Instructions for reviewing this hypothetical Case Study:

- Look for and identify actions that present potential promotional violations.
    - Can you see areas where FDA might have concerns?
- Identify obvious promotional violations.
- Look for and identify actions that do not present any promotional compliance issues.

Topics for discussion:

1. Company overview (please see enclosed glossary for medical terminology which might not be familiar)
2. Company Press Release
3. Social media posts on Twitter, and LinkedIn. This example involves both company and follower posts which share, re-tweet and comment.
4. Trade show displays in and around a conference

1. Company Overview

Miracle Beat, Inc., is a medical device manufacturer of diagnostic and cardiac interventional devices to diagnose as well as treat atrial fibrillation (afib). Miracle Beat's top selling diagnostic device, HeartEval, holds the CE marking certification in Europe and also has 510(k) clearance in the U.S. HeartEval is an external sensor, cardiac monitoring device with the ability to diagnose atrial fibrillation, worn by patients and then returned back to their physician's office for further evaluation and treatment planning.

The HeartEval System in Europe and in the U.S. have the same indication as follows:

The HeartEval System is indicated for use in adult patients who have been evaluated by their health care provider as being asymptomatic or who may suffer from temporary symptoms such as fatigue, dizziness, palpitations, anxiety, fatigue, syncope, pre-syncope, shortness of breath, light headedness, or who are at risk of developing atrial fibrillation and where a software assisted analysis can identify potential cardiac causes of these symptoms. The device is a prescription use only, single use, continuous ECG device, contains an ECG recorder that can be worn up to 14 days during normal daily living activities.

Miracle Beat also has an additional device it manufactures, the HeartBlate, achieving record sales in Europe under the CE mark, with the following indication:

The HeartBlate catheter ablation system is intended to ablate cardiac tissue for the treatment of persistent atrial fibrillation (sustained beyond seven days, or lasting less than seven days but necessitating pharmacologic or electrical cardioversion) or longstanding persistent atrial fibrillation (continuous atrial fibrillation of greater than one year duration) in patients who are undergoing open concomitant coronary artery bypass grafting and/or valve replacement or repair.

The HeartBlate is not approved or available for sale in the United States. However, the device is being studied under an approved IDE (Investigational Device Exemption) in the HeartBeat Study and just completed enrolling all patients. The study is expected to conclude in approximately one year with the ultimate goal of achieving PMA approval for this class III device. The study will evaluate the device's safety and efficacy in treating atrial fibrillation by establishing that the device eliminates persistent and long-standing atrial fibrillation in a clinically significant proportion of treated patients.

2. Press Release

Miracle Beat Completes Enrollment of HeartBeat Study

Clinical Study to Demonstrate Ongoing Safety and Effectiveness of
SILICON VALLEY, Calif., October 17, 2019 (GLOBE NEWSWIRE) – Miracle Beat, Inc., a pioneer in the development and commercialization of medical devices to diagnose and treat complex cases of atrial fibrillation has completed enrollment in its HeartBeat Study, required by the FDA is a prospective, non-randomized, multicenter, real-world study to confirm the safety and performance results from its European HeartBeat-One Study, which was used to obtain the CE marking certification.

Miracle Beat enrolled patients (150) who were diagnosed and suffer from atrial fibrillation in more than 7 centers in the U.S. to determine if the previous, superior safety results from the original European study could be replicated in more patients with more operators in a real-world setting. The study's objective is to evaluate the safety and efficacy of the HeartBlate system to treat symptomatic persistent AF patients where pharmacologic treatment has been unsuccessful. This patient population will be evaluated based on a sustained normal sinus rhythm for a period

of 90 days. The patient population is limited to adults between the ages of 18 and 80 years of age.

“I am excited about the ground breaking results of the HeartBlate device to eliminate the symptoms of atrial fibrillation,” said Mary Jones, MD, a HeartBeat Principal Investigator and the trial’s leading enroller. “Our focus now shifts to follow-up and monitoring of these patients and the collection of high quality data.”

“We could not be more proud of HeartBlate’s ability to eliminate the symptoms of afib, offering our customers and patients the opportunity to get their lives back to normal,” said John Bigshot, Miracle Beat’s Chief Executive Officer. “We have an ultimate goal of treating an even younger patient population as this technology continues to be investigated with the potential for it to be an important tool for pediatric populations as positive clinical data unfolds.”

Miracle Beat’s HeartBlate device is commercially available for the treatment of atrial fibrillation in Europe and select other geographies; they are limited to investigational use in the United States under the HeartBlate IDE Study.

About Atrial Fibrillation[1]

Atrial fibrillation is an irregular and often rapid heart rate that can increase one’s risk of strokes, heart failure and other heart-related complications. During atrial fibrillation, the heart's two upper chambers (the atria) beat chaotically and irregularly — out of coordination with the two lower chambers (the ventricles) of the heart. Atrial fibrillation symptoms often include heart palpitations, shortness of breath and weakness. Episodes of atrial fibrillation may come and go, or one may develop atrial fibrillation that doesn't go away and may require treatment.

About Miracle Beat, Inc.

We are a medical device company focused on developing and commercializing products intended to transform the way atrial fibrillation is treated. We aim to establish a new standard of care for medical device treatment of this condition around the world.

Caution Regarding Forward-Looking Statements

This press release may contain forward-looking statements regarding Miracle Beat’s current expectations. Words such as “may,” “might,” “will,” “should,”

[1] www.mayoclinic.org 2019

"believe," "expect," "anticipate," "estimate," "continue," "predict," "forecast," "project," "plan," "intend" or similar expressions, or statements regarding intent, belief, or current expectations are forward-looking statements. These statements are not guarantees of future performance and are subject to certain risks, uncertainties and assumptions that are difficult to predict.

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Possible discussion points:

- Should the word "superior" be replaced with an alternative one such as "excellent" or something else? What criteria would allow for the ability to make a superlative claim?
- Does the principal investigator make superiority claims and/or far reaching comments? Why or why not?
- Does the CEO overreach in his comments concerning a pediatric population? Why or why not?
- Does the forward looking statement protect the company? Why or why not?

3. Social Media Posts

Background: Miracle Beat enjoys a large social media presence on Twitter, Facebook and LinkedIn. The company likes to promote its CE marked HeartBlate device on social media, directing its posts to an international audience, typically highlighting successful cases that were performed outside the United States, and accompanies those posts with "Important Safety Information" hyperlinks stating the CE marking regulatory status with clear language stating the device is not approved or available for sale in the U.S. The company's Marketing team feels strongly in its prerogative to reach out to their international audience. However, the company's Regulatory Affairs team has advised that doing so could be risky because there is no way to exclude a U.S. audience from such information, thereby having this audience not protected by FDA's concern for public health. The company's CEO is willing to take the risk of highlighting the international approved only devices so long as the content is truthful, non-misleading and

provides clear links to the ISI (Important Safety Information) which states the regulatory status both in and outside the U.S.

Social media post featured on LinkedIn and Twitter:

"Great discussion in Barcelona today at ACT for HeartBlate ablation system case reviews featuring Professor Carlos Estrada of High Tech Hospital who moderated the presentation and discussed real world procedural outcomes." An Important Safety Information (a "bit.ly" link directs readers to this statement:

Caution: In the United States, Heart Beat's HeartBlate devices are investigational devices, limited by Federal (or United States law) to investigational use. Miracle Beat's HeartBlate device is commercially available in certain countries outside the U.S. Please contact your local Miracle Beat representative for specific country availability or please visit www.MiracleBeat.com.

Possible discussion points:

- Does the original post make a product claim? Why or why not?
- This post is seen by Miracle Beat Twitter follower and prominent physician in the U.S., Dr. Cure, who "retweets" this post and adds *"Great cases today using HeartBlate achieving no afib. Patients doing great."*
- Miracle Beat then elects to reply to this tweet, *"Thank you, Dr. Cure, for your interest in these important cases."*
- Can or should FDA really step in here and tell the company that posts involving its own legally marketed devices with approval outside the U.S. that they are inappropriate and/or prohibited? If yes, does this stance interfere with Free Speech?
- Does the company's reply thanking the doctor violate pre-promotion of an unapproved device?
- If social media is not permitted to U.S. companies to communicate with its international customers, is the only alternative a press release which are now commonly used in social media? Where is the line drawn?
- Would the situation be different if it were an international physician who re-tweeted vs. a U.S. physician?

4. Trade show displays in and around a conference.

Miracle Beat has a booth at the largest U.S. cardiovascular conference in the world, **CHA** (Cardiac Healing Association) which has a 65% international audience registration with the remaining attendees physically practicing in the U.S. The company is also a sponsor of this event. Miracle Beat has chosen to segregate its booth into a U.S. and international sections, separating the two sides of the booth with a physical border. Company representatives staffing the booth will be asking attendees where they practice before allowing entry into the international section. However, anyone walking by can see the HeartBlate poster display, which does have signage stating the CAUTION IDE statement, identifying that the device is investigational in the U.S. and holds the CE marking certification in Europe.

Miracle Beat has also chosen to create a banner on an escalator at the convention, not near its booth, stating, "Got Afib? Come visit Miracle Beat booth #222."

Possible discussion points:

- Do the company's efforts in distinguishing a U.S. and international section of the booth seem reasonable?
- Some audience members may recognize that displaying a 510(k) device under review with FDA is acceptable, provided no orders are taken and no claims are made concerning the device but there is no regulatory provision to display an IDE device at present. Is it worth the risk for companies to move forward with the approach that Miracle Beat has taken? Why or why not?
- Is the banner acceptable? Why or why not?

Glossary

Asymptomatic – (of a condition or a person) producing or showing no symptoms.

Atrial fibrillation or "afib" – Atrial fibrillation (also called Afib) is an irregular heartbeat. Normally, the heart contracts and then relaxes in a regular rhythm, moving blood from the upper chambers (atria) into the ventricles. In Afib, the atria beat irregularly instead of in a steady pattern. Due to this irregularity, people with atrial fibrillation are at a higher risk of blood clots, heart failure, stroke and other heart-related complications.

Catheter ablation system - is used when long-term medications or electrical cardioversion are either not effective or not an ideal choice for the patient. An electrical map of the heart is charted, which tells the physician which areas of the heart are causing electrical signals that interfere with the proper rhythm. During the ablation, a catheter is gently guided to the heart, and the physician carefully destroys the problem tissue using radiofrequency, laser or cryotherapy.

Electrical cardioversion – is a procedure used to return an abnormal heartbeat to a normal rhythm. This procedure is used when the heart is beating very fast or irregular. This condition is called an arrhythmia.

Pharmacologic cardioversion – taking medications to help the heart stay in a normal heartbeat.

Syncope/pre-syncope – temporary loss of consciousness caused by a fall in blood pressure. Pre-syncope is a sensation of lightheadedness, dizziness or a feeling that one might faint.

Open concomitant – is an open-heart, surgical procedure that uses ablation or energy sources to scar the tissue causing the heart's rhythm to be disrupted. The word "concomitant" simply means that the procedure is combined with another open heart surgery.