# UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

#### **COMMISSIONERS:**

Jon Leibowitz, Chairman J. Thomas Rosch Edith Ramirez Julie Brill Maureen K. Ohlhausen

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

DOCKET NO. C-4375

# **DECISION AND ORDER**

The Federal Trade Commission ("Commission") having initiated an investigation of certain acts and practices of the respondents named in the caption hereof, and the respondents having been furnished thereafter with a copy of a draft complaint that the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge the respondents with violation of the Federal Trade Commission Act, 15 U.S.C § 45 *et seq.*; and

The respondents, their attorney, and counsel for the Commission having thereafter executed an agreement containing a consent order ("consent agreement"), an admission by the respondents of all the jurisdictional facts set forth in the aforesaid draft complaint, a statement that the signing of said consent agreement is for settlement purposes only and does not constitute an admission by the respondents that the law has been violated as alleged in the complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it has reason to believe that the respondents have violated the Federal Trade Commission Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such consent agreement on the public record for a period of thirty (30) days, and having duly considered the comments filed thereafter by interested persons pursuant to Section 2.34 of its Rules, now in further conformity with the procedure

prescribed in Section 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

- 1. 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. The Commission has jurisdiction of the subject matter of this proceeding and of respondents, and the proceeding is in the public interest.

# <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.

**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.

# III.

**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.

**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: Brain-Pad, Inc., FTC File No. 122-3073.

**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 on November 15, 2032, 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.

By the Commission, Commissioner Rosch dissenting.

Donald S. Clark Secretary

SEAL: ISSUED: November 15, 2012