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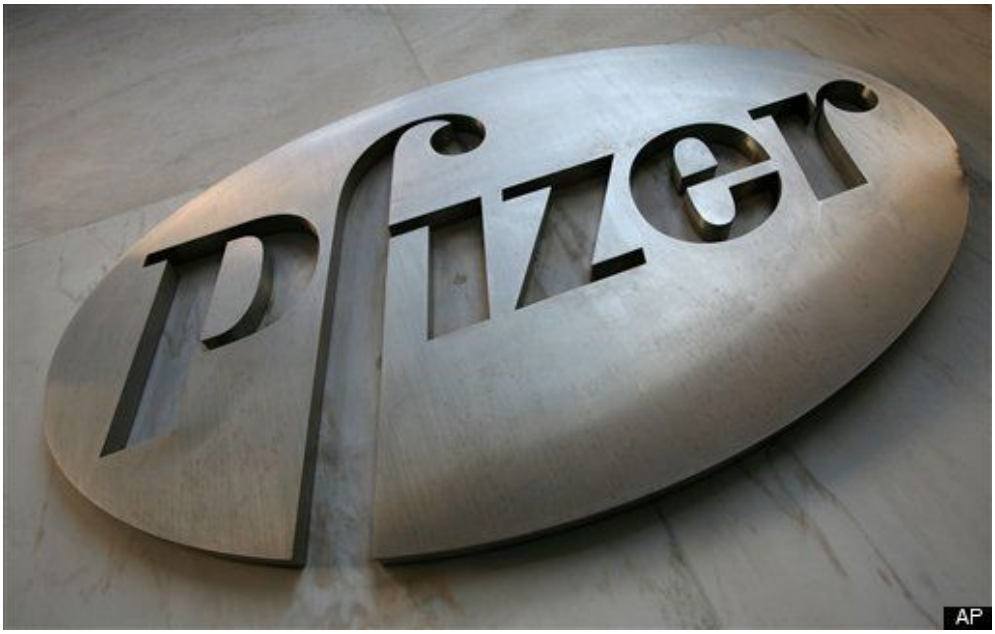
Pfizer Rapamune Lawsuit: Pharma Giant's Subsidiary Accused Of Targeting 'High-Risk' Black Patients For Unapproved Use Of Drug

By Marcus Baram



Scroll down for the complaint

This story has been updated

In a stunning whistleblower lawsuit, the world's largest pharmaceutical company is being sued over the dangerous practice of illegally promoting a kidney transplant drug for unapproved uses — and targeting African-Americans, even though they are at high risk of complications.

Two former hospital sales representatives, Marlene Sandler and Scott Paris, originally filed their suit in 2005 but the case was recently unsealed. The amended complaint against Pfizer and Wyeth was filed this week, as reported by the Pharmalot blog.

use of Rapamune, a kidney transplant drug which generated $376 million in sales in 2008, encouraging its sales force to promote the drug for heart, lung, liver, and pancreas transplants even though Rapamune was never approved for those procedures. The Food and Drug Administration warned against such off-label use of Rapamune in 2004 and 2007.

The suit claims:

> *"Wyeth trained and encouraged its sales representatives to market Rapamune for*
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> *uses outside those listed on the FDA-approved label and to misrepresent and withhold clinical*
>
> *information regarding the safety and efficacy of Rapamune. As a result of Wyeth's wrongdoing,*
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> *patients were put at risk of serious physical and financial harm, including: the disruption or*
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> *discontinuation of stable treatment regimens; increased costs associated with treating side effects caused or exacerbated by Rapamune; life-threatening side effects such as anemia, bone marrow suppression, inhibited wound-healing, proteinuria, blood clots, leukopenia, thrombocytopenia, liver failure, pulmonary dehiscence; and death."*

Off-label promotion of drugs has become one of the most controversial issues in the pharmaceutical industry, and has led to a host of federal indictments and massive settlements. Just last September, Pfizer agreed to plead guilty to criminal charges and to pay more than $2 billion in fines to settle allegations regarding its market practices, which included the off-label promotion of the antipsychotic Geodon and the antibiotic Zyvox.

One of the most stunning allegations in the Sandler-Paris suit, is that Wyeth targeted African-American patients for unapproved use of the drug "even though they didn't have data supporting its use in that population," reports BNet.com. "Blacks are considered "high-risk" patients for kidney transplants because of their more vigorous immune response to new organs. Rapamune reduces immune response so patients don't reject their new kidneys."

patient populations — Philadelphia's Einstein Medical Center and New York's SUNY Downstate Medical Center.

Some hospitals, including the famed Mayo Clinic, raised concerns with Wyeth Global Medical Affairs that patients given the drug were experiencing "very serious side effects," but "nothing was done," according to the complaint.

The suit alleges that several prominent doctors, including the clinical research director of the prestigious Cleveland Clinic, were involved in helping promote the use of Rapamune.

The suit describes a speakers list of 18 physicians who could talk about off-label use of drugs. One of those cited was the Cleveland Clinic's Dr. Stuart Flechner, who was available to speak about the use of Rapamune "for an honorarium of $2,000 or "prorated $15,000." Flechner, a fellow of the American College of Surgeons, was named one of the Top Doctors in America, according to the clinic's Website.

When doctors at Mt. Sinai Medical Center expressed concerns about using Rapamune as part of a specific regimen, Wyeth brought in Flechner to talk to them:

> *"Wyeth paid Dr. Flechner to assist in the marketing of the unapproved combination of Cellcept, an IL-2 receptor antagonist and Rapamune in order to overcome these objections and secure Rapamune sales."*

In addition to the lawsuit, federal prosecutors have opened a criminal investigation into Wyeth's promotion and marketing of Rapamune. Pfizer, in a regulatory filing on February 26,

District of Oklahoma.

Pfizer issued the following statement to HuffPost:

> *"Pfizer is committed to patient safety and to ensuring that information provided to physicians for Rapamune is consistent with its FDA-approved indications. We are very confident that the current promotional practices surrounding this product are fully compliant with all legal requirements.*
>
> *"Rapamune was first approved by the FDA in 1999 for the prophylaxis of organ rejection in patients 13 years or older receiving kidney transplants. As the science has evolved, so, too, has our labeling information for Rapamune, which includes the appropriate caveats about treatment areas where safety and efficacy have not been established."*

Wyeth's former National Director of Transplant Sales Joe McCafferty, who allegedly selected Philadelphia's Einstein Medical Center as the focus of the firm's sales plan for Rapamune, did not return calls for comment left on his cellphone.

A spokesman for the Cleveland Clinic was not able to provide a comment in time for publication.

READ the complaint:

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