or more of use.<sup>13</sup> Market forces have also failed to remedy the problem. In spite of the fact that contact lens sales generate \$150 million per year in revenue for Bausch & Lomb, competitors have not come forward to expose the company's labeling practices.<sup>14</sup> Doctors have also been slow to alert patients to the fact that these differently packaged labels are identical, perhaps due to confusion within their own ranks. Although examination of the lenses would reveal to any optometrist that the lenses are identical, they seldom have cause to conduct such an examination. Thus, the current inquiry into the matter did not begin until a single optometrist became curious about the fact that Bausch & Lomb used the same pair of trial lenses to fit patients for two ostensibly distinct products.<sup>15</sup>

In spite of the concerns raised above, the FDA initially approved Bausch & Lomb's labeling scheme, and has yet to voice any concern or reservation regarding this approval.<sup>16</sup> The certainty of FDA officials, however, is not shared by officials elsewhere in the government. In April of 1993, the District Attorney's Office for Ventura County, California submitted a letter to the FDA requesting that the agency reconsider its approval of the labeling scheme. In response, however, the FDA not only refused to take action, but stated that Ventura County would be exceeding its jurisdiction if it attempted to take independent action against Bausch

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<sup>12</sup>While it could be argued that the refilling and reuse of the eye dropper container could increase the chance of the lens solution becoming contaminated, and the corresponding chance that these contaminants would be introduced into the eye, the risk is no greater than other risks of contamination to which the contact lens user is routinely subjected. The risk is akin to that presented by refilling and reusing a lens storage or cleaning apparatus, or by simply leaving a lens solution container uncapped.

<sup>13</sup>Clark and Phillips, *supra* note 2, at 152.

<sup>14</sup>Kenneth N. Gilpin, *Suit Against Bausch & Lomb Is Judged a Class Action*, N.Y. TIMES, Nov. 3, 1994, at D5.

<sup>15</sup>*Contact-lens Prices Change in the Blink of an Eye*, *supra* note 1, at 490 (Dr. Robert Pazen, a California optometrist, first brought the contact lens labeling issue to the attention of the Ventura County District Attorney's Office).

<sup>16</sup>Constance Sommer, *D.A. Questions FDA Approval of Lens Labels; Consumer: Bausch & Lomb Is Accused of Marketing the Same Product Under Three Different Brand Names and Prices*, L.A. TIMES, Sept. 4, 1993, at B1.

& Lomb.<sup>17</sup> The FDA reasoned that as long as the lenses were effective for their intended purpose, there was no reason to deny approval of their labeling, and that disputes involving manufacturer pricing were not an appropriate area for FDA involvement.<sup>18</sup> Undeterred by the FDA's response, opponents of these labeling practices have continued to take various other forms of action against Bausch & Lomb, including litigation in federal court based on claims of consumer fraud.<sup>19</sup>

### III. Contact Lens Labeling as Misbranding

The FDA's assertion that the contact lens labeling practices in dispute merely constitute a pricing issue which is outside the agency's area of concern clearly conflicts with both past agency action and the provisions of the FDCA which the FDA is charged to enforce. There are two principle provisions of the FDCA which are pertinent to the contact lens labeling issue. The first deals exclusively with the misbranding of drugs and medical devices, and states that such a product shall be deemed misbranded if its labeling is "false or misleading in any particular."<sup>20</sup> This provision is further refined by the second; a list of factors for the decisionmaker to consider when evaluating whether a particular label is "misleading."<sup>21</sup> This second provision applies to all labels, whether affixed to food, drugs, cosmetics, or medical devices, and states that not only should "representations made or suggested by a statement" on a label be taken into account, but "the extent to which the labeling... fails to reveal facts material in light of such representations" as well.<sup>22</sup>

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<sup>17</sup>*Id.*

<sup>18</sup>*Contact-lens Prices Change in the Blink of an Eye*, *supra* note 1, at 490.

<sup>19</sup>*See Digest*, *supra* note 4, at B11 (suit filed against Bausch & Lomb regarding contact lens pricing practices and alleging fraudulent marketing); Gilpin, *supra* note 12, at D5 (Judge U.W. Clemon of the United States District Court in Birmingham, Alabama allows lawsuit against Bausch & Lomb by three consumers to proceed as a class action).

<sup>20</sup>Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 352(a) (1988). The FDCA also describes a number of specific actions which will constitute misbranding in the drug and device context, including the failure to include a label bearing the name and place of business of the manufacturer, an accurate statement of the quantity of contents, or adequate directions for the product's use. *See id.* at § 352(a)-(t).

<sup>21</sup>*Id.* at § 321(n).

<sup>22</sup>*Id.*

Due to the long history of manufacturer misbranding of medical devices both in Europe and the United States,<sup>23</sup> both of these provisions, or their precursors in prior incarnations of the FDCA, have been the subject of important judicial opinions. Thus, while the FDA often enforces the FDCA's misbranding provisions through more informal, and less well publicized, action today, judicial precedent exists by which to measure the agency's consistency in this area.

#### 1. Standard of Consumer Knowledge

In order to evaluate whether the misbranding of a product has misled a consumer, it is first necessary to establish some baseline standard for consumer intelligence. This is especially difficult in the field of drugs and medical devices, due to the vast differences in medical knowledge throughout the American public. Both a small child and a Nobel laureate are equally likely to require the use of crutches. The courts have not arrived at a single standard, but have espoused a number of more and less forgiving positions. Among the most forgiving is that espoused in *United States v. Vitamin Industries, Inc.*<sup>24</sup> In that case, which involved false claims by a vitamin manufacturer that its product would restore lost vitality and combat a lack of vigor and energy.<sup>25</sup> The court stated that although the standard is "the average person," special allowance must be made for "susceptible groups" to whom such claims are particularly aimed.<sup>26</sup> The specific susceptible group at issue was the elderly, to whom the product's claims of renewed vigor were directed.<sup>27</sup> On the less forgiving

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<sup>23</sup>See Hutt, *supra* note 2, at 99. There is evidence of the misbranding of medical devices in England as far back as 1745, at which time a "celestial bed" connected to electric coils was marketed as a cure for sterility. The earliest example of such activity in the U.S. occurred in the late 1700s when three inch rods of brass and iron were promoted as eliminating disease from the body. *Id.* at 99-100.

<sup>24</sup>See 130 F. Supp. 755 (D. Neb. 1955). See also *United States v. Article of Drug*, 263 F. Supp. 212 (D. Neb. 1967) (espousing special allowance for susceptible groups).

<sup>25</sup>See *id.* at 760.

<sup>26</sup>See *id.* at 767.

<sup>27</sup>See *id.* (In the case of the elderly, the court noted, the products claims constituted a "message that they are longing to hear; and with pathetic eagerness they receive and embrace it. They are especially to be regarded in these circumstances, for it is to them and their faltering faculties, physical and mental, that the message of the labeling is oriented.").



end of the spectrum, the court in United States v. Pinaud, Inc. held the standard to be “purchasers... of normal capacity.”<sup>28</sup> Most other courts have taken a middle course between these two positions, but, while the concern of the *Vitamin Industries*’ court for susceptible groups has not gained general acceptance, its more forgiving approach has generally prevailed.<sup>29</sup> For better or for worse, the courts have interpreted the FDCA as legislation designed to protect a group of *very* gullible consumers.

Attempting to apply these various standards is not made a great deal easier by the knowledge that the consumer group in question is composed of contact lens wearers. It is difficult, though not impossible, to argue that contact lens wearers constitute a “susceptible group” under *Vitamin Industries*. On average, contact lens wearers, unlike the elderly, are no more likely to suffer from the type of reduced physical and mental capacity that would impede their ability to evaluate claims on product labels than the general population. Similarly, their affliction – impaired vision – is unlikely to produce the type of judgment clouding desperation that frequently afflicts other susceptible groups, such as the overweight. While it could be argued that lens wearers are a vain and self conscious lot, as demonstrated by their choice of expensive and potentially dangerous contact lenses over inexpensive and potentially unfashionable eye glasses, this provides a rather weak basis for classification as “susceptible.” Any susceptibility due to vanity is also offset by the fact that contact lenses are considered luxury cosmetic items under many health plans, making the typical lens wearer a person of higher socio-economic status and correspondingly greater consumer savvy. Thus, the typical lens wearer seems more appropriately governed by the “purchaser... of normal capacity” standard of *Pinaud*. Yet even under this less forgiving standard, the question remains: would a consumer of “normal capacity”

expect a company to market an identical product under four different brand names with four different sets

<sup>28</sup>1938-1949 FDLI Jud. & Admin. Rec. 526, 529 (S.D.N.Y. 1949). *See also* United States v. 1 Device... Radiant Ozone Generator, 1949-1950 FDLI Jud. & Admin. Rec. 139, 143 (W.D. Mo. 1949) (standard is the “ordinary person”); United States v. Vrilium Products, Co., 1949-1950 FDLI Jud. & Admin. Rec. 210,214 (N.D. Ill. 1950) (same).

<sup>29</sup>*See, e.g.*, United States v. Article Consisting of 216 Cartoned Bottles... “Sudden Change,” 409 F.2d 734 (2d Cir. 1969) (the standard is “the ignorant, the unthinking and the credulous”); United States v. 62 Packages... Marmola Prescription Tablets, 48 F. Supp. 878 (W.D. Wis 1943) (the standard is “the vast multitude, which includes the ignorant, the unthinking and the credulous”); United States v. An Article of Food... “Schmidt’s Blue Ribbon,” 1969-1974 FDLI Jud. Rec. 139 (D. Md. 1973) (the standard is “the often unthinking and gullible consumer”).

of instructions at four different prices?

Establishing a baseline for consumer intelligence, however, is not the only prerequisite to an effective misbranding inquiry. Establishing a baseline level of consumer caution or attentiveness is equally important. Consumer intelligence merely determines whether an individual will be able to understand and evaluate the information on a product label. Considering this factor alone, however, presumes that the consumer was skeptical enough to examine the label in the first place, which is certainly not always the case. Once again the courts have failed to reach consensus on a standard, although there is less disagreement than in the case of consumer intelligence. The least forgiving standard was adopted in *United States v. Articles of Drug*, which involved the misbranding of Vit-Ra-Tox; a product labeled as the sole solution to nationwide nutritional problems impervious to the effects of synthetic vitamins.<sup>30</sup> Addressing the issue of consumer skepticism, the majority stated that, when applying the FDCA, courts should not assume that the public will exercise “great selectivity and caution in what they choose to believe of what they hear or read.”<sup>31</sup> Nevertheless, it cautioned, misbranding claims cannot be based on “strained and distorted interpretation[s] of the text.”<sup>32</sup> Other courts have adopted slightly more lenient verbal formulas,<sup>33</sup> but the overall effect of their application differs little from the *Articles of Drug* standard. Just as courts presume that the typical consumer is extremely gullible, they also presume that he is remarkably oblivious.

Applying these standards to contact lens wearers is a bit easier than applying the standards for consumer intelligence. The baseline level of the lens wearer’s caution or attentiveness is determined primarily by two things that the typical lens wearer is not. The first is that he is not a medical professional. As a result, the lens wearer is unlikely to question scientific claims, such as the wearing instructions for a particular lens,

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<sup>30</sup>See *Articles of Drug*, 263 F. Supp. at 216. (The product’s label consisted of a pamphlet entitled “Your Life.” The first chapter stated that a great majority of the population was sick. The second chapter described Vit-Ra-Tox as the sole solution.).

<sup>31</sup>*Id.*

<sup>32</sup>*Id.*

<sup>33</sup>See, e.g., *Vitamin Industries*, 130 F. Supp. at 767 (the standard is “people of ordinary... discrimination”); *62 Packages... Marmola Prescription Tablets*, 48 F. Supp. at 878 (the standard is “the credulous who, when making a purchase, do not stop to analyze”).

or even to ponder them at length. Since contact lenses are available by prescription only, the lens wearers incentive to question scientific claims is reduced even further. He will leave these concerns to the expertise of his doctor. The second thing the typical lens wearer is not is a consumer advocate. Thus, it is unlikely that he will purchase, or even investigate, brands of contact lenses other than the one his doctor recommends. Both the recommendation of his physician, and the reality of the conditions of the purchase and sale of prescription drugs and devices— which involves the storage of products in a controlled area, beyond the reach of consumer perusal — create an information asymmetry by inhibiting the normal tendency to engage in comparison shopping. As a result, even under the strictest standards for both consumer intelligence and caution, it is unrealistic to believe that the typical lens wearer will not be misled by the disputed labeling practices. Just as a consumer of “normal capacity” would not necessarily divine that four differently branded products from a single manufacturer are identical, a consumer exercising less than “great selectivity and caution” would almost certainly fail to notice that ingredients listed on the product recommended by a trusted eye care professional are identical to those listed on a differently branded product locked safely behind the pharmacist’s counter. The fact that 65% of consumers continue to purchase the most expensive brand of lens seems to bear this assertion out.<sup>34</sup>

Even this analysis, however, presents a deceptively strict view of judicial interpretation of the FDCA’s misbranding provisions. The courts’ vision of the typical consumer as an individual of limited knowledge and limited attentiveness is supplemented by the fact that the FDCA’s misbranding provisions may be invoked even if no consumer has been actually misled. In *United States v. Dotterweich*, the Supreme Court held that a contrary interpretation would literally require a re-writing of the FDCA, which clearly identifies a “false or misleading label” as an example of misbranding.<sup>35</sup> Requiring both elements for a finding of misbranding,

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<sup>34</sup>See *infra* note 11 and accompanying text.

<sup>35</sup>See *Dotterweich*, 320 U.S. 277 (1943) (The Court held that replacing the “or” in 21 U.S.C. § 352(a) with an “and” would amount to an unwarranted disregard of the clear meaning of the words.). See also *United States v. One Device... the Ellis Microdynameter*, 224 F. Supp. 265 (E.D. Penn. 1962) (rejecting the argument that admittedly false claims regarding the disease detecting capacity of a string galvanometer did not constitute misbranding because purchaser was not misled by them).

the Court held, would run counter to the FDCA's goal of consumer protection.<sup>36</sup> As a result, even if the disputed contact lens labeling practices were held to be a clumsy ploy apparent to all consumers, or if lens wearers in general were held to be an extraordinarily knowledgeable and attentive consumer group, the misbranding inquiry would not be at an end. The lens manufacturer would still be liable if the claims on its packaging were held to be false; a standard which itself has been the subject of ample judicial development.

## 2. Misbranding by Ambiguity and Omission

Rather than requiring direct and intentional falsehoods, the courts have sought to further the FDCA's goal of consumer protection by adopting a broad reading of the "false and misleading" language of the Act's misbranding provisions. As experts on the flexibility of language, judges were unwilling to permit a level of technical compliance with the FDCA that would simply affect the form, rather than the existence, of consumer deception through labeling. The most forceful statement of this position came in the Supreme Court's opinion in *United States v. Ninety-Five Barrels of... Apple Cider Vinegar*.<sup>37</sup> There the Court held that, because the term "cider" refers to juice, a product made entirely from dehydrated apples could not be labeled as "apple cider vinegar."<sup>38</sup> Writing for the majority, justice Butler stated:

Deception may result from the use of statements not technically false or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity, as well as from statements which are false. It is not difficult to choose statements, designs and devices which will not deceive. Those which are ambiguous and liable to mislead should be read favorably to the accomplishment of the purpose of the act.<sup>39</sup>

This standard was subsequently modified by two important refinements, the first of which concerned the scope of the label examination. Instead of focusing on a single statement, courts were admonished to examine the

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<sup>36</sup>See Dotterweich at 277 (the goal of the FDCA is to keep misbranded drugs and devices out of the channels of commerce).

<sup>37</sup>265 U.S. 438 (1924).

<sup>38</sup>See *id.* at 443 (The name "apple cider vinegar" included in the brand did not represent the article to be what it really was; and, in effect, did represent it to be what it was not, – vinegar made from fresh or unevaporated apples.)

effect of the label as a whole.<sup>40</sup> The second refinement specifically addressed the category of claim to which the public is most susceptible: scientific assertions. The courts refused to accept the inherent uncertainties of research as a defense, and held that scientific half-truths, like half-truths of any other variety, constituted misbranding under the FDCA.<sup>41</sup>

In applying the principles established in these cases to the medical device context, the courts have arrived at a number of decisions that are suggestive of appropriate FDA action regarding the contact lens labeling controversy. Two such decisions are *United States v. Ellis Microdynameter*, in which a string galvanometer was held to be misbranded as a result of exaggerated disease detection claims<sup>42</sup>, and *United States v. One Device, Intended for Use as a Colonic Irrigator*, in which a colonic irrigator was held to be misbranded as a result of exaggerated disease prevention claims.<sup>43</sup> In neither case was the determination of misbranding premised on the proposition that the device itself was misidentified, nor on the proposition that the device was entirely useless.<sup>44</sup> Rather, after consideration of the label as a whole, the court determined that claims of specialized functions contributed to an overall impression that was liable to mislead. The disputed contact lens labeling practices present a parallel situation. Although the device itself is not misidentified – the label clearly indicates that contact lenses are contained within – and cannot be described as useless – its vision correcting capacity is not in dispute – it is nevertheless misbranded by claims of a specialized function. Just as the label of the string galvanometer proclaimed a specialized ability to detect disease, and that of the

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<sup>40</sup>See *United States v. Six Dozen Bottles... 'Dr. Peter's Kuriko,'* 158 F.2d 667, 669 (7th Cir. 1947) (pamphlet used as labeling held to constitute misbranding when considered in its entirety, although no statement contained therein was literally false).

<sup>41</sup>See, e.g., *Research Laboratories v. United States*, 167 F.2d 410, 418 (9th Cir. 1947) (“the scientific half-truths in the labeling alone make out a case of misbranding”).

<sup>42</sup>See *Ellis Microdynameter*, 224 F. Supp. 265, 267 (E.D. Penn. 1962) (the device’s label falsely claimed that it was capable of detecting a number of serious diseases ranging from acidosis to uremia).

<sup>43</sup>See *Colonic Irrigator*, 160 F.2d 194, 199 (10th Cir. 1947) (the device’s ambitious label falsely claimed that it was a cure-all for every ill, whether known or unknown).

<sup>44</sup>See *Ellis Microdynameter*, 224 F. Supp. at 266 (the device was useful for measuring the degree of resistance to electrical current on the skin); *Colonic Irrigator*, 160 F.2d at 197 (the device was useful for flushing the intestines).

colonic irrigator proclaimed a specialized ability to prevent disease, the labels of the disputed contact lenses proclaim a specialized ability to treat specific visual ailments. A lens labeled for extended wear, for example, purports to be appropriate for a certain set of conditions – dryness of the eye, susceptibility to infection, or whatever other conditions compel a doctor to recommend one method of lens use as opposed to another – for which a lens labeled for daily wear is not. The cases are thus distinguishable only on the basis of the magnitude of danger presented to a consumer who falls victim to the labeling ruse. Postponing trips to the doctor as a result of reliance on an Ellis Microdynameter is certainly more hazardous than overpaying for a pair of contact lenses. Magnitude of danger alone, however, is not an effective barometer of FDA enforcement priorities. *Apple Cider Vinegar*, after all, merely involved the substitution of dehydrated apples for the plump, juicy real thing, and thereby demonstrates that cumulative effects and the establishment of effective precedent are equally important considerations.

The courts have addressed one particular form of misbranding by ambiguity with great specificity: contradictory statements on labels. In order to create the desired impression in consumers, while still remaining within the letter of the law, manufacturers have sought to mollify the misleading character of certain label statements through the inclusion of explanations. The courts, however, have rejected this practice as a permissible interpretation of the FDCA in a number of cases. In *H.N. Heusner & Son v. Federal Trade Commission*, for example, a cigar producer labeled a product produced entirely with Pennsylvania tobacco as Havana Smokers, then attempted to assuage this deception through inclusion of a legend stating that the cigars were made in the U.S. and only from U.S. tobacco.<sup>45</sup> In its determination of misbranding, the court held that [t]he purchaser can be guided by either label or legend, but not by both.<sup>46</sup> These principles have served to govern both self-contradictory statements included in a label's fine print,<sup>47</sup> and those made more

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<sup>45</sup> See *Heusner*, 106 F.2d 596,597 (3d Cir. 1947).

<sup>46</sup> *Id.* See also *El Moro Cigar Co. v. Federal Trade Commission*, 107 F.2d 429,431 (4th Cir. 1945); *Progress Tailoring Co. v. Federal Trade Commission*, 153 F.2d 103, 105 (7th Cir. 1943).

<sup>47</sup> See *United States v. Six Dozen Bottles... 'Dr. Peter's Kuriko'*, 158 F.2d 667, 669 (7th Cir. 1947) (In holding a pamphlet used as labeling for a laxative to constitute misbranding, the court stated that this page of the pamphlet alone, considering the

boldly in disclaimers.<sup>48</sup> The size or conspicuousness of the contradictory statements is thus not the primary issue, but their very presence. The fact that a second statement *might* undo the deception of the first is simply not enough to preserve the label's legality.

Application of these decisions to the contact lens labeling controversy clearly undermines one of the manufacturer's principle defenses. While it could be argued that any consumer confusion resulting from the different brand names and directions for use would be countered by the fact that an identical list of ingredients is printed on each lens label, this amounts to characterizing the list of ingredients as a disclaimer. Such an argument is little more than *Pasadena Research Laboratories v. United States* in reverse.<sup>49</sup> In that case, a drug manufacturer argued that a false claim in the list of ingredients was countered by a contradictory statement elsewhere on the label,<sup>50</sup> whereas here a device manufacturer argues that a false claim elsewhere on the label is countered by a contradictory statement in the list of ingredients. *Stare decisis* dictates that the finding of misbranding in the former should govern in the latter. In fact, the argument for misbranding is even stronger in the contact lens context because, barring an unusual level of medical knowledge on the part of the consumer, the contradiction between the two statements will become apparent only when two or more different lens labels are compared. Only after comparison of the list of ingredients on, for example, lenses

labeled exclusively for daily wear and lenses labeled exclusively for extended wear will the consumer realize

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form of its arrangement, the ailments which are listed in large type and the limitation with reference thereto in small type, in connection with the pictures of persons evidently in misery and distress, furnishes a basis for a finding that the representations were misleading.).

<sup>48</sup>See *Pasadena Research Laboratories v. United States*, 169 F.2d 375, 383 (9th Cir. 1948) ([T]he purchaser of 'Indoform' could be guided either by the labeling 'thyroid substance,' which implies the presence of a therapeutic ingredient, or by the 'disclaimer' of the presence of any such ingredient Obviously, the implication of presence and the negation of presence cannot both be true.)

<sup>49</sup>See *id.*

<sup>50</sup>See *id.* at 383 (the drug's list of ingredients stated that it contained "thyroid substance" while a contradictory disclaimer stated that "This preparation does not contain any known therapeutically useful constituent"). An even more direct parallel emerges from the food labeling context in *United States v. 432 Cartons... Candy Lollipops*, 292 F. Supp. 839 (S.D.N.Y. 1968). There the court held that candy labeled as "Liquor Flavored Lollipops" was misbranded in spite of the fact that the list of ingredients disclosed that the product contained no liquor. *Id.* The court went on to state that "even though the actual ingredients are stated on the outside of a carton, false or misleading statements inside the carton may lead to the conclusion that the labeling is misleading, since a true statement will not necessarily cure or neutralize a false one contained in the label. *Id.* at 841.

that the lists, and the products, are identical. Presuming that an optometrist will not prescribe both brands to a single patient, and that the average consumer will hesitate to pester the pharmacist, such comparisons will take place infrequently, and the conflicting claims will remain undiscovered.

The courts have also interpreted the FDCA's misbranding provisions as barring deception through omission. The text of the Act clearly addresses both affirmative representations and "the extent to which the labeling... fails to reveal facts material in light of such representations."<sup>51</sup> In spite of this provision, drug and device manufacturers have continued their attempts to mislead consumers through omissions, with varying degrees of success. Once again, however, the case most analogous to the contact lens labeling controversy is *Pasadena Research Laboratories*. In addition to labeling its product with self-contradictory statements, the drug manufacturer in that case failed to disclose the fact that certain ingredients, which were not present, were necessary to activate those that were.<sup>52</sup> This omission created the impression that the drug was especially suitable for the treatment of certain conditions for which it was not. Similarly, omission of the fact that both lenses labeled exclusively for daily wear and those labeled exclusively for extended wear are identical creates the impression that each is especially suitable for treatment of a specific visual ailment. By attempting to justify these labeling practices as an effort to limit consumer confusion about proper lens usage, manufacturers confirm that this is the impression they are seeking to create. Thus, by permitting these practices to continue, the FDA not only fails to uphold the FDCA, but inflicts very real costs on consumers, of which overpayment for contact lenses is just the beginning.

#### IV. Contact Lens Labeling as Overwarning

<sup>51</sup>Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(n) (1988).

<sup>52</sup>*See Pasadena Research Laboratories*, 169 F.2d at 383 (label stating that drug contained "thyroid substance" constituted misbranding because it failed to disclose that without iodine the substance was therapeutically inactive). *See also* Northern Trust Company v. Upjohn Company, 572 N.E.2d 1030,1036-37 (Ill. App. Ct. 1991) (package insert constituted misbranding because it failed to disclose that cardiac arrest was a possible side effect of pregnancy interruption drug).



The most serious of the costs inflicted on consumers by the FDA’s failure to act are those that can be attributed to the phenomenon of overwarning. While the term “overwarning” generally triggers images of overly detailed labels and mountains of small print, the practices at issue here are simply another manifestation of the same problem. Labeling an ordinary contact lens as a lens exclusively for daily wear in order to prevent the consumer from wearing it in any other manner is, in effect, a warning against improper usage. Carried into other contexts, this standard might permit, for example, the labeling of ordinary aspirin as “Meal Time Aspirin” to ensure that consumers take it with food, or “Aspirin 3” to ensure that consumers take it precisely three times per day. Each product could then, like the disputed contact lenses, be labeled with distinct directions and sold at independent, and vastly differing, prices.

While it is uncertain whether the FDA has actually endorsed this reasoning, the agency’s failure to act could be construed as a tacit approval of the manufacturer’s public adoption of this position. Whether it is the FDA’s official reasoning or not, however, the effects on the public from the agency’s failure to act will remain the same. The FDA’s failure to recognize, or willingness to permit, these effects suggests that its non-action is rooted in two incorrect assumptions. The first of these is that more warning is necessarily good. But due to the fact that consumers can make use of only a limited amount of information, it is the optimal level of warning that is desired – that level at which any more or any less information would increase the sum of accident and avoidance costs – rather than the highest level.<sup>53</sup> The second is that warnings are costless. Although many of the costs of warning are unseen, they are nonetheless significant, and go far beyond the cost of additional ink to put a few more words on a label.<sup>54</sup>

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<sup>53</sup>See W. LANDES AND RICHARD POSNER, *THE ECONOMIC STRUCTURE OF TORT LAW* 280-84 (1987) (discussing optimal warnings in the tort context); A. POLINSKY, *AN INTRODUCTION TO LAW AND ECONOMICS* 25-36 (discussing optimal warnings in the contracts context).

<sup>54</sup>See James Henderson, Jr. and Aaron Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn*, 65 N.Y.U. L. REV. 265, 297 (1990) (“the greatest part of the costs of overwarning are nonmonetary and easily ignored”); Aaron Twerski et al., *The Use and Abuse of Warnings in Products liability – Design Defect Litigation Comes of Age*, 61 CORNELL L. REV. 495, 513 (1976) (“The reason for the trend toward overwarning is clear. Warnings are an *apparently inexpensive* mode of dealing with risks.”).

## 1. Impact on Warning Effectiveness

One of the biggest costs resulting from overwarning is the reduction in warning effectiveness resulting from consumer confusion. In order to be effective, a warning must be both unambiguous and easily understood; two goals which are often in conflict.<sup>55</sup> Raising the complexity of a warning scheme reduces ambiguity, but such benefits are soon outweighed by reductions in comprehensibility. The confusion generated when the complexity of a warning scheme exceeds consumer comprehension most often manifests itself in an inability to prioritize among warnings. Unable to direct substantial attention to every warning, and without sufficient information to gauge which are most important, the consumer is reduced to a course of almost random conduct devoid of safety gains. In fact, overwarning may divert a consumer's attention from other important product information – most notably, directions for use – leading to an overall decline in consumer safety.<sup>56</sup> Even consumers who are more adept at sifting information, and are thus less likely to be overwhelmed by the sheer volume of warnings, may not experience safety gains. Many simply trade one form of confusion for another, avoiding information overload by unconsciously selecting bits and pieces of the available risk data, but consequently basing their subsequent decisions on only a fraction of the relevant facts.<sup>57</sup>

There are a number of ways in which the consumer confusion resulting from the over-specialized labeling of contact lenses could endanger consumer safety and health. The first and most obvious effect of this variety of overwarning is distortion of consumer choices. An individual whose doctor recommends the use of lenses on an extended wear basis, for example, might choose to forego the use of contact lenses all together based

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<sup>55</sup>See Victor Schwartz and Russell Driver, *Warnings in the Workplace. The Need for a Synthesis of Law and Communication Theory*, 52 CINCINNATI L REV. 38, 61 (1983) (the manner in which the information in a product warning is expressed is as important as the information itself, and includes considerations of clarity and comprehensibility).

<sup>56</sup>See Lars Noah, *The Imperative to Warn: Disentangling the 'Right to Know' from the "Need to Know" About Consumer Product Hazards*, 11 YALE J. ON REG. 293, 384 (1994) ("One quite serious possibility is that overwarning will distract consumers from attending to the directions for proper use, thereby increasing the chance of injuries resulting from product misuse.").

<sup>57</sup>See Jason Pezner, *Grading the Report Card: Lessons from Cognitive Psychology, Marketing, and the Law of Information Disclosure for Quality Assessment in Healthcare Reform*, 12 YALE J. ON REG. 207,2238-39 (1995) ([C]onsumers may unconsciously avoid overload by selectively accessing subsets of presented information. As a result, choices are based on a fraction of the significant data.").

on the fact that the lenses labeled specifically for extended wear are beyond his means. Denied critical information by the overwarning scheme – such as the fact that cheaper lenses labeled for some other specialized use are, in fact, identical – the individual may resort to a less appropriate solution to his visual problems, such as eye glasses, or may even leave the problem uncorrected. Similarly, an individual concerned by the expense of rewetting drops could decide to use them too infrequently, unaware that another product he has probably also purchased – rinsing solution – may perform the same function. The consequences of this misdirected action, however, are more severe, and could actually include damage to the eyes. These dangers can only be magnified by the transmission of the disputed labeling practices to other contexts, where the dollar differentials may be greater and the health effects more severe. The FDA would thus be wise to consider not only the danger its inaction presents to contact lens wearers, but the to the class of drug and medical device users as a whole.

The danger of consumer confusion, however, is not the only hazard of overwarning. The danger of warning dilution is equally great. Presented with a sea of warnings in every conceivable form, the typical consumer may come to doubt their seriousness. In order for a warning to accomplish its purpose – that is, to promote compliance – it must first grab the viewer’s attention. Because attention is a quantity which the average consumer has in only a limited supply, warnings must be selective in order to be effective.<sup>58</sup> As selectivity decreases, the consumer is confronted with a barrage of risk information that no longer seems to accurately depict the relative hazardousness of the consumer’s lifestyle. The consumer’s ability to discriminate between warnings is thereby compromised, and significant risks are dismissed as readily as those which are superfluous.<sup>59</sup> Excessive warnings are thus not only ineffective in and of themselves, but actually decrease the

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<sup>58</sup>See Twerski et al., *supra* note 54, at 514 (Warnings “must call the consumer’s attention to a danger that has a real probability of occurring and whose impact will be significant. One must warn with discrimination since the consumer is being asked to discriminate and to react accordingly.”).

<sup>59</sup>See Schwartz and Driver, *supra* note 55, at 60 (“when warnings become commonplace, they lose their most important characteristic – the ability to focus the user’s attention on a real and immediate danger.”). See also Noah, *supra* note 56, at 381 (“There is a danger that the addition of warning statements to labeling may distract consumer’s attention from existing warnings about more serious risks as well as other important information.”).

effectiveness of prior warnings. After a certain threshold is passed, consumers begin to ignore the majority of risk information, and actually make poorer decisions.<sup>60</sup>

In order to determine whether the over-specialized labeling of contact lenses constitutes the type of warning which contributes to dilution, it is first necessary to determine whether the labeling practices communicate the presence of a substantial risk. A careful examination, however, reveals that any risk the disputed labeling practices do convey is wholly illusory. This species of warning thus moves a step beyond even the highly controversial warnings for saccharin and ozone depleting substances, which many deemed too insubstantial to merit mention.<sup>61</sup> While these warnings were criticized for diverting consumer attention from more important concerns,<sup>62</sup> they at least address risks which are real, however insignificant. Wearing contact lenses labeled for daily wear on an extended wear basis, in contrast, presents no risk whatsoever. The lenses themselves are equally appropriate for either use, with any risk entirely dependent on the particular visual impairment of the wearer. The danger of warning dilution resulting from these labeling practices is thus twofold. The first is that lens wearers, and the users of other drugs and devices as these practices spread, will come to regard excessive warnings not only as exaggerations, but as complete fabrications. Such an effect can only reduce compliance rates. The second, and more serious, is that consumers will come to regard the product identity itself – that is, the brand name and corresponding directions – as simply another warning to be disregarded. If, starting with contact lenses, consumers can no longer believe that the product name on the package accurately describes the identity of the product within, then all labeling requirements are reduced to the functional equivalent of a uniform plain brown wrapper.

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<sup>60</sup>See Pezner, *supra* note 57, at 238 (“Consumers provided with too much information disregard most of it and therefore make objectively poorer decisions.”). See also James Bettman et al., *Cognitive Considerations in Designing Effective Labels for Presenting Risk Information*, 5 J. PUB. POL’Y & MARKETING 1, 7 (1986) (primary concern in creating warning labels is to provide sufficient information for informed choices without overwhelming consumers); Debra Scammon, “Information Load” and Consumers, 4 J. CONSUMER RES. 148, 148-55 (1977) (increased information load adversely affects consumer recall).

<sup>61</sup>See Noah, *supra* note 56, at 382 (“[C]ongressional warning requirements for tobacco products and alcoholic beverages generally adhere to this policy of alerting consumers only to substantial risks, but statutory labeling requirements for saccharin and ozone depleting substances are somewhat more suspect in this regard.”).

<sup>62</sup>See *id.*

Not all consumers, however, will react to the increasing number and variety of warnings by tuning them out. Although overwarning may act as a kind of vaccination, increasing the resistance of certain consumers to risk information, others will remain highly susceptible. Unfortunately, alarming these warning-sensitive consumers can have an equally negative impact on overall warning effectiveness. Rather than reducing dangers to consumer health, the most extreme forms of excessive warning can be added to the list of those dangers. These warnings can lead to a constant state of heightened consumer anxiety, the stress of which can result in serious physical and psychological ins.<sup>63</sup> Consumer health can also be compromised by the inappropriate investments of time and resources which excessive warnings spur. Rather than focusing on only significant risks, there is a real danger that consumers will overinvest in a distorted conception of safety.<sup>64</sup> There is also a danger that consumers will curtail or halt the use of relatively safe products.<sup>65</sup> Such decisions are not costless, and could result in health risks from inappropriate or reduced treatment which far outweigh those associated with continued product usage.

The consumer alarm, like the consumer confusion, generated by overwarning in the contact lens context is most likely to manifest itself in consumer decisions to forego the use of contact lenses. Whether a consumer's determination that a particular variety of contact lenses is beyond his resources is based on confusion regarding the over-specialized labeling, or the conclusion that such labeling is a legitimate safety precaution, the result is the same. While this cost may at first glance seem minimal, such a judgment rests on the assumption that contact lenses are used exclusively for cosmetic purposes. A person who engages in sports, work, or other activities which involve rapid head movements, however, may find eye glasses impractical.

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<sup>63</sup> See Howard Beales, *Benefits and Costs of Label Information Programs*, in *PRODUCT LABELING AND HEALTH RISKS: BANBURY REPORT 6*, at 243,258-59 (Louis A. Morris et al. eds., 1980) (the secondary effects of excessive warning include "health-threatening stress").

<sup>64</sup> See Henderson and Twerski, *supra* note 54, at 296 ("[T]he few persons who might continue to take warnings seriously in an environment crowded with warnings of remote risks would probably overreact, investing too heavily in their versions of 'safety.'"). See also Franklin and Mais, *Tort Law and Mass Immunization Programs: Lessons from the Polio and Flu Episodes*, 65 CALIF. L. REV. 754, 759, 774 (1977).

<sup>65</sup> See Noah, *supra* note 56, at 387 (noting that agencies should take the health hazards associated with discouraging use of safe products into account when imposing warning requirements).

Permitting labeling to alarm such people to the point that they choose to forego corrective lenses subjects not only the individuals themselves, but those around them, to greater risk of injury. But these risks pale in comparison to those resulting from the misallocation of resources. By definition, each consumer who overpays for lenses or lens solution as a result of these labeling practices – which, as mentioned previously, currently includes at least 65% of lens purchasers – is overinvesting in a distorted conception of safety. This overinvestment is almost certainly accompanied by an underinvestment somewhere else in each consumer’s personal healthcare budget; an underinvestment which can only expand as these labeling practices spread to other contexts.

## 2. Impact on Professional Credibility

Focusing on the content of a warning as the sole determinant of its effectiveness, however, amounts to addressing only half of the issue. The source of the warning is an equally important factor.<sup>66</sup> Even the most carefully crafted and reasonable warning, if issued from a source that is not particularly knowledgeable or that is compromised by a conflict of interest, will elicit only sparse compliance. The most critical attribute of the source of the warning is thus its credibility.<sup>67</sup> A source, like an individual, must develop this attribute over time. Through a history of interaction with consumers, the source slowly endeavors to influence their mental apparatus in a manner which will allow the warning process to function effectively.<sup>68</sup> Overwarning – especially overwarning of a conspicuous nature – impedes this consumer-source exchange by equipping the consumer’s mental apparatus with skepticism and doubt. Rather than alerting the public to risks, warnings of

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<sup>66</sup>See Schwartz and Driver, *supra* note 55, at 59, 62 (asserting that both the content and the sender of a warning message must be credible in order to induce compliant behavior).

<sup>67</sup>See *id.* at 63 (“[T]he effectiveness of a product warning will depend, in part, on the credibility of its source.”). See also A. SCHNEIDER ET AL., ORGANIZATIONAL COMMUNICATION 93-96 (1975) (describing the manner in which the effectiveness of communication is influenced by the sources credibility).

<sup>68</sup>See Twerski et al., *supra* note 54, at 515 (“The warning process, in order to have impact, will have to select carefully the items which are to become part of the consumer’s mental apparatus.”).

this nature place the credibility of the source in doubt, and generate public cynicism regarding the prospect of warning labels in general.<sup>69</sup> Actions with regard to only a few products, by damaging source credibility, can thus put an entire warning regime in jeopardy.

With credibility established as the paramount requirement of a warning's source, there are two possible sources which are immediately eliminated. The first of these is drug and device manufacturers. In addition to their obvious self interest – which establishes that their warnings will be motivated by the desire to maximize sales and minimize liability, rather than by the desire to protect consumers – manufacturers are disqualified for several other reasons. The first of these is their myopic focus. A manufacturer's knowledge of risk is often limited to those hazards which are associated with its own products, and may be incomplete in even that respect.<sup>70</sup> Manufacturer knowledge regarding the impact of warnings is similarly limited. While manufacturers are capable of anticipating the effects of warnings on their own customers, they cannot foresee the manner in which these warnings will impact the overall regime created by the multitude of warnings in the marketplace.<sup>71</sup> Finally, manufacturers possess very limited and specialized powers of communications. Although they must be able to communicate with consumers to sell their wares, business complexities dictate that the distance between manufacturer and consumer can be great, such that manufacturers may not be in the best position to influence all users of their products.<sup>72</sup>

Although lacking the type of self interest which characterizes manufacturers, courts also suffer from a lack of credibility which disqualifies them as an efficient source of warnings. Perhaps the most significant reason for this lack of credibility has been the courts' historical inability to recognize the costs associated with excessive

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<sup>69</sup> See Noah, *supra* note 56, at 383 (“[P]roliferation of hazard statements could drown out other more important information on product labels and foster public cynicism about warning statements generally.”).

<sup>70</sup> See Schwartz and Driver, *supra* note 55, at 62 (“Many manufacturers... may be able to predict neither the end-use of their products nor the risks associated with that use.”).

<sup>71</sup> See *id.* (“The manufacturer will not always be in the best position to design and distribute a product warning.”). See also D. BERLO, *THE PROCESS OF COMMUNICATION: AN INTRODUCTION TO THEORY AND PRACTICE* 45-49 (1960) (describing the information necessary to design product warnings and emphasizing the need for contextual information).

<sup>72</sup> See Schwartz and Driver, *supra* note 55, at 63 (“A manufacturer separated from those who use its product by a distribution system it does not control will have limited ability to anticipate and meet the informational and motivational needs of the product user.”)

warning. Although many courts have minimized these costs in their opinions, a decision of the Maryland Court of Appeals – *Moran v. Fabergé, Inc.*<sup>73</sup> – remains the most notorious. There the majority stated that:

[T]he cost of giving an adequate warning is usually so minimal amounting only to the expense of adding some more printing to a label, that this balancing process will almost always weigh in favor of an obligation to warn of latent dangers.<sup>74</sup>

This cavalier attitude regarding the vast array of costs associated with excessive warning is exacerbated by the other shortcomings of the courts as a source of risk information. Like manufacturers, for instance, the goal of courts in establishing warning requirements is not necessarily consumer safety. Instead, their primary motivation is often the desire to establish dear standards for liability in order to determine compensation for injuries which have already occurred.<sup>75</sup> The fact that many warning requirements are elaborated in product liability cases provides an additional impediment. The attention of the court in such instances must be focused on a single risk, to the exclusion of all others, resulting in a tendency to exaggerate the magnitude of that risk.<sup>76</sup> Warning requirements produced in this manner are thus distorted, and reflect only those risks which have been the subject of litigation.<sup>77</sup>

Consumers are consequently left with only two credible sources of warning information in the medical device context: the FDA and prescribing physicians. Because of its role in enforcing the FDCA, the FDA has the broadest knowledge of the drug and device field of any consumer protection organization. It has also established its credibility by exercising restraint, avoiding the tendency toward over-regulation which has plagued other agencies.<sup>78</sup> Engaging in overwarning, even if through approval of the ill-considered labeling practices

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<sup>73</sup>332 A.2d 11 (Md. 1975).

<sup>75</sup>See Schwartz and Driver, *supra* note 55, at 60 (“Courts that have preferred quantity of information over quality of communication not only allow, but also encourage, manufacturers to design legalistic warnings intended more to escape liability than to prevent accidents.”)

<sup>76</sup>See *id.* at 60 n.108 (“Products liability cases tend to focus on the particular hazard that caused the plaintiffs injury, not the full array of possible hazards.”).

<sup>77</sup>See *id.* at 60-61 n.108 (noting that court mandated warnings appear comprehensive only because they are the result of hundreds of narrowly focused suits).

<sup>78</sup>See Hutt, *supra* note 2, at 113 ([T]he FDA has succeeded in exerting sufficient regulatory control to protect public health,



of contact lens manufacturers rather than through its own regulation, places this longstanding credibility in danger. Although knowledge of these practices is not yet widespread, they have recently received attention from several major publications and television news programs.<sup>79</sup> News coverage of continuing consumer fraud litigation will also serve to raise public awareness, as well as to highlight the FDA's lack of action. Consumers who discover that the FDA has sanctioned the labeling which prompted their vast overpayment for lenses as a new means of preventing product misuse will take subsequent warnings with a grain of salt. While a warning regime which requires excessive reading will induce skepticism, a regime which requires hard earned cash could induce skepticism of an all together different order. An agency which allows one to be bilked in the name of safety, after all, is not likely to be regarded as a trusted protector.

The FDA's failure to take action also impinges on the credibility of prescribing physicians. Although doctors themselves are unable to take corrective action against lens manufacturers, and may in fact be misled by the disputed labeling practices to the same degree as their patients,<sup>80</sup> they are nonetheless likely to be held responsible by angry consumers. This result flows from the nature of the doctor-patient relationship; the foundation of doctors' credibility as a warning source. The very strength of this bond of trust, generated by the kind of close association that an administrative agency cannot imitate,<sup>81</sup> will fuel a correspondingly strong reaction when the patient feels this trust has been abused. A consumer's realization that he paid over twenty times too much for his contact lenses, while his doctor said nothing, will almost certainly create that feeling. However unwarranted these sentiments might be, they have already taken root, manifesting them-

selves in exhortations like these from a Denver newspaper: "Don't be a patient, be a consumer.... Quiz your while at the same time avoiding over-regulation that would discourage medical device innovation and harm public health."). *But see* STAFF OF SUBCOMM. ON OVERSIGHT AND INVESTIGATIONS OF THE HOUSE COMM. ON ENERGY COMMERCE, 98th Cong., 1st Sess., REPORT ON MEDICAL DEVICE REGULATION: THE FDA'S NEGLECTED CHILD (Comm. Print 98-F 1983); Adler, *The 1976 Medical De vice Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 FOOD DRUG COSM. L.J. 511 (1988).

<sup>79</sup> See *infra* notes 3-19 and accompanying text.

<sup>80</sup> See Noah, *supra* note 56, at 382-383 (noting that the excessive use of warning labels may lead to the confusion of physicians as well as consumers).

<sup>81</sup> See Schwartz and Driver, *supra* note 55, at 63 (noting the superior credibility of physicians with users of prescription drugs).

examiner about how strictly you must follow recommended wearing schedules, and ask whether a cheaper lens will do for you.”<sup>82</sup> Such advice goes beyond consumer education, and advocates a defensive posture with healthcare professionals that erases the distinction between patient and consumer. This distinction has bolstered compliance with physician issued warnings for decades. It would be truly irresponsible for the FDA to passively submit to its abolishment.

## V. Conclusion

The FDA’s refusal to take action to halt the over-specialized labeling of contact lenses and lens solution is inconsistent with current interpretations of the FDCA and the long term policy interests of the agency. Not only do these labeling practices clearly implicate the FDCA’s misbranding provisions, but their continuing use compounds the problem of overwarning, leading to an overall decline in warning effectiveness. While current consumer fraud litigation against lens manufacturers could provide temporary relief for lens wearers, it cannot provide the type of comprehensive solution the problem requires. Over-specialized labeling has been an economic boon for certain lens manufacturers, and while the lack of competitor protest has been surprising, there is no reason to believe that others in the drug and device industry have not taken notice. The FDA would thus be wise to adopt a general policy regarding these practices *before* the flood of over-specialized labels hits the marketplace. It is always best to act preventatively in the area of consumer health and safety, and the time for prevention is now.

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<sup>82</sup>Lesley Alderman, *Shopping Around for Contact Lenses Can Be an Eye-Opening Experience*, DENVER POST, Sept. 18, 1994, at H-12.