LE Magazine July 2007

On The COVER

The Untapped Healing Potential of DMSO

By Sue Kovach

Despite decades of research and thousands of studies attesting to its health-promoting properties, dimethyl sulfoxide (DMSO) remains virtually unknown to the medical professional and the public.

This inexpensive compound demonstrates potent anti-inflammatory and analgesic properties, has been shown to relieve painful musculoskeletal and urinary conditions, and may even fight Alzheimer's disease and cancer. Unfortunately, its widespread acceptance and use has been stymied by the FDA and their allies in the pharmaceutical industry.

For more than 40 years, Dr. Stanley Jacob has been battling the establishment over DMSO. In this article, Dr. Jacob reveals new data showing the potential of DMSO in treating brain trauma injuries that afflict more than 50,000 Americans each year.

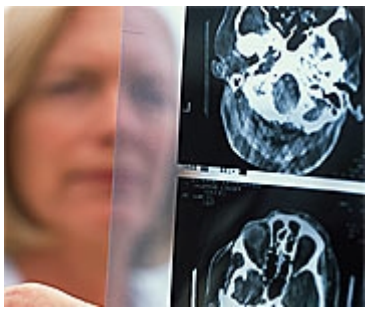
DMSO: EXTENSIVELY RESEARCHED, CRIMINALLY IGNORED

Dimethyl sulfoxide (DMSO) is an anti-inflammatory and analgesic compound that holds promise in managing a wide range of debilitating health conditions. DMSO is an approved pharmacological agent in more than 125 countries, and its safety and therapeutic effects are backed by nearly 50 years of research and more than 10,000 scientific articles on its biological implications.

Unfortunately, the vast health-promoting potential of DMSO has gone unfulfilled in America, suppressed by a combination of bureaucratic ineptitude and pharmaceutical industry lobbying. In the United States today, DMSO is approved to treat only one medical condition: interstitial cystitis, or chronic inflammation of the bladder wall. Recent findings on DMSO's ability to help manage the effects of head injury have renewed interest in the many potential therapeutic applications of this versatile compound.

TREATING HEAD TRAUMA

Traumatic brain injury is the most common injury of soldiers returning from the war in Iraq. In light of this, new clinical trials using DMSO to manage the elevated intracranial pressure common to such injuries are now being approved.



At the forefront of this work is Stanley Jacob, MD, a pioneering DMSO researcher and member of the Life Extension Foundation's Scientific Advisory Board. Having conducted research on DMSO and its many medical uses since the early 1960s, Dr. Jacob is often called "the father of DMSO" in honor of his life's work in trying to bring this unique compound to the forefront of contemporary medicine. His resolve in the face of government and drug industry obstacles is legendary. A faculty member at the Oregon Health and Science University in Portland, Dr. Jacob maintains that DMSO can be an effective treatment for closed head trauma and holds promise for other conditions such as spinal cord injuries and embolic stroke.

"Closed head trauma is severe trauma from a blunt injury, where the head hasn't been opened," he explains. "It's the type of injury that could occur in a car accident, such as a severe concussion causing unconsciousness. With this type of injury, the brain swells against the hard bone of the skull, causing brain cells to die. It also diminishes blood supply and oxygenation, and causes a major shift in electrolytes within the brain. To treat these conditions, DMSO is administered intravenously as soon as possible after the injury occurs."

According to Dr. Jacob, "DMSO is a potent free-radical scavenger and diuretic that reduces swelling and improves blood supply to the brain. This improves blood oxygenation to brain tissue. Injured brain cells often aren't dead. When these cells get

increased blood supply and more oxygen, and when the free radicals are scavenged, dying cells can recover, and brain swelling is reduced very rapidly."

Dr. Jacob notes that in studies conducted from 1978 to 1982, "we observed that when the human brain was treated with intravenously administered DMSO after a head injury, the swelling could be reduced within five minutes. No other treatment comes close to acting that quickly. In patients given other commonly used therapeutic agents such as intravenous barbiturates, the brain continued to swell. We've known about DMSO's efficacy for this type of injury for a long time."

Astonishingly, however, the Food and Drug Administration (FDA) has not approved any new pharmacological agent of significance for the treatment of traumatic brain injury in more than three decades. With so much attention focused on the plight of severely injured soldiers returning home from war, Dr. Jacob is leading the charge to gain FDA approval of DMSO to treat this type of injury. He believes that DMSO would be more effective than some current therapies such as removing parts of the brain to reduce swelling.

"In my opinion, DMSO has the potential to be the pharmacologic treatment of choice for traumatic brain injuries from combat," says Dr. Jacob. "There's nothing that comes close to it in efficacy."

Dr. Stanley Jacob currently serves as the Chairman of Abela Pharmaceuticals, Inc. Based in Orange County, California, Abela Pharmaceuticals was formed in 2005 for the purpose of developing and clinically testing DMSO and DMSO-related products. The company's mission is to bring DMSO to market for the treatment of injuries and conditions affecting the central nervous system, including traumatic brain injury, stroke, and Alzheimer's disease.

Dr. Jacob and his colleagues previously sponsored preliminary clinical trials of DMSO on traumatic brain injury patients in Europe. The results of the trial were remarkable, with an 80% survival rate (about twice the historical rate of 30-40%) and 70% of the patients experiencing a favorable outcome (far higher than the historical rate of less than 10%).[1]

Based primarily on these results, the FDA has given Abela's Investigational New Drug application "fast track" designation and will allow the company to clinically test DMSO on traumatic brain injury patients. The controlled, multi-center study is equivalent to a Phase 2b trial, and is expected to begin later this year.

ACCIDENTAL DISCOVERY OF DMSO

DMSO has a long list of primary pharmacological actions, including fighting inflammation, relieving pain, improving blood supply, scavenging free radicals, softening scar tissue, and effects that may benefit autoimmune conditions.[2] So why is a treatment shown in decades of studies to be safe and effective for so many conditions not approved for more than one medical use? The answer may lie in DMSO's long, controversial history, which includes the many years Dr. Jacob has spent researching and fighting for its approval.

A simple compound once described as a cheap industrial solvent, DMSO is in fact a byproduct of the paper manufacturing process, and was first isolated in the mid-1800s by a Russian chemist. In the early 1960s, when one paper manufacturing company in the Pacific Northwest decided to explore DMSO's possible commercial uses, its fascinating medical potential began to emerge.

Washington state-based Crown Zellerbach Corporation asked one of its staff chemists, Dr. Robert Herschler, PhD, to investigate other potential uses for DMSO. Dr. Herschler observed that DMSO could penetrate the leaves of plants, and believed it might be useful in carrying nutrients and fungicides into diseased trees.[3]

Dr. Jacob, then assistant professor of surgery at the University of Oregon Medical School (later renamed the Oregon Health and Science University), learned of British research showing that DMSO acted like a medical "antifreeze" to protect blood cells frozen for storage. He was intrigued, as his major research interest was the preservation of organs for transplantation. Before coming to Oregon, Dr. Jacob was on the faculty of Harvard Medical School and had worked with Massachusetts Institute of Technology (MIT) researchers to develop an apparatus for freezing a kidney from the inside out by way of the kidney's vasculature, thus avoiding a shell of ice encircling the kidney. In Oregon, Dr. Jacob saw DMSO as a potential chemical means of protecting organs from freezing. He contacted Crown Zellerbach and was introduced to Dr. Herschler, and the two teamed up to investigate DMSO's medical potential.

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EARLY DMSO RESEARCH SHOWS PROMISE

Early studies in animals and humans showed that DMSO rapidly penetrates the skin and quickly relieves the pain and inflammation associated with injuries such as ankle sprains. Drs. Jacob and Herschler thought DMSO could effectively treat arthritis and possibly act as a drug-delivery system. Their first paper on DMSO's pharmacology, published in the journal Current Therapeutic Research in 1964, drew the attention of a number of pharmaceutical interests and made headlines in Oregon newspapers. It was quickly picked up by the New York Times.

"A front-page Times article that called DMSO the most exciting thing in medicine created a great deal of interest," Dr. Jacob recalls. "Six pharmaceutical firms were licensed by Crown Zellerbach to begin wide and well-funded evaluations of DMSO's safety and effectiveness. The studies primarily used DMSO applied topically to the skin."

According to Dr. Jacob, three companies—Merck, Centex, and Squibb—found DMSO to be safe and effective for a wide array of musculoskeletal problems like tendonitis and osteoarthritis. Minor side effects included a garlicky breath odor, temporary itching, flaking, and burning at the application site, and occasional nausea or drowsiness. While the companies submitted New Drug Applications to the FDA in 1965 stating that DMSO was safe and effective and ready to be a prescriptive agent, ongoing animal toxicity research revealed that DMSO caused changes in laboratory animals' eyes (myopia, or nearsightedness). Although no such problems were seen in humans, the FDA grew concerned. Then, on September 9, 1965, the Wall Street Journal reported the death of an Irish woman after undergoing DMSO treatment for a sprained wrist. Although no autopsy was conducted, drug company officials speculated the death was the result of an allergic reaction to DMSO.[4]

DMSO WHAT YOU NEED TO KNOW

- An inexpensive compound called dimethyl sulfoxide (DMSO) holds great promise in managing a diverse array of health conditions, yet has largely been ignored by the medical community.
- Originally discovered as a byproduct of paper manufacturing, DMSO has demonstrated remarkable anti-inflammatory, analgesic, and antioxidant properties.
- DMSO is currently approved for only one clinical indication: interstitial cystitis, a painful chronic inflammatory condition of the urinary bladder.
- One of DMSO's most promising roles is treating severe closed head trauma. Research by Dr. Stanley Jacob shows that DMSO relieves brain swelling and restores blood flow and oxygenation following such injuries.
- Studies suggest further applications for DMSO in fighting illnesses such as arthritis, fibromyalgia, Alzheimer's disease, and ulcerative colitis.
- DMSO's benefits are largely unknown and unavailable to the US public, primarily because it is an inexpensive compound that is ineligible for patenting by pharmaceutical companies.

FDA OVERREACTS, HALTS DMSO RESEARCH

Dr. Jacob recalls that the FDA "halted all studies of DMSO on November 10, 1965, even though they had data in their files on more than 70,000 patients submitted by approximately 1,500 physicians in the US showing its safety and effectiveness."

FDA critics contend that the agency overreacted in halting the studies, considering how unconcerned the agency appears today with the number of deaths that occur from both trial and approved pharmaceuticals.

According to Jack de la Torre, MD, PhD, who has researched DMSO's role in treating central nervous system injuries, "Years ago the FDA had a sort of chip on its shoulder because it thought DMSO was some kind of snake-oil medicine. There were people there who were openly biased against the compound, even though they knew very little about it."[5]

Adding to the FDA's skepticism was that, in many ways, DMSO simply sounded too good to be true. Says Dr. Jacob, "In the 1890s, if someone had said, 'I have this little white pill and if you take it, it will relieve pain, reduce inflammation, protect you if you have a heart attack, and so on,' you'd say, 'Well, I don't believe it.' Yet aspirin does all those things. DMSO is similar in that it doesn't fit the 'one-pharmacologic-agent-for-one-indication' philosophy of the FDA".

Since DMSO was knocked off track, it has been a grueling uphill battle for Dr. Jacob and other researchers trying to get FDA approval of DMSO for any use.

FDA LATER RECONSIDERS DMSO

Dr. Jacob resolutely continued his work on DMSO. In 1971, he and his colleagues brought so much pressure on the FDA that it commissioned the National Academy of Sciences (NAS) to evaluate the DMSO controversy. The NAS published its findings in 1972, concluding that DMSO was a promising and probably safe and effective agent. The FDA was unmoved. Dr. Jacob, however, finally achieved success and some vindication when the agency approved DMSO for treating interstitial cystitis in 1978.

In 1980, DMSO re-emerged in the media, causing the public and even Congress to take note. Continued pressure from Dr. Jacob and other researchers led to congressional hearings, and demands for federal studies of DMSO were introduced in several bills. Unfortunately, none of these bills ever left committee, and a provision in another bill was deleted just before passage.

As the leading expert on DMSO, Dr. Jacob was called to testify at a hearing before the US Senate Subcommittee on Health. "DMSO is one of the few agents in which effectiveness can be demonstrated before the eyes of the observers," he told the committee. "If we have patients appear before the committee with . . . sprained ankles, the application of DMSO would be followed by objective diminution of swelling within an hour. No other therapeutic modality will do this." At the time, ongoing studies of DMSO's treatment potential covered a range of conditions, including stroke, breast and prostate cancer, head injuries, bursitis, herpes, retinitis pigmentosa, spinal cord injury, and arthritis. The results showed much promise.[3]

Public demand for DMSO grew strong and the FDA went on the defensive after millions watched Dr. Jacob appear on the CBS investigative series 60 Minutes. An "underground" market in DMSO sprung up, with sales rumored to be over a billion dollars a year. This, Dr. Jacob notes, was from selling not pharmaceutical-quality DMSO, but rather so-called "underground" DMSO. It was not illegal to sell DMSO, and the public could purchase the industrial product virtually anywhere, from the local health food store to the dry cleaners, ice cream shops, hobby stores, and from the trunks of cars. It was also inexpensive: distributors paid about $1 a pint in bulk, and consumers were happy to pay about $20 a pint for a product that brought relief for conditions such as arthritis and sports injuries.[3] The FDA, however, began seizing DMSO from distributors and retailers. It became harder to obtain, and eventually the furor died down. For Dr. Jacob and other DMSO researchers, however, the battle with the FDA continues to this day.

FOCUS ON PROFITS PREVENTS DMSO RESEARCH

An additional (though related) obstacle to DMSO's widespread use is its lack of potential profitability for drug companies. The few early patents granted on DMSO expired in 1987, and without patent protection for the DMSO molecule itself, drug companies cannot make money on it. Sales of so-called underground DMSO have moved to the Internet, where buyers usually cannot be certain of the strength or purity of the chemical-grade and industrial-quality product offered.

A search of the medical literature turns up more scientific articles about or referring to DMSO than for penicillin, cortisone, or aspirin. The future of DMSO, according to Dr. Jacob, lies not so much in its use alone in topical administration, but more likely mixed with other substances and given by injection or intravenously—an area he would like to explore.

"We're not dealing with just another chemical, we're dealing with what I always call a therapeutic principle," Dr. Jacob explains. "A given drug or medicine will treat a given disease or more, but a therapeutic principle is an entirely new concept in therapy." Dr. Jacob believes that DMSO, like aspirin, will have a profound effect on many areas of medicine.

CONCLUSION

Despite DMSO's long and frustrating history, its true value as a medicinal agent may still be undiscovered. Dr. Jacob and other researchers believe DMSO will be looked on quite favorably in the years to come, as more evidence of its safety and efficacy accumulates—and particularly as new investigations explore its use in treating closed head trauma.

"It's fallacious when people talk about DMSO in the same breath as other substances that don't have a good scientific basis," says Dr. Jacob. "While they might say that the story of some other agent is like the story of DMSO, there's really nothing quite like DMSO in its history and potential usefulness."

To learn more about Abela Pharmaceuticals, contact Abela's CEO, Dr.Colette Cozean, at 949-855-2885.

DMSO'S MANY POTENTIAL MEDICAL APPLICATIONS

Since the early 1960s, DMSO's pharmacological actions and efficacy have been documented in hundreds of laboratory studies. According to Dr. Stanley Jacob, DMSO holds promise in treating the following conditions:

Alzheimer's disease. DMSO has been shown to dissolve amyloids, the proteins that occur in the hallmark brain lesions of patients with Alzheimer's and almost invariably lead to the functional loss and eventual death of brain cells.

Arthritis. With its ability to penetrate tissues, DMSO shows value in reducing pain and inflammation in osteoarthritis, rheumatoid arthritis, and possibly gout.

Atherosclerosis. In laboratory animals, DMSO has demonstrated its ability to retard the development of atherosclerosis induced by dietary cholesterol, as well as suppress the accumulation of cholesterol in tissues despite severe hypercholesterolemia (elevated blood levels of cholesterol).

Down's syndrome. Researchers have noted that when children born with Down's syndrome were treated with DMSO, mental and neurological functions improved in a number of areas.

Drug extravasation injury. When chemotherapy drugs exude into surrounding tissues (extravasate), the effects are highly damaging. DMSO application significantly improved anthracycline-associated extravasation tissue injury in a study conducted by Stephen B. Strum, MD, a member of the Life Extension Foundation's Scientific Advisory Board.

Fibromyalgia. According to Dr. Jacob, 70% of fibromyalgia patients he treated with DMSO for several years experienced benefits with no side effects. He believes these effects were due to pharmacological actions of DMSO such as free-radical scavenging, analgesia, anti-inflammation, softening of scar tissue, reduction of muscle spasms, and stimulation of healing.

Herpes. DMSO has been used to enhance penetration of alpha-interferon ointment in the treatment of herpes.

Interstitial cystitis. Instilling DMSO in the urinary bladder is an FDA-approved palliative treatment for this chronic inflammatory condition.

Malignancy. Researchers concluded DMSO exerts a significant survival advantage in gastric cancer.

Plastic surgery adjunct. DMSO has been shown to aid healing and reduce pain and swelling.

Prostatitis. Significant symptomatic relief occurred when DMSO was injected by catheter into the prostatic urethra.

Reflex sympathetic dystrophy. DMSO helps relieve the pain of this condition, an autonomic nervous system disorder characterized primarily by overwhelming pain in the extremities. Dr. Jacob notes that in Holland, a physician is breaking the law if he does not prescribe topical DMSO for reflex sympathetic dystrophy.

Scleroderma. In basic work done at the Cleveland Clinic, topical DMSO was found to have an anti-inflammatory effect while increasing blood supply to the skin.

Spinal cord injury. Data shows that if DMSO is given intravenously within the first 45-60 minutes after injury, the number of laboratory animals that recover was much higher than in those not receiving DMSO. Dr. Jacob says this is an area he would like to pursue, noting, "If we have 10,000 severe spinal cord injuries per year in the US—quadriplegic and paraplegic—there could be fewer patients who will need long-term care."

Stroke. DMSO combined with a sugar that fuels energy production was well tolerated in elderly stroke patients, and could be

of benefit in reducing neurological disability after stroke.

Ulcerative colitis. In controlled human studies, orally administered DMSO produced some improvement in the condition.

For more information, please visit Dr. Jacob's website at www.dmso.org.

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