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FDA MUST REFORM ITS ARBITRARY DRUG NAME REVIEW PROCESS

by

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The drug approval process is lengthy and complicated. Long before an application is submitted to the Food & Drug Administration (FDA) for review, drug companies typically select a name for their new product. It is well known that FDA carefully reviews data in the new drug application (NDA). It is not well known, however, that FDA has taken an increasingly active role in reviewing potential proprietary brand names. Unfortunately, FDA's process for evaluating proposed drug names occurs very late in the NDA review process and is unpredictable, highly discretionary, and non-transparent. Equally problematic are delays in rendering decisions which make it extremely difficult for manufacturers to obtain review of any unfavorable decisions.

FDA exercises expansive authority over the review of proposed brand names for drugs. A product is considered "misbranded" and may not be legally marketed if its labeling — including its name — is false or misleading. A name may be considered false or misleading if it incorrectly implies more therapeutic benefits than warranted, minimizes risk, or otherwise misstates drug characteristics. FDA may also reject a proposed drug name if it is similar enough in spelling or pronunciation to be confused with the established name of a drug or ingredient that is already on the market. This can create a risk that prescribers, pharmacists, and consumers might confuse it with another drug, causing a patient to take the wrong medication with potentially harmful consequences.

The statutes and regulations conferring authority on FDA do not specify how it should determine whether a product's spelling or pronunciation is "too" similar to another. FDA has yet to develop its own guidance or publish its own standards. Instead, FDA uses its own name evaluation process, developed without public input, which does not define standards.

FDA's process is as follows: An "expert panel" reviews the proposed name against standard compendia and references, compiling a list of proprietary names and non-proprietary names that are believed to have the potential to be confused with the proposed name. These names are subjected to handwritten comparisons to assess the likelihood of errors that might result if the proposed name were confused with other names due to handwriting or verbal pronunciation. Finally, the names provided by the expert panel and the results from the prescription analysis studies are evaluated,

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taking into consideration factors that can increase or alleviate the risk of confusion, e.g., treatment indications (whether the two drugs are for very different diseases); patient populations; formulations; dosage amounts or forms; storage locations; and, possibly, the potential for harm if the patient takes the wrong drug. FDA's focus apparently has been on the possibility of a dispensing error, not the ultimate clinical consequences if an error occurs.

While this may seem relatively straightforward, it is not. Agency personnel subjectively judge whether a prescriber or consumer might confuse the proposed name with another. Because FDA has not published standards, it is not clear how it is determined that a name is "too" confusing, or how much weight is assigned to the different variables. Proposed names have been rejected even when the prescription analysis studies revealed no actual errors, merely because a small number of agency personnel thought that the name *might* be confused with an existing name.

FDA's review of proposed brand names can yield inconsistent and unpredictable outcomes. A trademark infringement case, *Kos Pharmaceuticals v. Andrx Corp.*, 369 F. 3d 700 (3d Cir. 2004), is a prime example. Kos sued Andrx for registering and using the brand name "Altacor," despite sixty documented instances of actual confusion and error with Kos's already-marketed drug named "Advicor." Although both drugs are anticholesterol medications, FDA approved the name "Altacor" because it concluded that the danger to patients who took one medication when they were prescribed the other would be minimal. FDA also claimed that the difference in prescription strengths of the drugs reduced the risk of error among pharmacists. A unanimous U.S. Court of Appeals for the Third Circuit rejected FDA's views, finding that marketplace confusion between Advicor and Altacor was likely, particularly given the overlapping market for the two drugs and that confusion had in fact occurred sixty times. Yet, although FDA accepted the name Altacor, it has rejected product names where there was no evidence of confusion. And, when names are rejected, the agency often provides little explanation to the applicant.

Applicants are frequently surprised by FDA's decisions. Drug companies regularly use outside consulting groups that are experts in the naming process, as well as in-house experts. The name is also reviewed by the Patent and Trademark Office to determine whether it is confusingly similar to other names. The proposed name is published in the "Official Gazette," allowing for public input. Despite the companies' own reviews, the use of consultants, and the extensive scrutiny a brand name receives by the PTO and the public for a trademark, one out of every three names submitted to FDA is rejected. *Strategies to Reduce Medication Errors*, FDA CONSUMER MAGAZINE, May-June 2003, available at http://www.fda.gov/fdac/features/2003/303_meds.html.

FDA has talked about publishing guidelines to assist companies in selecting brand names deemed acceptable to the agency. In March 2003, FDA announced plans to issue a guidance describing the process a company should use, prior to submitting a name for FDA approval, to determine whether it might lead to a medication error. The goal of the guidance was to aid drug companies by encouraging them to use clear, known standards for drug name acceptability.

However, FDA now says that the guidance on medication error prevention analysis is “up in the air at this point” and that it doesn’t “anticipate that being released any time soon.” *FDA Drug Name Guidance Is ‘Up in the Air,’ Agency Tell DIA*, THE PINK SHEET, June 28, 2004, at 18.

FDA also fails to provide timely feedback on names that it finds objectionable. While FDA may learn the name of the drug when the clinical studies are still ongoing, and certainly when the NDA is submitted, it often does not give a decision until shortly before completing review of the drug. Thus, companies may not learn of a name’s rejection until near the very end of the approval process. *See* Laura Johannes, *Separacor Says FDA Clears Sleep Aid*, WALL ST. J., Dec. 16, 2004, at D2 (FDA ordered name change after company had received an approvable letter due to similarity to other drug’s name). FDA has said its approach is “first come, first served,” where the company whose drug is approved first will get to keep the name over another company whose proposed name might be considered confusingly similar. The problem with this system is that it deprives the company of any real opportunity to appeal the decision. (While a company can appeal a final denial, there are no time limits by which FDA must decide the appeal.) No matter how arbitrary or wrong the decision, the pressure to launch the product essentially compels the company to acquiesce and use a name that FDA will approve as soon as possible. In effect, the ability to appeal to gain approval of the preferred name is held hostage by the need to start selling the new drug. FDA’s delayed rejection deprives companies of their chance to challenge FDA’s decision. Conversely, if FDA were to provide feedback early in the process, a company that objected to FDA’s decision would have time to appeal.

The financial consequences of FDA’s delayed denials are not trivial. Companies often want to use a single, global name. Strategic product development is hampered as marketing plans to use one name in the United States and abroad are destroyed. Materials developed to launch the drug will have to be discarded. The money spent trademarking the name has been wasted. Companies often begin to inform doctors about their pending new drug, by name, before approval is obtained. These investments in establishing brand equity are significantly devalued.

FDA’s rejection of a name without any substantial evidence could also implicate the First Amendment. Proprietary drug names are regularly registered as a trademark. Before the PTO registers a mark, it searches other trademarks and determines whether the proposed mark and an established mark might be confused. A name thus reviewed and registered on the Principal Register is statutorily presumed to be valid. Yet, when FDA rejects a registered trademark on the ground of possible confusion, it is effectively substituting its judgment for the PTO’s. And since a trademark is a commercial expression that is protected by the First Amendment, FDA’s unwarranted rejection of a registered trademark may be unconstitutional. In order to avoid First Amendment concerns, FDA must have sufficient evidence that a trademark is misleading. As the district court found from a challenge to agency speech restrictions, FDA must demonstrate that “the restricted speech, by nature, is more likely to mislead than to inform.” *Washington Legal Foundation v. Henney*, 56 F. Supp. 2d 81, 85 (D.D.C. 1999), *vacated*, 202 F. 3d 331 (D.C. Cir. 2000). In addition, the agency’s trademark evaluation process must not restrict protected expression beyond what is necessary to serve its interest. The First Amendment places the burden on the government to provide proof that

its actions materially advance the purported interest. FDA's subjective review, conducted in a manner that essentially precludes an appeal, raises real questions as to whether FDA meets the requisite constitutional standard.

FDA's rejection of a registered trademark may also deprive the company of its property without due process of law or just compensation, in violation of the Fifth Amendment of the U.S. Constitution. PTO approval of a proposed mark confers a property right on the owner to use the mark in commerce. The property value of the mark, in the form of brand equity, increases as the time for drug approval nears, and as the company invests more money into the launch of the product under that mark. If the company has already launched the product under that mark in other countries, its value is even greater. FDA's act of overruling the PTO and preventing a company from using its registered trademark deprives the manufacturer of its property without due process or just compensation. Finally, this type of decision making is inconsistent with the Administrative Procedure Act.

It is unfair, if not unconstitutional, to allow subjective, arbitrary, and belated FDA decisions to determine whether a proposed brand name can be used, particularly when FDA's decision occurs long after PTO has determined that the name meets the statutory standards for trademark registration. Lacking standards, the agency rejects names without adequate factual foundation. Lacking transparency, companies must attempt to predict what FDA reviewers will consider too confusing. Lacking time limits by which FDA must make a decision about a name, companies are forced to either forgo an appeal or delay the launch of a new product.

It is in no one's interest for confusingly similar names to cause medication errors, or for misleading trade names to be used. It is equally in no one's interest to have a process where names are subjectively and secretively evaluated without formal criteria and rejected without evidence, or where decisions are announced so late in the process that no meaningful right of appeal exists. FDA needs to promptly reform its name confusion and medication errors review process.