QUARTERLY NEWSLETTER OF THE CALIFORNIA SOCIETY OF ADDICTION MEDICINE

CSAM Introduces New Forum for Dialogues in Addiction Medicine

Perspectives on Hythiam's Prometa Treatment for Addiction

By Timmen Cermak, MD, Editor

As the new editor of CSAM's Newsletter, I am excited to introduce the FORUM. Each newsletter, I will choose an issue that would benefit from being elevated to the surface, where open discussion of different perspectives can advance our understanding of the issue, and of each other. Views will be presented not in a Pro-Con, Point-Counterpoint framework, but rather as examples of differing perspectives. Dialogue will be the most important goal for each FORUM.

FORUM COMMENTARY

There are two important themes threading through the two perspectives on Hythiam's Prometa that possess particular relevance for addiction medicine, both in terms of their impact on the practice of treating addiction and the special expertise practioners in our field can bring to an understanding of these themes. Both themes are far larger than the issues presented by Hythiam's Prometa; but the perspectives expressed by Smith/Torrington and Rawson/McLellan, on pages 2-3 of this newsletter, clearly illustrate the two themes.

The first theme involves the question of what standards of evidence need to be met for a treatment to achieve "evidence-based" status. By submitting itself to the rigors of evidence-based medicine, the addiction field has substantially increased its credibility. The more clarity we develop regarding the different standards of evidence required for a potential treatment to warrant further investigation, clinical trials, widespread adoption as an available treatment, or being recognized as the standard of care, the easier task we will have evaluating Hythiam's claims for Prometa's safety and efficacy. Even Prometa's advocates support the need for more rigorous, double-blind and properly controlled studies. As with all new and potentially helpful treatments, we can hope that the results of these studies will be positive while simultaneously evaluating them through a highly critical, even skeptical lens.

The second theme involves the role of marketing new therapies, especially direct marketing to the consumer, and most especially when the treatment has not yet met the most rigorous tests for safety and efficacy. This issue transcends addiction medicine, pervading the whole of medicine. We will not resolve it on our



own without a resolution that involves the entire pharmaceutical industry's relationship to medicine. However, where we feel the best interests of those suffering from addictive disease are being impacted, we have an obligation to identify and debate that impact. The issues here are complex. In a free society, it is often difficult to distinguish between brave and innovative approaches being championed by a few and treatments that are being prematurely promoted for financial gain or out of unrealistic enthusiasm. We have two effective, though often slow, mechanisms for making this distinction: scientific research and our collective clinical judgment, arrived at through open dialogue. Thus - the CSAM Addiction Medicine FORUM.

ABOUT PROMETA

he Prometa treatment for addiction (based on flumazenil, gabapentin, and hydroxyzine) was empirically developed by Dr. Legarda in Madrid about 6 years ago. Hythiam is a publicly traded healthcare management and services corporation formed about 3 years ago that promotes and provides Prometa treatment. To date, more than 700 patients have undergone the treatment in the US and more than 2000 worldwide.

Important questions and strong opinions about Prometa and Hythiam, in a spectrum from positive to negative, have been circulating without producing much constructive dialogue. The following FORUM is designed to raise whatever issues exist to the level of productive debate.