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RE: Vaporous Hyperoxia Therapy (VHT) by Vaporox

I have served as Vaporox's Primary Investigator for multiple clinical studies since 2019. As the company's Medical Director, I have contributed to their product direction since that time.

While using Vaporox's VHT devices in my private practice, I have had the opportunity to observe this technology from research, clinical, and business perspectives from its early stages, through FDA clearance of their second-generation "VHT-200" device, and into its commercial rollout. All along the way, I have been consistently impressed by the healing efficacy of VHT.

In 2019, I was introduced to Vaporox by a colleague. At the time, the new CEO was tasked with validating the efficacy of the technology. As one of the leading wound care providers for lower limbs in the Denver area, I was asked to lead a clinical study with the original FDA-cleared "VHT-100" device. I was initially skeptical because the device appeared rudimentary. However, the fundamentals of delivering micronized vapor to hyper-saturate a wound to absorb oxygen were conceptually sound, and it ultimately proved to be very effective in practice.

During the 2019 clinical trial, my colleagues and I treated several dozen patients with VHT. What stood out right away was that VHT quickly filled in wounds and promoted the growth of granulation tissue. Our study showed that the therapy contributed to the rapid granulation of wounds, likely from increased vascularity. This is consistent with other studies showing that VEGF spikes and stimulates angiogenesis and promulgation of granulation tissue.

In my experience, wound tissue quality and wound depth are the first components to improve when using VHT. After the 2019 clinical trial, I used the VHT-100 for two years, successfully treating multiple wounds that were thought to be beyond healing.

I recently began treating a patient with chronic osteomyelitis and a tunneling wound of 2.5 centimeters in depth. After approximately two weeks of VHT treatments, the depth of the patient's wound has been reduced to just 1.25 cm.

I have also successfully treated multiple Wagner 4 wounds and even one Wagner 5 wound with VHT. The consistent finding has been that VHT promotes the growth of granulation tissue at the periphery of the eschar, preventing exposure of bone as the eschar lifts, thus resulting in fewer amputations. I have multiple other cases showing similar trends.

The science behind VHT is solid. Ultrasonic vapor (mist) allows controlled hydration, as the small particle size allows the mist to penetrate microcapillaries and improve circulation without the need for positive or negative pressures on the wound. This reduces pro-inflammatory cytokines and matrix metalloproteases. Wounds revascularize faster in a moist environment than under dry conditions. Angiogenesis also occurs in a more orderly fashion in moist wounds.

Oxygen induces vascular endothelial growth factor mRNA levels, increases macrophage proliferation, and increases the number of endothelial progenitor cells (EPCs) at wound sites. EPCs typically travel to the sites of injury and are essential for the formation of new blood vessels and wound healing. Hyperoxia enhances the mobilization of EPCs from the bone marrow to the peripheral blood circulation. The increased presence of EPCs at the wound site correlates with accelerated wound healing.

I firmly believe that the propagation of granulation tissue is one of the keys to vaporous hyperoxia therapy's success, leading to our exceptional healing rates. VHT fills in wounds more quickly than any other treatment I have used.

Vaporox received FDA clearance for their next-generation device, the VHT-200, in March of this year. The new device is modern, easy to use, low maintenance, and even more comfortable for the patient. It has also been anecdotally demonstrated to be even more effective at healing wounds, especially during the first weeks of treatment, where we regularly experience 60% or more wound closure by volume.

Additionally, I believe VHT complements Cellular Tissue Products ("CTPs"). Although I do not use CTPs in my office, I have extensive experience using CTPs in my work at a local wound care center. I have found that CTPs are excellent products for "growing skin" but are not indicated until the wound has a healthy granular base without considerable depth. Accordingly, the combination of VHT and CTPs can significantly improve healing outcomes.

Sincerely,

Dustin Kruse, DPM, MA, FACFAS

I am a board-certified podiatrist in a private practice in Colorado. I have extensive training and experience in reconstructive and trauma surgery, elective surgery, general podiatric medicine, and diabetic foot care. I studied chemistry, sports medicine, and bioethics at Case Western Reserve University in Cleveland before earning my Doctor of Podiatric Medicine degree at the Ohio College of Podiatric Medicine. I completed my residency at Highlands/Presbyterian St. Luke's Medical Center in Denver, where I specialized in foot and ankle surgery and was the chief resident. I was the former President of the Colorado Foot & Ankle Society (Colorado chapter of the APMA) and am currently a Director of the American Board of Foot and Ankle Surgery (ABFAS).

Statement of conflict of interest. I am a customer, vendor, and investor in Vaporox. In my professional opinion, all the statements in this letter are accurate and defendable.