

## Complaint

## IN THE MATTER OF

**BRAIN-PAD, INC.****AND****JOSEPH MANZO**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF  
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket No. C-4375; File No. 122 3073**Complaint, November 15, 2012 – Decision, November 15, 2012*

This consent order addresses Brain-Pad, Inc.'s advertising and promotion of mouth guards. The complaint alleges that respondents did not have a reasonable basis to represent in advertising and on packaging for their mouth guards that they reduced the risk of concussions. The complaint further alleges that the respondents made the false and misleading claim that they possessed scientific studies that proved their concussion-reduction risk claims because, in fact, they did not have such evidence. The consent order prohibits the respondents from misrepresenting that any product will reduce the risk of concussions or reduce the risk of concussions from lower jaw impacts.

*Participants*

For the *Commission*: Victor DeFrancis and Andrew Wone.

For the *Respondents*: Patrick Wolfe, Jr., Zarwin, Baum, DeVito, Kaplan, Schaer & Toddy P.C.; Bridget Calhoun, Crowell & Moring LLP.

**COMPLAINT**

The Federal Trade Commission, having reason to believe that Brain-Pad, Inc., a corporation, and Joseph Manzo, an individual ("Respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

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,

## Complaint

controls, or participates in the policies, acts, or practices of BPI, including the acts or practices alleged in this complaint. His principal office or place of business is the same as that of BPI.

3. Respondents have labeled, advertised, promoted, offered for sale, sold, and distributed, throughout the United States, “Brain-Pad”-branded mouth guards (“Brain-Pad mouth guards”) to consumers. Brain-Pad mouth guards are “devices” within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

4. The acts and practices of Respondents, as alleged herein, have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.

5. Respondents have disseminated or caused to be disseminated advertisements for Brain-Pad mouth guards, including, but not limited to, the attached Exhibits A through F. These advertisements contain the following statements and depictions, among others:

- a. **Product Packaging:** Brain-Pad Pro+  
(front of package)



Complaint

Brain-Pad Pro+ (back of package)

**PRO+**

PROTECTION | PERFORMANCE | ENDURANCE  
DOUBLE INJECTION DUAL ARCH DESIGN

**Triple Benefits**

- 1. Creates & Maintains Brain Safety Space
- 2. Lower Channel Jaw Stabilizer
- 3. Opens Airway

ALL RIGHTS RESERVED.  
OTHER U.S. & FOREIGN PATENTS PENDING.  
MADE IN TAIWAN.

Tested and proven to reduce risk of internal head injuries and concussions from lower jaw impacts

Exclusive high-impact inner material helps absorb concussive blows

Gel form liner molds firmly to teeth supporting entire dental arch

Air Flow Clench & Breathe™ technology enhances breathing and endurance

Protects upper and lower teeth, lips, tongue

Fits over braces

30 second custom fitting instructions inside

Can be worn with or without included strap

Increases helmet safety and effectiveness

Approved for Mandate by: International Kickboxing Federation, International Sport Karate Association, and Kick International

Includes hard shell anti-microbial storage case

Latex Free

\$12,000 Dental Insurance Warranty

## Complaint

- b. **Product Packaging:** Brain Pad LoPro+  
(front of package)



## Complaint

## Brain Pad LoPro+ (back of package)



The Patented BRAIN-PAD repositions & secures the lower jaw in a safety position, reducing the risk of concussions from lower jaw Impacts.

**With Other Mouthguards:**



Protects only the UPPER TEETH!

**Brain Injuries!**

Clench No Air

IMPACT

Jaw can Slam the TMJ & base of skull!

Upon Impact, the Lower Jaw can SLAM into the TMJ & the Base of the Skull!

**With The BRAIN-PAD®**



Securely Locks & Cushions Teeth & Jaw!

**Brain Safety!**

CLENCH and BREATHE

IMPACT

Helps Prevent Jaw from Slamming TMJ & base of the Skull!

**CREATES NEW BRAIN SAFETY SPACE!**

The Patented BRAIN-PAD transmits the impact energy away from the base of the skull to the BRAIN-PAD!



WITH THE BRAIN-PAD

UPPER ONLY! Mouthguards allow clench.

New 'streamline design' Secures & Cushions lower jaw while protecting ALL teeth!

Use 1 strap

\* NEW STRAP, LANYARD or STRAPLESS attachment system!

Offers constant mouth breathing - Even while CLENCHING!

Patented inner injection process creates a shock absorber that helps reduce lower jaw impact concussions!

CUSTOM MOLDS TO ALL TEETH!



2 straps included for:

NEW-LANYARD style "NON-HELMETED" or HELMETED USE!

**Patented "PROTECTION & PERFORMANCE" in 1 Package!**

**System Includes:**

Boiling Stick, Protective Case

Warranty, Warnings, Care, and Custom Fitting Instructions.

\* Meets & exceeds all youth, high school & Collegiate Regulations



CAN UNLOCK MUSCULAR POTENTIAL! CUSHIONS TEETH!

LPP-06 Black/Clear JUNIOR SIZE



7 57920 80050 9

"STRAP / STRAPLES in-one" Model!

Manufactured exclusively by Brain-Pad, Inc., 322 Fayette St., Conshohocken, PA 19383, 610.397.0893 www.brainpads.com

Copyright 2000-2007 Brain-Pad, Inc.

Protected under U.S. & Foreign Patents: # 5,936,379, # D493,578S, # D500,896S, # D523,994, # D525,749, # D526,093, # D526,095, # D527,848, # D530,863, # D532,559, # D537,986S, # D537,987S, # 000408947-0001, # 000408947-0002, # CA2251072

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## Complaint

- c. **Product Packaging:** Brain-Pad Pro-Plus Junior  
(front of package)



## Complaint

## Brain-Pad Pro-Plus Junior (back of package)



**The patented **BRAIN-PAD**<sup>®</sup>**  
Positions, Secures & Cushions the  
lower jaw in a Safety Position, reducing  
the risk of concussions from the lower  
jaw slamming into the TMJ, base of the  
skull and brain.

**With Other Mouthguards**

Bottom  
Teeth & Jaw  
Slide & Slam!

**Brain  
Injuries!**

Clench  
No Air!

IMPACT

Jaw Slams TMJ and base of skull!

**Upon Impact, the Lower Jaw  
can SLAM into the TMJ & the  
Base of the Skull!**

**With The **BRAIN-PAD**<sup>®</sup>**

Secures &  
Cushions  
Teeth & Jaw!

**Brain  
Safety!**

CLENCH  
and  
BREATHE!

IMPACT

Helps Prevent Jaw from  
Slamming TMJ & base of the Skull!

**CREATES  
NEW  
BRAIN  
SAFETY  
SPACE!**

**The Patented **BRAIN-PAD** transmits  
the impact energy away from the brain  
to the **BRAIN-PAD**!**

**! MAXIMUM BREATHING !**



Increased airway space  
WITH THE **BRAIN-PAD**!

"UPPER ONLY" Mouthguards -  
airway closure

Only upper & lower channels can secure & stabilize Jaw  
Position while protecting the upper  
AND lower teeth!



Use  
1 strap

\* NEW:  
STRAP,  
LANYARD or  
STRAPLESS  
attachment  
system!

Offers constant  
mouth breathing -  
Even while  
CLENCHING!

Patented  
inner injection  
process creates a  
shock absorber that  
protects against lower  
jaw impact concussions!

30 sec. Boil-N-Bite  
CUSTOM FIT

- OR -

2 STRAPS  
included for:  
NEW - LANYARD style "NON-HELMETED" or HELMETED USE!

**Patented "**PROTECTION & PERFORMANCE**" in 1 Package!**

**System Includes:**  
PRO+PLUS, 2 Optional Straps,  
Storage Case, Warranty, Warnings,  
Care & Custom Fitting Instructions.

\* Meets & exceeds all youth,  
high school & Collegiate Regulations



CAN UNLOCK  
MUSCULAR POTENTIAL!  
CUSHIONS TEETH!

WPRY-2004 JUNIOR SIZE  
BLACK/GRAY



7 57920 50510 7

Manufactured exclusively by Brain-Pad, Inc., 322 Fayette St., Copstahocken, PA 19428 610-397-0893 www.brainpad9.com  
Copyright 2000-2007 Brain-Pad, Inc.  
Protected under U.S. & Foreign Patents: # 5,836,376, # D493,578, # D500,895S, # D523,994, # D525,748, # D526,093,  
# D526,095, # D527,546, # D53,0863, # D532,560, # D543,403, # 100488947-0001, # 000488947-0002,  
# CA2251072. All Rights Reserved. Other U.S. & Foreign Patents pending. Made in Taiwan. PRO+PLUS 08/02/07

## Complaint

- d. **Product Packaging:** Brain-Pad LoPro Fem  
(front of package)



## Complaint

## Brain-Pad LoPro Fem (back of package)



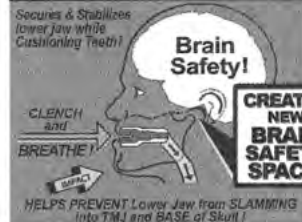
**Your Brain With Upper Mouthguards**



**Brain Injuries**

Upper mouthguards can induce internal head injuries & limit breathing!

**Your Brain With The BRAIN-PAD**



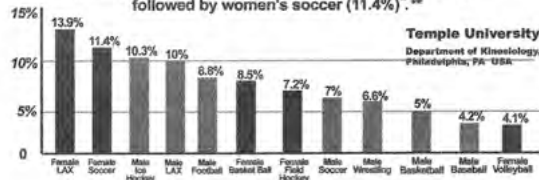
**Brain Safety!**

The Patented **BRAIN-PAD** transmits the impact energy away from the base of the skull to the **BRAIN-PAD**!

**GET MORE AIR!**



"Of all the reported injuries, women lacrosse players (13.9%), reported the highest percentage of suffering a concussion during a game followed by women's soccer (11.4%)".<sup>1,2</sup>



**Temple University**  
Department of Kinesiology,  
Philadelphia, PA-USA

<sup>1,2</sup> Female athletes were found to be at a greater risk for suffering concussions during games compared to male athletes

**System Includes:** Boiling Stick, Storage Pouch, Warranty, Warnings, Care, & Custom Fitting Instructions.



UNLOCKS CARDIOVASCULAR & MUSCULAR POTENTIAL!  
CUSHIONS TEETH!



WFL-200 Blue/Clear

\* Frank Hillary, Ph.D., Kessler Med. Rehab. Research and Educ. Corp. Colleen Mann, Philip Schatz Ph.D. Saint Joseph's University, Dept. of Psychology, Philadelphia PA.

\*\* Total Participants - SGMA INTERNATIONAL 200 CastleWood Dr., North Palm Beach, FL 33408-5696 - .382 concussion ratio per 1000 AES (estimated 35 AES per participant).

\*\*\* Epidemiological considerations of concussions among intercollegiate athletes. - Covassin T, Swannik CB, Sachs ML. Appl Neuropsychol 2003; 10(1): 12-22. Correspondence: Tracey Covassin, Department of Kinesiology, Temple University, Philadelphia, Pennsylvania, USA, (email: tracey.covassin@temple.edu). (Copyright © 2003, Lawrence Erlbaum Associates).

Manufactured exclusively by Brain-Pad, Inc., 322 Fayette St., Conshohocken, PA 19428. 610.357.0693. www.brainpads.com  
Copyright 2000-2006 Brain-Pad, Inc. Protected under U.S. & Foreign Patents. # 5,636,379, # D493,578S, # D500,895S, # D523,994, # D525,749, # D526,093, # D526,095, # 000468947-0002, # CA2251672.  
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LoPro Female  
US 15.96

## Complaint

- e. **Product Packaging:** Brain-Pad Double mouth guard  
(front of package)



## Complaint

f. **Internet Website: [www.brainpads.com](http://www.brainpads.com)**

VIDEO: (Brain-Pad Commercial featuring Joseph Manzo) (Transcript at Exhibit A)

ON SCREEN: BRAIN PAD

Protective & Performance Solutions

BIOMECHANICALLY TESTED

REDUCES RISK OF CONCUSSIONS!

For All CONTACT SPORTS

(Exhibit A at 3).

\* \* \*

MALE ANNOUNCER: So much attention is now being paid to concussions, literally a contusion to the brain.

ON SCREEN: THE IMPORTANCE OF JAW POSITION

MALE ANNOUNCER: And Brain Pad may be on the verge of a huge breakthrough in prevention after 15 years of hard work and belief.

(Exhibit A at 4).

\* \* \*

JOSEPH MANZO: Every time we got a school involved with it, at the end of the year, they would say, wow, man, our concussions went from nine to zero or nine

to one. You know, it was just this constant feedback. My head -- we don't play with the headaches anymore.

(Exhibit A at 5).

## Complaint

g. **Print Advertisement** (Exhibit B) (BP00075)

(depiction of MMA fighter and Brain-Pad mouth guard)

**MMA ORGANIZATIONS****FIGHT CONCUSSIONS****with BRAIN-PAD!**h. **Print Advertisement** (Exhibit C) (BP00157)

‘Creates and retains’  
a TMJ/Brain Safety  
Space protecting  
the TMJ AND Base  
of Skull & Brain

Helping Coaches . . .  
REDUCE  
CONCUSSION  
RISK

\* \* \*

**“BIO-MECHANICALLY TESTED & PROVEN”****REDUCES THE RISK OF CONCUSSIONS****FROM: FACEMASK IMPACTS, CHIN CUP****FORCES & DIRECT LOWER JAW IMPACTS!**i. **Print Advertisement** (Exhibit D) (BP00131)**PROTECTION & PERFORMANCE!**

Protects TMJ & Brain from Jaw Impacts

- Reduces the risk of **Concussion**

## Complaint

**Only ‘Jaw Joint Protectors’ Reduce the Risk of  
Concussions & Internal Head Injuries.**

j. **Email Advertisement** (Exhibit E) (BP00254 – 55)

(Headline) Athletes Turn to Brain-Pad Mouth Guards  
for Concussion Protection

\* \* \*

As Congress prepares to examine the issue of concussions in the NFL, NCAA, and high school sports for the second time on January 4, a Pennsylvania company has been successfully marketing a mouth guard device designed to protect players from the probability of a concussion caused by lower jaw impact.

\* \* \*

“We have said for years that concussions are serious injuries and should be avoided at all costs,” says Joe Manzo, President of Brain-Pad. “The devastating effects of concussions can have a lasting impact on athletes and their families. . . . When used properly, there is a 40 percent reduction of impact energy to the base of the skull, these forces can cause a concussion or knock out as boxers call it. Athletes from the NFL to the MMA and at every level from professional to local youth leagues are recognizing the significant health benefits of our Brain-Pad mouth guards to offer protection against these dangerous injuries.”

k. **Point of Purchase Display** (Exhibit F) (BP00308)

**BRAIN PAD**

**BIOMECHANICALLY TESTED:**

**REDUCES RISK OF CONCUSSIONS!**

## Complaint

6. Through the means described Paragraph 5, including the statements and depictions contained in the advertisements attached as Exhibits A through F, among others, Respondents have represented, expressly or by implication, that:

- a. Brain-Pad mouth guards reduce the risk of concussions; and
- b. Brain-Pad mouth guards reduce the risk of concussions from lower jaw impacts.

7. Through the means described in Paragraph 5, Respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 6, at the time the representations were made.

8. In truth and in fact, Respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 6, at the time the representations were made. Therefore, the representation set forth in Paragraph 7 was, and is, false or misleading.

9. Through the means described in Paragraph 5, including the statements and depictions contained in the advertisements attached as Exhibits A through F, among others, Respondents have represented that:

- a. scientific studies prove that Brain-Pad mouth guards reduce the risk of concussions; and
- b. scientific studies prove that Brain-Pad mouth guards reduce the risk of concussions from lower jaw impacts.

10. In truth and in fact, scientific studies do not prove that Brain-Pad mouth guards reduce the risk of concussions or reduce the risk of concussions from lower jaw impacts. Therefore, the representations set forth in Paragraph 9 were, and are, false or misleading.

11. The acts and practices of Respondents as alleged in this complaint constitute unfair or deceptive acts or practices, and

## Complaint

the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

**THEREFORE**, the Federal Trade Commission, this fifteenth day of November, 2012, has issued this complaint against Respondents

By the Commission.

Complaint

**Exhibit A****OFFICIAL TRANSCRIPT PROCEEDING****FEDERAL TRADE COMMISSION**

|            |                                                                                       |
|------------|---------------------------------------------------------------------------------------|
| MATTER NO. | 1223015                                                                               |
| TITLE      | ANTI-CONCUSSION PRODUCTS                                                              |
| DATE       | RECORDED: DATE UNKNOWN<br>TRANSCRIBED: NOVEMBER 21, 2011<br>REVISED: JANUARY 10, 2012 |
| PAGES      | 1 THROUGH 8                                                                           |

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BRAIN PAD COMMERCIAL

Complaint

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FEDERAL TRADE COMMISSION

I N D E X

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|----------------------|--------------|
| <u>RECORDING:</u>    | <u>PAGE:</u> |
| Brain Pad Commercial | 3            |

## 2

In the Matter of: )  
Anti-Concussion Products ) Matter No. 1223015  
 )  
----- )  
Date Unknown

For The Record, Inc.  
(301) 870-8025 - [www.ftrinc.net](http://www.ftrinc.net) - (800) 921-5555

## Complaint

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1 P R O C E E D I N G S

2 - - - - -

3 B R A I N P A D C O M M E R C I A L

4 MALE ANNOUNCER: While long-time anchor stores  
5 like Flaco Shoes still line Fayette Street, this  
6 storefront houses the most modern in technology and --

7 JOSEPH MANZO: Onto the face mask.

8 MALE ANNOUNCER: -- football. This company is  
9 called Brain Pad. Got that? Brain Pad.

10 MALE INTERVIEWER: Is your primary push into  
11 football or boxing or any sport with this?

12 ON SCREEN: Joseph Manzo

13 PRESIDENT, CEO

14 JOSEPH MANZO: Football, boxing, MMA. MMA is  
15 like taking over.

16 ON SCREEN: Brain Pad photo

17 Model: PRO+PLUS

18 MALE ANNOUNCER: This may look like a sports  
19 mouthpiece, but as the name implies, it protects more  
20 than teeth.

21 ON SCREEN: BRAIN PAD

22 Protective &amp; Performance Solutions

23 BIOMECHANICALLY TESTED:

24 REDUCES RISK OF CONCUSSIONS!

25 For All CONTACT SPORTS

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## Complaint

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1 JOSEPH MANZO: The way the product is designed  
2 is that it brings the lower jaw forward about a half a  
3 millimeter in front of your upper teeth and the thickness  
4 of the unit brings your jaw down, so you get this down  
5 and forward motion, creating a safety space here.

6 ON SCREEN: Actual Lab Impact Test

7 JOSEPH MANZO: No matter if you're taking  
8 direct hits, lateral hits, it's keeping -- these are the  
9 strongest bones in the skull. So, a lot of that energy  
10 is absorbed there and into the jaw joint protector.

11 MALE ANNOUNCER: So much attention is now being  
12 paid to concussions, literally a contusion to the brain.

13 ON SCREEN: THE IMPORTANCE OF JAW POSITION

14 MALE ANNOUNCER: And Brain Pad may be on the  
15 verge of a huge breakthrough in prevention after 15 years  
16 of hard work and belief.

17 ON SCREEN: PROTECTION PERFORMANCE ENDURANCE

18 BRAIN PAD ,

19 PROTECTION

20 Creates this:

21 BRAIN SAFETY SPACE!

22 PERFORMANCE

23 Jaw/TMJ alignment

24 promotes Strength &

25 Competitive Edge

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1                   **ENDURANCE**  
2                   **Creates Increased**  
3                   **Constant Breathing-**  
4                   **EVEN WHILE CLENCHING!**  
5                   **ON SCREEN: Joseph Manzo**  
6                   **PRESIDENT, CEO**  
7                   JOSEPH MANZO: Every time we got a school  
8                   involved with it, at the end of the year, they would say,  
9                   wow, man, our concussions went from nine to zero or nine  
10                  to one. You know, it was just this constant feedback.  
11                  My head -- we don't play with the headaches anymore.  
12                  MALE ANNOUNCER: Finally, a big breakthrough  
13                  and now a breakout from Brain Pad's humble beginning in  
14                  Conshohocken.  
15                  JOSEPH MANZO: The product is available in all  
16                  500 Sports Authority stores --  
17                  **ON SCREEN: SPORTS AUTHORITY**  
18                  **"Spring into...Sport Safety!"**  
19                  Brain-Pad's 2011 Jaw-Joint Protector  
20                  Mouth Guard Series  
21                  Brain-Pad  
22                  **"Jaw-Joint Protectors" are a patented Sport**  
23                  **Safety Technology!**  
24                  **REDUCES Jaw Impact CONCUSSION Risk!**  
25                  Includes: Dental Warranty, hard-shell anti-

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1       microbial case, optional strap & custom fitting  
2       instructions  
3               PROTECTION    PERFORMANCE    ENDURANCE  
4       JOSEPH MANZO:  -- and it's in over 1,000  
5       Walmart stores.  
6               ON SCREEN:  BRAIN PAD advertisement  
7       JOSEPH MANZO:  We have at least 500 mom-and-pop  
8       retailers, single brick and mortar retail outlets.  
9               ON SCREEN:  BRAIN PAD  
10              IMPACT PROTECTIVE  
11              ALL AGES  
12              HEADBANDS & WRISTBANDS  
13              WITH IMPACT ABSORBENT INNER MATERIAL  
14              YEAR-ROUND PROTECTION for ALL  
15              SPORTS, ACTIVITIES & ALL AGES!  
16       JOSEPH MANZO:  So, the product is easily  
17       accessible now.  
18              ON SCREEN:  BRAIN PAD  
19              PROTECTIVE & PERFORMANCE SOLUTIONS  
20              JAW-JOINT PROTECTORS  
21              322 FAYETTE STREET  
22              CONSHOHOCKEN, PA  
23              WWW.BRAINPADS.COM  
24              610-397-0893  
25       MALE ANNOUNCER:  Brain Pad is located at 322

For The Record, Inc.  
(301) 870-8025 - [www.ftrinc.net](http://www.ftrinc.net) - (800) 921-5555

## Complaint

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1       Fayette Street and their website will show and tell you  
2       all you need to know at [www.brainpads.com](http://www.brainpads.com). And you can  
3       reach them by phone at (break in recording) 97-0893.

4               **(The recording was concluded.)**

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FEDERAL TRADE COMMISSION DECISIONS  
VOLUME 154

## Complaint

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## 1                    C E R T I F I C A T I O N   O F   T Y P I S T

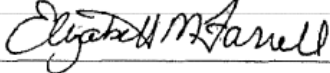
2

3                    MATTER NUMBER: 12230154                    CASE TITLE: ANTI-CONCUSSION PRODUCTS5                    TAPING DATE: DATE UNKNOWN6                    TRANSCRIPTION DATE: NOVEMBER 21, 20117                    REVISED: JANUARY 10, 2012

8                    I HEREBY CERTIFY that the transcript contained  
9                    herein is a full and accurate transcript of the tapes  
10                    transcribed by me on the above cause before the FEDERAL  
11                    TRADE COMMISSION to the best of my knowledge and belief.

12

13                    DATED: JANUARY 10, 2012

14                    

15

16                    ELIZABETH M. FARRELL

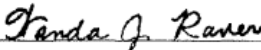
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## 18                    C E R T I F I C A T I O N   O F   P R O O F R E A D E R

19

20                    I HEREBY CERTIFY that I proofread the transcript for  
21                    accuracy in spelling, hyphenation, punctuation and  
22                    format.

23

24                    

25

WANDA J. RAVER

For The Record, Inc.  
(301) 870-8025 - [www.ftrinc.net](http://www.ftrinc.net) - (800) 921-5555

Complaint

## Exhibit B

11/2009 *Worldwide* MMA ~~Mag~~ *MAG.*

**Brain-Pad**  
PROTECTIVE SOLUTIONS

MMA ORGANIZATIONS  
FIGHT CONCUSSIONS  
with BRAIN-PAD!

SECURES JAW!  
CUSHIONS JAW!  
PROTECTS TMJ!  
PROTECTS BRAIN!  
UNLOCKS STRENGTH!  
CLENCH for POWER!  
CLENCH & BREATHE DESIGN!

"I've worn  
The Brain-Pad  
HP Model  
for 11 yrs -  
I WILL NOT  
FIGHT  
WITHOUT IT!"  
- Champion  
Cung Le  
Official mouth guard of:

Model: WPR-300  
HIGH PERFORMANCE

UCL  
UNIVERSITY OF CALIFORNIA  
LOS ANGELES

BRAIN-PAD® NO LIMIT - PATRONS DISCOUNT - Enter Code: BRMMA

**IS YOUR MOUTH GUARD  
MAKING YOU ... SICK?**

Bacteria on mouth guards can get into your:  
LUNGS STOMACH BLOOD-STREAM  
Case study by: Thomas Gleason, DDS, PhD  
Professor at The Academy of General Dentistry

**NATUREZONE™**  
ORAL APPLIANCE SANITIZER & DEODORIZER

3000x  
MORE  
EFFECTIVE  
than  
chlorine!

**KILLS DEADLY:  
MRSA, STAFF,  
Bacteria  
Viruses  
& fungi -  
IN A FAST  
3mins!**

PERSONAL  
UV/OZONE  
GENERATOR  
Sanitizes  
Deodorizes  
8,000 hr Bulb  
No tablets. No refills.  
Battery Powered -  
for use anywhere!

Brain-Pad, Inc.  
610-397-0893  
www.brainpads.com  
info@brainpads.com  
Distributorships available

Designed for: sport guards - night guards - retainers - dental appliances - tooth brush heads

BP00075

## Complaint

## Exhibit C



**"BIO-MECHANICALLY TESTED & PROVEN"**  
**REDUCES THE RISK OF CONCUSSIONS**  
**FROM: FACEMASK IMPACTS, CHIN CUP**  
**FORCES & DIRECT LOWER JAW IMPACTS!**



\*Includes: Two Baffle Membranes, Foam Insulators, Antimicrobial Cores, Coated Lining



**NHSCA 10% Discount Promo Code: NHSCA**

Purchase models WPR-2004 or 3XS-WP and use code NHSCA for 10% discount. Order from Sports Authority or visit [www.brainpad.com](http://www.brainpad.com) Order Section 10% Page



See mechanical Head Form Testing



Research & Results

Only Brain Pad has been RECOMMENDED for participation by National Football League Coaches.



Brain Pad Product is an OFFICIAL LICENSEE

Even for better protection and low Brain Pad Jaw-Joint Protection™, see 3



Order from [www.brainpad.com](http://www.brainpad.com)

English and Spanish Order Sheet



I never had a concussion. I've always worn Brain Pad.



800-597-9653 [www.brainpad.com](http://www.brainpad.com)

Emailer for National High School coaches Association

July 2011

BP00157

Complaint

## Exhibit D

11/2010 MARK AUTHORITY MARK.

**Brain-Pad®** **Jaw Joint Protectors™**

**PROTECTION & PERFORMANCE!**  
Protects TMJ & Brain from Jaw Impacts

- Reduces the risk of **Concussion**
- **Dual Arch** protective designs
- Offers **Clench & Breathe** technology
- Protects Upper and Lower Braces

*Creates and maintain brain safety space*

3XS-NP (non-strap)  
3XS-WP (with-strap)

*Tapered Channel Ends  
Remove need to trim!*

*Lower channel  
jaw stabilizer*

*Opens  
airway*

PRO+®  
Helmet tether included

**NEW** HIGH-IMPACT Gel-pad Inserts!

Intl. Combat Sport Organizations Mandate  
Dual Arch Mouth Guard Designs -

**Only 'Jaw Joint Protectors' Reduce the Risk of  
Concussion & Internal Head Injuries.**

Brain-Pad® Designs create a Jaw Joint / Brain 'Safety Space'!

Protected under U.S. Patent(s),  
Foreign Patent(s) and/or Patent(s) Pending.  
©2010 Brain-Pad, Inc. All Rights Reserved.

**Brain-Pad®** 610 397 0893 [www.brainpads.com](http://www.brainpads.com) [info@brainpads.com](mailto:info@brainpads.com)

BP00131

## Complaint

## Exhibit E

Andrew Piacine, Brain-Pad Inc

Subject:

FW: Athletes Turn to Brain-Pad Mouth Guards

Bates # CC-21 from 2009 to 2011 Delivery Date: Wednesday, December 30, 2009 at 3:05 PM EST Sent 2909 opens 569

**Brain-Pad, Inc.**

December 29, 2009 10:00 AM Eastern Time

**Athletes Turn to Brain-Pad Mouth Guards for Concussion Protection**

*Bi-molar mouth guard line is tested and proven to stabilize the jaw and protect the temporomandibular joint during sports-related impact*

CONSHOHOCKEN, Pa.--As Congress prepares to examine the issue of concussions in the NFL, NCAA, and high school sports for the second time on January 4, a Pennsylvania company has been successfully marketing a mouth guard device designed to protect players from the probability of a concussion caused by lower jaw impact.

"I treat many athletes looking for teeth, mouth and jaw protection on the playing field," says Dr. Robert B. Mongrain, DMD. "I recommend Brain-Pad to all my patients who play aggressive contact sports. Protecting the lower jaw and TM joints is critical to minimize the risks of potential concussions. I am glad to see that institutions like the NFL and Congress are finally taking a serious look at the dangers of these injuries and putting more emphasis on protection and recovery."

Unlike traditional mouth guards that offer protection for either the upper or lower teeth only, Brain-Pad is a dual arch, bi-molar, mouth guard. The Brain-Pad technology repositions the lower jaw while protecting both the upper and lower teeth. The jaw is stabilized into a neutral position, creating a safety space that greatly reduces the risk of jaw impact concussions and TMJ injuries. When put into place, the Brain-Pad mouth guards also open the airway in the throat 100 percent, allowing users to breathe better and gain a competitive advantage.

"We have said for years that concussions are serious injuries and should be avoided at all costs," says Joe Manzo, President of Brain-Pad. "The devastating effects of concussions can have a lasting impact on athletes and their families. We have designed these mouth




## Complaint

unprotected area for athletes. When used properly, there is a 40 percent reduction of impact energy to the base of the skull, these forces can cause a concussion or knock out as boxers call it. Athletes from the NFL to the MMA and at every level from professional to local youth leagues are recognizing the significant health benefits of our Brain-Pad mouth guards to offer protection against these dangerous injuries."

The House Judiciary Committee, chaired by Representative John Conyers, D-Michigan, will hear testimony on Monday to examine the NFL's response to concussion injuries and assess the protocols or lack thereof, in place for college and high school football players. Scheduled witnesses include NFL neurologist Ira Casson, DeMaurice Smith, the executive director of the NFL Players Association, David Klossner, the NCAA's director of health and safety and Dr. Bennet Omalu, a neuropathologist and primary researcher into brain damage in football players.

Brain-Pad mouth guards are available at leading athletic retailers including Wal-Mart® stores nationwide, and retail between \$7 and \$30 based on the model.

**ABOUT BRAIN-PAD, INC.**

A privately held corporation, founded in 1995 specifically for the promotion, manufacture, and sale of customized Brain-Pad® dual-arch mouth-guards designed to reduce the risk of concussion from lower jaw impacts while increasing endurance and performance. Brain-Pad, Inc. has become a leader in technology development in this field. Its Brain-Pad® products are available in retail and wholesale outlets as well as through distributors, contact sports leagues, professional organizations, school teams at intermediate, high-school, college, and university level. Brain-Pad® products are well-accepted by professional sports athletes in boxing, mixed martial arts, football and many other contact sports. Brain-Pad® products also include shock-absorbing wrist, arm and head-bands as well as: juniors', women's, men's, and professional athlete's dual-arch protective and high performance mouth-guards.

Additionally, Brain-Pad, Inc. recently developed, patented, and commercially released a premium ultra-violet/ozone oral appliance sanitizer, the NatureZone™, available to the retailers and distributors but exclusively distributed to the professional dental industry by Henry Schein, Inc., the largest global distributor of dental and medical products to dentists, dental laboratories and physicians.

Brain-Pad, Inc.'s corporate headquarters are located in Conshohocken, Pennsylvania. For product or company details contact 610-397-0893, [info@brainpads.com](mailto:info@brainpads.com), or visit [www.brainpads.com](http://www.brainpads.com)

Photos/Multimedia Gallery Available: <http://www.businesswire.com/cgi-bin/mmg.cgi?eid=6127151&lang=en>

**Contacts**

Brain Pad Protective Solutions

Bill Samuel

Director of Sales

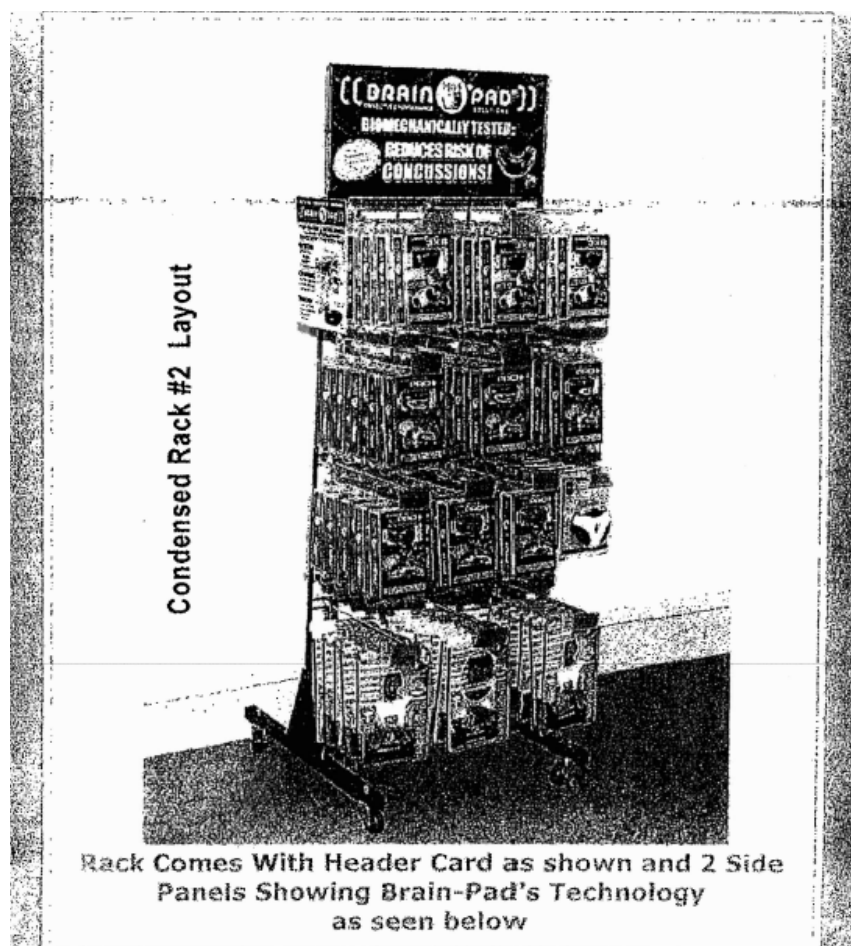
[bsamuel@brainpads.com](mailto:bsamuel@brainpads.com)

[www.brainpads.com](http://www.brainpads.com)

1-888-424-9477

Forward email

Complaint

**Exhibit F**

## Decision and Order

**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,

## Decision and Order

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.

**ORDER****DEFINITIONS**

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

- A. 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.
- B. “Respondent Manzo” shall mean Joseph Manzo and his agents, representatives, and employees.
- C. “Respondents” shall mean respondent BPI and respondent Manzo.
- D. “Commerce” shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
- E. “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.
- F. “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.
- G. The term “including” in this Order shall mean “without limitation.”
- H. 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.

## Decision and Order

**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.

## Decision and Order

**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.

**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.

## Decision and Order

**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 [Debrief@ftc.gov](mailto:Debrief@ftc.gov) 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.

**VII.**

**IT IS FURTHER ORDERED** that respondent Manzo, for ten (10) years after the date of issuance of this Order, shall notify

## Decision and Order

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 [Debrief@ftc.gov](mailto:Debrief@ftc.gov) 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.

**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.

## Analysis to Aid Public Comment

*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.

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT**

The Federal Trade Commission (“FTC” or “Commission”) has accepted, subject to final approval, an agreement containing a consent order from Brain-Pad, Inc. and Joseph Manzo, an officer and director of the corporation (“respondents”).

The proposed consent order (“proposed order”) has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement’s proposed order.

This matter involves respondents’ advertising and promotion of mouthguards. According to the FTC complaint, respondents did not have a reasonable basis to represent in advertising and on packaging for their mouthguards that they reduced the risk of concussions. The FTC further alleges that the respondents made the false and misleading claim that they possessed scientific studies that proved their concussion-reduction risk claims because, in fact, they did not have such evidence.

## Analysis to Aid Public Comment

The proposed consent order contains provisions designed to prevent respondents from engaging in similar acts and practices in the future. Part I of the proposed order prohibits the proposed respondents from misrepresenting that any product will reduce the risk of concussions or reduce the risk of concussions from lower jaw impacts.

Part II of the proposed order prohibits proposed respondents from misrepresenting, with respect to any Covered Product, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research, including, but not limited to, any misrepresentation that scientific studies prove that such product reduces the risk of concussions or reduces the risk of concussions from lower jaw impacts. The proposed order defines “Covered Product” as any (1) mouthguard or (2) equipment used in athletic activities that is intended to protect the brain from injury.

Part III of the proposed order prohibits proposed respondents, in connection with the marketing of any Covered Product, from misrepresenting the health benefits, health-related performance, or health-related efficacy of such product.

Parts IV through VIII of the proposed order require respondents: to keep copies of any documents relating to any representation covered by the order; to provide copies of the order to certain of their personnel; to notify the Commission of changes in corporate structure that might affect compliance obligations under the order; to notify the Commission of changes in corporate business or employment as to proposed respondent Joseph Manzo individually; and to file compliance reports with the Commission. Part IX provides that the order will terminate after twenty (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

## Complaint

## IN THE MATTER OF

**ALAN B. MILLER**  
**AND**  
**UNIVERSAL HEALTH SERVICES, INC.**

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF  
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND  
SECTION 7 OF THE CLAYTON ACT

*Docket No. C-4372; File No. 121 0157*  
*Complaint, October 5, 2012 – Decision, November 27, 2012*

This consent order addresses the \$517 million acquisition by Alan B. Miller and Universal Health Services, Inc. of certain assets of Ascend Health Corporation. The complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by removing an actual, direct, and substantial competitor from one local market for acute inpatient psychiatric services. The consent order requires UHS to divest its Peak Behavioral Health Services facility, and all relevant assets and real property in the local market encompassing El Paso, Texas and its suburb, Santa Teresa, New Mexico.

*Participants*

For the *Commission*: *Chester Choi, Michelle Fettehnan, Janelle Filson, Jeanne Nichols, and Nancy Park.*

For the *Respondents*: *Robin Landis and Christine Varney, Cravath, Swaine & Moore LLP.*

**COMPLAINT**

Pursuant to the Clayton Act and the Federal Trade Commission Act (“FTC Act”), and by virtue of the authority vested in it by said Acts, the Federal Trade Commission (“Commission”), having reason to believe that Respondent Universal Health Services, Inc. (“UHS”), a corporation controlled by Alan B. Miller and subject to the jurisdiction of the Commission, has agreed to acquire Ascend Health Corp. (“Ascend”), a corporation subject to the jurisdiction of the Commission, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that