UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

In the Matter of	-
BRAIN-PAD, INC., a corporation, and	
JOSEPH MANZO, individually and as an officer of Brain-Pad, Inc.	

FILE NO. 122-3073

AGREEMENT CONTAINING CONSENT ORDER

The Federal Trade Commission ("Commission") has conducted an investigation of certain acts and practices of Brain-Pad, Inc. and Joseph Manzo ("proposed respondents"). Proposed respondents, having been represented by counsel, are willing to enter into an agreement containing a consent order resolving the allegations contained in the attached draft complaint. Therefore,

IT IS HEREBY AGREED by and between Brain-Pad, Inc., by its duly authorized officers, Joseph Manzo, and counsel for the Federal Trade Commission that:

1. Proposed respondent Brain-Pad, Inc. ("BPI") is a Pennsylvania corporation with its principal office or place of business at 322 Fayette Street, Conshohocken, Pennsylvania 19428.

2. Respondent Joseph Manzo is the President of BPI. Individually or in concert with others, he formulates, directs, controls, or participates in the policies, acts, or practices of BPI. His principal office or place of business is the same as that of BPI.

3. Proposed respondents admit all the jurisdictional facts set forth in the draft complaint.

4. Proposed respondents waive:

a. Any further procedural steps;

b. The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law; and

c. All rights to seek judicial review or otherwise challenge or contest the validity of the order entered pursuant to this agreement.

5. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission, it,

together with the draft complaint, will be placed on the public record for a period of thirty (30) days and information about it will be publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify proposed respondents, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision in disposition of the proceeding.

6. This agreement is for settlement purposes only and does not constitute an admission by proposed respondents that the law has been violated as alleged in the draft complaint, or, that the facts as alleged in the draft complaint, other than the jurisdictional facts, are true.

7. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of Section 2.34 of the Commission's Rules, the Commission may, without further notice to the proposed respondents, (1) issue its complaint corresponding in form and substance with the attached draft complaint and its decision containing the following order in disposition of the proceeding, and (2) make information about it public. When so entered, the order shall have the same force and effect and may be altered, modified, or set aside in the same manner and within the same time frame provided by statute for other orders. The order shall become final upon service. Delivery of the complaint and the decision and order to proposed respondents' addresses as stated in this agreement by any means specified in Section 4.4(a) of the Commission's Rules shall constitute service. Proposed respondents waive any right they may have to any other manner of service. The complaint may be used in construing the terms of the order, and no agreement, understanding, representation, or interpretation not contained in the order or the agreement may be used to vary or contradict the terms of the order.

8. Proposed respondents have read the draft complaint and consent order. Proposed respondents understand that they may be liable for civil penalties in the amount provided by law and other appropriate relief for each violation of the order after it becomes final.

<u>ORDER</u>

DEFINITIONS

For purposes of this Order, the following definitions shall apply:

1. Unless otherwise specified, "respondent BPI" shall mean Brain-Pad, Inc., a corporation, its successors and assigns and their officers, and each of the above's agents, representatives, and employees.

2. "Respondent Manzo" shall mean Joseph Manzo and his agents, representatives, and employees.

3. "Respondents" shall mean respondent BPI and respondent Manzo.

4. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

5. "Competent and reliable scientific evidence" shall mean tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results.

6. "Covered Product" shall mean any (1) mouthguard or (2) equipment used in athletic activities that is intended, in whole or in part, to protect the brain from injury.

7. The term "including" in this Order shall mean "without limitation."

8. The terms "and" and "or" in this Order shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.

I.

IT IS ORDERED that respondents, directly or through any corporation, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product, in or affecting commerce, shall not represent, in any manner, expressly or by implication, including through the use of a trade name, product name, endorsement, depiction, or illustration, that such product will:

- A. reduce the risk of concussions; or
- B. reduce the risk of concussions from lower jaw impacts,

unless the representation is true, non-misleading, and, at the time of making such representation, respondents possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

II.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research, including, but not limited to, any misrepresentation that:

- A. scientific studies prove such product reduces the risk of concussions; or
- B. scientific studies prove such product reduces the risk of concussions from lower jaw impacts.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale or distribution of any Covered Product, in or affecting commerce, shall not represent in any manner, expressly or by implication, including through the use of a trade name, product name, endorsement, depiction, or illustration, the health benefits, health-related performance, or health-related efficacy of any such product, unless the representation is true, non-misleading, and, at the time of making such representation, respondents possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

IV.

IT IS FURTHER ORDERED that respondent BPI, and its successors and assigns, and respondent Manzo shall, for five (5) years after the last date of dissemination of any representation covered by this Order, maintain and upon reasonable notice make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in its possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

V.

IT IS FURTHER ORDERED that respondent BPI, and its successors and assigns, and respondent Manzo shall deliver a copy of this Order to all current and future principals, officers, directors, and other employees having responsibilities with respect to the subject matter of this Order, and shall secure from each such person a signed and dated statement acknowledging receipt of the Order. Respondents shall deliver this Order to current personnel within thirty (30) days after date of service of this Order, and to future personnel having responsibilities with respect to the subject matter of this Order within thirty (30) days after the person assumes such position or responsibilities.

VI.

IT IS FURTHER ORDERED that respondent BPI, and its successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporation that may

affect compliance obligations arising under this Order, including, but not limited to, dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. *Provided, however*, that, with respect to any proposed change in the corporation about which respondent learns fewer than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to <u>Debrief@ftc.gov</u> or sent by overnight courier to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: <u>Brain-Pad, Inc.</u>, FTC File No. 122-3073.

VII.

IT IS FURTHER ORDERED that respondent Manzo, for ten (10) years after the date of issuance of this Order, shall notify the Commission of the discontinuance of his current business or employment, or of his affiliation with any new business or employment. The notice shall include respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to <u>Debrief@ftc.gov</u> or sent by overnight courier to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: <u>Brain-Pad, Inc.</u>, FTC File No. 122-3073.

VIII.

IT IS FURTHER ORDERED that respondent BPI, and its successors and assigns, and respondent Manzo, within sixty (60) days after the date of service of this Order, shall each file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of their own compliance with this Order. Within ten (10) days of receipt of written notice from a representative of the Commission, respondents shall submit additional true and accurate written reports.

IX.

This Order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the Order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this Order that terminates in less than twenty (20) years;
- B. This Order's application to any respondent that is not named as a defendant in such complaint; and

C. This Order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that respondent did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Part as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

Signed this day of		, 2012.
		BRAIN-PAD, INC.
Dated:	By:	Joseph Manzo, President
Dated:	By:	Joseph Manzo, individually and as an officer of Brain-Pad, Inc.
	By:	Patrick J. Wolfe, Jr. Zarwin Baum DeVito Kaplan Schaer & Toddy P.C. Counsel for Respondents Brain-Pad, Inc. and Joseph Manzo
	By:	Bridget E. Calhoun Crowell & Moring LLP Counsel for Respondents Brain-Pad, Inc. and Joseph Manzo
	By:	VICTOR DeFRANCIS ANDREW WONE Counsel for the Federal Trade Commission

APPROVED:

MARY K. ENGLE Associate Director Division of Advertising Practices

DAVID C. VLADECK Director Bureau of Consumer Protection