Legal Backgrounder

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FDA LIMITS ON DUAL TRADEMARKS TREAD ON PATIENT SAFETY AND LAW

by

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On April 19, 2001, in a typical example of FDA "podium policy," Jerry Phillips, FDA's Associate Director for Medications Error, took the microphone during the Annual Meeting of the Food and Drug Law Institute. He announced that there were too many "unnecessary" drug trademarks. The FDA Center for Drug Evaluation and Research ("CDER") would now "strongly discourage" the use of multiple trademarks by the same company for the same active ingredient. FDA had sparingly allowed their use particularly when a stigma existed to discourage an important new use of an existing drug.[1] A well known case involved the anti-depressant Prozac® (fluoxetine) to treat pre-menstrual dysforic disorder ("PMDD") under the trade name Sarafem.® Phillips announced that this new policy directive would be included in draft guidance and in a revision to CDER's *Manual on Policy and Procedure* ("MaPP"). Neither the guidance or the MaPP provision, if drafted, has been publicly released.

On August 15, 2002, the FDA Center for Biologics Evaluation and Research ("CBER") did release a new procedure related to its review of dual trademarks. In the CBER *Manual of Standard Operating Procedures* (SOPPs) related to "Review of CBER Regulated Product Proprietary Names," it stated that a proprietary name will not be accepted if the name is a different name for an essentially identical product for a different indication. CBER SOPP 8001.4 (Aug. 15, 2002). CBER expressed concern about double dosing where practitioners and patients may not understand or realize that two products with different names may be the same. It also speculated that the use of different names for the same product may pose problems in the collection and management of adverse drug reaction reports. There was no public input into preparation of this SOPP, or substantiation for the concerns expressed.

Below is an analysis of the legal and policy implications if FDA decides to prohibit dual trademarks *de facto* (in-fact, even if official policy has not been developed). The *de facto* prohibition is inflexible, unwise, detrimental to public health and safety and is not substantiated by any relevant evidence. Finally, the decision

[1] Other examples of the use of FDA approved dual trademarks by the same manufacturer for two products with the same active ingredient include: triamcinolone (Nasacort (allergies) and Azmacort (asthma)) (1991); bupropion (Wellbutrin (depression) and Zyban (smoking cessation)) (1997); finasteride (Propecia (male pattern baldness) and Proscar (benign prostatic hyperplasia)) (1997), budesonide (Pulmicort (asthma) and Entocort and Rhinocort (allergy)) (2001); and tazarotene (Tazorac (acne) and Avage (facial wrinkling)) (2002).

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is arguably illegal both under the process provisions of the Administrative Procedure Act ("APA") that require public input, and based on First Amendment commercial free speech protections.

Background. In July 2000, prior to announcing the chilling message that any use of the dual trademark would be "strongly discouraged," Mr. Phillips published an article in *Pharmacuetical Executive* magazine. He detailed the criteria that would be used by that office to evaluate proposed Rx drug trade names (trademarks). Mr. Phillips explained that the Office of Post-Marketing Drug Risk Assessment ("OPDRA"), despite limited resources at FDA, would institute its own testing to review trademarks. OPDRA would provide a uniform consultative safety risk assessment and make recommendations. The primary decision on the suitability of proprietary names would rest with the responsible reviewing division director or director of the Office of Drug Evaluation. Decisions could be appealed through CDER's formal dispute resolution procedures. The dominant focus would be reducing the potential for medication errors associated with look-alike or sound-alike names. CDER has since established an Office of Drug Safety ("ODS") and transferred review of drug trademarks to the ODS Division of Medication Errors and Technical Services ("DMETS"), for which Mr. Phillips is Director.

Adoption of different trademarks by different innovator and generic companies for drugs with the same active ingredient has generally been acceptable to FDA. However, use of more than one trademark by the same company for drugs with the same active ingredient, in FDA's view, unduly proliferates trademarks, raising the probability of product mix-ups. It may cause confusion among patients and health care providers leading to double dosing. FDA's view can be summarized as; if it is the same stuff, it should have the same name, even if it is a different dose, mode of administration or different indication. Manufacturers generally favor the use of dual trademarks because they: (1) help market products in different therapeutic classes to different consumers; and (2) avoid discouraging a drug's use if its other uses carry some social stigma (e.g., depression, urinary dysfunction, HIV or other sexually transmitted disease).

The Patent and Trademark Office ("PTO") has generally taken the position that a trademark is a valuable commercial right with an exclusive use in the owner. Use of this commercial property should not be inhibited unless the name is likely to cause confusion, merely descriptive of goods or services, primarily a surname, or is immoral, deceptive, etc. 15 U.S.C. § 1052. While FDA reportedly recognizes that most proprietary names have completed a registration review by PTO, it believes that PTO and FDA serve two fundamentally different purposes. FDA "cannot base its safety risk assessment only on the issue of confusing similarity that PTO addresses," according to Mr. Phillips. OPDRA assessment is based on "the clinical context in which the product will be used." Phillips, *Pharmaceutical Executive*, July 2000, at 66, 68.

Basis of FDA Regulatory Authority. FDA's regulatory authority over the review of drug proprietary names is limited. Generally, a product is "misbranded," and, therefore, illegally marketed, if its trademark, or other labeling, is "false or misleading in any particular." 21 U.S.C. § 352(a). According to FDA, the labeling of a drug may be misleading by reason (among others) of:

> (3) The employment of a fanciful proprietary name for the drug or ingredient in such a manner as to imply that the drug or ingredient has some unique effectiveness or composition when, in fact, the drug or ingredient is a common substance…"
>
> (5) Designation of a drug or ingredient by a proprietary name that, because of similarity in spelling or pronunciation, may be confused with the proprietary name or the established name of a different drug or ingredient. 21 C.F.R. §201.10(c)(3), (5).

In the context of dual trademarks, FDA has taken the concept of "confusion" beyond its statute and regulations to determine independently whether a prescriber or consumer could be confused by two drugs made by the same company which contain the same active ingredients, but have different names. These drugs, however, can have different doses, different dosage forms and are often used for dramatically different indications. Prohibition on the use of dual trademarks was made with no referenced substantive survey data or other quantitative evidence of potential medical mistakes, no public input, and in a marketplace where tens of thousands of trade names and line extensions operate autonomously by manufacturer.

Legal Authority. It is arguably illegal for FDA to take the *de facto* blanket position that it will not

allow, or will "strongly discourage," the use of more than one trademark by one manufacturer for products containing the same active ingredients. The basis of this legal conclusion is summarized below. Other arguments and legal theories exist. Only a summary legal analysis is provided.

Dual Trademarks are Not Misleading. In denying a sponsor the use of a trademark, FDA has the burden to substantiate its position if challenged. The regulations only specify that a name that implies some unique effectiveness, or is similar in spelling or pronunciation to another marketed drug, is misleading. FDA conducts testing to eliminate any of these risks before a proprietary drug name is approved. FDA assumes that trademarks have no real value; that dual trademarks are unnecessary and more trademarks increase the potential for medication errors; and that dual trademarks will lead to increased risk of double dosing. At a minimum, in order to meet its burden, if challenged, FDA would likely be required to show that there exists a significant number of reports of medical errors caused by the dual trade names.

Public Input Is Required through Level I Guidance or Informal Rulemaking. FDA has been vulnerable to criticism that it used illegal informal administrative mechanisms to expand or interpret its authority.[2] For this reason, on February 14, 2000, it proposed a more formalized process to adopt informal guidance and seek public input. On September 19, 2000, a final rule was published that added new regulations related to good guidance practices. 65 Fed. Reg. 56468 (Sept. 19, 2000) added 21 C.F.R. § 10.115. Throughout this rulemaking, FDA agreed to observe a new process defined in its administrative regulations. Level 1 guidance would require public input before changes in Agency policy were enforced. Level 1 guidance was defined as including guidance documents that set forth changes in interpretation or policy that are of more than a minor nature. 21 C.F.R. § 10.115(c)(1)(ii). It also included highly controversial issues. *Id.* at (iv). Generally, policy changes that affected more than one individual sponsor, or class of sponsors, and had general application were classified as Level 1. Here, in its "podium policy" on dual trademarks, FDA seems to have fallen into its old ways of adopting policy changes without the benefit of public input or an administrative record, and without going through an established procedural framework. At a minimum, a view that dual trademarks are misleading and will no longer be approved, falls within the definition of a change in interpretation or policy that should require Level 1 guidance before implementation.

A strong argument also exists under the APA as applied to FDA that an outright *de facto* ban on dual trademarks is a substantive rule[3] that requires notice and comment rulemaking and not merely guidance. A large body of law exists to determine what actions constitute interpretative rules which can be adopted through FDA guidance versus substantive rules requiring informal notice and comment rulemaking. A complex five-factor test is generally used to determine if agency action is "substantive." Many of these factors apply here. In particular, if a genuine ground for difference of opinion on the wisdom of a policy exists, or if the rule results in a deprivation of preexisting rights, the notice and comment rulemaking procedure is a "meaningful and important requirement." *St. Francis Mem. Hospital v. Weinberger*, 413 F. Supp. 323 (N.D. Cal 1976) (holding that a regulation requiring the capitalization of interest expenses rather than expensing constituted a substantive rule, and failure to comply with the notice and comment procedures of the APA rendered it invalid). Here, dual trademarks that were granted previously will no longer be granted. Sponsors have been deprived of an important property right. Notice and comment rulemaking is required.

Trademarks are Protected Commercial Speech. Washington Legal Foundation and others opposing FDA's heavy-handed approach to speech refined the application of commercial free speech rights to drug products through a line of cases including *WLF v. Henney*, 56 F. Supp. 2d 81 (D.D.C. 1999); 202 F.3d 331 (D.C. Cir. 2000); *Pearson v. Shalala,* 130 F. Supp.2d 105 (D.D.C. 2001); and *Thompson v. Western States*

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[2]Section 105 of the FDA Modernization Act of 1997 (P.L. 105-115) addressed this concern. It added Section 701(h) to the FDCA (21 U.S.C. § 371(h)) which provided that for guidance documents which set forth changes in interpretation or policy that are of more than a minor nature, complex scientific issues or highly controversial issues, FDA shall insure public participation prior to implementation of guidance documents, unless FDA determines that such public participation is not feasible or appropriate, in which case public comment shall be provided for upon implementation and taken into account. § 701(h)(1)(C).

[3]A "rule" is defined as an agency statement of general or particular applicability and future effect designed to implement, interpret or prescribe law or policy. 5 U.S.C. § 551(4).

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Medical Center, 122 S. Ct. 1457 (2002). The courts in all those cases adopted the four-prong test which would apply to FDA actions on dual trademarks in *Central Hudson Gas & Electric Corporation v. Public Service Commission*, 447 U.S. 557, 566 (1980). The first test is whether dual trademarks are lawful activities that are not false or misleading. It is likely that the court would view dual trademarks as lawful and not misleading since FDA approved at least six of them. They are not expressly prohibited by the Food, Drug, and Cosmetic Act or its implementing regulations. FDA would have the burden of demonstrating that provider confusion or medical errors rendered such trademarks misleading. In the absence of hard data compiled from adverse event reports, it is unlikely that FDA could sustain this evidentiary burden.

Once the bona-fide nature of the practice was established, the other elements of the *Central Hudson* analysis would include: (1) does a substantial government interest exist in prohibiting the speech; (2) does the ban on dual trademarks directly advance that interest; and (3) is the ban more extensive then necessary to achieve the given objective? FDA's weakest link in this chain of proof, which it has the burden to establish, is demonstrating that its ban directly advances a legitimate government interest. FDA may have an interest in preventing prescriber confusion and medical errors. The Agency would be required to prove, however, that dual trademarks cause medical errors and misprescribing. To meet this burden, mere conjecture is insufficient. FDA must offer concrete proof that the "the harms it recites are real and that its restriction will in fact [substantially] alleviate them." Even if it presents credible evidence, FDA will have to demonstrate that a total ban is necessary to eliminate medical errors. In the past, the courts have disfavored total bans on protected speech and suggested creative alternatives that are less burdensome.

Impermissible Taking Under Fifth Amendment. A credible argument also exists that prohibiting use of a dual trademark constitutes an impermissible taking of the sponsor's property without just compensation in violation of the Fifth Amendment of the U.S. Constitution. The courts have held that trademarks constitute property, and that analogous property is protected by the takings clause of the Fifth Amendment. *See Maltina Corp. v. Cawy Bottling Co.,* 462 F.2d 1021, 1027 (5th Cir. 1972) (trademarks are treated as property under the laws and policy of the U.S. including the Constitution); *Ruckelhaus v. Monsanto*, 467 U.S. 986, 1003-04 (1984) (trade secret property is protected by the takings clause of the Fifth Amendment).

Arbitrary and Capricious Agency Action. The APA provides that FDA action may be set aside if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. § 706(A)(2). Many actions taken by FDA have been challenged using this standard of proof. Generally, the courts shift the burden in such cases to the administrative agency to demonstrate at least "a rational connection between the facts found and the choice made" by the regulator. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983). In this case, FDA established no administrative record or basis for its prohibition on dual trademarks. An argument that dual trademarks are misleading or cause medication errors has not been substantiated. The reverse is likely true. Different names for different indications likely allow prescribers and their patients to use the correct drug in the correct dose and dosage form with fewer prescribing errors. The court would likely consider two facts. First, the MedWatch adverse event reports attributable to existing dual trademarked drugs are likely no higher than single trademark drugs, and may even be lower. Second, FDA permitted dual trademarks in limited circumstances until 2002. It would be arbitrary and inconsistent to revoke that policy without a sufficient administrative record to support the new policy. FDA also continues to allow proliferating generic products with the same ingredients to use different trademarks rather than merely the generic name of the active ingredient(s), as well as over-the-counter drug line extensions.

Recommendations. FDA should allow dual trademarks using its current strict review process applied to all drug trademarks based on a proper application of the false or misleading labeling standard. If FDA has significant data suggesting that double dosing has been more than a theoretical concern in this area, all companies submitting trademarks for FDA's review would likely benefit from official Level 1 guidance from the agency. That guidance could describe the procedure and considerations used in evaluating drug trademarks. It should list the circumstances under which dual trademarks would, and would not, be appropriate, as well as risk mitigation techniques that could be employed by manufacturers (e.g. disclosure on labeling and promotion materials linking the two trademarks). In this case, these alternatives might include, among others: (1) disclosure on labeling linking the two brands (e.g., Zyban and Wellbutrin contain the same active ingredient); or (2) limited use of dual trademarks under designated criteria (e.g., social stigma, or if dosage, dosage form or indications are sufficiently differentiated to prevent medical error, etc.).

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