

# The Reappearance of Procaine Hydrochloride (Gerovital H3) for Antiaging

Recently in the United States, advertisements have been appearing on the Internet and in some magazines about what to many may seem to be yet another fountain of youth drug. The drug is called Gerovital H3, but what might be surprising is that it is simply the dental anesthetic procaine hydrochloride (novocaine), or what some claim, along with different product names, are various preparations of procaine hydrochloride. Equally surprising is that in the 1950s, this drug was once the toast of the town among Hollywood stars and heads of state. A few U.S.-based antiaging and longevity clinics have begun to advertise Gerovital H3 in pill form and as intravenous infusions despite the fact that the U.S. Food and Drug Administration (FDA) banned it in 1982.<sup>1</sup> Particularly interesting for this Journal's readers is that it was a National Institute on Aging commissioned review published in the *Journal of the American Geriatrics Society* in 1977 that played an important role in the FDA ban.<sup>2</sup>

Governmental bodies such as the FDA are relied upon to protect their citizens from drugs that do not do what they are claimed to do or are unsafe, yet in communist Romania, the opposite occurred with the state-sponsored marketing of Gerovital H3. In the early 1950s, the immortality-obsessed Nicolae Ceausescu and his wife, Elena,<sup>3</sup> the latter of whom was the country's Director of Science and Technology, supported the creation of an institute to create an immortality drug. In 1956, a paper titled "A new method for prophylaxis and treatment of aging with Novocain-eutrophic and rejuvenating effects" was published in the now discontinued journal *Therapiewoche*.<sup>4</sup> The author and director of the Geriatrics Institute of Bucharest, Ana Aslan, claimed:

Phenomenal improvement in the psychic, physiological, and social functioning of 189 elderly subjects who had undergone procaine (Novocaine) therapy over a period of ten years. Patients bedridden with arthritis and rheumatism were mobile again, living normal lives; hypertension and angina pectoris vanished. Severely disoriented psychiatric patients recovered; memory, concentration and perception were restored; extrapyramidal rigidity in Parkinson's disease diminished. Hair growth was stimulated, repigmentation of gray hair occurred in some cases, flaccid senile skin regained its turgor and became tight and smooth, the subjects looked ten

years younger. A notable reduction in mortality rates were also reported.<sup>5</sup>

The Ceausescu government enthusiastically seized upon the claim and took on responsibility for manufacturing and distributing Gerovital H3, eventually facilitating its administration in 144 clinics across Romania. The communist regime, with the assistance of Dr. Aslan, then established an antiaging resort and clinic for foreigners in a former villa located in Otopeni. In 1971, Dr. Aslan was given the distinction of Hero of Socialist Labor. The Romanian government claimed that many celebrities came to the clinic, including "Mao Tse-toung, Charles de Gaulle, Pablo Picasso, Sir Winston Churchill, Charlie Chaplin, Marlene Dietrich, Nicolae and Elena Ceausescu, Konrad Adenauer, Aristotle Onassis, and John F. Kennedy."<sup>6</sup>

With such celebrity and no reasonable scientific basis for such a panacea-like effect, the mainstream medical scientific community became increasingly incredulous. In the 1970s, the National Institute on Aging commissioned a thorough evaluation of the studies and claims surrounding Gerovital H3. The conclusion of that work was that, except for a possible mild monoamine oxidase (MAO) inhibitor effect that would potentially ameliorate depression, there was no scientifically credible evidence supporting the claims that procaine is beneficial in treating age-related diseases or syndromes.<sup>2</sup> A plausible explanation for why some subjects might have experienced some improvements in health was that, in addition to receiving Gerovital H3, they were receiving other interventions such as exercise, stress reduction, and healthy nutrition. Thus, a glaring problem for the demonstration of any benefit associated with Gerovital H3 or similar compounds is the absence of any double-blind, placebo-controlled trials demonstrating a significant improvement in the outcomes that antiaging doctors and entrepreneurs claimed.<sup>2,7</sup>

Several studies were performed to further investigate a possible MAO inhibitory effect from procaine hydrochloride and any subsequent neurocognitive benefit. These have been summarized in a relatively recent *Cochrane Review* that concluded in 2008 that there is no evidence that procaine and its preparations demonstrate a benefit in treating or preventing cognitive impairment or dementia.<sup>8</sup> The reported risks of dizziness, restlessness, migraine headache, and systemic lupus erythematosus outweighed the minimal, if any, benefit.

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Since September 17, 1982, the FDA has banned the importation into or distribution within the United States of Gerovital H3 (also known, according to the FDA, as KH3, GH3, procaine hydrochloride, Trofibial H3, Aslavital, and Zell H3). The latest revision of FDA Import Alert 61–01 (3/11/2011) states that “Gerovital (KH3) which generally consists of some form of Procaine HCL is regarded as a new drug for all indications when offered for the conditions for which it was found effective under DESI 763. It requires an approved Abbreviated New Drug Application (ANDA) for legal marketing.” The alert goes on to state: “These products are frequently accompanied by promotional literature or labeled as a cure-all for such ailments as old age, premature graying of hair, wrinkling of skin, mental disorders, insomnia, decreased sexual vigor, rheumatism, arthritis, heart problems, depression, etc.”<sup>1</sup>

Despite it being more than 30 years since the ban, Gerovital H3 appears to have experienced a recent rebound in marketing and sales in the United States, primarily because of Internet-based marketing. A search for “Gerovital H3” on Google or Yahoo! results in more than 300,000 hits. Inquiring patients and the public generally should be informed about the approved and unapproved uses of procaine hydrochloride and that there is no scientific evidence supporting any systemic health benefits or “antiaging” effects of the drug.

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