Innovative Health Solutions’ Response to NPR Story:
Questions Raised About Study of Device to Ease Opioid Withdrawal

**Introduction**

Jake Harper’s NPR story, *Questions Raised About Study of Device to Ease Opioid Withdrawal*, presented a biased and misleading view of the NSS-2 BRIDGE device. To address his story’s factual inaccuracies, this document provides a comparison to many of Harper’s claims with facts backed by the IHS team and its research.

**Fact Checking**

*Inaccuracy:*

Innovative Health Solutions (IHS), the device maker, has marketed the BRIDGE for opioid withdrawal for more than a year, even before it had clearance for that use from the Food and Drug Administration.

*Fact:*

IHS did not market the BRIDGE for opioid withdrawal prior to FDA clearance. The original 510(k)-cleared BRIDGE device was indicated for use in the acute and chronic pain population. Pain is highly prevalent in this patient population, which led some clinicians to adopt in their treatment of patients. Subsequently, IHS received clearance for a next generation product – the NSS-2 BRIDGE – with a claim that it could reduce the symptoms of opioid withdrawal.

What Mr. Harper may be referring to, and what he asked IHS about previously, were conversations with policymakers in a non-promotional setting about future applications for IHS technology. In that context, as we explained to Mr. Harper, IHS has every right to discuss ongoing development and future activities, but Mr. Harper chose to ignore our input.

*Inaccuracy:*

An investigation by Side Effects Public Media and NPR reveals that researchers working with Innovative Health Solutions, maker of the BRIDGE, submitted to a medical journal a study that wasn’t what it appeared to be. But it seems that they instead conducted a clinical trial that skirted FDA rules and ethical norms, using vulnerable people suffering from addiction as test subjects.

*Fact:*

Mr. Harper asked IHS questions around this allegation before publishing this article. We responded in detail, but he chose to ignore our responses, so we summarize them here. First, at the time data used in the publication were being obtained there was no study; the patients being treated were NOT part of a clinical trial. All patients were under the care of licensed addiction specialists who take care of patients based on clinical guidelines for purpose of treatment, not clinical investigation. Some physicians chose to use the BRIDGE device as an...
adjunct to therapy since current therapies often fall short of alleviating pain during withdrawal, and physicians determined it might help their patients through their practice of medicine.

With regard to communications amongst physicians, as a leader in the field and President of American Society of Addiction Medicine (Midwest Chapter), Arturo Taca, MD, who co-authored the journal article Mr. Harper is referencing, was contacted by providers to help them find solutions to improve the treatment of opioid withdrawal. He shared his ideas with other providers, which included close monitoring of patients, specifically throughout the first hour of treatment which is a critical period for patients going through withdrawal. All communications were about treating patients, not clinical research.

Long after Dr. Taca began using the technique in his practice, Adrian Miranda, MD, then at the Medical College of Wisconsin, approached Dr. Taca with the idea for a retrospective analysis of the de-identified patient data. Because Dr. Taca had previously spoken with physicians about use of the device in managing withdrawal, he and Dr. Miranda were able to identify physicians who might have pertinent data to share.

There was never an intent on the part of the Company to collect data for research purposes of conduct a prospective clinical trial, nor did any such trial occur.

**Inaccuracy:** The FDA then relied on the results of the study in making its decision to clear the BRIDGE for marketing as a treatment for opioid withdrawal.

**Fact:** This statement is not accurate. The FDA reviewed several studies submitted by IHS prior to making its decision to clear the NSS-2 BRIDGE for marketing. These included, among others, a pre-clinical mechanistic study and a placebo-controlled trial using this technology to treat abdominal pain in children, and a published evaluation regarding the safety of similar technologies in over 1,200 patients.

**Inaccuracy:** Arturo Taca, MD, one of the authors of a peer-reviewed publication, had a non-disclosed conflict of interest because he has a pending patent on a study protocol he could one day license to IHS.

**Fact:** This claim is misleading and speculative, and ignores that IHS itself holds two issued patents. US Patent #’s 9,662,269 & 9,839,577. We do acknowledge that the Dr. Taca, one of the article authors, has a patent pending that includes addressing treatment of patients with IHS technology. However, IHS has no financial relationship with Dr. Taca.

Our understanding is that the nondisclosure was an oversight, and as stated in the article, the authors went through the proper channels with the journal to correct this information several
months ago, and has not called the results of the study into question. The oversight was the result of the fact that he had (and still has) no patent, nor had or has a financial relationship with IHS.

**Inaccuracy:** Clinical trials also require informed consent from patients to make sure they understand the risks and benefits of participation. But it's unclear if patients in the Bridge study even knew they were part of an experiment.

**Fact:** As discussed above there was no prospective clinical trial. The authors of the published study that Mr. Harper is referring to analyzed de-identified patient data from clinical practices which had chosen of their own volition to use the BRIDGE. Patients were not unaware of an experiment, there simply was no “experiment” at the time of their treatment.

**Inaccuracy:** Experts we consulted found the ethical and regulatory issues in the study troubling. “In an ideal world, the journal would retract the article and the FDA would take the product off the market until an appropriate study was done,” said Diana Zuckerman, president of the National Center for Health Research.

**Fact:** It is unclear whether Mr. Harper provided false and misleading information to Dr. Zuckerman to illicit this response, or took the quotation out of context – both tactics he used in other interviews. There is no question about the veracity of the data, and it was thoroughly peer reviewed and assessed by FDA.

**Inaccuracy:** Andy Chambers, an addiction psychiatrist, said the message fits a disturbing pattern: The opioid epidemic was fueled by pharmaceutical companies making misleading claims about the risk of addiction with opioid painkillers. Now, Chambers said, Innovative Health Solutions appears to be ignoring the role of science and overstating its evidence to exploit the addiction treatment market.

**Fact:** The accusation that Innovative Health Solutions is “overstating evidence to exploit the addiction treatment market,” is unfounded. The NSS-2 Bridge has only been marketed as an aid to reduce the symptoms of opioid withdrawal following thorough FDA review and issuance of a de novo marketing authorization.

Also, the claim that a company which markets a clinically proven single-use device which can aid in reducing withdrawal symptoms is in any way comparable to the marketing of products promoting chronic unsafe use of addictive medicines that has contributed to the opioid epidemic is unhinged.
Interviews

In addition to fact checking, the IHS team interviewed the same three BRIDGE providers mentioned in Harper’s story: Jeff Mathews, Katrina Lock and Paul Finch. The Q/A provided below demonstrates factual inaccuracies and the misquoting of sources. All three providers can be contacted upon request to verify their statements and confirm the inaccuracies in Mr. Harper’s piece.

1. Do you believe the article Questions Raised About Study of Device to Ease Opioid Withdrawal is a fair and unbiased representation of the conversations and comments you had with Jake Harper?
   a. Jeff Mathews: This article is a misrepresentation of our clinic, its objectives and our hospitality to Mr. Harper. It is apparent Mr. Harper was not interested in anything but a slanted piece against the BRIDGE.
   b. Katrina Lock: The story was very biased and did not portray my conversations with Harper. Bits and pieces were stolen to form his opinion.
   c. Paul Finch: Totally not; the story was put in a light that is not correct. The whole focus of Harper’s article was wrong. Rather than pointing fingers we should be linking arms and inventors should be rewarded. This is America, this is a crisis and the BRIDGE works. Harper even interviewed a patient while he was getting the BRIDGE put on and Harper heard in the patient’s voice how the BRIDGE was working. Harper, however, didn’t include that interview in his article.

2. Were any of your comments taken out of context or mischaracterized?
   a. Jeff Mathews: I do. Specifically, the part where Harper said, “Mathews indicated he would be sending James’ data to the company.” That never absolutely, positively never happened and would have been a violation.
   b. Katrina Lock: Many of my comments were taken way out of context of our conversation.
   c. Paul Finch: Yes, my statement about the BRIDGE not “being perfect” was taken out of context. No medicine is perfect. Of course, there’s a better BRIDGE coming someday, but that doesn’t mean we don’t use what we have now. The BRIDGE is one of the best tools to manage opioid withdrawal. So, Harper took my comment way of out of context.

3. Was your experience with IHS and the BRIDGE fairly represented in the article?
   a. Jeff Mathews: No, I don’t think so at all. I think Harper came in with a specific intent to hatchet everything. For what purpose, I have no idea. That might be the worst article I’ve ever seen.
   b. Katrina Lock: Not at all. I have had very positive results with the BRIDGE.
c. Paul Finch: The IHS team has been very helpful in every way. Dr. Taca is a hero and I don’t think any of that came out in the article.

4. Have you ever been paid or influenced by IHS to report inaccurate or false information?
   a. Jeff Mathews: No. The devices provided by Innovative Health Solutions were not tied to any recommendations, money or any other forms of compensation.
   b. Katrina Lock: I have never been paid or directed by IHS to report false information.
   c. Paul Finch: Absolutely not. I’m a provider; if there was a better BRIDGE on the market, I’d buy it. This is the best we have.

5. Have you ever seen a BRIDGE device that did not reduce a COWS score in your patients?
   a. Jeff Mathews: No one believes it the first time they hear about it, until they see it work. We have never had a BRIDGE that doesn’t significantly reduce a COWS score, never.
   b. Katrina Lock: In the many devices I have placed, I have always observed dramatic drops in COWS scores.
   c. Paul Finch: I’ve used this device more than 100 times. One time I put the BRIDGE on and immediately the pain increased. I called Dr. Taca and asked what I should do and he said to put it on the other ear. When I did that, it worked fine. So, I appreciated Dr. Taca and his availability.

6. Having been involved with IHS and its representatives for one to two years, do you feel IHS has ever attempted to provide anything other than the facts and the truth about their products?
   a. Jeff Mathews: Absolutely not. I have been involved in this from the very beginning and have talked to many caregivers, facilities, counselors and the IHS team is in this for all the right reasons.
   b. Katrina Lock: I have never heard anything other than facts from IHS’ team. They are more honorable than most companies and are very upfront. Their product speaks for itself and seeing is believing. It’s not a hard sell; once you see it, you want to be part of it.
   c. Paul Finch: No, never. In fact, they’ve always been helpful and forthcoming. Sometimes we don’t understand everything about it but tell me a medicine where we do. I always appreciate their factual backup.

7. Do you believe the FDA made a good decision when clearing the BRIDGE for use as an aid to reduce the symptoms of opioid withdrawal?
   a. Jeff Mathews: Absolutely. This thing works. We know it works, I’ve seen it with my own eyes.
b. Katrina Lock: The FDA’s decision to approve the BRIDGE for opiate withdrawals was a wonderful accomplishment and will help further the battle against opiate addiction and the current crisis we are facing.

c. Paul Finch: Absolutely. Finally, there is a little bit of recognition. Finally, someone is seeing that the BRIDGE actually does work and it is worth the traction.

8. What does this technology offer your patients and how important is it to see it supported and not attacked?

a. Jeff Mathews: It allows the patients a pathway to get to the medicine and treatment that is bearable. This BRIDGE works to allow them to get to the next step. Are there things that can go wrong? Sure, there are. But’s it’s not the BRIDGE that causes things to go wrong, it’s patients not using the technology correctly.

b. Katrina Lock: The BRIDGE offers hope to my patients who are afraid of withdrawals or the point they are at in their life does not allow for a 7 to 14-day withdrawal process. The BRIDGE offers freedom to avoid withdrawal symptoms while opiates are metabolizing out of the body. The most common reason for continued opiate use is fear of withdrawal symptoms. If we can take away that factor, allow them to continue working and living with minimal withdrawal symptoms the better chance we have at reaching recovery.

c. Paul Finch: When I can pull a BRIDGE out of my drawer and put it on a totally symptomatic patients, I know the timing of the device works and I say, “You should feel better... right about now.” The symptom relief is huge.
Additional comments by Jeff Mathews

“I have reviewed the text of the NPR article written by Jake Harper. This article is a misrepresentation of our clinic, its objectives and our hospitality to Mr. Harper. It is apparent that Mr. Harper was not interested in anything but a slanted piece against the BRIDGE Device. Specifically:

1. “Jeff Mathews’ treatment program” this is absolutely not true. This is a County Health Department based program under the direct supervision of the Medical Director.
2. The devices provided by Innovative Health Solutions were not tied to any form of data, recommendations, money or any other forms of compensation.
3. “James, the patient at the Union County clinic, also said he didn’t know he was part of a study when he got the Bridge.”- James was not part of any study
4. “James signed a document just before he got the BRIDGE, but it was so faded it was difficult to read.”-The document that is referred to is called Treatment Informed Consent, it is a computer generated document printed via a laser printer. I have attached a copy of what it looks like. I cannot provide the document that James signed due to HIPPA constraints, but it is identical.
5. “They haven’t tried to contact me or nothing,”-Our Clinic attempted to contact this patient the day before his scheduled BRIDGE removal-NO Answer. Our Clinic attempted to contact this patient the day of his BRIDGE removal.
6. “Autumn Howard, a 30-year-old patient who used the BRIDGE in Mathews’ program in April 2016, said staff told her the device was experimental, but she couldn’t remember being told she was part of a study because her withdrawals were too intense.”-She was NOT a part of any study.”

Additional Comments by Autumn Howard

Autumn Howard, who was also interviewed in Harper’s story, had this to say about the BRIDGE when interviewed by IHS for press release in March 2018.

“The BRIDGE saved my life. I was in awe. There is no way I could have withdrawn naturally. I had tried before, and I never made it more than a day or two. My life is not perfect, but it is a million times better than it was.”

Conclusion

The IHS team remains confident in the NSS-2 BRIDGE’s effectiveness and the research that was conducted in order to obtain clearance from the US Food and Drug Administration. The team looks forward to watching the NSS-2 BRIDGE change the face of the opioid epidemic and save lives.