

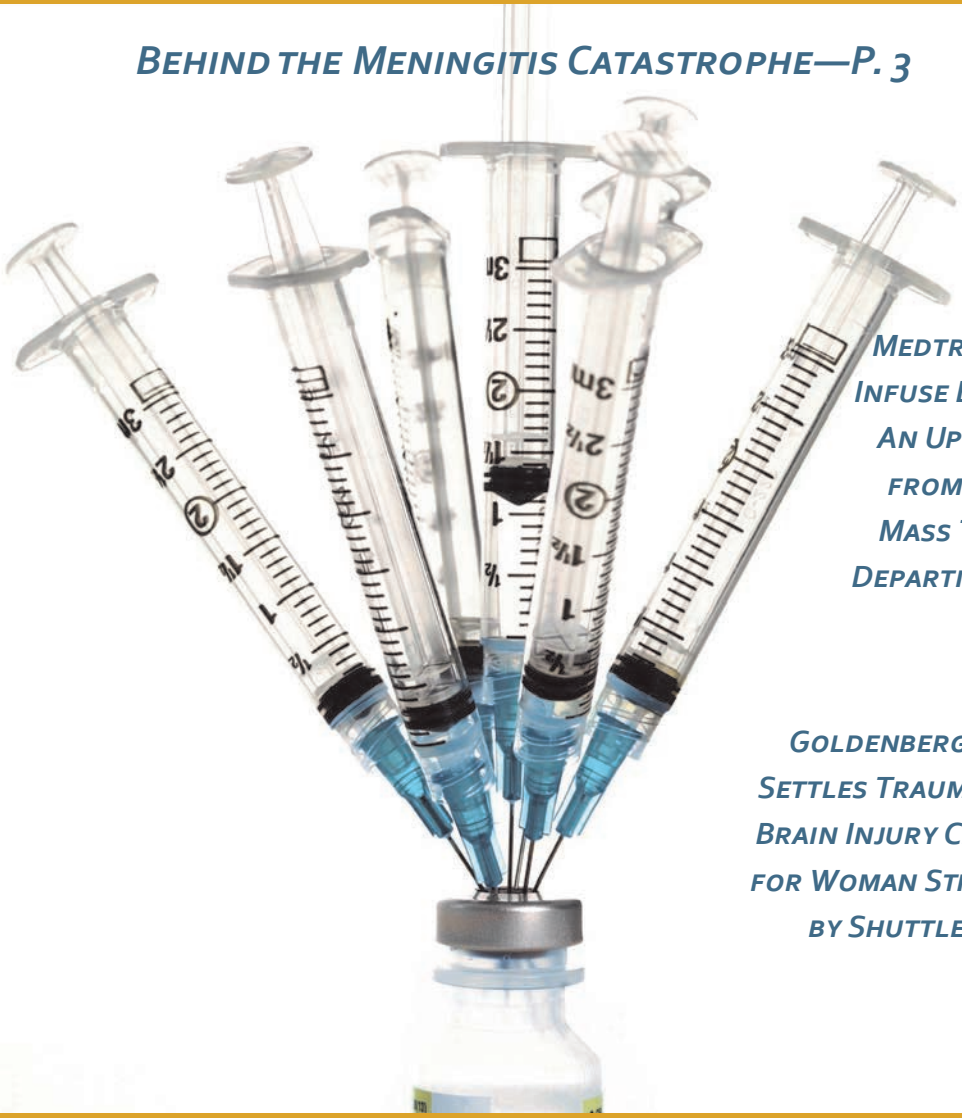


# G-LAW

*A publication  
for the clients  
and friends of  
GoldenbergLaw,  
PLLC*

*"Promoting Safety Through Accountability"*  
Spring 2013

## ***BEHIND THE MENINGITIS CATASTROPHE—P. 3***



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INFUSE BMP:  
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FROM OUR  
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DEPARTMENT  
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SETTLES TRAUMATIC  
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FOR WOMAN STRUCK  
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A message from

Stuart Goldenberg

The steroid contamination story of the New England Compounding Center ("NECC") is as predictable as it is tragic. Exposing at least 14,000 people to a dangerous fungus resulting in deaths, injuries and serious illnesses does not happen by accident. NECC was a dirty lab. Any inspection would have revealed that. However, there was minimal oversight because compounding pharmacies are not governed by the FDA. The combination of big profits and minimal regulation is a recipe for disaster.

We have seen photographs taken during an inspection of the NECC site conducted by the FDA and the Centers for Disease Control and Prevention (CDC). The inspection revealed air-conditioning ducts, autoclaves and drug vials contaminated with greenish black and white filamentous matter. Even the "clean room" had cracks in it and showed growths of bacteria and mold. However, these conditions do not appear to be the result of any lack in finances. According to *Boston Globe*, the four family members who cofounded NECC paid themselves a combined \$16 million last year.

It has now been reported by CBS News and 60 Minutes that a lab technician *warned* his supervisor at the NECC that these drugs were going to harm people. His concerns were ignored. This conduct is not only deplorable—it is criminal.

The distributors and medical clinics that purchased from the NECC are also responsible for using due care in obtaining safe drugs for their patients. The NECC was selling these products at a cheaper price than other facilities and was clearly acting as a manufacturer—not a pharmacy. Any visit to the facility would have raised serious safety concerns.

GoldenbergLaw is leading the way to protect the injured victims of this disaster. We are part of the national Contaminated Steroid Litigation Group. We represent a great number of people who have been exposed and will continue to fight for justice on their behalf.

#### Stay in the Loop with GoldenbergLaw!

Our social media sites are a great way to keep up on safety news and updates, as well as any updates we have on our mass tort cases.

You can also show your support for what we do by becoming involved. Next time you're logged on, make sure to visit us at:

**Facebook:** [facebook.com/GoldenbergLaw](https://facebook.com/GoldenbergLaw)

**Twitter:** [@Goldenberg\\_Law](https://twitter.com/Goldenberg_Law)

**LinkedIn:** [linkedin.com/company/goldenberglawpllc](https://linkedin.com/company/goldenberglawpllc)

**Google Plus:** [GoldenbergLaw, PLLC](https://plus.google.com/GoldenbergLaw,PLLC)

**Blogs:** [catastrophicaccidentresourcecenter.com](https://catastrophicaccidentresourcecenter.com)

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[productrecallresourcecenter.com](https://productrecallresourcecenter.com)

[toxicortortresourcecenter.com](https://toxicortortresourcecenter.com)



# Behind the Meningitis Catastrophe

*Alarming Inadequacies in the Management and Oversight of Drug Compounding Centers*

This past September, the news of contaminated drugs coming from New England Compounding Center (NECC) causing fungal meningitis shocked the country. But was it that shocking? Loose regulation and emphasis on profits is a lethal combination.

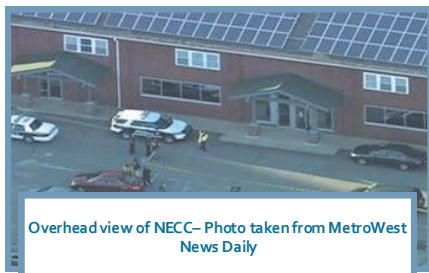
It has been several months since the New England Compounding Center (NECC) recalled the three lots of drugs tied to the deadly outbreak. Unfortunately, even after this amount of time, recipients have not been able to breathe a sigh of relief. As new reports of meningitis have diminished over time, other infections have been linked to the drugs and can take longer to detect.

The next emerging cause for concern is spinal infection, including **epidural abscess, phlegmon, arachnoiditis, discitis, or vertebral osteomyelitis**. New sets of instructions for health professionals suggest re-evaluating patients and obtaining an MRI for many of them to detect these spinal infections.

We believe that over 14,000 people were exposed/injected with the contaminated

***Although the source of the contaminated drugs has been identified as and isolated to the NECC, this outbreak sheds light on larger-scale, regulatory issues.***

*Pharmacy compounding is a practice in which a licensed pharmacist combines, mixes or alters a drug to fill a prescription tailored to the individual medical needs of a patient. Unlike pharmaceutical manufacturing companies, compounding pharmacies are not subject to FDA regulation. Instead, they are more loosely monitored by state pharmacy boards.*



Overhead view of NECC— Photo taken from MetroWest News Daily

drugs. There were over 70 hospitals/clinics that administered the drugs, including 6 locations in Minnesota. The NECC declared bankruptcy at the end of December. In late January, Bankruptcy Court Judge Henry Boroff made the decision to freeze the owners' personal assets.

It is clear that bankruptcy and litigation will play a large role in obtaining compensation for affected patients. It will likely be necessary to take additional actions against clinics and/or hospitals that administered the drugs, the owners of the property and possibly contractors. It will also be important for people with claims to give the bankruptcy court timely notice of their claim.

**GoldenbergLaw has taken a lead role in pursuing actions against negligent parties behind this disaster. Anyone exposed to this contaminated drug may have a claim.**

# Medtronic Infuse BMP: Past, Progress and Preemption



## PAST

In June of 2011, *The Spine Journal* devoted an entire issue to criticizing the safety of Medtronic's product Infuse BMP (bone morphogenetic protein). Infuse BMP is a liquid protein used in spinal fusion surgeries as an alternative to bone graft. When the FDA approved Infuse in 2002, it was only designed to be used in certain types of fusion surgeries. *The Spine Journal* revealed that Medtronic had not only downplayed the risks of using BMP in off-label ways (beyond what the FDA had reviewed and approved) but that Medtronic had allegedly promoted off-label uses and sponsored misleading research indicating the product was safe. In actuality, many patients who had BMP used in their spinal fusion surgeries experienced severe complications like bone overgrowth, nerve damage, inflammatory reactions, and the need for additional surgeries.

## PROGRESS

Fast forward to October 2012 when the U.S. Senate Committee on Finance released its own investigation into Medtronic's fraudulent behavior. Upon examining thousands of pages of documents – confidential emails, financial records, and information about the clinical trials – the Committee found that Medtronic was "heavily involved in drafting, editing, and shaping the content of medical journal articles." **The report shows that Medtronic paid its "Key Opinion Leaders" approximately \$210 million in sham royalties and consulting fees to promote the off-label use of Infuse.** Email correspondence showed that Medtronic employees and their paid Key Opinion Leaders who authored the studies suppressed many of the adverse events associated with Infuse, portraying the product as safer than it really was to the FDA, patients, and doctors alike. The Senate's report brought Medtronic's fraudulent conduct to light, revealing that Medtronic's fierce marketing and falsified research pose serious risk to patients.

## PREEMPTION

Preemption is a constitutional principle that allows federal law to override state law. If the FDA, a federal agency, approves a device through full pre-market approval (PMA) process, then under some circumstances people injured by that product cannot use state law to obtain a legal remedy. In other words, the claim is "preempted." Medtronic is aggressively trying to hide behind the doctrine of preemption to attempt to avoid responsibility. We do not believe that preemption should apply, because Medtronic promoted unsafe uses and because the product was not used in the manner approved by the FDA (that is, if it was used "off-label"). So far, Colorado, Florida and California state courts have ruled in favor of plaintiffs, dismissing Medtronic's motions to disqualify the case on the basis of preemption. However, a few states have upheld Medtronic's motions. The litigation is undoubtedly still in its early stages, but recent rulings are encouraging for plaintiffs. GoldenbergLaw and its partner The Branch Law Firm have begun filing cases in Minnesota State Court. We have assembled a superstar team including Lou Bograd and Wil Fluegel to help us defend the motions on preemption.

**The road to justice may be bumpy, but we will continue to help lead the AAJ National Litigation Group against Medtronic and to fight for our clients injured by this product.**

## Dangerous Drugs and Devices

**GoldenbergLaw** is currently investigating claims involving these products and has 27 years of experience handling dangerous drug and device cases.

Contact us at 612-333-4662 or 855-333-4662.

**Medtronic Infuse BMP Bone Graft** Used in spinal fusion surgeries— Causes unwanted bone growth, inflammatory reaction, severe arm and leg pain and possibly cancer.  
\*\*See page 4



**Propecia/ Proscar** (finasteride) - Causes severe and persistent sexual dysfunction in men and is also linked to prostate cancer.



**Topamax** An anti-seizure medication—causes birth defects such as cleft palate and cleft lip.



**Actos** A blood sugar control medication for Type II diabetics—causes bladder cancer.



**Accutane** An acne medication— causes Crohn's Disease or Ulcerative Colitis.



**Granuflo** A dialysis solution that can cause low blood pressure, myocardial infarction (heart attack), stroke, metabolic alkalosis and cardiopulmonary arrest



**Yaz/Yasmin/Ocella; NuvaRing** Female contraceptives that can cause dangerous blood clots.



**Metal-on-Metal Hips** Cause loosening, pain, high metal levels in the blood and a need for replacement surgery. Includes DePuy ASR, DePuy Pinnacle and other models.



**Stryker Rejuvenate and ABG II hip Systems** Modular hip systems—can cause elevated metal levels in blood-stream and/or need for revision.



**Transvaginal Mesh, Bladder slings, TVT Tape** Causes tissue erosion, device failure, need for additional surgery to remove or manipulate device.



**Fosamax** An osteoporosis drug—can impair body's ability to repair damage to bones, leading to femur fractures or jaw necrosis; possible link to esophageal cancer.



**Mirena IUD** Contraceptive that can cause abscesses, pelvic inflammatory disease, embedment in or perforation of uterus, erosion of adjacent areas, and other related problems.





# CATASTROPHIC PERSONAL INJURY

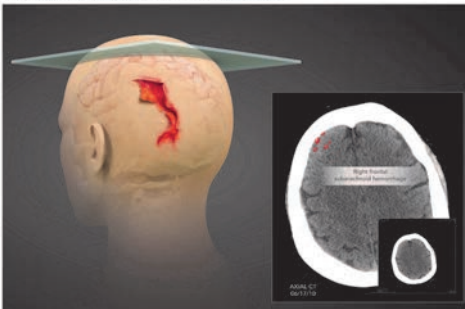
## GoldenbergLaw Settles Claim for Traumatic Brain Injury Victim

**G**oldenbergLaw is pleased to report it recently resolved a catastrophic injury case for a brain-injured client.

On a beautiful summer day, Rebecca (client's name has been changed for confidentiality reasons) sat on a bench at the Minneapolis - St. Paul International airport, awaiting a shuttle to take her to the hotel. Suddenly and without any warning, the shuttle lurched forward, bolting over the curb and crashing into Rebecca. She was catapulted from the bench, hitting a cement barrier and striking her head on the ground. Four other individuals were also injured in the incident.

When paramedics and authorities arrived, they found Rebecca lying unconscious in a pool of her own blood. Medical examination revealed she sustained a head laceration, extending all the way to her brain, blunt trauma with loss of consciousness, skin tear to the right hand/wrist area, and a sub-arachnoid hemorrhage to the right front convexity of the brain (See diagram).

TRAUMATIC BRAIN INJURY WITH HEAD LACERATION



The shuttle driver claimed to have forgotten to put the vehicle in park before he exited the van. When he realized the mistake, he allegedly jumped back in to correct the problem, hitting the gas pedal by mistake.

In the years following the incident, Rebecca experienced post-concussive symptoms,



which included severe headaches, impaired motor function, nausea, memory loss, post-traumatic stress disorder, as well as prolonged hip, elbow and shoulder pain. Yet, in the face of all these hurdles, she fought to overcome her injuries. Rebecca has bravely conquered some of the physical and emotional hurdles she experienced from that tragic day, yet still struggles intermittently. Despite these serious and life-impairing injuries, the defendant's insurance company refused to make a reasonable offer of settlement.

GoldenbergLaw agreed to represent Rebecca and vigorously litigated the case. The defense hired experts who claimed Rebecca had made a near full recovery from her incident and had no lasting objective or neurologic findings. GoldenbergLaw retained a neuropsychologist, a psychologist, and a brain injury specialist to substantiate Rebecca's diagnosis and her permanent injuries.

The case proceeded to mediation without success. Our firm prepared for trial and forwarded all of our exhibits to the defendant, including the exhibit shown to the left. As a result of our preparation, the case then resolved for a significant confidential sum. We are happy for Rebecca and glad to have provided her with a means of moving on with her life. We wish her and her husband all the best.



**T**eresa Scholtz has worked on over 600 cases since she started as a legal assistant at GoldenbergLaw. Working exclusively on mass tort cases, she is responsible for ordering and reviewing records, drafting demands, serving discovery, working up and filing cases, organizing inventory of files, and updating clients on the status of their cases. In addition to helping our clients, she serves as the main point of contact for other counsel that we work with on mass tort litigations.

### Get to Know Teresa:

**Do you have any pets?**

Yes—we have a Yellow Lab named Sunny and we recently adopted a German Shepard mix named Max.

**If you won the lottery, what is the first thing you would do?**

Pay all my bills, then take a lavish vacation!

**What was your favorite food when you were a child?**

Artichokes dipped in mayonnaise.

**What's the #1 most played song on your iPod?**

You Are The Best Thing...Ray LaMontagne

**What is one of your favorite quotes?**

And in the end, it's not the years in your life that count. It's the life in your years. —Abraham Lincoln

**What's your favorite indoor/outdoor activity?**

Indoor: reading

Outdoor: gardening

**What chore do you absolutely hate doing?**

Scrubbing toilets and bathtubs

**What is your favorite form of exercise?**

Dance parties in the living room.

**What is your favorite part about working at GoldenbergLaw?**

Getting to know the clients and trying to help them when times are hard

**What are you looking forward to this spring/summer?**

My wedding, hanging out and entertaining guests at our pool, and gardening



Pictured: Teresa with her three kids  
Grace (11), Ben (8), and Jack (4)

Stuart Goldenberg recently spoke at the AAJ Winter Convention in Miami and at the HB Pharmaceutical Conference in Los Angeles on Medtronic Infuse Bone Graft Litigation.

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## **Areas of Expertise**

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Catastrophic Injury

Insurance Disputes