

1 TO DEFENDANTS: DHHS, EDS, & NHIC:
2

3
4 Pursuant to Federal Rule of Civil Procedure 34, you are required to produce the
5 following documents and things.
6

7 INSTRUCTIONS
8

9
10 1. Pursuant to Federal Rule of Civil Procedure 34, you must respond in writing to
11 each item and category set forth herein within thirty (30) days plus two (2)
12 additional for the Express Mail overnight delivery, stating, with respect to each item
13 and category, that you will produce as requested, or the specific objections to each
14 item and category.
15

16 2. Pursuant to Federal Rule of Civil Procedure 34, you must produce documents
17 and things as they are kept in the usual course of business, or organized and labeled
18 to correspond to the categories in this Request.
19

20
21 3. In responding hereto, you must produce all responsive documents in your
22 possession, custody or control, or in the possession, custody or control of your
23 offices, divisions, agencies, or affiliates, or any of your officials, managers,
24 administrators, directors, officers, agents, employees, assistants, staff, attorneys,
25 accountants, or other representatives. A document is within your control if you have
26 the right to secure the document or a copy thereof from another person having
27 possession, custody, or control thereof.
28

1
2
3
4 **4. Pursuant to Federal Rule of Civil Procedure 34(a), the documents that you**
5 **must produce are both paper documents and all “writings, drawings, graphs, charts,**
6 **photographs, phone records, and other data compilations from which information**
7 **can be obtained, translated, if necessary, by [you or your agents] through detection**
8 **devices into reasonably usable form or ... any tangible things....” This definition is**
9 **incorporated in all uses of the words “documents,” “records,” and similar words in**
10 **the following categories.**

11
12 **5. In responding hereto, you must produce all responsive documents available**
13 **and you must also supplement your responses and production as required by**
14 **Federal Rule of Civil Procedure 26(e).**

15
16
17 **6. If any responsive document was, but is no longer in your possession, custody,**
18 **or control, state whether it is (a) missing or lost, (b) destroyed, (c) transferred**
19 **voluntarily or involuntarily to others, or (d) otherwise disposed of; and in each**
20 **instance identify the name and address of its current or last known custodian, and**
21 **state the circumstances surrounding such disposition.**

22
23 **7. If you claim any privilege or assert any objection, whether based on statute,**
24 **common law, or otherwise, as a ground for not producing any requested document,**
25 **please furnish a list identifying each document for which the privilege or objection is**
26 **claimed, together with the following information:**

27
28 **(a) the privilege being asserted;**

1 **(b) the person on whose behalf the privilege is asserted;**

2
3
4 **(c) a precise statement of the facts on which the claim of privilege is based;**

5
6 **(d) identify the purported privileged document including:**

7
8
9 **(i) its nature, e.g., letter, memoranda, tape, etc.;**

10
11 **(ii) the date it was prepared;**

12
13
14 **(iii) the date the document bears;**

15
16 **(iv) the date the document was sent;**

17
18
19 **(v) the date it was received;**

20
21 **(vi) the name of the person who prepared the document;**

22
23
24 **(vii) the names of the persons who received the document;**

25
26 **(viii) the name of each person to whom it was sent or was intended to be**
27 **sent, including all addressees and all recipients of copies; and**
28

1 (ix) a statement of whom each identified person represented or purported to
2 represent at all relevant times.

3
4
5 8. If part of any responsive document is withheld under claim of privilege
6 pursuant to Instruction 7, any non-privileged part of such document must be
7 produced with the portion claimed to be privileged protected by protective order of
8 the court.

9
10 9. You must produce each requested document in its entirety, without deletion
11 or excision (except as qualified by Instructions 7 and 8 above), regardless of
12 whether you consider the entire document to be relevant or material.

13
14
15 10. The singular shall include the plural, and the disjunctive shall include the
16 conjunctive, and vice versa, to produce the broadest document production.

17
18 **DOCUMENTS AND THINGS REQUESTED**

19
20
21 1. with respect to Michael H. Jordan, and his Board of Directors from 2003 to
22 the present: all calendars, schedules, notices, listings, agendas, letters,
23 faxes, emails, memos, digital media, audiotapes, transcripts, minutes,
24 notes, agendas, other correspondence, images, and other records except
25 billing records that pertain to the Medicare beneficiaries on transfer factor
26 immunomodulatory therapy.

1 **2. with respect to Bruce Quinn, M.D., Ph.D., M.B.A. all calendars, schedules,**
2 **notices, listings, agendas, letters, faxes, emails, memos, digital media,**
3 **audiotapes, transcripts, minutes, notes, agendas, other correspondence**
4 **and other records except billing records that pertain to the Medicare**
5 **beneficiaries on transfer factor immunomodulatory therapy.**

6
7
8 **3. law, federal code, protocol, manual, policy, directive or standard used by**
9 **Bruce Quinn, M.D., Ph.D., M.B.A. to determine the medical necessity of**
10 **transfer factor immunomodulatory therapy**

11
12 **4. law, federal code, protocol, manual, policy, directive or standard used by**
13 **Bruce Quinn M.D., Ph.D., M.B.A. to determine that a Medicare physician**
14 **provider should have known that services were not covered**

15
16
17 **5. protocol, manuals, policies, or standards used by Bruce Quinn, M.D., Ph.D.,**
18 **M.B.A. to determine that the rights of the Medicare provider physician and**
19 **the 26 Medicare beneficiaries in the Local Coverage Determination Appeal**
20 **policies are consistent with federal laws including but not limited to: the**
21 **Medicare Act of 1965, the Medicare Modernization Act of 2000, The**
22 **Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act**
23 **of 2003, and Federal anti-competition laws**

24
25 **6. with respect to Craig Haug, M.D. all calendars, schedules, notices, listings,**
26 **agendas, letters, faxes, emails, memos, digital media, audiotapes,**
27 **transcripts, minutes, notes, agendas, other correspondence, images, and**
28

1 other records except billing records that pertain to the Medicare
2 beneficiaries on transfer factor immunomodulatory therapy

3
4
5 7. with respect to Daniel Schreiner, CMS Ombudsman, all calendars,
6 schedules, notices, listings, agendas, letters, faxes, emails, memos, digital
7 media, audiotapes, transcripts, minutes, notes, agendas, other
8 correspondence and other records except billing records that pertain to
9 the Medicare beneficiaries on transfer factor immunomodulatory therapy

10
11 8. protocol, manuals, policies, or standards used by Daniel Schreiner, CMS
12 Ombudsman, to determine that the rights of the Medicare provider
13 physician and the 26 Medicare beneficiaries in the Local Coverage
14 Determination Appeal policies were consistent with federal laws including
15 but not limited to: the Medicare Act of 1965, the Medicare Modernization
16 Act of 2000, The Medicare, Medicaid, and SCHIP Benefits Improvement
17 and Protection Act of 2003, and Federal anti-competition laws

18
19
20 9. law, federal code, protocol, manual, policy, directive or standard used by
21 Daniel Schreiner, CMS Ombudsman, to determine that a Medicare
22 physician provider should have known that services were not covered

23
24 10. law, federal code, protocol, manual, policy, directive or standard used by
25 Daniel Schreiner, CMS Ombudsman, to determine that new patient
26 appointments, consultations, and other services, not transfer factor
27 immunomodulatory therapy, could be denied reimbursement
28

1 **11. curriculum vitae, job description, continuing education, in-house training,**
2 **dates of employment of:**

- 3
- 4 a. Donald Adams, M.D.
- 5 b. Commander Mary Ellen Bruk
- 6 c. Diane Caradeuc
- 7
- 8 d. Ann Backoff Dalton
- 9 e. Theresa DeBell, R.N.
- 10
- 11 f. Tom Horowitz D.O.
- 12
- 13 g. Michael H. Jordan
- 14
- 15 i. Craig Haug, M.D.
- 16
- 17 j. Arthur Lurvey, M.D.
- 18
- 19 k. Christine Plumb
- 20
- 21 l. Bruce Quinn, M.D., Ph.D., M.B.A.
- 22
- 23 m. Carlos Rivera
- 24
- 25 n. Daniel Schreiner
- 26
- 27 o. Regina Solis, R.N.
- 28

25 **11. names, curriculum vitae, job description, dates of employment of all DHHS,**
26 **EDS, and/or NHIC staff who consulted on Medicare beneficiaries on**
27 **transfer factor immunomodulatory therapy (dialyzable leukocyte extract)**
28

1 **12. names, contact information, curriculum vitae, disclosure of conflicting**
2 **financial interest of all outside consultants who formally or**
3 **informally consulted on the Medicare beneficiaries and / or transfer**
4 **factor immunomodulatory therapy**

5
6
7 **13. the current DHHS CMS contract with Electronic Data Systems and/or**
8 **National Heritage Insurance Company**

9
10 **14. with respect to the CMS or NHIC website statements relating to transfer**
11 **factor immunomodulatory therapy :**

12
13 **a. all calendars, schedules, notices, listings, agendas, letters, faxes,**

14 **b. emails, memos, digital media, audiotapes, transcripts, minutes,**
15 **notes, agendas, other correspondence, images, and other records**
16 **any and all documents**

17
18 **c. each and every website revision, dates, and reason for the revision**

19
20 **d. names and curriculum vitae of all parties who participated**

21 **e. protocol used for developing the website information**

22 **f. protocol of the methodology used in selecting medical, scientific**
23 **and /or legal references**

24 **g. protocol of the methodology used in rejecting medical, scientific**
25 **and /or legal references**

26
27 **h. names of all medical, scientific and/or legal references available**
28

1 that were used and not used

2 i. protocol for notifying the referenced Medicare physician provider of
3 the existence of this website reference

4 j. protocol used for selecting and rejecting information regarding the
5 one transfer factor expert mentioned

6
7
8 **15. any and all communication record between Bruce Quinn, M.D., Ph.D., M.B.A.**
9 **and California Medical Association Vice President, Elizabeth McNeill, with**
10 **respect to transfer factor immunomodulatory therapy and or the Medicare**
11 **beneficiaries**

12
13 **16. information received from or sent to members of the U.S. Congress**
14 **regarding transfer factor immunomodulatory therapy**

15
16 **17. law, federal code, protocol, manual, policy, directive or standard for the**
17 **questionnaires sent to Medicare beneficiaries asking personal and**
18 **medical questions and telling them not to tell their Medicare physician**
19 **provider**

20 **18. with respect to these secret questionnaires:**

21 a. any and all internal communication

22 b. names of all contributors

23 c. any other documentation as to why all the patient positive
24 responses were totally disregarded

25
26
27
28 **19. with respect to Medicare beneficiaries' letters to Dr. Lurvey:**

- 1
- 2 a. the names of parties who read the letters
- 3
- 4 b. protocol or internal policy followed with respect to the disposition
- 5 of these letters
- 6
- 7 c. any communication sent in response to the Medicare beneficiaries

8 **20. with respect to outside consultants used to make a determination of medical**

9 **necessity with respect to transfer factor immunomodulatory therapy:**

- 10
- 11 a. protocol and or criteria used to select outside consultants
- 12
- 13 b. name and contact information for all consultants
- 14
- 15 c. curriculum vitae of all consultants
- 16
- 17 d. exactly what DHHS CMS and / or EDS NHIC told these consultants
- 18
- 19 e. documents, scientific articles, references that these consultants
- 20 were given and by whom
- 21
- 22 f. clinical experience that these consultants have with transfer factor
- 23 immunodulatory therapy
- 24
- 25 g. research experience these consultants have with transfer factor
- 26 immunodulatory therapy
- 27
- 28 h. publications of these consultants with respect to transfer factor
- immunodulatory therapy
- i. what patient records were these consultants given
- j. disclosure of potential financial conflict of interest of the consultant

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

k. all data provided by outside consultants

l. any and all documentation that shows the consultants were told their opinion could be used to stop ongoing successful medical care of the Medicare beneficiaries

21. name of the parties who determined and or wrote that the transfer factor immunomodulatory therapy articles were not in the "normative" medical literature in a letter to the Medicare provider physician.

22. protocol, training, policies, and or standards for the time guidelines followed in the preliminary determination

23. protocol, training, policies and or standards for the time guidelines followed in the final determination

24. any and all documents and communication related to the November 20, 2003 meeting with the Medicare physician provider

25. law, federal code, protocol, manual, policy, directive or standard regarding Tom Horowitz, D.O.'s recommendation that Medicare physician provider form a Political Action Committee to buy your Medicare codes because that's the way it's now done

26. law, federal code, protocol, manual, policy, directive or standard that led to Donald Adam, M.D.'s statement: "Here's your immunologist" when referring to Tom Horowitz, D.O.

1 **27. with respect to Theresa DeBell, R.N.'s statement to members of the U.S.**
2 **Congress**

3
4 **a. law, federal code, protocol, manual, policy, directive or standard**
5 **regarding statements to Medicare beneficiary US Congressmen that the**
6 **Medicare physician provider was dispensing an OTC dietary**
7 **supplement**

8 **b. source of her information**

9 **c. name of her supervisor accountable for her work product**

10 **d. reason she was non-responsive to telephonic and written**
11 **correspondence from the Medicare physician provider and Medicare**
12 **beneficiaries**

13 **e. reason she refused to retract the false statement**

14 **f. corrective counseling that was given**

15
16
17 **28. law, federal code, protocol, manual, policy, directive or standard regarding**
18 **the demand for three years of retroactive financial liability of this Medicare**
19 **physician provider**

20
21 **29. With respect to Christine Plumb's directive to the Medicare physician**
22 **provider to continue billing as per the CMS Ombudsman's office**

23
24 **a. name of the person who told Mrs. Plumb to contact the Medicare**
25 **physician provider and tell her to bill, which would be the same charges**
26 **already rejected on the same patients, which would be fraudulent**
27 **insurance billing, a federal crime**
28

1 **b. law, federal code, protocol, manual, policy, directive or standard that**
2 **would have protected the Medicare physician provider for following this**
3 **Mrs. Plumb's advice**

4
5
6 **30. with respect to 788 pages of scientific and medical articles on transfer**
7 **immunomodulatory therapy submitted by the Medicare physician provider as**
8 **legal representative for the 26 Medicare beneficiaries: the names and**
9 **curriculum vitae of all parties who read the articles with all dates and notes**

10
11 **31. EDS NHIC protocols, policies, standards, manuals and or training to be in**
12 **compliance with Federal anti-competition law**

13
14 **32. CMS Region IX Commander Mary Ellen Bruk gave the Medicare physician**
15 **provider a different code to use to bill transfer factor immunomodulatory**
16 **therapy so Medicare beneficiaries' care would continue uninterrupted. She**
17 **instructed the Medicare physician provider to contact Carlos Rivera regarding**
18 **use of this code.**

19
20 **a. We request documentation as to why Carlos Rivera was totally unresponsive**
21 **to the Medicare physician provider and any documents or communication**
22 **between Commander Bruk and Carlos Rivera**

23
24 **b. protocol, policy or directive Carlos Rivera followed in being non- responsive**
25
26
27
28

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

Dated: March 27, 2007

By: _____

Dorothy Calabrese, M.D.

By: _____

Paul Messer

1 **PROOF OF SERVICE**

2
3 I am a resident of the County of Orange, State of California. I am over the age of 18 and not a
4 party to the within action. I may be reached through the medical practice of Dorothy
Calabrese, M.D. at 24953 Paseo de Valencia, Suite 4A, Laguna Hills, California 92653-4342.

5 On March 28, 2007 I served the foregoing document described as:

6 Case No: SACV06-1217 CJC (RNBx) PLAINTIFFS' REQUEST FOR PRODUCTION
7 OF DOCUMENTS AND THINGS TO: DEFENDANT DEPARTMENT OF HEALTH AND HUMAN
8 SERVICES, ELECTRONIC DATA SYSTEMS AND NATIONAL HERITAGE INSURANCE COMPANY
[Fed. R. Civ. P. 34]

9 on all parties in this action by placing true copies thereof enclosed in sealed envelopes
10 addressed as follows:

11 John A. Conkle
12 Conkle, Kremer & Engel
13 3130 Wilshire Boulevard, Suite 500
Santa Monica, CA 90403-2351

14 U.S. Attorney Civil Process Clerk
15 300 North Los Angeles Street
16 Room 7516
Los Angeles, CA 90012

17 These USPS Overnight mailings were deposited in a USPS mail deposit box with postage thereon
18 fully prepaid at San Juan Capistrano, CA in the ordinary course of business.

19 I am aware that on motion of the party served, service is presumed invalid if postal cancellation
date is more than one day after date of deposit for mailing in this proof.

20 I declare under penalty of perjury under the laws of the State of California and the United
21 States that the above is true and correct, and that this Proof of Service was executed this 28th
22 day of March, 2007.

23
24
25 _____
26 Marguerite Kennedy
27
28