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OF ORIGINAL FILED
Los Angeles Superior Court

JUL 30 2008

John A. Clarke, Executive Officer/Clerk

By _____, Deputy

SUPERIOR COURT, STATE OF CALIFORNIA
COUNTY OF LOS ANGELES

AMERICAN ENVIRONMENTAL SAFETY
INSTITUTE, a non-profit California
corporation,

Plaintiff,

v.

THE PROCTER & GAMBLE
DISTRIBUTING COMPANY, an Ohio
corporation, et al.,

Defendants.

CASE NO. BC 334309

[Hon. Mary Thornton House]

**[PROPOSED] CONSENT JUDGMENT
ONLY AS TO DEFENDANT SHEFFIELD
PHARMACEUTICALS**

Complaint Filed: June 1, 2005

Location: Dept. 17

Trial Date: October 14, 2008

This Consent Judgment is entered into by and between the plaintiff American Environmental Safety Institute ("AESI"), on the one hand, and defendant Sheffield Pharmaceuticals ("Sheffield"), a Connecticut corporation, on the other hand.

1. Definitions. As used in this Consent Judgment, the following definitions shall apply:

1.1. "**Toothpaste Products**" includes any toothpaste products previously (i.e., at any time up to or prior to the entry of this consent judgment) sold in California by Sheffield, whether or not such products continue to be sold, as well as all toothpaste products sold by Sheffield in or into California in the future (i.e., at any time after entry of this consent judgment).

1.2. "**Lead**" means the chemical element lead (Pb) and lead compounds as defined in section 12000 of Title 22 of the California Code of Regulations.

1 1.3. “Hydrated Silica” is the naturally-occurring mined material used as a gentle
2 abrasive in the Toothpaste Products.

3 1.4. “ppm” means parts per million.

4 1.5. “Party” shall mean AESI and Sheffield, and when used in the plural shall mean
5 both of them.

6 **2. Background.**

7 2.1. AESI is a non-profit California corporation dedicated to investigating
8 environmental and public health hazards affecting children and adults in their regular daily lives.
9 AESI is based in Palo Alto, California, and was incorporated under the laws of the State of
10 California in 1998. AESI is a “person” within the meaning of Health & Safety Code
11 § 25249.11(a), and brought this enforcement action in the public interest pursuant to Health &
12 Safety Code § 25249.7(d).

13 2.2. AESI served a 60-day “Notice of Violation” (the “Notice”) on Sheffield. AESI
14 served the Notice on February 12, 2008, pursuant to California Health and Safety Code section
15 25249.7(d) and section 12903 of Title 22 of the California Code of Regulations.

16 2.3. The Notice alleged, among other things, that Sheffield was in violation of the Safe
17 Drinking Water and Toxic Enforcement Act of 1986, Health and Safety Code sections
18 25249.5 *et seq.* (“Proposition 65”) for failing to warn purchasers of Toothpaste Products sold in
19 California that the products allegedly expose users to Lead.

20 2.4. For purposes of this Consent Judgment only, the Parties stipulate that this Court
21 has jurisdiction over the allegations of the violations contained in the Notice, that venue is proper
22 in the County of Los Angeles, and that this Court has jurisdiction to enter this Consent Judgment.
23 No public prosecutor has commenced an action regarding the matters raised in the Notice.

24 2.5. Sheffield denies that any Toothpaste Products have been or are in violation of
25 Proposition 65 or any other law, and further contend that all of their Toothpaste Products have
26 been and are safe for use as directed. Sheffield, however, wishes to resolve this matter without
27 further litigation or cost.

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1 **2.6.** The Parties enter into this Consent Judgment to settle claims alleged in the Notice
2 and AEST's complaint (the "Complaint") in this action against Sheffield, to avoid prolonged and
3 costly litigation, and to promote the public interest. By executing and complying with this
4 Consent Judgment, no party admits any facts or conclusions of law including, but not limited to,
5 any facts or conclusions of law regarding any violations of Proposition 65, or any other statutory,
6 common law or equitable claim or requirement relating to or arising from the Toothpaste
7 Products. This Consent Judgment shall not be construed as an admission by Sheffield as to any
8 of the allegations in the Notice and/or the Complaint.

9 **3. Injunctive Relief.**

10 **3.1. Actions as to Hydrated Silica.**

11 (a) Within 60 days of the entry of this Consent Judgment by the Court,
12 Sheffield shall establish and thereafter maintain a Lead (Pb) specification of 4.5 parts per million
13 ("ppm") for any Hydrated Silica to be used in Sheffield's Toothpaste Products that is obtained by
14 a Settling Defendant 60 days after its Lead specification is established.

15 (b) The 4.5 ppm Lead standard shall be demonstrated by the Defendant's
16 hydrated silica supplier using the following testing protocol:

17 (1) once every six months, the hydrated silica supplier shall select five

18 (5) randomly chosen grab samples from a lot of hydrated silica that is ready for
19 shipment to the Defendant, and the supplier shall test a composite of the 5 grab
20 samples;

21 (2) using a sample preparation method that permits recovery of at least
22 that amount of Lead in the sample that is bioavailable to humans, test the prepared
23 sample using Inductively Coupled Plasma/Mass Spectrometry ("ICP/MS") or
24 Inductively Coupled Plasma/Optical Emission Spectrometry ("ICP/OES")
25 laboratory equipment and protocols for Lead detection to demonstrate compliance
26 with the 4.5 ppm specification for Lead in hydrated silica for use in toothpaste;

27 (3) failure of this testing protocol shall require rejection by the supplier
28 of the test lot, with written notice of that rejection provided to the Defendant

1 customer, and a re-review by the supplier of its methods then in use to meet the
2 4.5 ppm Lead specification; and

3 (4) the test protocol set forth above must then be conducted on the next
4 three lots of hydrated silica in succession; if any of these three additional lots fails
5 this test protocol, then the next five lots must be tested, until all lots in a test group
6 of five demonstrate compliance with the 4.5 ppm Lead specification.

7 (c) Because Hydrated Silica is a mined substance, Sheffield cannot ensure that
8 Hydrated Silica with a Lead specification of 4.5 ppm will be commercially feasible at all times.
9 If Hydrated Silica with a Lead specification of 4.5 ppm becomes commercially unfeasible,
10 Sheffield will make every reasonable effort to use Hydrated Silica with the lowest level of Lead
11 feasible from the Hydrated Silica suppliers able to meet Sheffield's quality and volume
12 requirements. Any Party choosing to use Hydrated Silica that does not meet the Lead
13 specification of 4.5 ppm shall provide prompt notice to AESI of that election.

14 **3.2. Feasibility.** The term "feasible" as used in this Consent Judgment means
15 "reasonable" considering: (1) the availability and reliability of a supply to Sheffield of Hydrated
16 Silica meeting a Lead specification not to exceed 4.5 ppm; (2) the cost to Sheffield of using such
17 Hydrated Silica; (3) the performance characteristics, including, but not limited to, formulation
18 compatibility, performance, safety, taste, efficacy and stability, of an ingredient in any
19 Toothpaste Product or the Toothpaste Products as a whole; (4) the lawfulness of the alternative
20 (for example, no such alternative can be allowed to render Sheffield's Toothpaste Products
21 unlawful under state or federal law); and (5) other reasonable considerations. Notwithstanding
22 any other provision in this Consent Judgment, Sheffield shall be required to fulfill only those
23 obligations respecting Lead in their Toothpaste Products that are feasible as described in this
24 paragraph.

25 **3.3. Naturally Occurring Lead.** Any Lead remaining in Sheffield's Toothpaste
26 Products after Sheffield has undertaken those actions required by Paragraphs 3.1 and 3.2, above,
27 is deemed "naturally occurring" within the meaning of section 12501 of Title 22 of the California
28 Code of Regulations.

1 **3.4. Confirmation of Compliance.** AESI, at its sole expense, shall have the right for
2 three (3) years after the date of the entry of this Consent Judgment to request samples of the
3 Hydrated Silica manufactured to the specification level of 4.5 ppm and perform independent
4 testing of the material.

5 **3.5. Injunctive Relief Applies Only in California.** All of the foregoing injunctive
6 relief shall apply only to Toothpaste Products sold for use within California.

7 **3.6. Full and Complete Compliance.** Compliance by Sheffield with the terms of this
8 Consent Judgment shall be deemed to constitute its full and complete compliance with
9 Proposition 65 with respect to the provision of warnings for chemicals contained in or otherwise
10 associated with its Toothpaste Products.

11 **4. Settlement Payments.**

12 **4.1** In keeping with the concept of, but in lieu of, statutory penalties and/or restitution,
13 under the statutes set forth in the Complaint, Sheffield shall pay to the Trust Account of the
14 Carrick Law Group, P.C. in immediately available funds the sum of \$65,000.00 ("Settlement
15 Proceeds") within five (5) days from the entry of this Consent Judgment. Carrick Law
16 Group P.C. shall disburse these funds to AESI (a) to pay its attorneys' fees of \$31,200.00
17 pursuant to those parties' written contingent fee agreement; and (b) to further the remedial
18 purposes established under Proposition 65 by providing funds for AESI's ongoing costs of
19 monitoring compliance with this Consent Judgment, as well as for its future investigational and
20 enforcement activities regarding toxic chemicals and Proposition 65, in a manner that is
21 consistent with the private enforcement mechanism and funds allocation scheme established by
22 Health & Safety Code §§ 25249.7(d) and 25249.12(d) and AESI's non-profit mission.

23 **4.2 Attorney's Fees and Costs.** Apart from the payments to be made pursuant to
24 paragraph 4.1 above, each party shall bear its own attorneys' fees and costs.

25 **5. Termination of All Claims; Claims Covered and Released.**

26 **5.1.** This Consent Judgment includes the resolution of all claims asserted in the Notice
27 and the Complaint, as well as all potential claims that were considered or could have been
28 brought by AESI on behalf of the public interest and the general public regarding Lead in

1 Sheffield's Toothpaste Products. This Consent Judgment is a final and binding resolution
2 between AESI, on behalf of the public interest and the general public, and Sheffield and its
3 affiliated entities described below, of any and all alleged violations of Proposition 65 and any
4 other statutory or common law claims that were or could have been asserted against Sheffield or
5 purchasers or sellers of Sheffield's Toothpaste Products arising from or related to a listed
6 Proposition 65 chemical in Sheffield's Toothpaste Products up through the date of entry of this
7 Consent Judgment, including, but not limited to, any claims for attorneys' fees and costs. In
8 addition, this Consent Judgment is a final and binding resolution between AESI, on behalf of the
9 public interest and the general public, and Sheffield, and its affiliated entities as described below,
10 of any and all alleged violations of Proposition 65 and any other statutory or common law claims
11 that could be asserted against Sheffield or purchasers or sellers of Sheffield's Toothpaste
12 Products arising from or related to Lead in Sheffield's Toothpaste Products after the date of this
13 Consent Judgment to the extent those Toothpaste Products meet the injunctive relief requirements
14 stated in paragraphs 3.1 and/or 3.2 above. AESI, on behalf of the public interest and the general
15 public, hereby releases Sheffield, its affiliated companies, officers, directors and employees and
16 any suppliers to Sheffield or distributors, wholesalers, or retailers of Sheffield's Toothpaste
17 Products from and against the claims described in this paragraph relating to Sheffield's
18 Toothpaste Products; however, AESI expressly does not release any claims which AESI does not
19 have the authority to release, including specifically and without limitation any personal injury
20 claims (or claims directly related to personal injuries).

21 **6. Covenant Not To Sue.** AESI and Sheffield agree that with regard to those matters that
22 AESI has herein released and that are described above, neither AESI nor Sheffield will ever
23 institute a lawsuit or administrative proceedings against any other Party, nor shall any Party
24 assert any claim of any nature against any person or entity hereby released, with regard to any
25 such matters which have been released.

26 **7. Application of Consent Judgment.** Paragraphs 5 and 6 of this Consent Judgment shall
27 apply to, be binding upon, and inure to the benefit of, the Parties, their divisions, subdivisions,
28 subsidiaries, affiliates, merged entities, acquired entities, successors, predecessors and assigns,

1 and the directors, officers, employees, counsel, and agents of each of them, as applicable, and
2 will inure to the benefit of the Parties' parent companies, and all of their suppliers, distributors,
3 wholesalers, retailers and contract manufacturers, and all of their respective directors, officers,
4 employees, counsel, and agents.

5 **8. Modification of Consent Judgment.**

6 **8.1.** This Consent Judgment may be modified or terminated upon written agreement of
7 Sheffield and AESI, with approval of the Court, or upon noticed motion for good cause shown.
8 The grounds for modification of this Consent Judgment include, but are not limited to, the
9 infeasibility of obtaining or using Hydrated Silica with a lead specification of 4.5 ppm in
10 Sheffield's Toothpaste Products as outlined in Paragraphs 3.1(b) and 3.2; provided that, in such
11 case of infeasibility, Sheffield is permitted, but not required, to seek modification of this Consent
12 Judgment. Any party seeking to modify this Consent Judgment must first give notice to each
13 other Party in writing of any proposed modification of this Consent Judgment with the basis for
14 the proposed modification. The Parties shall meet and confer in good faith and attempt to reach
15 agreement on proposed modification of the Consent Judgment. If a resolution is not reached
16 within forty-five (45) days of the notice, the Party seeking modification may move the Court to
17 modify this Consent Judgment.

18 **8.2.** The Parties agree that if AESI enters into a settlement agreement with another
19 toothpaste manufacturer or distributor in the future that imposes injunctive relief that is less
20 burdensome from the provisions contained in this Consent Judgment and the settlement
21 agreement is entered as a Consent Judgment, Sheffield has the right to seek modification of the
22 Consent Judgment pursuant to Paragraph 8.1 to allow Sheffield to modify this Consent Judgment
23 to provide for the same injunctive relief imposed on the other toothpaste manufacturer or
24 distributor.

25 **9. Governing Law.** This Consent Judgment shall be governed by, and construed in
26 accordance with, the laws of the State of California, without regard to conflict of laws principles.

27 **10. Entire Agreement.** The Parties declare and represent that no promise, inducement or
28 other agreement has been made conferring any benefit upon any party except those contained

1 herein and that this Consent Judgment contains the entire agreement pertaining to the subject
2 matter hereof. This Consent Judgment supersedes any prior or contemporaneous negotiations,
3 representations, agreements and understandings of the Parties with respect to such matters,
4 whether written or oral. Parol evidence shall be inadmissible to show agreement by, between, or
5 among the Parties to any term or condition contrary to or in addition to the terms and conditions
6 contained in this Consent Judgment. The Parties acknowledge that each has not relied on any
7 promise, representation or warranty, expressed or implied, not contained in this Consent
8 Judgment.

9 **11. Challenges.** Subject to their rights to apply for a modification of this Consent Judgment
10 for good cause shown under Paragraph 8 hereof, the Parties agree that they, individually or
11 collectively, will not seek to challenge or to have determined invalid, void or unenforceable any
12 provision of this Consent Judgment or this Consent Judgment itself. The Parties understand that
13 this Consent Judgment contains the relinquishment of legal rights and each Party has, as each has
14 deemed appropriate, sought the advice of legal counsel, which each of the Parties has encouraged
15 the other to seek. Further, no Party has reposed trust or confidence in any other Party so as to
16 create a fiduciary, agency, or confidential relationship.

17 **12. Construction.** This Consent Judgment has been jointly negotiated and drafted. The
18 language of this Consent Judgment shall be construed as a whole according to its fair meaning
19 and not strictly for or against any Party.

20 **13. Authority to Stipulate to Consent Judgment.** Each signatory to this Consent Judgment
21 represents and warrants that the signatory has all requisite authorization, power, and legal right
22 necessary to execute and deliver this Consent Judgment and to perform and carry out the
23 transactions contemplated by this Consent Judgment. No other or further authorization or
24 approval from any person will be required for the validity and enforceability of the provisions of
25 this Consent Judgment.

26 **14. Cooperation and Further Assurances.** The Parties hereby will execute such other
27 documents and take such other actions as may be necessary to further the purposes and fulfill the
28 terms of this Consent Judgment.

1 **15. Counterparts.** This Consent Judgment may be executed in counterparts and has the same
2 force and effect as if all the signatures were obtained in one document.

3 **16. Notices.**

4 **16.1** All correspondence and notices required by this Consent Judgment to AESI shall
5 be sent to:

6 Roger Lane Carrick
7 The Carrick Law Group, P.C.
8 350 S. Grand Avenue, Suite 2930
9 Los Angeles, CA 90071-3406
10 Tel: (213) 346-7930 – Fax: (213) 346-7931
11 E-mail: roger@carricklawgroup.com

12 **16.2** All correspondence and notices required by this Consent Judgment to Sheffield
13 shall be sent to Sheffield as follows:

14 **SHEFFIELD PHARMACEUTICALS**

15 Thomas H. Faria
16 President
17 Sheffield Pharmaceuticals
18 170 Broad Street
19 New London, CT 06320
20 Phone: (860) 442-4451
21 Fax: (860) 442-0356
22 E-mail: thfaria@sheffield-
23 pharmaceuticals.com

24 With a copy to:
25 Richard C. Coffin, Esq.
26 Barg Coffin Lewis & Trapp
27 350 California Street, 22nd Floor
28 San Francisco, CA 94104-1435
Phone: (415) 228-5400
Fax: (415) 228-5450
E-mail: rcc@bcltlaw.com

18 **17. Motion for Approval of Consent Judgment.** Following the execution of this Consent
19 Judgment by the Parties, counsel for AESI shall promptly prepare and submit to the Court a
20 motion seeking the Court's approval of this Consent Judgment.

21 **18. Entry of Stipulation For Entry of Consent Judgment Required.** This Consent
22 Judgment shall be null and void, and without any force or effect, unless fully approved as
23 required by law and entered by the Court. If the Court does not enter this Consent Judgment, the
24 execution thereof by Sheffield or AESI shall not be construed as an admission by Sheffield or
25 AESI of any fact, issue of law or violation of law.

26 **19. Jurisdiction.** This Court shall retain jurisdiction of this matter to implement this Consent
27 Judgment.

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1 20. Compliance with Reporting Requirements. AESI shall comply with the reporting form
2 requirements referred to in Health and Safety Code section 25249.7(f) and established in Title 11
3 of the California Code of Regulations sections 3000-3008. Copies of all such reports shall be
4 supplied to Sheffield as provided in Paragraph 16.2.

5 21. Non-Interference in Settlement Approval Process. The Parties will cooperate, as well
6 as use their respective best efforts, to secure the Attorney General's approval of this Consent
7 Judgment, and not to seek his disapproval of any portion of this Consent Judgment.

8 **IT IS SO STIPULATED:**

9 DATED: July 16, 2008 AMERICAN ENVIRONMENTAL SAFETY
10 INSTITUTE, a non-profit California corporation
11 By: *Dallen Green*
12 Title: PRESIDENT

14 DATED: _____ SHEFFIELD PHARMACEUTICALS
15 By: _____
16 Title: _____

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6 as use their respective best efforts, to secure the Attorney General's approval of this Consent
7 Judgment, and not to seek his disapproval of any portion of this Consent Judgment.

8 **IT IS SO STIPULATED:**

9 DATED: _____ AMERICAN ENVIRONMENTAL SAFETY
10 INSTITUTE, a non-profit California corporation

11 By: _____

12 Title: _____

13
14 DATED: 7/10/08 _____

SHEFFIELD PHARMACEUTICALS

15 By: Thomas M. Jura _____

16 Title: President _____

1 **THE COURT HEREBY FINDS AND ORDERS:**

2 1. In light of the findings below, and based upon the Court's review of the proposed
3 Consent Judgment executed by the Plaintiff AESI and Defendant Sheffield, and the papers filed
4 in support of this Motion to Enter the proposed Consent Judgment, and in a manner consistent
5 with Code of Civil Procedure § 664.6, the Court finds that this settlement agreement is just, and
6 serves and will serve the public interest, as follows:

7 2. Because no warnings are required by the foregoing stipulated Consent Judgment,
8 this Court does not have to make any finding regarding compliance with warnings under the
9 provisions of Health & Safety Code §§ 25249.5-25249.13.

10 3. The Parties' agreement that no civil penalties are warranted is in accord with the
11 criteria set forth in Health & Safety Code §§ 25249.7(b)(2) and 25249.7(f)(4)(C), in that
12 payments as set forth in section 4 of the Consent Judgment totaling \$65,000.00, in lieu of such
13 penalties, to Plaintiff (a) to pay its attorneys' fees of \$31,200.00, and (b) to further the remedial
14 purposes established under Proposition 65 by providing funds for Plaintiff's ongoing costs of
15 monitoring compliance with this Consent Judgment, as well as for its future investigational and
16 enforcement activities regarding toxic chemicals and Proposition 65, are consistent with the
17 private enforcement mechanism and funds allocation scheme established by Health & Safety
18 Code §§ 25249.7(d) and 25249.12(d) and AESI's non-profit mission.

19 4. Pursuant to Health & Safety Code §25249.7(f)(4)(B) and Code of Civil Procedure
20 §1033.5, the Court finds that the Consent Judgment's contractual provision at section 4 for the
21 Plaintiff to pay, pursuant to its written contingent fee agreement, to Carrick Law Group, P.C.,
22 attorneys' fees of \$31,200.00 from the financial relief set forth in section 4 of the Consent
23 Judgment, as well as the amount of these fees and costs, are reasonable under California law.

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1 5. In light of the findings made above, and based upon the Court's review of the
2 proposed stipulated Consent Judgment executed among the Parties, the Court finds that this
3 Consent Judgment is just, and serves and will serve the public interest.

4 **IT IS SO ORDERED, ADJUDGED, AND DECREED.**

5 JUL 30 2008
6 DATED: _____

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8 Mary Thornton House

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10 HON. MARY THORNTON HOUSE
11 JUDGE OF THE SUPERIOR COURT
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