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CLERK U.S. DISTRICT COURT
CENTRAL DIST. OF CALIF.
SANTA ANA

BY: _____

1 Ramon Lopez (CA State Bar #86361)
2 rlopez@lopezmchugh.com
3 Jason Ochs (CA State Bar #232819)
4 jochs@lopezmchugh.com
5 Lopez McHugh, LLP
6 100 Bayview Circle, Ste. 5600
7 Newport Beach, CA 92660
8 Telephone: 949.737.1501
9 Facsimile: 949.737.1504

6 William Audet (CA State Bar #117456)
7 waudet@audetlaw.com
8 Jason T. Baker (CA State Bar #212380)
9 jbaker@audetlaw.com
10 AUDET & PARTNERS, LLP
11 221 Main Street, Suite 1460
12 San Francisco CA 94105
13 Telephone: 415.982.1776
14 Facsimile: 415.568.2556

11 *Co-Lead Counsel for Plaintiff*
12 *and the Proposed Class*
13 *(Additional Counsel on Signature Page)*

15 UNITED STATES DISTRICT COURT
16 SOUTHERN DISTRICT OF CALIFORNIA

18 Jason M. Yamada, D.D.S., on behalf
19 of himself and others similarly
20 situated,

20 Plaintiff,

21 v.

22 Nobel Biocare Holding AG; Nobel
23 Biocare AB Nobel Biocare USA,
24 LLC. and DOES 1 through 10,

24 Defendants

CV10-04849 JHN(PLAX)

No. _____

CLASS ACTION COMPLAINT
FOR DECLARATORY RELIEF,
DAMAGES, INJUNCTIVE RELIEF
AND RESTITUTION

JURY TRIAL DEMANDED

1 5. The insertion of an ineffective, defective and damaging dental implant
2 leads to disappointed, concerned and questioning patients who have suffered injury
3 due to the placement and subsequent failure of a NobelDirect implant. These
4 patients have sought and will continue to seek redress and dental restoration from
5 the dentists who performed the original implant surgery.
6

7
8 6. The proposed class in this case is comprised of dentists throughout the
9 United States who implanted NobelDirect implants.
10

11 7. The proposed class of dentists did not know, and had no way of
12 knowing, that the NobelDirect implants were defectively designed, that incorrect
13 insertion protocols were promoted, that they would damage their patients and
14 would need to be surgically removed.
15

16 8. Despite the fact that they were sold a defective product by Nobel, the
17 Dentists need to address the needs of their patients and mitigate the harm that the
18 implants have caused and will cause to their patients, and mitigate the loss of
19 goodwill to their dental practices caused by the placement of the defective
20 implant. They must do this by removing the implants themselves or referring their
21 patients to a dental surgeon for restoration of the failed or removed implant with a
22 two-piece implant with newly fabricated crown, often covering all or part of the
23 costs of these procedures themselves.
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1 requiring his patients to undergo surgical removal of the implants, reconstruction,
2 replacement, and continued monitoring. In order to mitigate damage to his
3 patients' health and welfare and to mitigate damage to his dental practice's
4 goodwill, Dr. Yamada has repaired and will repair the damage free of charge,
5 including paying out of pocket for expenses and staff and professional time
6 involved with the repair procedures.
7
8

9 13. Defendant Nobel Biocare Holding AG is a limited liability company
10 incorporated under the laws of Switzerland with its principal place of business in
11 Zurich, Switzerland.
12

13 14. Defendant Nobel Biocare AB is a limited liability company
14 incorporated under the laws of Sweden with its principal place of business in
15 Gothenburg, Sweden.
16

17 15. Defendant Nobel Biocare USA, LLC is a limited liability company
18 incorporated under the laws of the State of Delaware with its principal place of
19 business in Yorba Linda, California. Upon information and belief, relevant
20 decisions to market the NobelDirect Implant to General Dentists, and to conceal
21 the fact that the NobelDirect implants were defective, were made in California by
22 agents and employees of Nobel Biocare USA, LLC.
23
24
25

26 16. Defendants are collectively referred to herein as "NOBEL."
27
28

1 17. NOBEL concentrates on the development, production and marketing
2 of dental implants, crowns and bridges as well as veneers and laminates as dental
3 prostheses.
4

5 18. NOBEL has four production centers in Sweden and the USA and its
6 own sales organizations in 33 countries.
7

8 19. NOBEL has a world market share of approximately 35 percent for
9 dental implants.
10

11 20. At all times relevant to this action, NOBEL was engaged in the
12 business of designing, licensing, manufacturing, distributing, selling, marketing
13 and/or introducing into interstate commerce, either directly or indirectly through
14 third parties or related entities, the dental implant known as and sold under the
15 trade name NobelDirect.
16

17 21. NobelDirect is a titanium single-piece dental implant.
18

19 22. NobelDirect was launched in 2004 and sold to practitioners in the
20 United States.
21

22 23. The implant was designed to be screwed directly into the jawbone
23 without having to first retract the gingival covering the alveolar crest bone.
24

25 24. NOBEL marketed the Nobel Direct as a dental implant that was easy
26 to install for the practitioner and therefore suitable for any dentist.
27
28

1 bone. The implant is recommended by defendants for placement without the need
2 for a surgical flap, followed by immediate loading of the implant.

3
4 32. When implanted as directed, the long, narrow, non-linear tapered
5 design of the implant leads to an excessively high amount of marginal bone loss
6 surrounding the implant. This occurs as a result of the defective design of the
7 implant, and is not a result of dentist-specific causes.

8
9 33. One study has concluded that after approximately one year, over 10%
10 of NobelDirect implants placed had already completely failed- i.e. they had to be
11 entirely removed from the patient's jaw. This study did not take into account the
12 number of implants that had serious complications but that had not yet been
13 removed.

14
15
16 34. Another study entitled "Short-term clinical results for NobelDirect
17 implants: a retrospective multicentre analysis" found "extensive marginal bone
18 loss" in more than 1/3 of the NobelDirect implants evaluated. The study
19 concluded that NobelDirect implants had "a poor clinical outcome" when
20 implanted as directed.

21
22
23 **Nobel Had Exclusive Knowledge Of The Defect.**

24
25 35. All of NobelDirect implants have the same defective design.

26 36. NOBEL had superior and exclusive knowledge of the defect, and
27 knew that the defect was not known or reasonably discoverable by the Plaintiff and
28

1 Class members prior to their purchase and/or implantation of the NobelDirect
2 implants.

3
4 37. Only NOBEL had access to information about the risk of implanting
5 the NobelDirect implants, including the dangers of implanting as directed: loaded
6 directly without using surgical flaps.
7

8 38. NOBEL failed to disclose, at and after the time of purchase, that the
9 NobelDirect implants were defective and not fit for their intended purpose.
10

11 39. Each NobelDirect implant comes in an identical sealed tube with
12 labeling on the outside. NOBEL has placed warning or instruction labels (for
13 various reasons), in the form of a sticker, on such tubes for *other* NOBEL implants,
14 but at no time did NOBEL place any sticker or language warning plaintiff or
15 members of the proposed class that the NobelDirect implants were defective, that
16 they had been found to have an extraordinarily high rate of failure, that they should
17 not be loaded directly nor implanted without the use of surgical flaps, that they had
18 not been adequately tested and/or that the implant was a prototype.
19
20
21

22 40. Each package label was defective and contained material omissions,
23 including that they:

- 24
25 a. Failed to warn of the increased risk of implant failure due to the
26 increased, non-linear tapered implant design causing increased
27 surrounding bone wall compression pressures at the time of insertion;
28

- 1 b. Failed to warn of the increased risk of implant failure from over-
2 torquing the implant at the time of insertion;
3
4 c. Failed to warn of increased risk of implant failure from heat transfer
5 during abutment grinding down the implant body to surrounding bone
6 wall;
7
8 d. Failed to warn of the increased risk of the use of flapless surgery for
9 insertion of the implant;
10
11 e. Failure to warn of the increased risk of implant failure due to
12 conducted vibrations down the body of the implant during abutment
13 grinding causing micromotion of the implant against the surrounding
14 bone;
15
16 f. Failure to warn of the increased risk of implant failure due to the
17 immediate functional loading of the implant;
18
19 g. Failure to warn of the increased risk of implant failure due to
20 increased marginal bone loss surrounding the implant;
21
22 h. Failure to warn of the increased risk of cosmetic failure due to
23 gingival retraction;
24
25 i. Failure to warn of the increased risk of cosmetic failure from metallic
26 discoloration of the gingival tissue;
27
28

1 j. Failure to warn of an overall unacceptable and abnormally high failure
2 rate.

3
4 41. Whether a dental implant will work for its intended purposes, and
5 whether, when implanted as directed, it will have an extraordinarily high risk of
6 bone resorption and failure is a fact that would be considered material by a dentist
7 in deciding whether to purchase or use a dental implant.

8
9 42. Had Plaintiff and other class members known of the implant's defect,
10 they would not have purchased or implanted the NobelDirect implants.

11
12 43. Plaintiff and the class further expect and assume Defendants will not
13 sell implants with known defects, and will immediately and properly disclose any
14 such defect to its dentists when they learn of the defect.

15
16 44. Plaintiff and the class expect and trust that Defendants will properly
17 design their implants and will effectively train dentists in how to surgically implant
18 the implants in order to avoid the risk of bone reabsorption and other complications
19 that will result in the failure and removal of the implant.

20
21 45. Plaintiff and the class relied on NOBEL's representations that the
22 NobelDirect implants could be implanted safely and effectively -- even by general
23 (nonspecialist) dentists -- without surgical flaps.

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26 **Nobel Has Misled Dentists Regarding the Implant's Effectiveness and Defects.**
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1 46. NOBEL has actively concealed the implant defect from Plaintiff and
2 Class members.

3
4 47. Upon information and belief, NOBEL failed to release internal
5 information regarding the NobelDirect's propensity to cause abnormally high rates
6 of bone resorption with gingival retraction and discoloration and other
7 complications leading to implant failure. This deception and withholding of
8 internal information, complaints and testing continue to the present day.

9
10
11 48. NOBEL marketed the NobelDirect implants as safe and effective for
12 use by general, non-specialist dentists without resorting to a surgical flap instead
13 promoting the use of an easier gingival punch insertion site. This marketing was
14 knowingly and intentionally false, and was intended to deceive general dentists
15 into believing this implant was a simple effective tool they could incorporate into
16 their practices, when in fact it was a dangerously defective implant that would soon
17 have to be removed.

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21 49. As a result of NOBEL'S practices, Plaintiff and Class members
22 purchased and implanted the NobelDirect implants which they otherwise would
23 not have purchased. Because of NOBEL'S practices, Plaintiff and the class
24 members now face a flood of complaints from injured dental patients who have
25 needed, and will need, immediate intervention to remove the defective implants.

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1 members number in the thousands, and are far too numerous to be individually
2 joined in this lawsuit.

3
4 54. Existence and Predominance of Common Questions: Common
5 questions of law and fact exist as to all members of the class and predominate over
6 questions affecting only individual class members. These common questions
7 include the following:
8

- 9
- 10 a. whether NobelDirect implants were defectively designed;
 - 11 b. whether NOBEL knows about the defect and, if so, how long NOBEL
12 has known of the defect;
 - 13 c. whether the defective nature of the NobelDirect implant constitutes a
14 material fact to the reasonable objective consumer (i.e. the dentists);
 - 15 d. whether NOBEL has and had a legal duty to disclose the defective
16 nature of the implants to Plaintiff and Class members;
 - 17 e. whether NOBEL breached implied or expressed warranties;
 - 18 f. whether NOBEL has engaged in unfair or fraudulent business
19 practices in violation of Business and Professions Code section 17200
20 *et seq.*, as alleged in this complaint;
 - 21 g. whether Plaintiff and the other class members are entitled to equitable
22 relief, including but not limited to a preliminary and/or permanent
23 injunction or declaratory relief.
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1 55. Typicality: Plaintiff's claims are typical of the claims of the class,
2 because, among other things, Plaintiff purchased and implanted NobelDirect
3 implants which contain the same defect found in all other NobelDirect implants.
4

5 56. Adequacy: Plaintiff is an adequate representative of the class because
6 his interests do not conflict with the interests of the members of the class he seeks
7 to represent. Plaintiff has retained counsel competent and experienced in complex
8 class action litigation, and Plaintiff intends to prosecute this action vigorously.
9
10 The interests of members of the class will be fairly and adequately protected by
11 Plaintiff and his counsel.
12

13 57. Superiority: The class action is superior to other available means for
14 the fair and efficient adjudication of this dispute. The injury suffered by each class
15 member, while meaningful on an individual basis, is not of such magnitude as to
16 make the prosecution of individual actions against NOBEL economically feasible.
17
18 Even if class members themselves could afford such individualized litigation, the
19 court system could not. In addition to the burden and expense of managing myriad
20 actions arising from the implant defect, individualized litigation presents a
21 potential for inconsistent or contradictory judgments. Individualized litigation
22 increases the delay and expense to all parties and the court system presented by the
23 legal and factual issues of the case. By contrast, the class action device presents far
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1 fewer management difficulties and provides the benefits of single adjudication,
2 economy of scale, and comprehensive supervision by a single court.
3

4 58. In the alternative, the class may be certified because:

- 5 a. the prosecution of separate actions by the individual members of the
6 class would create a risk of inconsistent or varying adjudication with
7 respect to individual class members which would establish
8 incompatible standards of conduct for NOBEL;
9
10 b. the prosecution of separate actions by individual class members would
11 create a risk of adjudication with respect to them which would, as a
12 practical matter, be dispositive of the interests of other class members
13 that are not parties to the adjudication, or substantially impair or
14 impede their ability to protect their interests; and
15
16 c. NOBEL has acted or refused to act on grounds generally applicable to
17 the class, thereby making appropriate final and injunctive relief with
18 respect to the members of the class as a whole.
19
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22 **FIRST CLAIM FOR RELIEF**

23 **(Declaratory Relief)**

24
25 59. Plaintiff re-alleges and incorporates herein by reference Paragraph 1
26 through Paragraph 58 as if fully set forth.
27
28

1 60. Defendant NOBEL Defendants designed, developed, tested,
2 manufactured, distributed, marketed, promoted, instructed and sold the
3 NobelDirect implants to Plaintiff and the class.
4

5 61. Plaintiff and the class had no knowledge, and no effective way to
6 know, that the NobelDirect implants were defectively designed with incorrect
7 insertion protocols promoted, would cause damage to their patients, and would fail,
8 requiring surgical removal from the patients' jaws.
9

10 62. Plaintiff and the class have had complaints from patients who have
11 been the victims of NobelDirect implants. These patients have complained and
12 sought help from plaintiff and the class – i.e. their dentists – and they will continue
13 to do so as the NobelDirect implants continue to fail and require removal.
14

15 63. Plaintiff and the Class cannot afford to simply ignore their patients'
16 complaints of failed or failing implants, refuse treatment or remedy, and refer those
17 patients to NOBEL for redress for their injury. To do so would mean catastrophic
18 injury to their dental practices and the reputation and word-of-mouth which are
19 critical to the dental practices of Plaintiff and the Class. It would also mean
20 abandoning their duty of care to their patients, and failing to prevent further
21 damage caused by the defective implants.
22

23 64. Instead, Plaintiff and the class, in order to mitigate the damage to the
24 health and welfare of their patients, to fulfill their duties and obligations as the care
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1 provider for their patients, and to mitigate damage to their own practice, must help
2 patients cure or stop the damage inflicted by the defective implant, including by
3 removing the implant or by referring patients to another dentist who can remove
4 the implant, and paying for the costs associated with that procedure and additional
5 procedures required for restoration.
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8 65. Plaintiff, on behalf of himself and the proposed class, seeks
9 declaratory relief from the Court including in the form of a declaration that
10 NobelDirect implants are defectively designed, that they lead to extraordinary bone
11 resorption and/or consequential failure of implants that requires removal, that
12 Plaintiff and the Class are not liable for this defect, and they are entitled to full
13 indemnification from NOBEL for any time and expense lost as a consequence of
14 this defect.
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19 SECOND CLAIM FOR RELIEF

20 (Implied Indemnity)

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22 66. Plaintiff re-alleges and incorporate herein by reference Paragraph 1
23 through Paragraph 65 as if fully set forth.
24

25 67. Defendant NOBEL designed, developed, tested, manufactured,
26 distributed, marketed, and sold the NobelDirect implants for sale to Plaintiff and
27 the class.
28

1 68. Plaintiff and the class had no knowledge, and no effective way to
2 know, that the NobelDirect implants were defectively designed, would cause
3 damage to their patients, and would fail, requiring surgical removal from the
4 patients' jaws.
5

6 69. Because manufacturers are held strictly liable for design defects,
7 Plaintiff, on behalf of himself and the proposed class, seeks indemnity from
8 NOBEL, the manufacturer, for damages Plaintiff and the class have suffered and
9 will suffer as a consequence of NOBEL'S defectively designed implant.
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14 **THIRD CLAIM FOR RELIEF**

15 **(Breach of Express Warranty)**
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18 70. Plaintiff re-alleges and incorporate herein by reference Paragraph 1
19 through Paragraph 69 as if fully set forth.
20

21 71. Defendants designed, developed, tested, manufactured, distributed,
22 marketed, and sold the NobelDirect implants for sale to Plaintiff and the class.
23

24 72. Defendants included an express warranty that was relied upon by
25 Plaintiff and class members in selecting the NobelDirect implants.
26

27 73. Defendants provided a defective product and failed to properly
28 inspect, test, and identify the implant's defects.

1 74. But for Defendants' conduct alleged herein and their breach of express
2 warranty, Plaintiff and the Class would not have suffered the damages and losses
3 alleged herein.
4

5 75. As a direct and proximate result of Defendants' breach of express
6 warranty, the Plaintiff and the Class have sustained, are sustaining, and will sustain
7 damages and losses as alleged herein.
8

9 **FOURTH CLAIM FOR RELIEF**

10 **(Breach of Implied Warranty)**
11
12

13 76. Plaintiff re-alleges and incorporates herein by reference Paragraphs 1
14 through Paragraph 75 as if fully set forth.
15

16 77. Defendants designed, developed, tested, manufactured, distributed,
17 marketed, and sold the NobelDirect implant for sale to Plaintiff and the class.
18

19 78. Defendants impliedly warranted that the NobelDirect implants were
20 properly designed, developed, tested, manufactured, distributed, marketed, and
21 sold and that the designs and materials were proper and of first-class and
22 workmanlike quality.
23

24 79. Plaintiff and the Class relied upon said warranties and believed that
25 said designs, work, and materials were of first-class workmanlike quality and fit
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1 for the intended use and purpose of a consumer vehicle to be driven with no
2 geographic or weather restrictions.

3
4 80. Defendants breached said warranty by designing, developing,
5 manufacturing, distributing, marketing, and selling the NobelDirect implants,
6 which were defective and not fit for their intended use.
7

8 81. Defendants provided defective implants and failed to properly inspect,
9 test, and identify the NobelDirect implant's defects.
10

11 82. But for Defendants' conduct alleged herein and their breach of implied
12 warranty, Plaintiff and the Class would not have suffered the damages and losses
13 alleged herein.
14

15 83. As a direct and proximate result of Defendants' breach of implied
16 warranty, the Plaintiff and the Class have sustained, are sustaining, and will sustain
17 damages and losses as alleged herein.
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21 **FIFTH CLAIM FOR RELIEF**

22 **(Unfair Business Practices: Violation California**

23 **Bus. & Prof. Code §§ 17200, et seq).**
24

25
26 84. Plaintiff, on behalf of himself and all others similarly situated,
27 realleges as if fully set forth, each and every allegation set forth herein. NOBEL'S
28

1 acts and practices, as alleged in this complaint, constitute unfair and/or fraudulent
2 business practices, in violation of the Unfair Competition Law, Cal. Bus. & Prof.
3 Code § 17200, *et seq.*
4

5 85. California Business and Professions Code § 17200, *et seq* prohibits
6 acts of “unfair competition,” which includes any “unfair” business practices.
7

8 86. NOBEL engaged in unfair business practices by failing to disclose to
9 Plaintiff and the Class the defects inherent in the NobelDirect implants, and,
10 among other things:
11

- 12 a. Engaging in conduct where the utility of that conduct is outweighed
13 by the gravity of the consequences to Plaintiff and other members of
14 the class;
15
- 16 b. Engaging in conduct that is immoral, unethical, oppressive,
17 unscrupulous, or substantially injurious to Plaintiff and other members
18 of the class
19

20 87. As a direct and proximate result of NOBEL’S unfair business
21 practices as alleged herein, Plaintiff and Class members have suffered injury in fact
22 and lost money or property, in that they purchased implants that they otherwise
23 would not have. Plaintiff and Class members have also suffered damages as a
24 consequence of NOBEL’S unfair conduct, including that they have had to conduct
25 implant removals and pay for incidental expenses, or pay for patients’ removals by
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1 other practitioners, in order to mitigate damage to the health and well being of their
2 patients and the further loss of goodwill to their business.

3
4 88. Meanwhile, NOBEL has sold more implants than it otherwise could
5 have, unjustly enriching itself thereby.

6
7 89. Plaintiff and Class members are entitled to equitable relief, including
8 restitutionary disgorgement of all profits accruing to NOBEL because of its unfair,
9 fraudulent, and deceptive practices, and declaratory relief, and a permanent
10 injunction enjoining NOBEL from its unfair, fraudulent and deceitful activity.
11

12 **SIXTH CLAIM FOR RELIEF**

13 **(Fraudulent Business Practices: Violation California**

14 **Bus. & Prof. Code §§ 17200, *et seq.*)**

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18 90. Plaintiff, on behalf of himself and all others similarly situated,
19 realleges as if fully set forth, each and every allegation set forth herein. NOBEL'S
20 acts and practices, as alleged in this complaint, constitute fraudulent business
21 practices, in violation of the Unfair Competition Law, Cal. Bus. & Prof. Code §
22 17200, *et seq.*
23

24
25 91. California Business and Professions Code § 17200, *et seq* prohibits
26 acts of "unfair competition," which includes any "fraudulent" business practices.
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- a. For an order certifying the Class and appointing Plaintiff and his counsel to represent the Class;
- b. For an Order Declaring NOBEL liable for the defects in their NobelDirect implant and requiring NOBEL to indemnify Plaintiff and the Class for all damages suffered as a consequence of the defective implants;
- c. For an order awarding compensatory damages to the Plaintiff and the class;
- d. For an order awarding Plaintiff and the members of the Class restitution, or other equitable relief as the Court deems proper;
- e. For an order enjoining NOBEL from continuing to engage in unfair business practices, as alleged herein, including precluding the further sale of NobelDirect implants;
- f. For an order awarding Plaintiff and the members of the Class pre-judgment and post-judgment interest;
- g. For an order awarding Plaintiff and the members of the Class reasonable attorneys' fees and costs of suit, including expert witness fees; and

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1 h. For an order awarding such other and further relief as this Court may
2 deem just and proper.
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5 DATED: June 30, 2010

6 By: 
7 Ramon Lopez
8 Jason Ochs
9 Lopez McHugh, LLP
10 100 Bayview Circle, Ste. 5600
11 Newport Beach, CA 92660
12 Telephone: 949.737.1501
13 Facsimile: 949.737.1504

14 William M. Audet
15 Audet & Partners LLP.
16 221 Main Street, Suite 1460
17 San Francisco CA 94105
18 Telephone: 415.982.1776
19 Facsimile: 415.568.2556

20 Stephen D. Ochs, M.D., J.D.
21 805 South Reserve St.
22 Missoula, MT 59801
23 Telephone: 406.549.6600
24 Facsimile: 406.549.1511
25
26
27
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