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The weather has certainly been a little unpredictable for spring, but hopefully there will be consistent warmth and sunshine soon. Of course, weather is something you can't count on; my team, however, is something you can always count on and trust.

Here at Jan Dils, Attorneys at Law, we get a lot of questions about medical device recalls. It can be particularly concerning to the millions of people having surgeries for an array of conditions. So, this month, we're starting with a broad understanding of the recall process. In the second article we are focusing on a specific lawsuit as it relates to complications from hernia mesh. About 90 percent of hernia repair surgeries in the U.S. use hernia mesh. The greater majority of these surgeries go well and help prevent reoccurrence. But for those who have experienced complications, the pain and suffering can be quite severe. Big Pharma is a force unto itself. However, our team is experienced and tenacious – we never hesitate to take them on if there is adequate proof of negligence. You may be entitled to receive compensation for damages, including medical bills, lost wages, and pain and suffering. We invite you to learn more about our team and areas of specialty at jandils.com. Of course, if you ever need Personal Injury advice, do not hesitate to give us a call at 877.526.3457. We won't take "no" for an answer.

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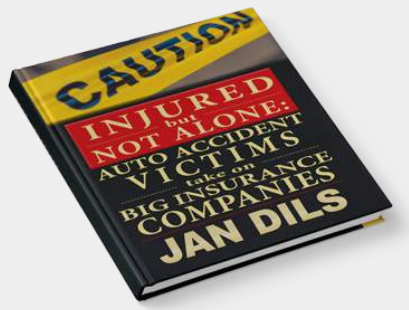

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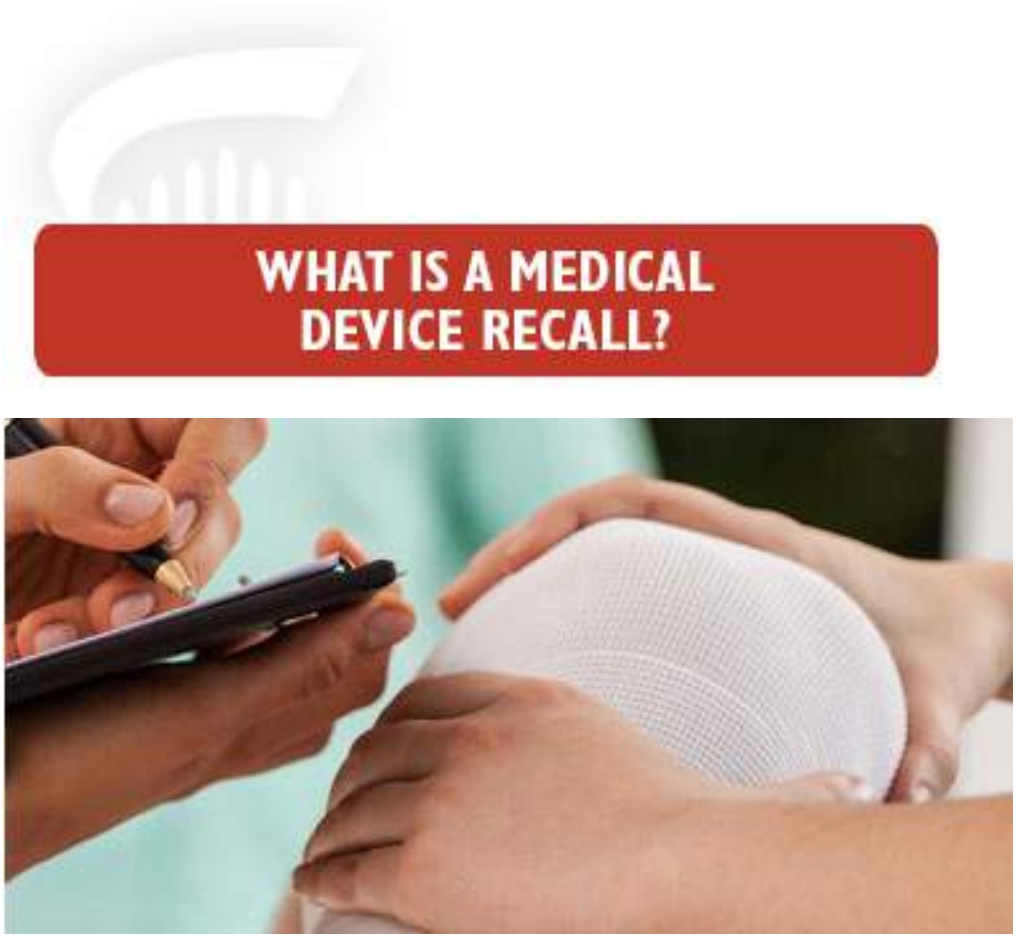

What Is a Medical Device Recall?

Each year, the number of medical devices and drugs on the market increases, and so do the recalls and safety alerts. In fact, on average, about 4,500 drugs and devices are pulled from the U.S. shelves annually. Manufacturers “voluntarily” pull problematic products off the market, but the U.S. Food and Drug Administration (FDA) has little enforcement power to force Big Pharma to remove problematic devices.

When a company learns that there is a problem with one of their medical devices, it proposes a **correction** or a **removal** depending on where the action takes place.

- **Correction** - Addresses a problem with a medical device in the place where it is used or sold.

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- **Removal -** Addresses a problem with a medical device by removing it from where it is used or sold.

The FDA uses the term “recall” when a manufacturer takes a correction or removal action to address a problem with a medical device that violates FDA law. Recalls occur when a medical device is defective, when it could be a risk to health, or when it is both defective and a risk to health.

A medical device recall does not always mean that you must stop using the product or return it to the company. A recall sometimes means that the medical device needs to be checked, adjusted, or fixed. If an implanted device (for example, an artificial hip) is recalled, it does not always have to be explanted from patients. When an implanted device has the potential to fail unexpectedly, companies often tell doctors to contact their patients to discuss the risk of removing the device compared to the risk of leaving it in place.

Examples of the types of actions that may be considered recalls:

- Inspecting the device for problems
- Repairing the device
- Adjusting settings on the device
- Re-labeling the device
- Destroying device
- Notifying patients of a problem
- Monitoring patients for health issues

Sometimes a company may be aware that there is a problem with a group of products, but it cannot predict which individual devices will be affected. To appropriately address the concern, the company may recall an entire lot, model, or product line.

Who Recalls Medical Devices?
In most cases, a company (manufacturer, distributor, or other responsible party) recalls a medical device on its own (voluntarily). When a company learns that it has a product that violates FDA law, it does two things:

- Initiates a recall (through correction or removal)
- Notifies the FDA

Legally, the FDA can require a company to recall a device. This could happen if a company refuses to recall a device that is associated with significant health problems or death. However, in practice, the FDA has rarely needed to require a medical device recall.

What does the FDA Do About Medical Device Recalls?
When the FDA learns of a company’s correction or removal action, it reviews the strategy the company proposes to address the problem, assesses the health hazard presented by the product, determines if the problem violates FDA law, potential violations of FDA requirements,

and if appropriate assigns the recall a classification (I, II, or III) to indicate the relative degree of risk.

- **Class I:** A situation where there is a reasonable chance that a product will cause serious health problems or death.
- **Class II:** A situation where a product may cause a temporary or reversible health problem or where there is a slight chance that it will cause serious health problems or death.
- **Class III:** A situation where a product is not likely to cause any health problem or injury.

Once classified, the FDA monitors the recall to ensure that the recall strategy has been effective. Only after the FDA is assured that a product no longer violates the law and no longer presents a health hazard, does the FDA terminate the recall.

How does the FDA Notify the Public about Medical Device Recalls? When a company initiates a correction or removal action, the FDA posts information about the action in the Medical Device Recall Database.

The FDA updates the Medical Device Recall Database after it classifies the recall and again after it terminates the recall.

In addition, the FDA may post company press releases or other public notices about recalls, market withdrawals, and safety that may potentially present significant risks to consumers or users of the product.

After a recall has been classified, the FDA notifies the public in the weekly Enforcement Report. In addition, the FDA posts consumer information about Class I and some Class II and III recalls in order to ensure that patients are aware of the seriousness of the potential health hazard posed by exposure to the product.

At Jan Dils, Attorneys at Law, we represent many clients who have been on the wrong side of a recall and deserved compensation. Some of these include bone cement, IVC Filters, ATTUNE® knee replacements and metal hip replacements resulting in painful and invasive revisions

or reconstructive surgeries.

If you or a loved one has experienced worsening problems due to a recalled medical device, you may be eligible to seek compensation for damages, including medical bills, lost wages, and pain and suffering. If you have questions or concerns, do not hesitate to contact us.

Sources:
https://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
https://www.fda.gov/MedicalDevices/Safety/ListofRecalls/default.htm

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Complications of Abnormal Hernia Repair

Hernia mesh surgeries are one of the most common surgeries performed in the United States today. Many different types of products can be used for surgical hernia repairs, including patches and plugs. Ethicon, a subsidiary of Johnson & Johnson, is the manufacturer of Physiomesh – a flexible composite mesh made of polypropylene that has been recalled and the subject of class-action lawsuits.

Surgeons in the U.S. use hernia mesh in approximately one million surgeries every year. Mesh can prevent a hernia from recurring. But hernia mesh can also cause serious complications. The Food and Drug Administration (FDA) blames recalled meshes for many reports of those complications.

The most common adverse events following hernia repair

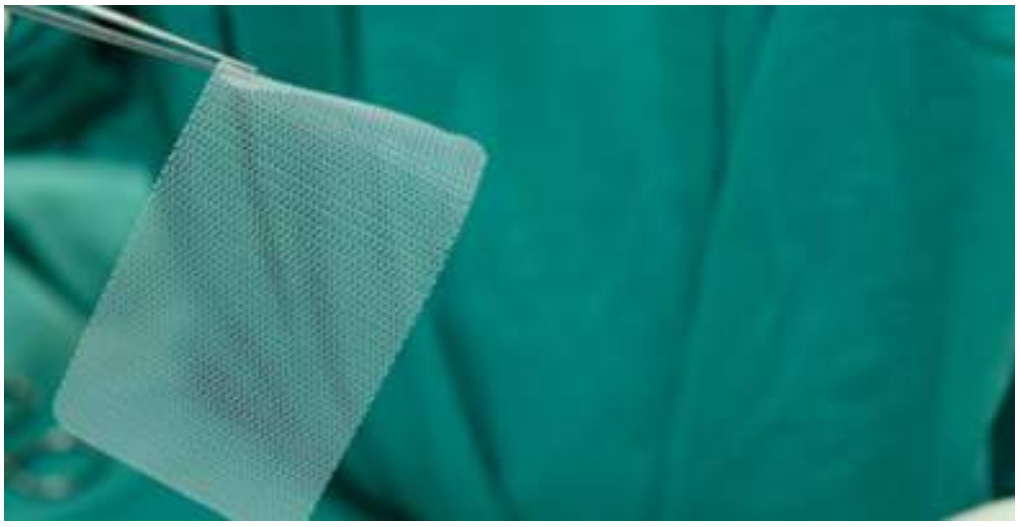
with mesh are pain, infection, hernia recurrence, adhesion, and bowel obstruction. Pain, infection, recurrence, adhesion, obstruction, and perforation are the most common complications associated with recalled mesh.

Jan Dils, Attorneys at Law has handled a number of these hernia mesh related cases. The basis for suit is that mesh manufacturers knew or should have known their products were defective but failed to warn people of the complications.

Hernia mesh lawsuits accuse device makers of several counts of negligence, including:

- Manufacturing a defective product
- Failing to adequately test hernia mesh
- Failing to warn the public about the risks of mesh
- Intentionally, knowingly and recklessly concealing information about the defective mesh
- Intentionally misrepresenting the quality and safety of hernia mesh
- Negligently designing and marketing unsafe hernia mesh

Federal courts have taken up more than 3,000 hernia mesh lawsuits in recent years after patients reported serious complications ranging from infections to organ damage. Hernia mesh lawsuits have already resulted in at least one verdict of $1.5 million and a settlement worth $184 million.



At least four manufacturers and 19 different products are embroiled in the latest wave of hernia mesh lawsuits. While Atrium and Ethicon products have been combined into MDLs, patients receiving Bard or Covidien mesh products have also brought individual lawsuits against those companies alleging complications.

If you or a loved one suffered complications or injury after hernia mesh surgery, you may have legal options. If you have any questions about this or other medical device recalls, please do not hesitate to contact us.

Consultations are always free.

Sources:
https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/HerniaSurgicalMesh/default.htm

https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/HerniaSurgicalMesh/default.htm

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Jan Dils, Attorneys at Law, handles Personal Injury Claims, Social Security and Veterans Disability for clients throughout West Virginia with offices located in Parkersburg-Beckley-Charleston-Huntington-Logan as well as one additional office located in Charlotte, North Carolina. But regardless of where you are located we are able to serve you or a family member nationwide.

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