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(54) Title: BREATH-POWERED NASAL DEVICES FOR TREATMENT OF TRAUMATIC BRAIN INJURY (TBI), INCLUDING
CONCUSSION, AND METHODS AND METHODS

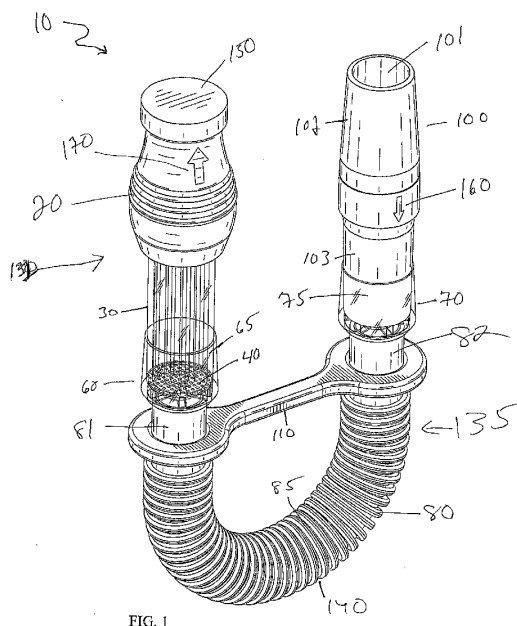


FIG. 1

(57) Abstract: The present invention is directed to a single-directional insufflator or breath-powered nasal device that provides unique dual airflow for propelling a drug substance into a nasal cavity, preferably deep into the superior nasal cavity and into the olfactory region and the trigeminal nerve mucosa, for rapid diffusion into the brain for the treatment of nasal and/or central nervous system ("CNS") injury, disease or disorder, especially brain injury, such as traumatic brain injury ("TBI"), including concussion, and methods regarding nasal treatment therewith. Breath-powered nasal devices for delivering a somewhat tight or confined, concentrated plume of drug substance deep into the nasal cavity to targeted sites, bypassing the blood brain barrier, namely the olfactory nerve to provide concentrated drug substance for direct absorption into the brain are disclosed. The confined plume of drug substance propelled from the nasal device by a patient's breath is narrow in the vertical resembling the diameter of the inner chamber in which the drug substance is stored. By forming this narrow or confined plume, a greater concentration of the drug substance can be deposited at the deeper nasally targeted sites. The breath-powered nasal devices of the present invention accomplish this unique advantage by the use of a novel dual elongated double-walled tube chamber comprised of an outer hollow chamber and the inner chamber in which the inner chamber is stabilized in the outer chamber by preferably two, three or more ribs. More specifically, the breath-powered nasal device uses the patient's own breath to blow air simultaneously at the same force rate through both chambers. As the blown air exits both chambers, the propelled air from the outer tube chamber surrounds the drug substance propelled from the

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inner tube chamber within the blown air forcing the drug substance to exit in a tight or confined, concentrated plume shape in the vertical, so that a higher concentration of drug substance reaches the targeted nasal sites, as compared to a conical fanned-out plume shape of drug substance exiting a single hollow chamber, as illustrated in FIGS. 44- 45. This unique feature allows diseases or injuries of the brain to be treated more effectively with a drug substance without or with minimized systemic or Blood Brain Barrier ("BBB") issue. The present invention uses a patient's natural breath to blow air through both the inner drug chambers to propel a drug substance from the inner drug substance chamber deep into the nasal cavity to targeted sites, bypassing the BBB, providing the potential to better treat central nervous system diseases such as traumatic brain injury, including concussions, migraines, epilepsy, insomnia, and post-operative pain, the latter of which is often remedied by opioids.