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DID FDA APPLY A REMEDY WORSE THAN THE DISEASE IN REFUSING TO CLEAR THE MARKET OF UNAPPROVED VERSIONS OF MAKENA?

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Did FDA Apply a Remedy Worse Than the Disease in Refusing to Clear the Market of Unapproved Versions of Makena?

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I. INTRODUCTION

On March 30, 2011, the U.S. Food and Drug Administration (FDA) issued a public statement announcing that it would not take enforcement action against pharmacies marketing unapproved versions of the pre-term labor drug Makena (hydroxyprogesterone caproate).[1] FDA's decision, which is directly at odds with the agency's well-established policies and practices, undermines the integrity of the new drug approval process, the goals of the Orphan Drug Act (ODA) and FDA's public health mission.

FDA publicly stated that its decision was based on what it called a "unique situation."[2] First, FDA explained that Makena's manufacturer, KV Pharmaceutical Company (KV), had "received considerable assistance from the federal government in connection with the development of Makena by relying on research funded by the National Institutes of Health to demonstrate the drug's effectiveness."[3] Second, FDA explained that Makena had already obtained seven years of marketing exclusivity under the ODA and had been approved under FDA's accelerated approval program after receiving expedited review. Third, FDA noted that unapproved versions of the active ingredient contained in Makena had been compounded by pharmacies for many years and that FDA had historically exercised enforcement discretion with respect to traditional pharmacy compounding. Finally, without specifically referencing the public outcry that had arisen over Makena's price, the agency stated that its decision was made "[i]n order to support access to this important drug."[4]

This article summarizes the purposes and objectives of the new drug approval process and the ODA and explains how FDA's policies and past practices restricting the marketing of unapproved versions of FDA-approved drugs were designed to further those purposes and objectives. The article concludes that FDA's recent decision to announce publicly that it would not "clear the market" of unapproved versions of Makena fundamentally undermines these goals and should be reversed.

POLICY RECOMMENDATIONS

FDA should:

- Publicly acknowledge that its decision not to take enforcement action against pharmacies marketing unapproved versions of Makena was erroneous and reverse that decision.
- Reaffirm its long-standing position that "traditional pharmacy compounding" does not include the compounding of commercially available drug products.
- Advise consumers to avoid compounded drug products when an FDA-approved product is available.
- Clear the market of unapproved drug products that undermine 1) the value of ODA exclusivity and 2) the incentives to study orphan drug indications.

II. BACKGROUND

In a move widely praised by patient advocacy groups, insurance companies, compounding pharmacies and politicians, FDA recently announced that it would not require unapproved versions of the pre-term labor drug Makena to be removed from the marketplace.[5] Makena, which recently was approved by FDA, is used to help pregnant women reduce the risk of having a pre-term baby.[6] FDA's decision, however, was a wholesale reversal of its prior position and, despite FDA's stated justification, was driven by the public outcry over the price of the FDA-approved drug, which KV initially set at $1,500 per dose.[7] Unapproved versions of the drug can be purchased for roughly $10 to $50 per dose.[8]

III. ISSUES IN DISPUTE

FDA's decision to allow cheap, unapproved versions of Makena to remain in the marketplace sets a dangerous precedent. The decision directly undermines the integrity of the approval process for new drugs, the ODA and the entire purpose of FDA itself. The agency exists to ensure that, among other things, drugs are safe and effective for their intended uses. FDA's decision will permit drugs that the agency has not approved—that may not contain the correct active ingredients, that may be subpotent or superpotent or that may not be manufactured under sanitary or sterile conditions according to FDA's standards—to be marketed and sold to pregnant women who have had a pre-term delivery of a baby in the past. To be sure, there are plenty of good reasons to resist rising drug prices. But if the ultimate objective is to live in a world of cheap drugs, then the logical remedy would be to rescind the Federal Food, Drug and Cosmetic Act (FDCA) and to abolish FDA, since the drug approval process administered by the agency is primarily responsible for the high cost of drugs in the United States. To paraphrase President James Madison, the "remedy" (abolishing FDA) would be "worse than the disease" (expensive drugs).[9]

FDA's drug approval process is designed to protect the public health. By ensuring that drugs are safe and effective for their intended uses and are manufactured and monitored according to FDA's high standards, FDA protects the public from unsafe products. But this is not cheap. To satisfy the requirements of FDA's drug approval process, which includes pre-clinical research on animals and multiple clinical trials on humans, pharmaceutical companies typically spend hundreds of millions of dollars to develop a new drug. Indeed, a study published in 2003 reported an average cost of approximately $800 million to bring a new drug to market.[10] Another study published in 2006 found that costs typically vary from around $500 million to $2 billion.[11] So-called "orphan" drugs, which are intended for a small patient population, are just as expensive to develop as drugs intended for large (and potentially more profitable) markets. Sponsors of orphan drug development, like all drug sponsors, are obliged to conduct costly research on animals and humans. After a drug is approved by FDA, sponsors must then spend hundreds of millions more to comply with all of the agency's post-approval requirements, such as following current good manufacturing practices, monitoring and reporting adverse events, and conducting post-approval studies.

As Adam Smith famously noted, "[i]t is not from the benevolence of the butcher, the brewer or the baker, that we expect our dinner, but from their regard to their own interest."[12] It is likewise not from the benevolence of pharmaceutical and biotechnology companies that we should expect life-saving drugs and biologics. To the contrary, to serve their own interests and stay in business, pharmaceutical and biotechnology companies must turn a profit. As a result, they must set the prices of their FDA-approved drugs at an amount that reflects the costs associated with developing and marketing those particular drugs. Indeed, to turn a profit, they must set the prices of their FDA-approved drugs even higher, to account also for the costs associated with their efforts to develop countless other drugs that do not live up to their initial promise and, ultimately, are never approved by FDA. According to the Pharmaceutical Research and Manufacturers of America, for about every 5,000 chemical compounds tested, only about five will be sufficiently promising to warrant testing on humans.[13] According to a study conducted by the Tufts Center for the Study of Drug Development, only 21.5 percent of drugs tested on humans will eventually be approved by FDA for marketing.[14] Thus, a company must, on average, study thousands of compounds to get just one drug approved by FDA.

IV. RESEARCH AND RESPONSE

If drugs can be marketed and sold without bearing the costs associated with FDA's rigorous drug approval process, then drug companies will not invest the money that it takes to get a novel compound through FDA. Understanding this, FDA publicly announced in a 2006 Compliance Policy Guide (CPG) that it would "clear the market" of all unapproved drugs that directly compete with an FDA-approved drug. In making the announcement, FDA specifically recognized that unapproved drugs "present direct challenges to the new drug approval" process, which is "designed to avoid the risks associated with potentially unsafe, ineffective and fraudulent drugs."[15] Indeed, FDA recognized that drug manufacturers would not expend the resources needed for obtaining FDA approval if competitors were not required to do the same. "Targeting drugs that challenge the drug approval or OTC drug monograph systems," FDA declared, "buttresses the integrity of these systems and makes it more likely that firms will comply with the new drug approval and monograph requirements, which benefits the public health."[16] Accordingly, the agency stated that it "intends to continue its current policy of giving higher priority to enforcement actions involving unapproved drugs in" such circumstances.[17]

In the statement announcing FDA's decision about Makena, the agency indicated that KV had already benefited from the government's assistance, thereby insinuating that any additional assistance in clearing the market of unapproved versions of the drug would constitute an undeserved windfall to the company. FDA is well aware, however, that its 2006 enforcement policy often (if not usually) results in an FDA-enforced monopoly for the first company to obtain approval of a compound. Notwithstanding that knowledge, FDA has—until now—consistently followed its policy, believing that the integrity of the new drug approval process is more important than denying the sponsor of an FDA-approved product an arguably undeserved windfall.

Quinine drugs are just one example. In December 2006, FDA approved a quinine drug for use in the treatment of malaria and then immediately cleared the market of all unapproved drugs containing quinine.[18] FDA did so, notwithstanding the fact that 1) the incidence of malaria in the United States is relatively low and quinine's real value was in its widespread use in the treatment of nocturnal leg cramps and 2) the agency's action would, in practical effect, result in a windfall for the manufacturer of the FDA-approved quinine drug product. In so acting, FDA explained that "[a]llowing continued marketing of unapproved drugs that compete against approved counterparts challenges the integrity of the drug approval system that is designed to avoid the risks associated with potentially unsafe and ineffective drugs, and puts companies that comply with the law at a disadvantage."[19] The agency further justified its enforcement action against unapproved quinine products by observing that "[a]llowing continued marketing of these unapproved drugs also undermines the incentives needed to conduct the scientific studies to determine the safety and effectiveness of drugs, which benefits the public health."[20]

More than 20 years prior to FDA's issuance of its clear-the-market CPG on marketed unapproved drugs, Congress in 1983 came to a similar conclusion regarding orphan drugs, i.e., that drug companies would not spend hundreds of millions of dollars to obtain FDA approval for drug products that would never be profitable. Because orphan drugs, by definition, treat only small patient populations, the likelihood of profitability was low. In response, Congress enacted the Orphan Drug Act,[21] which "was enacted in order to provide drug manufacturers with incentives to develop 'orphan' drugs—that is, drugs for the treatment of rare diseases or disorders that affect only small patient populations."[22] These incentives included research assistance, grants and tax benefits for companies that pursue development of orphan drugs.[23] In addition, Congress provided for seven years of marketing exclusivity for orphan drugs that obtain FDA approval.[24] Specifically, the ODA states that FDA "may not approve another application … for such drug for such disease or condition … until the expiration of seven years."[25] Ironically, FDA cited Makena's seven-year period of marketing exclusivity as a basis for subjecting it to competition from unapproved, compounded versions of the drug.[26]

Makena was approved by FDA in February 2011 for use in the reduction of the risk of certain pre-term births in women who have had at least one prior pre-term birth. Because Makena is an orphan drug, KV Pharmaceuticals obtained exclusive marketing rights for seven years under the Orphan Drug Act. Obtaining FDA's approval of Makena was expensive; to date, KV has spent more than $250 million to develop and market the drug.[27] It is expected that KV will spend millions more to manufacture and market the drug in compliance with FDA's regulations and to conduct the post-approval studies that FDA requires.[28] If it is forced to compete against cheaper, unapproved versions of Makena, then KV likely will have made a significant investment that it will never recoup.

V. IMPACT OF POLICY RECOMMENDATIONS

FDA's decision has the real potential to inhibit the development of new drugs, including orphan drugs. Indeed, the agency's decision is likely to have a chilling effect on companies considering the development of drugs that, but for FDA's intervention, would have to compete against cheap, unapproved versions of the same drug. FDA's actions almost certainly will have a negative impact on orphan drug research, which often is very expensive. The business justification for investing in expensive orphan drug research depends on the ability of drug companies to price their products so that their development is profitable. For example, Cerezyme, an orphan drug manufactured by Genzyme Corporation and approved for Gaucher disease, costs between $200,000 (children) and $600,000 (adults) per year.[29] Similarly, the Shire-manufactured Elaprase, an orphan drug approved for Hunter syndrome, costs between $300,000 and $400,000 annually.[30] If FDA deems $1,500 per dose to be "too expensive," and effectively rescinds orphan drug marketing exclusivity, will any drug company seriously consider developing much-needed therapies for rare diseases that cost 200 times that amount?

FDA's decision to cave to political pressure has had another consequence that will further chill companies considering the development of drugs that would have to compete against cheap, unapproved drugs with the same active ingredient(s): It has emboldened the very politicians who pressured FDA. For example, in the wake of FDA's decision on Makena, four members of Congress wrote to URL Pharma on May 23, 2011, demanding to know precisely why their FDA-approved treatment for gout, Colcrys, costs more than unapproved drugs containing the same active ingredient, colchicine.[31] URL was given until June 10, 2011, to provide these members of Congress with reams of confidential commercial information related to Colcrys. The same members wrote a similar letter to Avanir regarding the price of Nuedexta, an FDA-approved treatment for involuntary emotional outbursts known as pseudobulbar affect.[32] Nuedexta combines two active ingredients, quinidine and dextromethorphane. Apparently oblivious to the fact that the FDCA required Avanir to conduct costly clinical trials on the combined active ingredients to establish the safety and efficacy of the drug for pseudobulbar affect, the members of Congress demanded to know why Nuedexta costs significantly more than drugs that contain the individual active ingredients found in Nuedexta. Those drugs, however, were approved for other indications and were never studied for use together. In addition to confirming (through costly clinical studies) the efficacy of the combined drug ingredients for the new indication, Avanir was required to confirm the safety of the combination product as it is well known that combining two FDA-approved drugs can result in unexpected side effects.[33] Again, will drug companies seriously consider developing much-needed therapies if their pricing decisions will subject them to burdensome congressional oversight and require the disclosure of confidential commercial information?

FDA's explanation for its decision is not persuasive. In its announcement, FDA attempted to blame its refusal to clear the marketplace of unapproved versions of Makena on its policy authorizing traditional pharmacy compounding. FDA's invocation of its policy on traditional pharmacy compounding is clearly a pretext. The agency historically has taken the position that traditional pharmacy compounding does not include the compounding of a commercially available drug product. For example, FDA's CPG on pharmacy compounding expressly prohibits the compounding of drugs that are essentially copies of a commercially available drug product. In particular, it states that "when the scope and nature of a

pharmacy's activities raise the kinds of concerns normally associated with a drug manufacturer and result in significant violations of the new drug, adulteration or misbranding provisions of the Act, FDA has determined that it should seriously consider enforcement action."[34] One of the factors the agency considers in deciding whether to take enforcement action is whether the pharmacy engaged in "[c]ompounding drug products that are commercially available in the marketplace or that are essentially copies of commercially available FDA-approved drug products."[35]

Prior to its recent statement concerning Makena, FDA expected doctors to prescribe FDA-approved drug products when they were available. In a document entitled "The Special Risks of Pharmacy Compounding," FDA specifically recommends that consumers "protect themselves against inappropriate drug-compounding practices" by "ask[ing their] doctor if an FDA-approved drug is available and appropriate for [their] treatment."[36] FDA has explained that the reason for this policy is "that compounded drugs are not FDA-approved," which "means that FDA has not verified their safety and effectiveness."[37] The agency also has stated "that poor practices on the part of drug compounders can result in contamination or in products that don't possess the strength, quality and purity required," which is of particular concern for sterile drug products.[38] There is nothing about Makena, not even its price, that compels the agency to abandon its longstanding practice of protecting the public health by taking enforcement action against unapproved versions of FDA-approved drugs that are commercially available.

VI. CONCLUSION

FDA's refusal to follow its own policies and procedures and the principles underlying the Orphan Drug Act places political expediency over public health and undermines the agency's mission and legitimacy. FDA's remedy (abdicating its responsibility to clear the market of marketed unapproved drugs) is worse than the disease (Makena's relatively high price).

Our recommendations, if followed, would promote vital drug research, particularly for drugs that treat rare diseases or disorders that affect only small patient populations, and would protect the integrity of the new drug approval process. While we recognize that FDA is unlikely to do so, the agency and the public would be well-served by FDA publicly acknowledging its mistake and reversing its decision.

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