

EXHIBIT A

EXHIBIT A

ORIGINAL

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Nov 1 4 58 PM '07

CLERK OF THE COURT

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1 **COM**
2 MARK HENNESS, ESQ.
3 Nevada Bar No. 5842
4 HENNESS & HAIGHT
5 8972 Spanish Ridge Avenue
6 Las Vegas, Nevada 89148
7 (702) 862-8200
8 Attorneys for Plaintiff

**DISTRICT COURT
CLARK COUNTY, NEVADA**

9 ROGER MILLER, an individual,

10 Plaintiff,

11 vs.

12 DePUY SPINE, INC., a Massachusetts
13 corporation; JOHNSON & JOHNSON, Inc., a
14 New Jersey corporation; HUBER MEDICAL
15 SYSTEMS, a California Corporation; DOES I -
16 X; and ROE CORPORATIONS I - X, inclusive,

17 Defendants.

Case No.:
Dept No.:

*A551017
XVI*

COMPLAINT

18 COMES NOW Plaintiff, ROGER MILLER, by and through his attorney MARK G.
19 HENNESS, ESQ., of the law firm of HENNESS & HAIGHT, and for his causes of action against
20 Defendants, and each of them, alleges as follows:
21

GENERAL ALLEGATIONS

22 1. At all times relevant to these proceedings, Plaintiff, ROGER MILLER was and is a
23 resident of Clark County, Nevada.
24

25 2. Defendant DePuy Spine, Inc., is a Massachusetts corporation with its principal place of
26 business located in Raynham, Massachusetts.
27
28

1 3. Defendant Johnson & Johnson, Inc. is a New Jersey Corporation with its principal place
2 of business in New Brunswick, New Jersey.

3 4. Upon information and belief Defendant Huber Medical Systems and/or DOE/ROE
4 CORPORATION I sold, marketed or provided the subject product to Plaintiff and his physician.
5

6 5. The true names and capacities, whether individual, corporate, associate or otherwise of
7 Defendants named herein as DOES I through X and ROE CORPORATIONS I through X are
8 unknown to Plaintiff who therefore sues these Defendants by said fictitious names.

9 6. Plaintiff is informed and believes and thereon alleges that each of the Defendants
10 designated as Does and Roes are responsible in some manner for the events and happenings
11 referred to herein, and caused damages proximately to Plaintiff as herein alleged by *inter alia*,
12 manufacturing, designing or distributing defective products or component parts which were
13 unreasonably dangerous, negligently manufacture, designing or distributing products or
14 components which were unreasonably dangerous, and breaching implied or express warranties.
15

16 7. Such Does and Roes Defendants include the entity that provided the subject product to
17 Plaintiff's doctor who, in turn, implanted the device into Plaintiff's spine.
18

19 8. Such Does and Roes Defendants include the successors and predecessors in interest of
20 every other defendant.

21 9. At all times alleged herein, each Defendant was acting as the agent, servant, and
22 employee of each other Defendant.
23

24 10. Plaintiff will ask leave of this Court to amend his Complaint to insert the true names
25 and capacities of Does and Roes Defendants when the same have been ascertained and to join such
26 Defendants in this action.

27 ///

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1 11. All Defendants have had such minimum contacts with the state of Nevada so as to
2 confer jurisdiction over their persons by this Court.

3 12. On information and belief, DePuy Spine, Inc. of DePuy, Inc., a Johnson & Johnson
4 Company, and bills itself as "one of the world's leading designers, manufacturers and suppliers of
5 orthopaedic devices and supplies ... known throughout the medial world for the development,
6 manufacture, and marketing of innovative solutions for a wide range of spinal pathologies."

7
8 13. On information and belief, DePuy Spine, Inc. manufactures, markets and distributes
9 Charité artificial discs.

10
11 14. This case involves an artificial spinal disc researched, developed, manufactured,
12 marketed, promised, advertised, sold, and distributed by Defendants, and each of them, and
13 implanted into Plaintiff ROGER MILLER. The defective Charité disc was deployed and marketed
14 by Defendants, and each of them, for surgical implantation in certain patients, like Plaintiff
15 ROGER MILLER, with lumbar spine pathology.

16
17 15. The Charité disc implanted into Plaintiff ROGER MILLER is an artificial intervertebral
18 disc composed of metal and plastic and was designed to be implanted in certain patients to replace
19 a diseased or damaged intervertebral disc during a surgical procedure called spinal arthroplasty.

20
21 16. On information and belief, in or about 2003, DePuy acquired the Link Spine Group,
22 Inc., and the exclusive worldwide rights to Charité discs.

23
24 17. Charité discs are classified as medical devices. In order to market and sell Charité discs
25 in the United States, Defendants, and each of them, were required to obtain the approval of the
26 Food and Drug Administration ("FDA") pursuant to the Medical Device Amendments, 21 USC
27 §§360c *et seq.*, to the Federal Food, Drug and Cosmetic Act 21 USC §§ 301 *et seq.*

28 ///

1 18. In their efforts to gain approval for the Charité discs, Defendants, and each of them,
2 submitted to the FDA an application for Premarket Approval (“PMA”). PMA applications and
3 post-approval requirements are governed by mandatory federal regulations, directing, for example,
4 what information must be submitted to the FDA for review during and following the approval
5 process. 21 CFR 814 *et seq.*; 21 CFR 803 *et seq.*
6

7 19. On information and belief, in or about February, 2004, Defendants, and each of them,
8 filed their PMA application for Charité discs.

9 20. The FDA approved the sale of Charité discs in October, 2004, based upon information
10 supplied by Defendants, and each of them, and subject to certain post-approval reporting
11 requirements.
12

13 21. These requirements include, *inter alia*, compliance with performance specifications and
14 criteria established by Defendants, and each of them, and approved by the FDA.

15 22. On information and belief, the FDA’s October 26, 2004 notice of approval to
16 Defendants, and each of them, states “Failure to comply with the conditions of approval invalidates
17 this approval order.”
18

19 23. On information and belief, in or about 2004, Defendants, and each of them, began
20 selling Charité discs in the United States for use in patients, like Plaintiff, with lumbar disc
21 pathology at one level in the lumbar spine (L4-S1) and who have had no relief from low back pain
22 after at least six months of non-surgical treatment.

23 24. On or about November 2, 2005, the device was implanted in the Plaintiff by William D.
24 Smith, M.D. at Desert Springs Hospital, in Las Vegas, Clark County, Nevada.

25 25. Upon information and belief, the Charité disc implanted into Plaintiff was provided by
26 Huber Medical Systems, a California corporation, and/or DOE/ROE CORPORATION I.
27
28

1 26. Despite undergoing the implantation surgery, which Plaintiff did based upon
2 representations, express and implied, concerning the Charité disc, its alleged effectiveness in
3 treating the injuries, pathology and pain Plaintiff suffered from, and that this was the most
4 appropriate treatment option for Plaintiff as it was supposed to eliminate the potential for future
5 problems at other levels in his lumbar spine, Plaintiff continued and continues to suffer
6 progressively worsening, severe and debilitating back and leg pain, problems walking and
7 numbness in his legs. Plaintiff's problems have not abated since the implantation and instead have
8 worsened, affecting Mr. MILLER's ability to both work and participate in his activities of daily
9 living.
10

11 27. Plaintiff currently uses substantial amounts of pain medication in an attempt to manage
12 his pain.
13

14 28. Plaintiff has suffered substantial pain, disability, and medical expenses, lost wages and
15 has been unable to lead a normal life since the implantation.
16

17 29. At all times relevant to this action, Defendants, and each of them, knew or had reason
18 to know, that the Charité disc implanted into Plaintiff ROGER MILLER was neither safe nor
19 effective.
20

21 30. As a result of its defective design and manufacture, the Charité disc implanted into
22 Plaintiff ROGER MILLER caused serious physical trauma leading to a worsening of his pre-
23 implantation pain, disability, and requiring further, more evasive medical treatment as a direct
24 result of the implantation of the device.

25 31. Defendants, and each of them, knew or had reason to know of this tendency of the
26 Charité disc resulting risk of injury, and, by failing to disclose the information, prevented Plaintiff
27 and his physician from making an informed decision about the implantation of the device.
28

1 32. The subject medical device, provided, marketed, manufactured and sold by Defendants,
2 and each of them, failed to perform as warranted and violated the conditions of its approval set by
3 the FDA.

4 **FIRST CAUSE OF ACTION**

5 **[Strict products liability]**

6
7 33. Plaintiff re-alleges each and every allegation contained above as though fully set
8 forth herein.

9 34. Defendants, and each of them, are strictly liable to Plaintiff for designing,
10 manufacturing, and/or placing into the stream of commerce defective products or components
11 that were unreasonably dangerous for their foreseeable use. Specifically, the Charité disc
12 implanted in Plaintiff was defectively designed or manufactured resulting in an unreasonably
13 dangerous product.
14

15 35. The Charité disc implanted in Plaintiff was further defective for failing to perform in
16 the manner reasonably to be expected in light of its nature and intended function.
17

18 36. As a result of such defects, Plaintiff has suffered general and special damages in an
19 amount in excess of \$10,000.

20 37. As a further result of such defects, Plaintiff has incurred attorney's fees and costs,
21 and is entitled to reimbursement of said fees and costs together with prejudgment interest.
22

23 **SECOND CAUSE OF ACTION**

24 **[Negligence]**

25 38. Plaintiff re-alleges each and every allegation contained above as though fully set
26 forth herein.

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1 39. Defendants, and each of them, had a duty to Plaintiff to comply with FDA standards
2 and regulations, use reasonable care in the design, manufacture and testing of its device, provide
3 a safe product in design and manufacture and warn Plaintiff of defects at the earliest possible
4 date.

5
6 40. Defendants, and each of them, breached their duty of reasonable care to Plaintiff by
7 violating FDA requirements, standards and regulations; and incorporating a defect into the
8 design of the device implanted into Plaintiff, and failing to warn Plaintiff of the defects.

9
10 41. Such breaches of the FDA requirements, standards and regulations constituted
11 negligence per se.

12 42. Defendants, and each of them, breached their duty of reasonable care to Plaintiff by
13 negligently incorporating defects into the design of the device implanted into Plaintiff, and
14 failing to warn Plaintiff of the defects.

15 43. Defendants, and each of them, further breached their duty of care by manufacturing
16 and assembling the Charité disc in such a manner that it was prone to fail to operate as
17 advertised and warranted, both expressly and implied, thereby causing Plaintiff injury.

18
19 44. Defendants, and each of them, further breached their duty of reasonable care to
20 Plaintiff by failing to exercise due care under the circumstances and through the manufacture,
21 design and sale of the Charité disc which was in a defective condition as alleged above.

22 45. Defendants, and each of them, had a duty to design, manufacture, market and
23 distribute a reasonably safe product and components parts.

24
25 46. Defendants, and each of them, breached that duty by failing to design, manufacture,
26 market and distribute a reasonably safe medical device.

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1 47. Defendants, and each of them, knew, or in the exercise of ordinary care should have
2 known, that the Charité disc implanted into Plaintiff was defective and unreasonably dangerous
3 to Plaintiff, and others like him who had the device implanted in them.

4 48. Defendants, and each of them, owed Plaintiff a duty to take reasonable precautions
5 or steps to prevent the type of injury foreseeably suffered by Plaintiff as a result of the defective
6 and unreasonably dangerous product and its component parts.

7 49. Defendants, and each of them, breached that duty by failing to take reasonable
8 precautions or steps to prevent the type of injury foreseeably suffered by Plaintiff as a result of
9 the defective and unreasonably dangerous product and its component parts.
10

11 50. As a result of such defects, Plaintiff has suffered general and special damages in an
12 amount in excess of \$10,000.
13

14 51. As a further result of such defects, Plaintiff has incurred attorney's fees and costs,
15 and is entitled to recover said fees and costs together with prejudgment interest.
16

17 **THIRD CAUSE OF ACTION**

18 **[Breach of Express And Implied Warranties]**

19 52. Plaintiff re-alleges each and every allegation contained above as though fully set
20 forth herein.

21 53. Defendants, and each of them, expressly warranted to the Plaintiff by and through
22 Defendants, and each of them, and their authorized agents or sales representatives, in
23 publications, package inserts, the internet, and other communications, intended for physicians,
24 medical patients and the general public, that the Charité disc was safe, effective, fit and proper
25 for its intended use.
26

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1 54. Prior to the surgical implantation of the Charité disc, Defendants, and each of them,
2 provided, either directly or through others, certain documentation to the patients, including
3 Plaintiff, whereby Defendants, and each of them expressly warranted the safety efficacy and
4 durability of the Charité disc
5

6 55. Prior to the surgical implantation of the Charité disc, Defendants, and each of them,
7 provided, either directly or through others, certain documentation to the patients, including
8 Plaintiff, whereby Defendants, and each of them, expressly warranted the Charité disc would
9 restore natural motion to the lumbar spine, unlike a traditional lumbar fusion.
10

11 56. Defendants, and each of them, breached their express warranties by the facts that,
12 *inter alia*,

13 A. The safety of the Charité disc was not proven, and, rather, the Charité disc was
14 unsafe;

15 B. The efficacy of the Charité disc was not proven, and, rather, the Charité disc was
16 not efficacious;
17

18 C. The durability of the Charité disc was not proven, and, rather, the Charité disc
19 was not sufficiently durable; and

20 D. The Charité disc does not and did not restore natural motion.
21

22 57. Further, Defendants, and each of them, expressly and impliedly warranted Charité
23 disc to be safe, free of defects, fit for its intended use, merchantable, fit for the ordinary purpose
24 for which it was to be used, and fit for the particular purposes as described by Defendants, and
25 each of them.

26 58. By virtue of the facts described above, the Charité disc implanted in Plaintiff was
27 unreasonably dangerous and did not comport with the express and implied warranties.
28

1 59. Thus, contrary to and in breach of the express and implied warranties given by
2 Defendants, and each of them, the product in question is unreasonably dangerous, and in breach
3 of the aforementioned warranties.

4 60. Defendants, and each of them, expressly and impliedly warranted that the Charité
5 disc was fit for use as a medical device for the purpose described above.
6

7 61. Plaintiff specifically relied on Defendants' judgment and skill, express warranties,
8 and the implied warranties of merchantability and fitness for the particular purpose for which
9 Plaintiff selected and purchased the product for implantation.

10 62. Defendants, and each of them, by and through the sale of the Charité disc and its
11 component parts, expressly and impliedly warranted to the Plaintiff that the Charité disc was fit
12 for general and ordinary use and the purposes for which it was intended as well as the particular
13 purpose for which the Plaintiff used the product.
14

15 63. The Charité disc was not fit for use for general and ordinary use, its intended
16 purpose, nor the particular purpose for which the Defendants knew the Plaintiff intended to use
17 the Charité disc, and as a result of Defendants' breach of express warranties, and implied
18 warranties of merchantability and fitness for a particular purpose, Plaintiff sustained damages as
19 stated above and set forth below.
20

21 64. The Charité disc, and its component parts did not comply with the express or implied
22 warranties offered by Defendants, and each of them. The Defendants' breaches of warranty, as
23 set forth above were a proximate and foreseeable cause of the injuries suffered by Plaintiff.
24

25 65. As a result of such defects, and breaches of warranties, both express and implied,
26 Plaintiff has suffered general and special damages in an amount in excess of \$10,000.

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1 66. As a further result of such defects, Plaintiff has incurred attorney's fees and costs,
2 and is entitled to the recovery of said damages, together with prejudgment interest.

3 **FOURTH CAUSE OF ACTION**

4 **[Exemplary Damages Pursuant to NRS 42.001]**

5
6 67. Plaintiff re-alleges each and every allegation contained above as though fully set
7 forth herein.

8 68. The acts or omissions of Defendants, and each of them, were more than momentary
9 thoughtlessness, inadvertence, or error of judgment, but rather were done with a conscious
10 disregard, malice and oppression to the rights, welfare, or safety of the Plaintiff pursuant to
11 NRS 42.001.

12
13 69. Defendants, and each of them, possessed knowledge of the probable harmful
14 consequences of the wrongful acts described above, and willfully and deliberately failed to act
15 to avoid those consequences.

16
17 70. Plaintiff is therefore entitled to recover judgment against Defendants, and each of
18 them, in addition to compensatory damages, for exemplary damages for the sake of punishing
19 Defendants, and each of them.

20 **PRAYER**

21 WHEREFORE, Plaintiff, while expressly reserving the right to amend his Complaint at
22 the time of trial of the actions herein to include all items of damages not yet ascertained,
23 demands judgment against Defendants, and each of them, as follows:

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25 1. For a joint and several judgment against Defendants, and each of them, for
26 Plaintiff' general damages in excess of Ten Thousand Dollars (\$10, 000.00);

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2. For a joint and several judgment against Defendants, and each of them, for Plaintiff's special damages in excess of Ten Thousand Dollars (\$10,000.00);

3. For exemplary damages, in excess of Ten Thousand Dollars (\$10,000.00);

4. For prejudgment interest on Plaintiff's damages as allowed by law;

5. For reasonable attorneys' fees and costs of suit incurred herein; and,

6. For such other and further relief as the Court may deem just and proper.

DATED this 1 day of November, 2007.

HENNESS & HAIGHT

MARK G. HENNESS, ESQ.
Nevada Bar No. 5842
8972 Spanish Ridge Avenue
Las Vegas, Nevada 89148
Attorneys for Plaintiff

EXHIBIT B

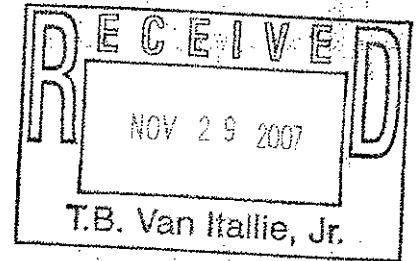
EXHIBIT B

NOV-26-2007(MON) 09:41 Legal Process Service

P. 002/019

/015

DISTRICT COURT
CLARK COUNTY, NEVADA



ROGER MILLER, an individual,

Plaintiff,

vs.

DePUY SPINE, INC., a Massachusetts corporation; JOHNSON & JOHNSON, Inc., a New Jersey corporation; HUBER MEDICAL SYSTEMS, a California Corporation; DOES I - X; and ROE CORPORATIONS I - X, inclusive,

Defendants.

Case No.: A550017
Dept. No.: XV1

NOTICE! YOU HAVE BEEN SUED. THE COURT MAY DECIDE AGAINST YOU WITHOUT YOUR BEING HEARD UNLESS YOU RESPOND WITHIN 20 DAYS. READ THE INFORMATION BELOW.

TO THE DEFENDANT. A Civil Complaint has been filed by the plaintiff(s) against you for the relief set forth in the Complaint.

Johnson & Johnson, Inc.

1. If you intend to defend this lawsuit, within 20 days after this Summons is served on you exclusive of the date of service, you must do the following:

- a. File with the Clerk of this Court, whose address is shown below, a formal written response to the Complaint in accordance with the rules of the Court.
- b. Serve a copy of your response upon the attorney whose name and address is shown below.

2. Unless you respond, your default will be entered upon application of the plaintiff(s) and this Court may enter a judgment against you for the relief demanded in the Complaint, which could result in the taking of money or property or other relief requested in the Complaint.

3. If you intend to seek the advice of an attorney in this matter, you should do so promptly so that your response may be filed on time.

Issued at the direction of:

HENNESSY & TRACHT

By:

MARK G. HENNESSY, ESQ.
Nevada Bar No. 5842
8972 Spanish Ridge Avenue
Las Vegas, NV 89148
(702) 862-8200
Attorneys for Plaintiff

CLERK OF COURT

By: *[Signature]* 11/1/07
Deputy Clerk
County Courthouse
200 Lewis Avenue
Las Vegas, NV 89101
NIDIA FLORES

EXHIBIT C

EXHIBIT C

December 6, 2007

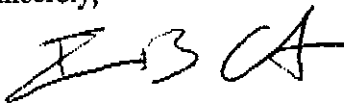
Robert R. McCoy
MORRIS PICKERING & PETERSON
900 Bank of America Plaza
300 South Fourth Street
Las Vegas, Nevada 89101

Re: Removal to Federal Court

Dear Mr. McCoy:

This letter shall serve as confirmation that Huber Medical consents to the removal of Roger Miller v. DePuy Spine, Huber Medical Systems, Inc., et al, filed with the Clark County District Court on November 14, 2007, Case No. A550017, to the appropriate United States Federal Court.

Sincerely,



Ian B. Carter, Esq.
On behalf of Huber Medical Systems, Inc.