The Dangers of

TAXOTERE

Hair Loss and Beyond

If you or someone you love suffered harm as a result of taking Taxotere, you may be eligible to obtain compensation to pay for your medical care, your lost productivity, your pain and suffering and other damages. In addition, by holding Taxotere's manufacturers accountable, you can help prevent other people from experiencing similar harm in the future.

R&B

REICH & BINSTOCK

ATTORNEYS AT LAW / *Founded in 1984*

The Dangers of TAXOTERE
Hair Loss and Beyond

Taxotere (docetaxel) was first approved by the U.S. Food and Drug Administration (FDA) in 1999 to treat patients with certain types of lung cancer, if platinum-based chemotherapy had already failed. In 2002, it was also approved to treat additional types of lung cancer, as well as lung cancer patients who had not had platinum-based chemotherapy. Then, in 2004, the FDA approved it for prostate cancer and breast cancer treatment, and later, in 2006, the FDA also granted its approval for the treatment of certain gastric cancers and cancers of the head and neck.

Since its approval, however, Taxotere use has been linked to a number of side effects, including permanent hair loss. Its manufacturer, Sanofi-Aventis, currently faces lawsuits in several jurisdictions. These lawsuits make various claims, including that the manufacturer failed to test the drug sufficiently and failed to warn patients that permanent hair loss might result.

What Is TAXOTERE?

Taxotere is a medication used to treat certain types of cancer in the head, neck, breasts, lungs, gastro-intestinal system, and prostate. Like many cancer medications, Taxotere works by attacking cancer cells in order to halt or limit their growth. The FDA's Patient Information Leaflet describes Taxotere as stiffening the supporting structure of a cancer cell, thereby making it more difficult for the cell to grow or reproduce.

For some treatments, Taxotere is combined with other cancer medications, such as cisplatin and fluorouracil. Several cycles of Taxotere–with or without other medications–may be given to a patient during chemotherapy.

TAXOTERE SIDE EFFECTS

From its December 1999 initial approval to treat non-small cell lung cancer, Taxotere's side effects have been noted in studies of the drug and FDA documentation. Observed side effects of Taxotere have included: anemia, neutropenia, increased infection risk, nausea, vomiting, anorexia, hair loss, and fatigue. Pain and hypersensitivity of the nervous system were also reported.

The 2004 Taxotere Patient Information Leaflet notes that, like many types of cancer medications, Taxotere can have a negative effect on bone marrow, which may result in anemia, low white blood cell counts, infections, and other conditions. Therefore, the leaflet advises that patients' doctors routinely look for a declining blood count.

The leaflet warns of side effects, in addition to those mentioned above, including muscle pain, fever and rash. The company's patient leaflet further states that "loss of hair occurs in most patients taking Taxotere," but "once you have completed all your treatments, hair generally grows back." However, lawsuits since filed against Sanofi-Aventis have alleged that this is a false assertion.

TAXOTERE & INJURIES

In December 2015, the FDA listed "permanent alopecia" among the adverse reactions reported by Taxotere patients: for these patients, hair they had lost during Taxotere treatment had never grown back. At that time, the FDA approved a change to Taxotere's safety labeling that included cases of permanent alopecia had been reported.This was not the first of the FDA's warnings or precautions regarding Taxotere. Previous warnings include:

- In April 2010, the FDA reported that, when Taxotere was used in conjunction with ketoconazole or protease inhibitors like ritonavir, some patients had scleroderma-like skin changes. And for some, the reaction was more serious: renal failure.
- In June 2013, the FDA listed several respiratory symptoms and conditions reported in Taxotere patients. Later that same year, the FDA noted cases of Taxotere patients with cystoid macular edema (CME), an eye disorder.
- In November 2014, the FDA warned physicians that the alcohol content in a dose of Taxotere could cause intoxication symptoms in some patients.

Meanwhile, independent studies of patients with hair loss related to docetaxel use were discovering that, for many patients, hair loss was not temporary. In a 2010 study in the Journal of the American Academy of Dermatology, researchers reported that it was more common for patients using newer chemotherapy medications, such as Taxotere, to have subsequent difficulty with hair regrowth, compared to patients using older medications.

A 2012 study, published in Annals of Oncology, followed 20 female patients treated with docetaxel and other medications for cancer. The study found that some patients failed to regrow their hair following treatment, and they were also unresponsive to some medical treatments designed to promote hair regrowth.

FDA

FDA RESPONSE

FDA Response to Taxotere Injury Reports
Between 2010 and 2016, the FDA updated its standards on docetaxel several times, requiring that warnings be placed on the medication's packaging regarding potential drug interactions, renal failure, skin conditions, eye disorders and the risk of permanent hair loss. The "black box" warnings for Taxotere include disclosures on a number of life-threatening risks, including the risk of liver toxicity, neutropenia, frequent infections and fluid retention.
On December 11, 2015, the FDA sent a letter to Sanofi-Aventis, approving the manufacturer's proposed changes to the Taxotere package insert of patient information: the changes included new language on permanent or irreversible alopecia. However, this addition was only made to the package insert text: it was not included in the insert's "black box" warnings.

ALLEGATIONS & LAWSUITS

Allegations and Lawsuits Concerning Taxotere

A number of lawsuits have been filed against Sanofi-Aventis, the manufacturers of Taxotere. Many of these lawsuits are regarding Taxotere's potential cause of permanent hair loss, with several alleging that Sanofi-Aventis knew about this risk for many years, but failed to sufficiently disclose it. Lawsuits also allege that Taxotere is defective, due to this potential to cause irreversible hair loss.

In January 2017, 705 cases were merged into a multi-district litigation (MDL) case in the Eastern District of Louisiana, which is proceeding through the pretrial process.

In March 2001, Aventis Pharmaceuticals issued a voluntary recall of Taxotere vials with lot numbers 0P273, 0T446, and 0T449, facing concerns that some vials had been mislabeled. The recall, however, is not related to the bulk of the current lawsuits

TAKE ACTION
OBTAIN FAIR COMPENSATION

Take Action to Obtain Fair Compensation for Your Taxotere Injuries
If you or someone you love suffered harm as a result of taking Taxotere, you may be eligible to obtain compensation to pay for your medical care, your lost productivity, your pain and suffering and other damages. In addition, by holding Taxotere's manufacturers to account, you can work to prevent other people from experiencing similar harm in the future.
The team at Reich & Binstock is working aggressively to help patients like you achieve a fair result. Partner Dennis Reich is on the litigation settlement negotiation team for Taxotere.

Please call our team at 877-643-3099 to schedule a private, free consultation; or explore more resources at http://www.reichandbinstock.com/.

Sources

"Approval Package." FDA CDER, December 11, 2015. http://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/020449Orig1s075.pdf
"FDA Approval for Docetaxel." National Cancer Institute: https://www.cancer.gov/about-cancer/treatment/drugs/fda-docetaxel
"MDL – 2740 Taxotere (Docetaxel) Products Liability Litigation." U.S. District Court for the Eastern District of Louisiana. http://www.laed.uscourts.gov/case-information/mdl-mass-class-action/taxotere
"Patient Information Leaflet, May 2004." U.S. Food and Drug Administration. http://www.accessdata.fda.gov-/drugsatfda_docs/label/2004/020449s028lbl.pdf
"Permanent chemotherapy-induced alopecia: case report and review of the literature." Journal of the American Academy of Dermatology (2010). https://www.ncbi.nlm.nih.gov/pubmed/20471136
"Permanent scalp alopecia related to breast cancer chemotherapy by sequential fluourouracil/epirubicin/cyclophosphamide (FEC) and docetaxel: a prospective study of 20 patients." Annals of Oncology (2012). https://academic.oup.com/annonc/article/23/11/2879/234091/Permanent-scalp-alopecia-related-to-breast-cancer
"Taxotere." National Cancer Institute: https://www.cancer.gov/publications/dictionaries/cancer-terms?cdrid=508678
"Taxotere: Full Prescribing Information." U.S. Food and Drug Administration. http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/020449s059lbl.pdf
"Taxotere: Safety Labeling Changes Approved by FDA Center for Drug Evaluation and Research (CDER)." http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm212079.htm