BY ROBIN ROBINSON

NAME THAT BRAND
A Pilot Program

Taking an active role in the PDUFA pilot naming evaluation program will be costly for the industry.

The eventual outcome of the FDA's two-year Proprietary Name Review pilot project may have positive implications for the industry in the long run, but in the short term, it means more money spent and more time pressure for marketers. Our experts say the burden on pharma companies to conduct their own testing and evaluation will multiply by 10 the cost of the drug naming process.

According to Nancy Globus, Pharm.D., director of operations at Med-ERRS, participating in the pilot may be extremely cost prohibitive.

"If sponsors comply with all of the requirements set out in the FDA's concept paper, it may cost them up to 10 times more than what they normally spend for premarket trademark safety testing," she says. "It's not only about the money, it's also more work. And there isn't any guarantee that the name will get approved by the FDA than if the company went through regular channels."

FAST FACT

The FDA rejects about 35% to 40% of proprietary drug names submitted each year.

The Star-Ledger

"The major concerns on everyone's mind is the timing and the cost," says Ahnal Purohit, Ph.D., president and CEO of Purohit Navigation. "The pilot is going to be expensive for companies to participate in; even if they go through the process, there is no guarantee the name is going to be approved."

Any company participating in the pilot will have to file two submissions for the same name at the same time: one under the traditional DMEPA review process and one under the pilot review. And that's not all: sponsors will have to come up with names for their drugs earlier in the pipeline, which will exert more pressure on the timeline. While big pharma companies may be better able to manage these challenges, the hurdles will be greater for smaller companies and smaller niche products, our experts say.

"Pharma companies will have to spend money earlier in the development timeline to secure a name and this may not jive with the financial realities of the product development curve," says Barry Schmader, chief creative officer at Dudnyk. "I'm not sure that biotechs and smaller pharma companies will be ready to spend that much money so early on. And what if a company has six or seven products in the pipeline — does it go ahead and spend the money and name every one of them?

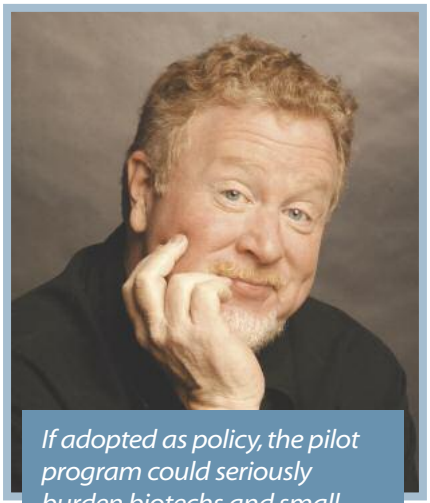
"Many biotech companies don't even name a compound until it is being licensed to a larger company, until they has enter into a co-marketing agreement, or until they submit an NDA," he adds. "This will be an easier situation for big pharma companies to manage, but some biotech companies just don't have the resources or the budgets."

Another issue with naming a drug so early on is that it's hard to determine if the name is going to work well for branding, Mr. Schmader says.

"It's rare that the same agency does the naming and the branding for a product, so there is already a disparity in the process, and naming a brand earlier only broadens this gap," he says.

Coming up with a name for a compound usually takes into account attributes or particular benefits or emotions that the compound might carry or convey.

"This approach will be more difficult than ever," Mr. Schmader says. "Clients ask us all the time whether a strategy can be executed against a name, can a brand be developed from the name, can a campaign be created, can a visual be developed? But, it is very hard to know if a name is going to work for all of these applications early on."



If adopted as policy, the pilot program could seriously burden biotechs and small companies.

BARRY SCHMADER
Dudnyk Healthcare Group

Pilot Navigation

During the pilot phase, the FDA plans to review 25 to 50 names (about one to two a month). According to Dr. Purohit, this sample size is not large enough to accurately quantify results by stratification, for example, company size, product, or therapeutic category, or to determine the reliability and validity of the proposed methodology. Also, the small or start-up companies may struggle to meet proposed statistical thresholds on both an operational and financial level and may opt out of the pilot program because it is too time consuming and cost prohibitive. While big pharma companies are the most likely players, the FDA says it wants sponsors of all sizes to participate. Our experts doubt that is going to happen.

Despite the pain, there could be gain in terms of a more standardized, clearer process with more

To participate in the FDA pilot program, it could cost sponsors about 10 times more than what they normally pay for premarket trademark safety testing.

DR. NANCY GLOBUS
Med-ERRS

Most companies and their branding partners will not be prepared to implement the FDA's proposed drug naming guidelines by 2012.

DR. AHNAL PUROHIT
Purohit Navigation

predictable outcomes. Pilot participants will better understand how the FDA will evaluate proposed names and will be able to better anticipate and meet the agency's more stringent requirements, according to Dr. Purohit. Taking part in the process will have the potential benefit of contributing to the best practice of developing and validating safe drug names and hopefully long-term predictability in the decision-making process from the FDA.

"The upside of this whole pilot program is that there will be some type of standardization and understanding of the FDA process and what the agency expects from sponsor submissions," she says.

Paul Dreyer, chief commercial strategist at Friday Morning, agrees that the joint effort between the FDA and the industry can only help both parties to better understand the naming process.

"I know of some companies that have had to make changes at the last minute when their brand name did not get approved, which is always problematic, especially after they have invested in pre-approval communications," he says. "Hopefully, understanding the FDA's process might reduce these situations."

At the end of the pilot program, the FDA will compare the results of its current review model with that of the pilot. There will be an evaluation and another public meeting in 2012, and the final guidance will come out of the results of that meeting.

If the FDA believes the industry did an adequate job of testing its own drug names, it will then shift the responsibility to the companies and abandon its naming review process.

The most obvious risk to any participant in the pilot program is the potential for a 'double jeopardy' scenario, says Brannon Cashion, senior VP, Addison Whitney.

"While the details of the pilot program are relatively clear, the details surrounding the potential outcomes for a sponsor are somewhat unclear," he says. "Since the pilot program is set up to review the proposed name in two different ways, I believe many sponsors are concerned about the potential that the traditional review by the FDA could yield an approval and the pilot review could yield a rejection. This certainly opens the door for the ultimate rejection of a proposed name, which would not have occurred had the sponsor not participated in the pilot program."

Therefore, coordinating the timing of the name application will be more crucial when participating in the pilot, Mr. Dreyer says.

"The question becomes, whether companies clear the name first for the trademark and then go to the FDA for review or do they go to the FDA review first and then clear the trademark?" he queries. "The last thing a company wants is a trademark that is cleared

PDUFA Pilot Name Review Program Predictions: Will They? Won't They?

Our experts provide their predictions as to whether pharma companies will participate in the pilot program.

BRANNON CASHION, Addison Whitney
I believe many companies in the industry will attempt to participate in the program. The FDA has stated it hopes to assemble 25 to 50 submissions in the two years of the program, and within these submissions it would like a broad range of different types of sponsor companies, anticipated indications, therapeutic uses, and so on.

PAUL DREYER, Friday Morning
I would imagine most companies will participate — I'd be very surprised if they don't.

DR. NANCY GLOBUS, Med-ERRS
It's a lot more money and more work. One incentive for companies to participate is that they will have some say as to what the final guidance will look like, but I think a lot of companies will sit back and wait.

MAUREEN MANGIAVAS, The Hal Lewis Group
Larger organizations with the means may opt to participate; others may wish to take a wait-and-see approach. The proposed process will be both labor intensive and expensive.

DR. AHNAL PUROHIT, Purohit Navigation
I predict that very few pharmaceutical companies will participate. There is little incentive for drug manufacturers to participate in the PDUFA pilot program since it does not necessarily increase the likelihood of drug name approvals.

BARRY SCHMADER, Dudnyk
I don't expect that many companies will be lining up too quickly. In fact, the agency may not have enough companies volunteer for the pilot program and participation may cease to be voluntary. The FDA may hand-pick companies to participate.

If the FDA offers a pilot, companies should participate; it can only be a plus.

PAUL DREYER
Friday Morning

The exhaustive nature of the process required to meet the requirements may diminish the creativity and promotional value of the approved name.

MAUREEN MANGIAVAS
The Hal Lewis Group

by the FDA, only to find out the name can't be used around the world."

He believes in the end, companies will have to develop the names, spend money to do the trademark searches, and then submit their selections to the FDA for review.

FAST FACT

At least 1,470 drug name pairs (both proprietary and generic) are reported to the USP and FDA for look-alike and sound-alike confusion.

The US Pharmacopeia

Avoiding Pilot Error

Nevertheless, the FDA's move to evolve the naming process is being welcomed by some in the industry.

"We've been waiting a long time for this," Dr. Globus says. "There were meetings held in 2003 and nothing happened for five years, despite an outcry from the industry for more transparency and a more predictive guideline. At the end of the next five years, when the pendulum swings back to a guideline that is somewhat less elaborate than the pilot programs, hopefully the rejection rate will go down and the process will be a bit more predictive."

According to Maureen Mangiavas, VP, marketing and strategy, at The Hal Lewis Group, the pilot process has the potential to help in the respect that it will make brand naming more transparent, objective, and data-driven.

"But on the flip side, the added time and money to complete the naming process as proposed will place an undue burden on some pharmaceutical companies, especially small and mid-size companies," she says.

And even if a company opts to not participate in the pilot program, expect drug names to get extra scrutiny during the program, Mr. Dreyer says.

"The FDA clearly states: 'this is our responsibility and we are going to do this under the auspices of drug safety,'" he says. "This means every brand name will be looked at in this framework — so whether a company decides to participate in the pilot program or not, the FDA will review each name, anyway."

The increased scrutiny won't stop there. If the pilot results in the transfer of responsibilities from the FDA to pharmaceutical manufacturers, this will likely lead to an increased level of scrutiny from the FDA regarding the industry's adherence to the methodologies put forth by the new guidance documents, Mr. Cashion says.

The pilot is a clear signal from the FDA that it is trying to be more transparent in the area of proprietary name review.

"The pilot also provides a common forum for all participants to collaborate on better ways to develop, evaluate, validate, and assess proprietary names," he says. "Finally, although less measurable, there is the continued focus on addressing the serious challenge of drug name confusion and prescription medication errors."

"I believe the process is certainly intended to help the industry, but I think the jury is still out on whether the outcome of the program will result in a set of best practices and objective review policies for both the industry and the FDA," Mr. Cashion says. ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

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BY ROBIN ROBINSON

FDA sheds light on PILOT PROGRAM

At press time, the FDA had not yet received any name submissions to its pilot program.

"Although we have fielded many questions, we have not had any formal requests for enrollment as of yet," FDA's Crystal Rice told PharmaVOICE in an exclusive interview.

According to Ms. Rice, the FDA agreed to develop and implement a pilot program that enables pharmaceutical firms participating in the pilot to evaluate proposed proprietary names and to submit the data generated from those evaluations to the FDA for review and the data will be analyzed during this pilot program.

The enrollment period for the pilot program began in October, the end of the FDA's fiscal year. The pilot will run for two years. Following the completion of this pilot program there will be a public meeting to discuss the findings of the results. Following the public meeting, a draft guidance will be issued.

FAST FACT

ASHP and the ISMP are partnering to develop the National Alert Network for Serious Medication Errors (NAN).

At this time, whether any of the learnings, best practices, or names of companies that enrolled would be made public is unclear.

"Until the public meeting, at least, I do not anticipate that we will be posting information regarding the participants or the findings," she says.

The FDA is firm about how many submissions it will accept for registration for participation by the month.

"The FDA will only accept up to two submissions per month," Ms. Rice says.

To manage the workload, applicants are required to register for the month they want. If their requested month is unavailable, they will be offered an alternate slot.

"If the alternate is not acceptable, the company can submit the proposed name for review in the traditional manner," Ms. Rice says. The same is true if a company wants to participate in the pilot but all slots are full.

For more information about the FDA's pilot program — Manual of Policies and Procedures (MaPP): Procedures for Handling Requests for Proprietary Name Review — please go to: thefederalregister.com/d.p/2009-10-01-E9-23620.

Emergency Alert

Two healthcare organizations have announced a new national alert system that helps prevent dangerous and repeated medication errors. The American Society of Health-System Pharmacists (ASHP) and the Institute for Safe Medication Practices (ISMP) are partnering to develop the National Alert Network for Serious Medication Errors (NAN).

A NAN alert will be triggered when a seriously harmful or potentially seriously harmful error has occurred.

The alert will include a description of the error, as well as recommendations as to how to prevent the same error in the future.

The alert network was created as a result of ASHP's I.V. Safety Summit held in 2007. The I.V. Safety Summit brought together top experts to discuss ways to help bring an end to deadly medication errors, such as the one that seriously harmed Dennis Quaid's infant twins.

The alerts will be archived and available to the public on the ASHP Website at ashp.org/iv-summit. ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

The PDUFA IV Proprietary Name Review Pilot Project

Two years ago (September 2007), the Prescription Drug User Fee Act (PDUFA IV) was expanded to strengthen the FDA's drug safety program, facilitating more efficient development of safe and effective new medications. As one of these goals, the FDA stated that it would use user fees to implement various measures to reduce medication errors related to look-alike and sound-alike proprietary names, unclear label abbreviations, acronyms, dose designations, and error-prone label and packaging designs.

In addition, the FDA agreed to develop and implement a pilot program to enable pharmaceutical firms participating in the pilot to evaluate proposed proprietary names and to submit the data generated from those evaluations to the FDA for review. The goals of the program are to minimize the use of names that are misleading or that are likely to lead to medication errors, to make the FDA's application review more efficient, and to make regulatory decisions more transparent.

At the end of the pilot, the FDA will evaluate the results to determine whether the model of industry conducting reviews, submitting the results to the FDA, and the FDA reviewing the data is feasible and a better model than the FDA conducting de novo reviews of proprietary names.

Source: PDUFA Pilot Project Proprietary Name Review Concept Paper. For more information, visit thefederalregister.com/d.p/2009-10-01-E9-23620.

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