SUPREME COURT OF THE STATE OF NEW YORK **Index No.103297/08**
COUNTY OF RICHMOND DCM PART 3 **Motion No.:001, 002**

CAROL KELLER,

Plaintiff

against

MEDTRONIC SOFAMOR DANEK, USA, INC.,
SPINALGRAFT TECHNOLOGIES, LLC,
REGENERATION TECHNOLOGIES, INC.,
BIOMEDICAL TISSUE SERVICES, LTD.,
MICHAEL MASTROMARINO,
JOSEPH NICELLI,
ABC BUSINESS ENTITIES 1-10 and
JOHN DOES 1-10,

Defendants

DECISION & ORDER

HON. JOSEPH J. MALTESE

The following items were considered in the review of the following motions to dismiss.

Papers	Numbered
Notice of Motion and Affidavits Annexed	1
Notice of Cross-Motion and Affidavits Annexed	3
Answering Affidavits	4
Replying Affidavits	5
Exhibits	Attached to Papers
Memorandum of Law	2

Upon the foregoing cited papers, the Decision and Order on this Motion is as follows:

Defendants Medtronic Sofamor Danek, USA, Inc ("Medtronic"), Spinalgraft Technolgies, LLC ("Spinalgraft") move pursuant to the New York Civil Practice Law and Rules (CPLR) § 3211(a)(7) to dismiss the plaintiff's complaint for failure to state a cause of action. Co-Defendant, Regeneration Technologies, Inc. ("RTI") cross-moves for the same relief. The motions are granted to the extent they seek the dismissal of the causes of action for, negligence, punitive damages, and respondeat superior.

Facts

On February 2, 2005, the plaintiff, Carol Keller, underwent a cervical corpectomy with the fusion at C3-C7. The surgery required that an allograft bone product supplied by Medtronic and produced by RTI be implanted into Ms. Keller. An allograft is a manufactured and processed human bone or tissue product obtained from a human cadaver and transplanted into a living person for medical reasons, including orthopedic surgery.

Biomedical Tissue Services, Ltd. ("BTS") is a company founded by Michael Mastromarino, an oral surgeon, and Joseph Nicelli, a master embalmer, to harvest human tissue from corpses for use in medical devices and implants. RTI utilized BTS's services to act as tissue recovery agents in order to provide it with the necessary human tissue needed to create allografts for distribution for surgical procedures.

A criminal investigation into the practices of Michael Mastromarino and his company, BTS, revealed that both he and his partner, Nicelli, harvested tissue and bones from human bodies, improperly obtained from various funeral homes. In the course of their harvesting, Mastromarino and Nicelli did not obtain the permission of the deceased person's family prior to removing tissue. As a result, the validity of medical records, death certificates and even the identities of the so-called "donors" were suspect. The tissue harvested and sold to RTI therefore was not subjected to the rigorous screening process necessary to identify whether the tissue came from individuals that suffered from infectious diseases or were too old to be considered viable tissue donors.

RTI's website displays the following information:

> RTI is committed to providing the safest and highest quality allografts for use in spine, sports medicine and other orthopedic surgeries. RTI holds the patents* on BioCleanse®, the only proven tissue sterilization process validated to eliminate viruses, bacteria, fungi and spores from tissue without impacting the structural or biomechanical integrity of the allograft. In addition to our

> sterilization capability, all donor tissue must meet strict criteria to be released for implantation. In addition to serological and medical record screening, high risk behavior is also evaluated. RTI performs multiple reviews, including:
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> Behavioral/Lifestyle Risk Assessment
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> Family/Next-of-Kin Interview
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> Medical Record Evaluation/Hospital Records
>
> Medical Examiner/Coroner's Report
>
> Medical/Social History Evaluation
>
> ***BioCleanse is covered by U.S. Patents 6,482,584; 6,613,278 and 6,652,818 and pending U.S. and foreign applications in the name of RTI Biologics, Inc.* [1]

The plaintiff's complaint alleges that both Medtronic and RTI had knowledge that BTS and its principals were not adhering to the standards listed on RTI's web site prior to the criminal investigation. The allegations contained in the plaintiff's complaint set forth that bone allografts have been linked to various complications that include viral, fungal and bacterial infections and death.

On or about October 14, 2005, RTI issued a voluntary recall of all tissue it received from BTS. Later in February of 2006 the Food and Drug Administration ("FDA") ordered BTS to close its operations. Subsequent to the February closure of BTS, the plaintiff's surgeon notified her that the bone allograft implanted into her cervical spine came from improperly obtained and dissected tissue harvested by BTS. At the same time Keller's surgeon indicated that she would need to undergo a battery of blood testing to determine if she contracted various infections.

Due to the improper records kept by BTS and RTI the plaintiff was unable to ascertain

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[1]http://www.rtix.com/ScienceAndSafety.aspx (Accessed March 30, 2009) prior link cited in plaintiff's complaint http://www.rtix.com/products/index.cfm was not functioning upon consideration of this motion. The cited website contains the same language cited in the plaintiff's complaint.

whether she received contaminated human tissue. As such the plaintiff alleges at paragraph twenty-eight of her complaint that she " . . . was one of the recipients of such contaminated, diseased and/or defective allograft bone products from RTI."

Medtronic subsidized a patient testing program to conduct the laboratory blood tests for the patients exposed to the human tissue harvested by BTS. At the present time, the plaintiff's blood has not tested positive for exposure to any infection or disease. While the plaintiff utilized the blood tests provided by Medtronic she alleges that a negative result does not assure freedom from disease. The plaintiff's complaint further alleges that since the bone allograft implanted into her cervical spine cannot be removed or replaced she remains at risk to develop illness in the future, highlighting the fact that the bone used the create the allograft was potentially taken from a "donor" too old to provide such tissue, or it may be arthritic. The plaintiff's complaint alleges that the true extent of the actions taken by the defendants will not be known until a significant period of time has passed.

The defendants, Medtronic, Spinalgraft and RTI move to have plaintiff's complaint dismissed pursuant to CPLR § 3211(a)(7) for its failure to state a cause of action citing generally to the facts that the plaintiff: 1) has not demonstrated proof of actual contact with any disease causing agent; and 2) that she has not manifested any disease.

Discussion

The scope of a court's inquiry on a motion to dismiss under CPLR § 3211 is narrowly circumscribed. The court must accept the facts alleged as true and determine simply whether the facts alleged fit within any cognizable legal theory. The court must accept as true not only the complaint's material allegations, but also whatever can be reasonably inferred therefrom in favor of the pleader. In ruling on a motion to dismiss the court is not authorized to assess the merits of the complaint or any of its factual allegations, but only to determine if, assuming the truth of the

facts alleged, the complaint states elements of a legally cognizable cause of action.[2]

Violation of NY General Business Law (GBL) § 349

Keller's complaint alleges that the defendants violated New York State's consumer protection law as defined by GBL § 349, which states in pertinent part that:

> [d]eceptive acts or practices in the conduct of **any** business, trade or commerce or in the furnishing of **any** service in this state are hereby declared unlawful.[3]

GBL § 349 carves out a private cause of action in subsection (h), which states in pertinent part that:

> . . . any person who has been injured by reason of any violation of this section may bring an action in his own name to enjoin such unlawful act or practice, an action to recover his actual damages or fifty dollars, whichever is greater, or both actions. The court may, in its discretion, increase the award of damages to an amount not to exceed three times the actual damages up to one thousand dollars, if the court finds the defendant willfully or knowing violated this section. The court may award reasonable attorney's fees to a prevailing plaintiff.[4]

In order to be successful in a private action under GBL § 349 a plaintiff must show: 1) the acts or practices of the defendant have a broad impact on consumers at large; 2) the act or practice is misleading in a material way, and 3) that the practice injured the plaintiff by reason thereof. The representations or omissions are limited to those likely to mislead a reasonable

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[2] *P.T. Bank Central Asia v. ABN Amro Bank N.V.*, 301 AD2d 373, [1st Dep't 2003]; *See also, Kevin Spence & Sons, Inc. v. Boar's Head Provisions Co.*, 5 AD3d 352, [2d Dep't, 2004].

[3] GBL § 349(a)[emphasis added].

[4] GBL § 349(h).

consumer acting reasonably under the circumstances.[5]

The New York Court of Appeals in *Karlin v. IVF America, Inc.* in overturning the Appellate Division held that the protection of GBL § 349 extended to medical service providers. In so doing the Court of Appeals reasoned that:

> [a] blanket exemption for providers of medical services and products is contrary to the plain language of the statutes, [referring to GBL §§ 349 and 350] Such an exemption is also contrary to legislative history, as supporters of the consumer protection bills recognize that consumers of medical services and products might be particularly vulnerable to unscrupulous business practices. In fact, in a memorandum to the Governor advocating section 350, the only example cited by the Attorney General to underscore the need for such legislation was an Arthritis and Rheumatism Foundation report concluding 'that through fraudulent advertising people suffering from painful diseases such as arthritis are being duped out of 250 million dollars annually.'[6]

It is clear that GBL § 349 is meant to apply medical service providers. Therefore the court's inquiry is limited to determining whether the four corners of the plaintiff's complaint sets forth a cause of action under the statute. Based on the allegations contained in the plaintiff's complaint, this court finds that the alleged dissemination improperly screened human tissue by the defendants into the stream of commerce where it would ultimately be implanted into individuals has a broad impact on consumers as a whole. Further, the plaintiff's complaint at paragraph 149(a),(b), (c), (d), (e) and (f) allege facts that indicate that the defendants offered information to potential consumers and users of its product that may be found to be misleading by a trier of fact. It is also uncontested that the human tissue implanted into the plaintiff was not what the plaintiff bargained for when she agreed to undergo her cervical spinal fusion. Based on

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[5] *Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank,* 85 NY2d 20, [1995].

[6] *Karlin v. IVF Am.*, 93 NY2d 282 [1999](internal citations omitted).

the foregoing the plaintiff alleges that she sustained personal injuries.

The court finds that the four corners of the plaintiff's complaint more than adequately alleges a cause of action on which relief may be granted.

Intentional Misrepresentation

The plaintiff's third cause of action for intentional misrepresentation sounds in fraud. The elements of a common law claim for fraud are: (1) that the defendant made material misrepresentations that were false; (2) that the defendant knew the representations were false and made them with the intent to deceive the plaintiff, (3) that the plaintiff justifiably relied on the defendant's representations, and (4) that the plaintiff was injured as a result of the defendant's representations.[7]

The plaintiff's complaint at paragraph 109 alleges that:

> [t]he Medtronic Defendants intentionally made numerous false, misleading, and fraudulent representations to the general public, including Plaintiff, and to Plaintiff's health care providers, by representing that the allograft bone product they distributed was properly procured, harvested, tested, and preserved in accordance with industry standards, Federal regulations and the laws of the State of Florida . . .

The plaintiff's complaint further alleges that the misrepresentations related to material facts that were relied on by the plaintiff to her detriment that caused her to undergo medical testing. As such the four corners of the plaintiff's complaint set forth a legally adequate cause of action for fraud.

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[7] *Cash v. Titan Financial Services*, 58 AD3d 785, [2d Dep't 2009].

Negligent Misrepresentation

The plaintiff's claim for negligent misrepresentation sounds in constructive fraud. The elements for a cause of action sounding in constructive fraud are: that (1) a representation was made, (2) the representation dealt with a material fact, (3) the representation was false, (4) the representation was made with the intent to make the other party rely upon it, (5) the other party did, in fact, rely on the representation without knowledge of its falsity, (6) injury resulted and (7) the parties are in a fiduciary or confidential relationship.[8]

The cause of action for constructive fraud, while similar to actual fraud omits the element of *scienter*.[9] However, in place of the *scienter* element, constructive fraud requires that the plaintiff allege a confidential or fiduciary relationship in its place.

The Appellate Division, Second Department held that a:

> . . . fiduciary relationship 'whether formal or informal, is one founded upon trust or confidence reposed by one person in the integrity and fidelity of another . . . [and] might be found to exist, in appropriate circumstances, between close friends . . . or even where confidence is based upon prior business dealings' . . . 'It is said that the relationship exists in all cases in which influence has been acquired and abused, in which confidence has been reposed and betrayed.' However, a conventional business relationship, **without more**, is a insufficient to create a fiduciary relationship. . . Rather, a plaintiff must make a 'showing of special circumstances' that could have transformed the parties' business relationship to a fiduciary one . . .[10]

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[8] *DelVechio v. Nassau County*, 118 AD2d 65, [2d Dep't, 1986].

[9] *Monaco v. New York University Medical Center*, 213 AD2d 167, [1st Dep't, 1995].

[10] *AHA Sales, Inc. v. Creative Bath Products, Inc.*, 58 AD3d 6, [2d Dep't 2008](emphasis added)..

The moving defendants argue that the plaintiff fails to demonstrate a "a relationship or bond" with them. This court does not agree.

A court's inquiry into the whether a fiduciary relationship exists extends beyond the determination whether such a relationship is memorialized in a writing. Instead, ". . . a court will look to whether a party reposed confidence in another and reasonably relied on the other's superior expertise or knowledge . . . Thus, the ongoing conduct between parties may give rise to a fiduciary relationship that will be recognized by the courts. . ."[11]

The Appellate Division, Second Department expounded on the definition of a fiduciary relationship in *Penato v. George.*[12] In that case, the Appellate Division, Second Department reasoned that a fiduciary relationship exists even in informal relationships ". . .whenever one man trusts in, and relies upon, another. . ."[13]

In this case the court must determine whether a fiduciary relationship exists between a manufacturer of a bone allograft and the subsequent recipient in order to survive a motion to dismiss. According to the allegations contained in the plaintiff's complaint, Medtronic entered into an exclusive agreement to distribute bone allografts produced by RTI.

The plaintiff alleges that RTI held itself out to the market as being vigilant guard against the spread of disease through its allografts. In particular, the plaintiff alleges that RTI subjected the donor tissue used in its alografts to a stringent screening process designed to eliminate a number of risks. According to paragraph 21 of the plaintiff's complaint, RTI's own published protocol requires "serological and microbiological tests to ensure the suitability of tissue and sterilization of the allografts."

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[11] *Wiener v. Lazard Freres & Co.,* 241 AD2d 114, [1st Dep't 1998](internal citations omitted).

[12] 52 AD2d 939, [2d Dep't, 1976].

[13] Id.

With respect to Medtronic, the plaintiff alleges at paragraph 37 of her complaint that it issued a statements assuring physicians, consumers and the plaintiff that " . . . the tissue we distribute has been processed using a validated cleansing and sterilization methodology designed to eliminate viruses, bacteria, fungi and spores. If we were not entirely confident in these processes and the safety profile of the tissue we distribute then we would not be providing it to our surgeon consumers and their hospitals."

The plaintiff alleges at paragraph 25 (a) through (c) that these statements were delivered by the defendants, Medtronic and RTI into the market even after the FDA cited the defendant RTI in 1999, 2000, and 2004. Furthermore, at paragraphs 12 and 59 the plaintiff alleges that the defendants, Mastromarino and BTS were not certified by the American Association of Tissue Banks (AATB) or properly licensed as a recognized blood and/or tissue bank; and that as a result of this fact, RTI and Medtronic ". . . knew or should have known that BTS and Mastromarino were not certified by the AATB and thus, given industry practice standards, were on notice to provide even more detailed scrutiny to BTS-supplied bone and tissue, paperwork and donor records."

The allegations contained in the plaintiff's complaint give rise to an affiliation that may go beyond a conventional business relationship and constitute a relationship that is fiduciary in nature. In this case the manufacturer creates a product that is cultivated from one person's anatomy for the subsequent implantation into another person. The moving defendants' product is not a purely artificial medical device that finds its way into patients. It is for that reason the defendants' business cannot be classified as a conventional business. It is the finding of this court that the type of business conducted by the defendants, Medtronic, Spinalgraft, and RTI, constitutes a "special circumstance" contemplated by the Appellate Division, Second Department in *AHA Sales, Inc. v. Creative Bath Products, Inc.*[14]

[14] *AHA Sales, Inc. v. Creative Bath Products, Inc.*, *supra*

It is the finding of this court that after giving the plaintiff's complaint every favorable inference, a fiduciary relationship may exist between the plaintiff and the defendants, Medtronic, Spinalgraft and RTI.

Even in the event that a fiduciary relationship is not established by the plaintiff between herself and the defendants, Medtronic, Spinalgraft and RTI, the Appellate Division, Second Department recognizes that a cause of action for constructive fraud may exist in a conventional business relationship absent a showing of a fiduciary relationship. In *Brown v. Lockwood,* the Appellate Division, Second Department evaluated whether a constructive fraud existed in a business context ". . . based upon promises of future performance."[15] The Appellate Division, Second Department recognized that claims of constructive fraud have been sustained ". . . where the defendant promisor has, or should have, superior and accurate knowledge concerning the matters to which his statements relate."[16] In evaluating that rule the Appellate Division, Second Department reasoned that:

> [s]uffice it to say that in purely business transactions the defendant against whom constructive fraud is alleged must have misled the plaintiff by false representations concerning the subject of his superior knowledge or expertise.[17]

The court further issued a statement advising that claims based on such a set of facts are rarely sustained.[18] However, at this procedural juncture this court cannot conclude that the conduct and the general position of the defendants, Medtronic, Spinalgraft and RTI, would not entitle the plaintiff to proceed under this theory.

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[15] *Brown v. Lockwood*, 76 AD2d 721, [2d Dep't 1980].

[16] *Id.*

[17] *Id.*

[18] *Id.*

Negligent and Intentional Infliction of Emotional Distress

The plaintiff's complaint alleges two separate causes of action for negligent and intentional emotion distress stemming from the implantation of a bone allograft that was not properly screened by the moving defendants, Medtronic, Spinalgraft and RTI. At paragraph 28 of the plaintiff's complaint she alleges that she, " . . was one of the recipients of such contaminated, diseased and/or defective bone products from RTI." The plaintiff's exposure to this bone product forced her to undergo testing to determine if she contracted any diseases as a result. The plaintiff asserts two causes of action in an attempt to recover for the emotional distress she experienced as a result of her contact with the bone allograft implanted in her cervical spine.

A claim for negligent infliction of emotional distress does not require a physical injury as a necessary element, such a claim must

> . . . be premised upon the breach of a duty owed to the plaintiff which either unreasonably endangers the plaintiff's physical safety, or causes the plaintiff to fear for his or her own safety . . . Moreover, a cause of action for either intentional or negligent infliction of emotional distress must be supported by allegations of conduct by the defendants 'so outrageous in character, and so extreme in degree, as to go beyond all possible bounds of decency. . .'[19]

The defendants argue that the plaintiff's causes of action must be dismissed at this juncture, as the plaintiff has not alleged that she developed any disease, nor has she demonstrated that she was not actually exposed to any disease.

The cases cited by the defendants involve similar factual situations in which the plaintiffs

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[19] *Sheila C. v. Povich,* 11 AD3d 120, [1st Dep't, 2004](internal citations omitted].

sought to recover for emotional distress claimed for exposure to the AIDS virus.[20] In each of those cases, the plaintiffs in question engaged in some sort of action that placed themselves in a position to be exposed to instruments that were in contact with an individual's bodily fluids. In *Kelly v. Our Lady of Mercy Medical Center*, the plaintiff pricked herself on a lancet. At the time of her exposure to the lancet approximately 25% of the hospital's patients were HIV positive. The plaintiff then began a course of treatment as if she was exposed to HIV. In *McLarney v. Community Health Plan*, a needle pricked the plaintiff when he removed trash from a medical facility. In that case, the plaintiff was told to proceed with a course of treatment as if he was exposed to the HIV virus. And in *Bishop v. Mount Sinai Medical Center*, the plaintiff alleged that as she exited a hospital facility a plastic dumpster careened off a loading dock and struck her. As she raised her hands to protect her face from impact she alleged she was cut by a sharp object. In each of the above cited cases, the plaintiffs causes of action for infliction of emotional distress were dismissed as it was never demonstrated that plaintiff was actually exposed to the HIV virus.

It is important to note that the factual situations presented in the above referenced cases differ considerably from the facts of this case. In each of the aforementioned cases, the plaintiffs inadvertently came into contact with untreated waste products that may have contained tainted bodily fluids.

The facts presented to this court differ considerably from those cited by the defendants. First, the plaintiff purposefully agreed to have a sterilized bone allograft implanted into her cervical spine. According to the plaintiff's complaint, she agreed to implant donor tissue into her cervical spine based on representations made to her through her health care providers that the donor tissue used in the bone allografts was subjected to a rigorous screening process. Additionally, representations were made to the market that the donor tissue received by the

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[20] *See, Kelly v. Our Lady of Mercy Med. Ctr.,* 279 AD2d 290, [1st Dep't, 2001]; *McLarney v. Community Health Plan*, 250 AD2d 310, [3rd Dep't]; *Bishop v. Mount Sinai Med. Ctr.*, 247 AD2d 329, [1st Dep't, 1998].

defendants was thoroughly screened and subject to further sterilization by a patented process.

Unlike the plaintiffs in the cases cited by the defendants, the plaintiff invited the implantation of foreign human tissue into her body in connection with a surgical procedure, based on representations by the defendants, Medtronic, Spinalgraft and RTI, that the bone allografts were sterile and safe for implantation. The defendants in the cases cited by, Medtronic, Spinalgraft and RTI, never took affirmative steps to represent that the bodily fluids introduced to those plaintiffs was sterilized or screened prior to their contact with the bodily fluid.

The Appellate Division, Second Department articulated the reasoning behind the actual exposure rule in *Brown v. New York City Health and Hospitals Corporation*.[21] In that case the court reasoned that:

> [r]equiring proof of actual exposure . . . will, we believe, insure that there is a genuine basis for the plaintiff's fear of developing the disease, that the fear is not based on public misconceptions about the disease, and that such claims are treated consistently. Moreover, we emphasize that '[t]he existence of the channel for infection makes the threat of infection much more of a real possibility to be feared and far more than a speculative worry. Liability in the absence of a channel could provoke a flood of ill-justified litigation. Of course, it is the channel for infection, not actual HIV transmission or infection, which much be proven. . .'[22]

A court's inquiry must therefore concern whether a plaintiff was exposed to a channel of infection to insure that the threat of infection was a real possibility to be feared. The facts of this case as presented in the plaintiff's complaint demonstrate that it was the defendants, Medtronic, Spinalgraft and RTI that informed the plaintiff that she was exposed to a channel infection. At paragraph 43 of the plaintiff's complaint the plaintiff alleges that:

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[21] *Brown v. New York City Health and Hospitals Corporation*, 225 AD2d 36, [2d Dep't, 1996].

[22] *Id.*

> [o]n or about October 14, 2005, Defendant RTI issued a voluntary recall of all tissue it received from BTS, "as a result of information regarding the accuracy of donor screening documentation" and acknowledged "a lack of assurance of donor identity as well as the risk of infectious diseases also exist.

At paragraph 46 of the plaintiff's complaint the plaintiff alleges that:

> . . . [she] received the alarming news from her surgeon . . . that the allograft bone product in her body had come from the improperly obtained and dissected tissue harvested by BTS, and processed and distributed by Defendant RTI and the Medtronic defendants. . .

At paragraph 48 the plaintiff alleges that she:

> . . . was advised by her surgeon that she must undergo blood testing to see if the allograft bone product she received and now carried in her body was infected with, *inter alia*, syphilis, HIV-1, HIV-2, AIDS, or hepatitis.

And finally at paragraph 49 the plaintiff alleges that:

> . . . Medtronic Defendants announced a Patient Testing Program, paid for by the Medtronic Defendants, to conduct laboratory blood tests on patients who had received allografts subject to the recall.

As the previously quoted language from the Appellate Division, Second Department's decision in *Brown v. New York City Health and Hospitals Corporation* makes clear, the requirement of actual exposure to an infectious disease where the disease is not present was formulated to prevent spurious law suits from flooding the courts. The court finds the holding of the Appellate Division, Third Department's decision in *Fosby v. Albany Memorial Hospital* compelling.[23] In that case the Appellate Division, Third Department held that a plaintiff may pursue a claim for negligent infliction of emotional distress absent proof of actual exposure to an

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[23] *Fosby v. Albany Mem. Hosp.*, 252 AD2d 606, [3rd Dep't, 1998].

infectious disease. Quoting the Court of Appeals in its decision, *Johnson v. State of New York*[24], the Appellate Division, Third Department held ". . . where, 'there exists an especial likelihood of genuine and serious mental distress, arising from special circumstances, which serves as a guarantee that the claim is not spurious'"[25] applied to claims where the plaintiff cannot demonstrate actual exposure to an infectious disease.

This court finds that the facts that the defendants, Medtronic, Spinalgraft, and RTI, represented that the human tissue used in the creation of the bone allografts utilized in the cervical fusion surgery performed on the plaintiff was screened and underwent a patented process to be disease free, and the plaintiff's reliance on those representation constitute the "special circumstances" contemplated by the court in the *Fosby* decision.[26]

Unlike the plaintiff in *Aberbach v. Biomedical Tissue Services, Ltd.*, where the Appellate Division, Second Department reversed the trial court's denial of a motion to dismiss with respect to negligent infliction of emotional distress, the plaintiff in this case alleged that she was exposed to infectious diseases.[27] As such the plaintiffs claims for negligent and intentional inflection of emotional distress cannot be dismissed.

Medical Monitoring

The plaintiff's complaint demands judgement against the defendants for the costs related to medical monitoring. In order to recover for a cause of action for future medical monitoring a

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[24] *Johnson v. State of New York*, 37 NY2d 378, [1975].

[25] *Fosby v. Albany Mem. Hosp, supra.*

[26] *See, Schulman v. Prudential Ins. Co.,* 226 AD2d 164 [1st Dep't, 1996](Court found that the erroneous report of a positive finding for HIV following a blood analysis constitutes a "special circumstance.")

[27] *Aberbach v. Biomedical Tissue Servs., Ltd.*, 48 AD3d 716, [2d Dep't, 2008].

plaintiff must establish: 1) that the plaintiff was exposed to a disease causing agent; and 2) that there is a "rational basis" for his or her fear of contracting a disease.[28] A "rational basis" has been defined as a clinically demonstrable presence of a toxins within the plaintiff's body or some physical manifestation of the existence the toxic contamination.[29]

The plaintiff's complaint alleges that the bone allograft implanted in her cervical spine was not properly screened by the defendants. Additionally, the plaintiff's complaint further alleges that the defendants recognized the defective nature of the bone allograft and issued a recall. As such, the plaintiff's complaint satisfies the first prong of the inquiry, in that the plaintiff was exposed to a disease causing agent.

Presently, the defective bone allograft is permanently fused to the plaintiff's cervical spine. In the *Abusio*[30] case cited by the defendants, the plaintiff came into contact with cancer causing agents in the environment. In this case the plaintiff argues that bone allograft implanted in the plaintiff's cervical spine, although currently free from the diseases such as HIV and syphilis, may still be defective due to the donor source. There is no question that potentially the disease causing material is in the plaintiff's body. The plaintiff contends that because the admittedly defective bone allograft may injure her in the future, the defendants should bear the cost of monitoring her condition and that of their bone allograft.

This court finds that the existence of the defective bone allograft in the plaintiff's body satisfies the second requirement, and that she has a "rational basis" for her fear of contracting a disease.

As such the plaintiff's cause of action for medical monitoring cannot be dismissed.

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[28] *Abusio v. Consolidated Edison Co. of N.Y.,* 238 AD2d 454, [2d Dep't, 1997].

[29] *Id.*

[30] *Id.*

Strict Liability/ Express and Implied Warranties

The plaintiff alleges that she should be permitted to assert causes of action against the defendants for strict products liability and breach of express and/or implied warranties. A threshold issue for consideration by the court is whether human tissue in the form of a bone allograft a product.

The defendants argue that the New York State Blood Shield statute, codified as Public Health Law (PHL) § 580(4), should be extended to encompass not only blood, but other human tissue inclusive of the bone allografts. PHL § 580(4) states in pertinent part that:

> [t]he collection, processing, storage, distribution or use of blood, blood components or blood derivatives for the purpose of diagnosis, prevention or treatment of disease is hereby declared to be a public health service and shall not be construed to be, and is declared not to be, a sale of such blood, blood components or blood derivatives, for any purpose or purposes whatsoever.[31]

In 2004, Justice Laura Jacobson of the New York Supreme Court sitting in Kings County examined such an argument in *Glasgow v. Chou*.[32] In determining whether New York state's Blood Shield statute encompassed human tissue the court considered judicial opinions from several sister states and concluded that the statute did in fact extend to protection to human tissue in the form of bone allografts.

Unlike the case before this court, the court in *Glasgow* evaluated the plaintiff's causes of action for strict liability and breach of implied and/or express warranties in the context of a

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[31] Public Health Law § 580.

[32] *Glasgow v. Chou*, [Sup Ct, Kings County, August 20, 2004, Jacobson, J., index No. 104849/01].

summary judgment motion after the completion of discovery. The current set of facts before the court differs further from those presented in *Glasgow*, in that the defendants in that case asserted for the record that:

> . . . [their] own handling, testing storage and use of the allograft material up to the point of its introduction into the plaintiff's person during the transplant procedure was in accordance with the strict sterile guidelines, protocols and procedures mandated by, as relevant, the American Association of Tissue Banks, the Federal Food and Drug Administration (FDA), generally accepted medical standards and practices and its own internal policies.[33]

Such factual conditions are not present in the case presently before the court. It is uncontested that defendants, Medtronic, Spinalgraft and RTI, utilized tissue that was woefully inadequately monitored, and was recalled by the FDA.

Furthermore, the out of state cases cited by the moving defendants, and relied upon by Justice Jacobson in her decision in *Glasgow* did not involve human tissue that was harvested with a flagrant disregard for industry standards and practices.[34]

While this court does not disagree that the Blood Shield statute should be extended to encompass human tissue, it remains to be seen whether a medical service provider of human tissue should benefit from its protection when it is alleged that it knowingly distributed tainted bone allografts into the stream of commerce.

As such, this court will not dismiss the products liability and the breach of implied and/or express warranties cause of action at this time.

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[33] *Id.*

[34] *See, Condos v. Musculoskeletal Transplant Foundation,* 208 F Supp 2d 1226, [D Utah 2002]; *Cryolife, Inc. v. Superior Court*, 110 Cal App 4th 1145, 2 Cal Rptr 3d 396, [Cal 2003]

Negligence

The plaintiff's cause of action sounding in negligence is dismissed pursuant to the Appellate Division, Second Department's decision in *Aberbach v. Biomedical Tissue Services, Ltd.*[35] The plaintiff fails to allege a cognizable injury as a result of the defendants' alleged negligence. In the event that the plaintiff does develop an injury stemming from the implantation of the allegedly contaminated bone allograft, she can then bring another action within three years of its discovery pursuant to CPLR § 214-c.[36]

As such, even after considering the complaint in the light most favorable to the plaintiff the defendants motion to dismiss the plaintiff's negligence claim is granted.

Respondeat Superior

The defendants' motion to dismiss the plaintiff's claim for respondeat superior is granted. Even giving the plaintiff's complaint every reasonable inference the court finds that there are no facts to support an allegation that the Mastromarino and Nicelli were acting within the scope of their employment at the human tissue was harvested.

Punitive Damages

The plaintiff's cause of action for punitive damages must be dismissed as New York does not recognize punitive damages as an independent cause of action.[37] Punitive damages are permitted when the conduct was not simply intentional, but evinced a high degree of moral turpitude and demonstrated such wanton dishonesty as to imply a criminal indifference to civil

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[35] *Aberbach v. Biomedical Tissue Services, Ltd.*, 48 AD3d 716, [2d Dep't, 2008].

[36] *See, Wolf v. A-One Oil, Inc.*, 216 AD2d 291, [2d Dep't, 1995].

[37] *Osborne v. Zomberg*, 16 AD3d 643, [2d Dep't, 2005].

obligations.[38] To warrant an award of punitive damages, there must be proof of recklessness, or a conscious disregard of the rights of others.[39] In the Second Department this proof must be demonstrated through clear and convincing evidence.[40]

While the court must dismiss the plaintiff's separate cause of action for punitive damages, it grants the plaintiff permission to amend her complaint to request punitive damages for specific causes of action heretofore pled.

Assault and Battery

While the plaintiff's complaint labels a claim for *assault* and battery the facts alleged sound in exposure to a toxic substances. As such CPLR § 214-c(2) applies, which states in part that:

> . . . the three-year period within which an action to recover damages for personal injury. . . caused by the latent effects of exposure to any substance or combination of substances, in any form, upon or within the body. . . must be commenced shall be computed from the date of discovery of the injury by the plaintiff or from the date when through the exercise of reasonable diligence such injury should have been discovered by the plaintiff, whichever is earlier.

The plaintiff underwent her cervical spine surgery on February 2, 2005. She was subsequently notified of the recall some time after the FDA announced the recall of the bone allografts sold by RTI from human tissue harvested by BTS on October 14, 2005. The plaintiff commenced this action on or about January 30, 2008. As such, even assuming the earliest date of knowledge, the plaintiff's claim is not time barred. Therefore, the court will not dismiss the

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[38] *Id.*

[39] 1 PJI3d 2:278, at 1487 [2008].

[40] 1 PJI3d 2:278, Comment, Caveat 1.

plaintiff's claims for *assault* and battery at this juncture.

Conclusion

The scope of a court's inquiry on a motion to dismiss under CPLR § 3211 is narrowly circumscribed. The court must accept the facts alleged as true and determine simply whether the facts alleged fit within any cognizable legal theory. The court must accept as true not only the complaint's material allegations but also whatever can be reasonably inferred there from in favor of the pleader. In ruling on a motion to dismiss the court is not authorized to assess the merits of the complaint or any of its factual allegations but only to determine if, assuming the truth of the facts alleged, the complaint states elements of a legally cognizable cause of action.[41] As such, the plaintiff's first, seventh, eleventh, and fifteenth causes of action are dismissed.

Accordingly, it is hereby:

ORDERED, that Defendants Medtronic Sofamor Danek, USA, Inc ("Medtronic"), Spinalgraft Technolgies, LLC ("Spinalgraft") motion and Co-Defendant, Regeneration Technologies, Inc. ("RTI") and cross motion are granted to the extent they seek the dismissal of the plaintiff's first, seventh, and eleventh causes of action; it is further

ORDERED, that the plaintiff may amend her complaint to include requests for punitive damages for specific causes of action heretofore pled; and it is further

ORDERED, that the parties report to DCM Part 3 on Tuesday, May 19, 2009 at 9:30 A.M. for a Preliminary Conference.

ENTER,

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[41] *P.T. Bank Central Asia v. ABN Amro Bank N.V.*, *supra.*

DATED: April 14, 2009

Joseph J. Maltese
Justice of the Supreme Court