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"Over the oxygen supply of the body, carbon dioxide spreads its protecting wings"

—Yale University **1935** | VALUE OF INHALATION OF CARBON DIOXIDE IN CLIMBING GREAT ALTITUDES)[1]

The medical community has appreciated the life sustaining benefits of delivering carbon dioxide (CO_2) to humans for more than 100 years. Even though LIFE may have found a way to live without oxygen[2], LIFE simply cannot exist without CO_2. Like water, CO_2 is vital for all life on Earth; and specifically, CO_2 is not a pollutant nor contaminant, and as such, carbon dioxide cannot intoxicate because it exists as a non-poisonous, non-toxic substance.[3] Of all the world's organic compounds, carbon dioxide (by far) represents the most important one for the sustainability of the biosphere (the whole of life on Earth).[4] Despite its versatility and non-toxic behavior, Mankind has historically had a "love-hate" relationship with CO_2 (e.g., advocates implicating it in "Climate Change"). But notably, physiologically, CO_2 is the body's most ubiquitous and chief hormone of the body; every tissue produces it, and it likely acts on every organ.[5] Critical to this discussion, humans are CARBOXIC BREATHERS, that is, rising CO_2 levels stimulate breathing — NOT falling O_2 levels.

To list just a few conditions that Mankind (with decades of literature support) has successfully, and therapeutically, utilized delivered CO_2:

1. Altitude Sickness[1,6,7,8]
2. Central Sleep Apnea[9,10,11,12]
3. Obstructive Sleep Apnea[13,14,15]
4. Orthostatic Intolerance & Postural Orthostatic Tachycardia Syndrome[16]
5. Seizures[17,18,19]
6. Migraines[20]
7. Congestive Heart Failure[21]
8. Carbon monoxide poisoning[22, 23]
9. Improved exercise physiology[24]
10. Improving Cerebral Blood Flow and cerebral hypoxia[25, 26]

—Notably, all scenarios utilized CANISTER—delivered CO_2! In fact, contrary to finding harmful effects of mildly elevated CO_2 (i.e., HYPERcapnia), ample evidence exists of great harm when CO_2 levels drop (i.e., HYPOcapnia).[27,28,29,30,31]

Delivery of up to 180-pound canisters of CO_2 therapeutic gas to subjects/consumers represents the overwhelming historical obstacle to commercialization of CO_2 therapies, as well as how to satisfy the FDA's valid concerns over its purity and safety of delivery. DeltaChase utilizes biomimicry (looking to Nature) to solve this conundrum. Following the lead of many CO_2 modulating animals, we fashioned a 3 oz "dead space" rebreathing apparatus, called the SAGE Rebreather™, which cleverly positions precise volumes of exhaled CO_2 gas within the respiratory column for rebreathing in the next inhalation. "Columns of flow" enable a feedback loop in mixing expired and ambient air, based on laminar versus turbulent flow. Moreover, proprietary algorithms (based on the subject's weight in conjunction with the desired levels of CO_2) allow us to offer customized rebreathed volumes of captured exhaled gasses, thereby locking the body into new

and improved homeostatic levels of CO_2.In most cases, therapeutic modulation occurs without even making the body's CO_2 rise out of its normal range — typically, just riding at the top of the normal range.

For clarity, this technology allows decades of vetted and corroborated CO_2 research, including safety to emerge from the "laboratory" to afford amazing benefits heretofore never deemed possible. As Rebreather Masks are not novel, (having been around for 70 years), our SAGE Rebreather registers with the FDA as a Class I 510 (k) EXEMPT from premarket notification; this means we enjoy an enviable smooth regulatory pathway to commercialization. On the other hand, the ability of our SAGE to "lock-in" specific CO_2 levels and not allow "run-away" CO_2 levels to occur (i.e., conceptually "fail-safe") frames our patentability. Future clinical trials need only develop data for new marketing claims, but not safety nor general efficacy.

In our CO_2 journey, a recent epiphany realized that many animals modulate themselves to higher CO_2 levels and seem to be highly resistant to many infectious pathogens (like Malaria and COVID-19). In fact, bats (that live in 6% CO_2) carry 80+ malaria species and over 450 Coronaviruses, without any apparent harm. Even though mosquitos (the main vector in Malaria) are their major source of nutrition, you would be hard pressed to ever find a bat dying of any form of malaria. Also, COVID-19 patients often present with LOW CO_2 levels and poor ventilation, so driving patients to VENTILATE with CO_2, as well as oxygenate, should dramatically improve the plight of the infected. Further, "we postulate a mechanism of action," whereby adding a higher inhaled CO_2 could/should reduce the virulence, viral load and perhaps the viral shedding of those treated by our SAGE Rebreather (discussion available but beyond the scope of this missive).

Measles, mumps, polio, and chickenpox are all examples of infectious diseases that were once very common but are now rare in the U.S. because vaccines helped to establish herd immunity. To develop this herd immunity, the "herd" MUST NOT DIE of the infection (which enables antibody production). We believe our technology can help those who contract the virus by improving their respiratory parameters, including respiratory rate, O_2 and CO_2 levels, work of breathing, sense of well-being, and extending the time-course to needing transfer to ICU care (if needed at all). We contemplate secondary studies testing the hypothesis that elevated CO_2 levels could also reduce viral loads, viral shedding, and mortality from COVID-19 infections. As the mechanism of action could correlate to other viral infections, these benefits may also join the fight against future pandemics (and even Malaria).

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FOOTNOTES

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