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Vitalethine Advisory

The Racing Medication and Testing Consortium (RMTC) has been informed by a representative of the Organization of Racing Investigators (ORI) of a substance called vitalethine that may be used on race horses.

The peer-reviewed literature on vitalethine is limited to an article published in *Cancer Research* in 1994 research paper.[1] In this paper, the authors discussed two formulations of vitalethine, vitalethine and vitalethine-4, that appears to be a dimer of vitalethine. The synthetic pathways to vitalethine and vitalethine-4 are complex and involve a very specific process for preparing these substances. Furthermore, the authors claimed that vitalethine and vitalethine-4 have several attributes that may be beneficial in treating various diseases including cancers.

The first of these professed abilities is increased erythropoiesis (red blood cell production) which was measured in red blood cell progenitors obtained from humans and mice and tested in the laboratory setting. Researchers claimed that concentrations of vitalethine-4 in the 10-100 pg/ml range stimulated erythropoiesis in cells in culture that have been deprived of natural erythropoietin. On the other hand, they claimed that vitalethine but not vitalethine-4 caused some erythropoiesis suppression in mouse red blood cells. The RMTC was unable to locate any published clinical trials to determine if these effects were observed in *in vivo* models in any species.

The second claimed benefit is that vitalethine modulates immune responses. Researchers added sheep red blood cells to mouse red blood cells treated with vitalethine and demonstrated that the foreign sheep red blood cells were lysed at a greater rate than were the mouse red blood cells treated with a placebo.

The final purported benefit is that vitalethine modulates the progression of neoplasia in *in vivo* models. The authors claimed a variety of malignant cells inoculated into mice were less likely to metastasize to the lungs and tumors were less likely to increase in size when the mice were treated with vitalethine.

The authors posited that the reason for vitalethine-4's effectiveness in increasing erythropoiesis is related to the molecule's structure. They noted that monomers of vitalethine actually inhibited red blood cell production whereas vitalethine-4 increased RBC production in culture samples.

[1] Knight, G.D., *et al.*, *Vitalethine Modulates Erythropoiesis and Neoplasia*, Cancer Research 54, 5623-35 (November 1994).

The published article also referenced unpublished data on β-alethine. This reference stated that this product also increased erythropoiesis. However, another article written by the same authors does not include the same claim of increased erythropoiesis as a result of use of β-alethine.[2]

The mention of β-alethine in the 1994 publication is particularly interesting in light of the current patent dispute surrounding vitalethine. The original research was done at the University of New Mexico by Galen Knight and a number of co-investigators. The University, after publication of the 1994 article, claimed that the vitalethine was really β-alethine. As of 2004, Dr. Knight and the University were involved in litigation over the patent for vitalethine.

Dr. Knight has established a website that discusses the benefits of vitalethine and provides what he claims is the mass spectral proof of the difference between vitalethine and β-alethine. The link to that website is: http://www.highfiber.com/~galenvtp/vtlvamas.htm. It provides structural information and mass spectral data for vitalethine and a number of other substances that Dr. Knight cites in his arguments concerning the differences between vitalethine and β-alethine. Note that Dr. Knight states that the mass spectral data for vitalethine were not as predicted because of deuterium exchange with exchangeable protons on vitalethine.

Vitalethine is not listed in the ARCI's Uniform Classification of Foreign Substances and is therefore assigned by default a Class 1 substance with a Category A penalty under ARCI Model Rules.

[2] Knight, G.D., *et al*., *Seemingly Diverse Activities of β-Alethine*, Cancer Research 54, 5636-42 (November 1994).