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# COMMERCIAL SPEECH, DRUGS, PROMOTION AND A TAILORED ADVERTISEMENT MORATORIUM

*Margaret Gilhooley*<sup>†</sup>

## INTRODUCTION

The commercial speech doctrine has had a major impact on drug regulation. This Article highlights two key current issues that illustrate this impact.<sup>1</sup> Part I of this Article will discuss the constitutionality of a tailored safety-moratorium on television advertisements for drugs with a high risk potential. Part II will discuss the constitutionality of imposing limitations on drug manufacturers' ability to distribute medical journal article reprints that discuss new but unapproved uses for drugs. This Article maintains that the safety risks to the public rightly deserve great weight under the commercial speech doctrine.

## PART I. SAFETY MORATORIUM ON DRUG TELEVISION ADVERTISEMENTS

While the law requires “adequate and well-controlled investigations”<sup>2</sup> before the US Federal Drug Administration (FDA) approves new drugs, the studies do not always account for risks that only become apparent once the drugs are administered to the general population. Patients also may have health conditions not considered during testing that lead to more side effects. The seriousness of the problem with post-approval risks was highlighted when Vioxx, a pain treatment for arthritis, was found to increase cardiovascular problems in a

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<sup>1</sup> For a detailed analysis of related topics on commercial speech and drug regulation, see Margaret Gilhooley, *Drug Safety and Commercial Speech: Television Advertisements and Reprints on Off-Label Uses*, 47 SAN DIEGO L. REV. 845 (2010) [hereinafter *Drug Safety*]. See also Margaret Gilhooley, *Constitutionalizing Food and Drug Law*, 74 TUL. L. REV. 815 (2000) [hereinafter *Constitutionalizing*]; Margaret Gilhooley, *Drug Regulation and the Constitution After Western States*, 37 U. RICH. L. REV. 901 (2003).

<sup>2</sup> 21 U.S.C. § 355(d)-(e) (2006).

study done after it was on the market.<sup>3</sup> To help prevent similar situations arising in the future, Congress authorized the agency to develop a post-market electronic surveillance program of Medicare records and, when available, private insurance company records.<sup>4</sup> The FDA can use the surveillance data to identify undiscovered risks after a drug becomes available for public use.<sup>5</sup> Congress also expanded the agency's authority to require warnings and additional drug testing to assess further any newly discovered risks.<sup>6</sup> Congress also considered imposing a moratorium on direct-to-consumer (DTC) advertisements until the post-approval risks could be assessed by FDA's surveillance and follow-up testing.<sup>7</sup>

The moratorium was not enacted, though, with Senator Kennedy explaining that some senators had concerns about its constitutionality.<sup>8</sup> While a tailored moratorium has merit, as discussed below, that position will be open to debate, and Congress may not be willing to adopt a moratorium.

#### A. Scope and Rationale for a Tailored Moratorium

A moratorium could take two forms. The most difficult constitutional issues would arise if Congress were to enact a categorical moratorium on advertisements for all newly-approved drugs until post-approval surveillance is completed. A more limited ban would "tailor" the moratorium to include only the drugs that cause the greatest concerns to safety.

Identifying tailoring criteria would require medical and scientific expertise, but potential moratorium candidates would seem to be those drugs for which "risk signals" of serious adverse effects are seen in

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<sup>3</sup> See Alice Dembner, *Maker Takes Vioxx Off Market, Heart Risk Known Earlier Some Say*, BOS. GLOBE, Oct. 1, 2004, at A1.

<sup>4</sup> See 21 U.S.C. § 355 (k)(3)-(4) (2010); *Drug Safety*, *supra* note 1, at 864-65.

<sup>5</sup> See *Drug Safety*, *supra* note 1, at 864-65.

<sup>6</sup> See 21 U.S.C. § 355(o)(3)(F) (2010) (warnings); *id.* § 355(o)(3)(B) (additional studies); Margaret Gilhooly, *Addressing Potential Drug Risks: The Limits of Testing, Risk Signals, Preemption and the Drug Reform Legislation*, 59 S.C. L. REV. 347, 363-65 (2008) [hereinafter *Potential Drug Risks*].

<sup>7</sup> For FDA's position on DTC advertising, see FDA, GUIDANCE FOR INDUSTRY: CONSUMER-DIRECTED BROADCAST ADVERTISEMENTS (1999), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070065.pdf>.

<sup>8</sup> 153 CONG. REC. S5755 (daily ed. May 9, 2007) (statement of Sen. Kennedy); see *Drug Safety*, *supra* note 1, at 866.

pre-approval testing, as occurred with Vioxx.<sup>9</sup> Cardiovascular effects were seen in the pre-approval testing for Vioxx, but a larger study was needed to provide evidence of the link.<sup>10</sup> The moratorium could also be appropriate for a new therapeutic drug class with a novel mechanism of action, as well as drugs used to treat patients with serious health conditions who might be at special risk if the drug posed unexpected problems.<sup>11</sup> For example, if a drug were for those who have already suffered a heart attack, there might be special concern for the consequences of unexpected adverse health effects. These patients have already demonstrated that they are vulnerable to an adverse health condition. Finally, if experts believe that there is substantial scientific uncertainty about the potential for additional risks that could affect public safety, a moratorium on DTC advertising for that drug should be considered.

Congress or the FDA should establish dispute procedures if the decision to place a moratorium on a specific drug is challenged. Such procedures could be modeled after those that govern challenges to FDA requests to conduct additional drug testing before approval.<sup>12</sup>

#### B. *Western States* and Advertisement Restrictions

The U.S. Supreme Court's decision in *Thompson v. Western States Medical Center*<sup>13</sup> is the leading case that sets forth the appropriate application of the commercial speech doctrine to drug regulation. *Western States* raised questions about the constitutional viability of a moratorium, since the Court recognized the need to consider additional disclosure statements as an alternative to speech restrictions.<sup>14</sup> The dissent, though, warned against "an overly rigid 'commercial speech' doctrine" for government decisions that affect "health and safety."<sup>15</sup>

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<sup>9</sup> See generally Margaret Gilhooley, *Vioxx's History and the Need for Better Procedures and Better Testing*, 37 SETON HALL L. REV. 941 (2007) (providing a regulatory history of Vioxx).

<sup>10</sup> See *Potential Drug Risks*, *supra* note 6, at 356-57.

<sup>11</sup> See *Drug Safety*, *supra* note 1, at 872-74.

<sup>12</sup> 21 U.S.C. § 355(o)(3)(F) (Supp. II 2006).

<sup>13</sup> 535 U.S. 357 (2002).

<sup>14</sup> See *id.* at 375.

<sup>15</sup> *Id.* at 389. See *Drug Safety*, *supra* note 1, at 868-71, for a more complete description of the differences between the majority and dissent's analysis.

## 1. Commercial Speech Test

The parties agreed that the advertising for the compounded drugs was commercial speech rather than fully-protected speech.<sup>16</sup> The first prong of the commercial speech test permits restrictions on speech that is unlawful activity or is misleading, but the government did not assert that this prong applied.<sup>17</sup> Under the remaining prong, to restrict speech, the government must show that there is a substantial government interest, which would be directly advanced by the restriction, and that the restriction is not more extensive than necessary.<sup>18</sup>

### a. Identifying a Substantial Government Interest

*Western States* concerned pharmacists who made “compounded” variations of FDA-approved drugs for patients with unique needs.<sup>19</sup> For example, pharmacists can make a drug without an ingredient to which the patient has an allergy, or make the drug in liquid form instead of a pill to permit easier swallowing. The FDA recognized the interest in serving individual needs but expressed concerns that pharmacies would compound untested variations of a drug on a large scale. As a result, Congress found consumer advertising of specific compounded drugs to be inappropriate, although pharmacies could advertise the availability of compounding services.<sup>20</sup> According to the Court, the government believed there was a substantial interest in preserving the integrity of the new drug approval system while balancing the need for compounds to meet individual needs.<sup>21</sup> The government argued that an advertisement restriction would help to differentiate when compounding became a guise for manufacturing unapproved drugs on a large scale.<sup>22</sup>

### b. More Extensive than Necessary and Advertising Restrictions

The agency in *Western States*, however, failed to show that the speech restriction would not be more extensive than necessary. Justice O'Connor found the advertisement ban to be excessive because the government failed to demonstrate why a ban on the use of large-scale manufacturing equipment or a cap on profits would not be an ade-

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<sup>16</sup> *W. States Med. Ctr.*, 535 U.S. at 366.

<sup>17</sup> *See id.* at 368.

<sup>18</sup> *See id.*

<sup>19</sup> *See id.* at 360-61.

<sup>20</sup> *Id.* at 370-71.

<sup>21</sup> *Id.*

<sup>22</sup> *See id.* at 368-69.

quate alternative to an advertising ban.<sup>23</sup> She emphasized that an advertisement restriction must be a “necessary as opposed to a merely convenient means” because “[i]f the First Amendment means anything,” speech restrictions “must be a last—not first—resort.”<sup>24</sup>

## 2. Dissent’s Commercial Speech Analysis and Role of Disclaimers

In dissent, Justice Breyer identified another substantial interest in prohibiting these advertisements.<sup>25</sup> According to magazine articles discussed in the dissent, DTC television advertisements for approved drugs pressure doctors to prescribe these drugs.<sup>26</sup> Justice Breyer inferred that similar advertisements for compounded drugs would also create patient demand that might pressure doctors to write more prescriptions for the unapproved variations.<sup>27</sup> The effect could lead to an increased safety risk resulting from the increased use of unapproved variations.

In reply, Justice O’Connor objected to the dissent’s “hypothesized justification” for the ban because the government had not advanced it.<sup>28</sup> Furthermore, she disagreed with Justice Breyer’s support, criticizing the weak evidence from the magazines that doctors would be pressured.<sup>29</sup> Justice O’Connor stated that a ban on consumer advertisements amounted to “a fear that people would make bad decisions if given truthful information.”<sup>30</sup> If the government feared that consumers might be confused about the risks of a compounded drug, this concern could be addressed by introducing a disclaimer on the drug’s label that the compound “had not undergone FDA testing and its risk were unknown.”<sup>31</sup>

Justice Breyer, in his dissent, maintained that the commercial speech test needs “a more lenient application . . . that reflects the need

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<sup>23</sup> *Id.* at 372 (delivering the majority opinion for the court).

<sup>24</sup> *Id.* at 373. See *Drug Safety*, *supra* note 1, at 867-71, for a fuller discussion of the commercial speech doctrine.

<sup>25</sup> *W. States Med. Ctr.*, 535 U.S. at 383-84.

<sup>26</sup> *Id.*

<sup>27</sup> *Id.*

<sup>28</sup> *Id.* at 373-74.

<sup>29</sup> *Id.* at 374. See *Drug Safety*, *supra* note 1, at 868-71, for a fuller discussion of the differences between Justices O’Connor and Breyer on the application of the commercial speech test in *Western States*. See *id.* at 874-75 for FDA findings on the impact the ads can have on doctors.

<sup>30</sup> *W. States*, 535 U.S. at 374 (citing 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996)).

<sup>31</sup> *Id.* at 376.

for distinctions . . . among forms of regulation.”<sup>32</sup> “Otherwise,” he continued, “an overly rigid ‘commercial speech’ doctrine will transform what ought to be a legislative or regulatory decision about the best way to protect the health and safety of the American public into a Constitutional decision . . . .”<sup>33</sup>

### C. DTC Moratorium after *Western States*

#### 1. Scope of Potential Safety Risk

The safety rationale for a DTC advertisement moratorium has a stronger safety basis than that presented in *Western States*. As previously noted, the pre-market testing for approved drugs is not sufficient to identify the full range of risks that may be present when the drug is administered to the public. A moratorium would permit doctors and the agency to assess the scope of these risks before deciding if additional precautions are needed. A tailored moratorium would be directed at the drugs for which the risk potential is the greatest.<sup>34</sup>

The DTC moratorium is also aimed at avoiding wide-scale safety risks.<sup>35</sup> Television drug advertisements reach a broad audience. Consequently, post-approval safety risks could affect a large number of users. The potential for harm from a nationally-advertised drug goes beyond the aggregate one considered in *Western States* from drugs compounded by pharmacies to meet special needs. Unlike the permanent advertisement ban considered in *Western States*, the DTC moratorium is for a temporary period while surveillance is underway to detect additional risks.

#### 2. Impact of Advertisements on Doctors

*Western States* criticized the dissent’s reliance on magazine surveys to show that consumer advertisements pressure doctors. FDA has done more surveys of doctors about the advertisements and this could be important data in any future litigation.<sup>36</sup> In light of *Western States*, though, the key consideration is likely to be whether a disclaimer in the DTC advertisements is a sufficient alternative. The risk of any disclaimer is that it will seem like boilerplate to consumers.

The overall effect of the advertisement is likely to be to invite viewers to seek prescriptions from their doctors. However, it does so

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<sup>32</sup> *Id.* at 389.

<sup>33</sup> *Id.*

<sup>34</sup> See *supra* Part I.A for a summary of potential risk criteria.

<sup>35</sup> See *Drug Safety*, *supra* note 1, at 876.

<sup>36</sup> See *id.* at 874-75.

at a time when the doctor does not have an adequate basis for assessing the drug's risk<sup>37</sup> because the agency is still in the process of conducting its post-approval surveillance. When the risk surveillance and assessment are still underway, there is merit to leaving the matter to the agency and to the doctor's professional assessment without the pressure that comes from television advertisements. Courts should recognize that public safety concerns should outweigh advertising interests during this period. The commercial speech test should give special weight to the risks to the general public as suggested by the dissent in *Western States*.

## PART II. DISTRIBUTION OF ARTICLE REPRINTS ON UNAPPROVED USES

There has been a long and contentious debate about the extent to which pharmaceutical companies may distribute to doctors reprints of articles from medical journals that discuss new applications of an otherwise-approved drug. FDA has recognized for many years that physicians may prescribe drugs for these new "off-label" uses as part of the practice of medicine,<sup>38</sup> and that drug companies may send doctors reprints of articles discussing new uses upon request by a physician.<sup>39</sup> FDA objected, though, to drug companies sending the reprints to doctors without a request, but lost in an initial court challenge.<sup>40</sup> FDA's recent Reprint Guidance accepts manufacturer-initiated distributions made in a non-promotional way.<sup>41</sup>

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<sup>37</sup> See *id.* at 875-76.

<sup>38</sup> Legal Status of Approved Labeling for Prescription Drugs; Prescribing for Uses Unapproved by the Food and Drug Administration, 37 Fed. Reg. 16,503 (Aug. 15, 1972) (to be codified at 21 C.F.R. pt. 130). While the agency has not issued a final rule based on the proposal, the agency refers to it as reflecting its policy. See PETER BARTON HUTT ET AL., FOOD AND DRUG LAW 820 n.1 (2007).

<sup>39</sup> See HUTT ET AL., *supra* note 38, at 548 (citing 59 Fed. Reg. 59,820, 59,823 (Nov. 18, 1994)).

<sup>40</sup> See *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *amended by* 36 F. Supp. 2d 16 (D.D.C. 1999), *appeal dismissed & vacated in part sub nom.* *Wash. Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. 2000).

<sup>41</sup> U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY, GOOD REPRINT PRACTICES FOR THE DISTRIBUTION OF MEDICAL JOURNAL ARTICLES AND MEDICAL OR SCIENTIFIC REFERENCE PUBLICATIONS ON UNAPPROVED NEW USES OF APPROVED DRUGS AND APPROVED OR CLEARED MEDICAL DEVICES (2009) [hereinafter GOOD REPRINT PRACTICES], available at <http://www.fda.gov/OHRMS/DOCKETS/98fr/FDA-2008-D-0053-gdl.pdf>.



### A. Earlier History

Historically, FDA has expressed its concerns that a manufacturer's unsolicited distribution of reprints on off-label uses would promote drugs for untested uses. During the Clinton Administration, the agency issued a Guidance Document indicating that this distribution could be an illegal promotion of an unapproved use of a drug.<sup>42</sup> In a lawsuit brought by the Washington Legal Foundation, (*WLF I*), a federal district court found that the Guidance unduly limited the companies' First Amendment commercial speech rights when the article stated that the use was not approved by FDA and was not misleading.<sup>43</sup>

In 1997, Congress renewed the FDA's authority to impose "user fees" on pharmaceutical companies seeking approval for new drugs through the Food and Drug Administration Modernization Act (FDAMA). FDAMA also stated the circumstances under which the agency would not object to manufacturer-initiated article distributions.<sup>44</sup> In part, the FDAMA required manufacturers to submit the article to the FDA so that it could assess the need for additional disclosures when needed, or even a supplemental drug application for the new use. FDA sought to have the district court reconsider its initial injunction in *WLF I* in light of the legislation. Instead the district court modified its initial injunction to find that the FDAMA provisions were "a kind of constitutional blackmail" to induce the companies to comply with its provisions or sacrifice their First Amendment rights.<sup>45</sup> The court enjoined the agency from limiting manufacturer-initiated distributions of article reprints when there was a disclosure that the use was not approved and the article contained no misleading information.<sup>46</sup>

On appeal, the court of appeals vacated the injunction without reaching the merits of the case. The court accepted the agency's argument that the Guidance and FDAMA provisions provided a "safe harbor" from enforcement and did not constitute an independent basis

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<sup>42</sup> See Advertising and Promotion; Guidances, 61 Fed. Reg. 52,800, 52,801 (Oct. 8, 1996).

<sup>43</sup> See *Wash. Legal Found.*, 13 F. Supp. 2d 51; *Constitutionalizing*, *supra* note 1, at 828-32; *Drug Safety*, *supra* note 1, at 878-80.

<sup>44</sup> 21 U.S.C. § 360aaa(b) (Supp. III 1994). The provision was in effect for seven years and has since lapsed by its terms.

<sup>45</sup> *Wash. Legal Found. v. Henney*, 56 F. Supp. 2d 81, 87 (D.D.C. 1999).

<sup>46</sup> *Id.* at 87-88.

for enforcement.<sup>47</sup> The court stressed that it was not criticizing the reasoning of the district court.<sup>48</sup>

During the Bush Administration, FDA stated that as a “matter of policy” and for resource reasons, it was “unlikely” to bring enforcement actions against distributions that complied with the lower court’s decision that had been vacated.<sup>49</sup>

## B. Reprint Guidance

### 1. Scope of Guidance

During the Bush Administration FDA issued a Reprint Guidance, addressing the circumstances under which manufacturer-initiated distributions would be appropriate.<sup>50</sup> The Reprint Guidance<sup>51</sup> recognized the “public health and policy justification” for allowing the dissemination of article reprints.<sup>52</sup> Under the Guidance, the article must be from a peer-reviewed journal, use controlled studies, and not contain misleading information.<sup>53</sup> In making a distribution of non-misleading articles, the pharmaceutical company must also state that the agency has not approved the use, and provide a bibliography of articles reaching the opposite conclusion of the articles being distributed, if any such contrary articles are in existence.

### 2. Criteria for Promotional Distributions

The Reprint Guidance also requires the journal article to be “distributed separately from information that is promotional in nature.”<sup>54</sup> Thus, if a pharmaceutical sales representative delivers a reprint to a

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<sup>47</sup> Wash. Legal Found. v. Henney, 202 F.3d 331, 335-37 (D.C. Cir. 2000). Some maintain that the “FDA reversed its position” by characterizing the guidance as merely a safe harbor. HUTT ET AL., *supra* note 38, at 553-54.

<sup>48</sup> Wash. Legal Found., 202 F.3d at 337 n.7.

<sup>49</sup> HUTT ET AL., *supra* note 38, at 554 (citing Letter from Margaret Dotzel, Assoc. Comm’r for Policy, Food & Drug Admin., to Daniel J. Popeo & Richard A. Samp, Wash. Legal Found. (Jan. 28, 2002)), available at [http://www.fda.gov/ohrms/dockets/dailys/02/Jan02/013002/01p-0250\\_pdn0001\\_01\\_vol2.pdf](http://www.fda.gov/ohrms/dockets/dailys/02/Jan02/013002/01p-0250_pdn0001_01_vol2.pdf).

<sup>50</sup> See News Release, Food & Drug Admin., FDA Proposes Guidance for Dissemination of Information on Unapproved Uses of Medical Products (Feb. 15, 2008), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116859.htm>.

<sup>51</sup> GOOD REPRINT PRACTICES, *supra* note 41; see also *Drug Safety*, *supra* note 1, at 880 (discussing Reprint Guidance during the Bush Administration).

<sup>52</sup> GOOD REPRINT PRACTICES, *supra* note 41.

<sup>53</sup> *Id.*

<sup>54</sup> *Id.*

physician during an office visit, promotional material may not be attached to the reprint and the reprint may not be discussed during the visit. By clear implication, the Guidance treats as “non-promotional” the sales representative directly handing the reprint to the doctor. This aspect of the Guidance is questionable, though, since the delivery brings the use to the doctor’s attention, and encourages the use. The Reprint Guidance should be revised to recognize the promotional aspect of distributions by sales representatives.<sup>55</sup>

### 3. Impact of Mass Mailings

The Reprint Guidance does not recognize the significance of mass-distributions by manufacturers of reprints. A general mailing brings to the doctor’s attention an article that he or she might not have read independently. Moreover, mass mailings to doctors can increase awareness of the article and increase the level of use and potential risks. These mass mailings have a greater impact and are appropriately an area for greater agency concern.

Furthermore, a distribution may be accompanied by a transmittal letter from the company that could be seen as an implicit endorsement for the new use. At a minimum, there should be a statement that the company is not endorsing the use and the doctor should make the decision solely based on medical standards.

## PART III. CONSTITUTIONALITY OF BROADER PROMOTIONAL TEST ON REPRINTS

The Reprint Guidance has not been changed by the Obama Administration and remains in effect.<sup>56</sup> This section provides an overview of constitutional objections that might arise if the agency were to revise the Guidance to define distributions by sales representatives and mass mailings by drug companies as promotional. While the medical articles are educational when published in medical journals, they assume a promotional aspect when distributed by drug companies to doctors. *Western States*, discussed earlier, provides the appropriate analytic framework.

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<sup>55</sup> In determining what is promotional, attention should be given to material that “explains” the uses of a product, as the Supreme Court found in determining the scope of the labeling provisions of the Act. *Kordel v. United States*, 335 U.S. 345 (1948).

<sup>56</sup> The Guidance was cited by the Government in a pending case that raised a broad commercial speech challenge to the FDA position, but which was dismissed as part of a fraud and abuse settlement. *Allergen v. FDA*, No. 1:09-cv-01879-JDB (D.D.C. Jan. 11, 2010); see Natasha Singer, *Maker of Botox Settles Inquiry on Off-label Use*, N.Y. TIMES, Sept. 2, 2010 at A1.

### A. Commercial Speech: Impact of Manufacturer-Initiated Distributions

As recognized in *Western States*, the government has a substantial interest in ensuring the integrity of the new drug approval system.<sup>57</sup> The distribution of article reprints has the potential to marginalize the new drug approval system. If distributions are permitted, drug companies may obtain approval for the easiest use for which safety and efficacy can be established, such as short-term pain relief. Once approved, manufacturers may distribute reprints on new uses for a more serious condition that involves a longer period of use for which the risks are more difficult to evaluate. Precluding these distributions until the supplemental New Drug Application (NDA) is obtained would directly advance the government's interest in ensuring the integrity of the drug approval system.

### B. More Extensive Than Necessary: Use of Disclosures

Litigants may also argue that a distribution restriction is more extensive than necessary because a disclosure about the lack of agency approval contained within the article reprint might be viewed as an adequate alternative. Disclosures, though, are not an adequate substitute for the agency review of the adequacy of the testing. A court of appeals rejected that alternative during a due process challenge to FDA drug prohibitions when cancer patients sought access to experimental drugs not approved by FDA.<sup>58</sup> A disclosure that the agency has not approved the study serves only as boilerplate that minimizes the agency role. The agency is an independent and expert assessor of studies. For example, the authors of journal articles may receive funding from the pharmaceutical company. While this funding would be disclosed with the distribution, the agency brings independence as well as expertise to its review. The agency can also obtain full access to all data from the clinical studies, which would permit an independent analysis of the claim's underlying support. Journal authors and reviewers may not have access to the same extent as the FDA.<sup>59</sup>

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<sup>57</sup> See *supra* Part I.B.

<sup>58</sup> *Abigail Alliance for Better Access to Developmental Drugs v. Eisenbach*, 495 F.3d 695 (D.C. Cir. 2007) (en banc), *cert. denied*, 128 S. Ct. 1069 (2008).

<sup>59</sup> See *Drug Safety*, *supra* note 1, at 885-89 (identifying the need to provide adequate disclosures).

### C. Post-Approval Risks and Need for Surveillance

Another safety reason exists for not regarding disclosures as an adequate alternative. When FDA approves a drug, additional risks may become apparent after the drug is administered to the general population. The pre-market testing does not have the scope to detect all the risks a drug may pose, as illustrated by the findings of cardiovascular risks for the painkiller Vioxx after it was on the market.<sup>60</sup> Congress has now provided for electronic surveillance of the post-market risks, and in some cases additional testing can be required. Drugs with new uses described in a reprint are also likely to have a potential for post-approval risks that are not found in the testing used to support the journal article. When a drug manufacturer distributes these reprints, the company does not file a supplemental NDA and thus does not pay the user fees that support surveillance of the risk from the new off-label use. The risks that occur from the off-label use may be reported in the general adverse risk reporting for the drug and perhaps may be found in any ongoing electronic surveillance for the original use, but it may be more difficult to track the new risks and associate them with the off-label use. Merely treating these uses as a “misuse” or a non-approved use does not capture the role of the reprint in bringing about the risk.

### CONCLUSION

Any effort to impose a tailored or general DTC moratorium or to restrict manufacturer-initiated distributions of medical article reprints to doctors on new uses of drugs is likely to lead to a constitutional challenge. The underlying issue is the extent to which Congress is limited to requiring a disclosure as the primary means to protect the public from safety risks once a drug is approved.

Congress should be able to enact laws that provide further protections for the public. A DTC advertisement moratorium should be permissible for drugs that have a special risk potential in order to provide time to assess the additional risks that come with widespread use. This category includes drugs for which risk signals were seen during clinical testing.<sup>61</sup> Congress should also be able to require drug manufacturers to obtain FDA approval of new uses for existing drugs before manufacturers may distribute medical articles through pharmaceutical sales representatives or general mailings to doctors.<sup>62</sup> Con-

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<sup>60</sup> See *id.* at 890; Dembner, *supra* note 3.

<sup>61</sup> See *supra* Part I.A, I.C.1.

<sup>62</sup> See *supra* Part II.B.

gress and the agency need to be able to protect the public from harm and they should not be limited to a boilerplate disclosure. The scope of *Western States* should be reexamined and reconsidered if it limits the government from being able to prevent harm to the public from prescription drugs adequately.

