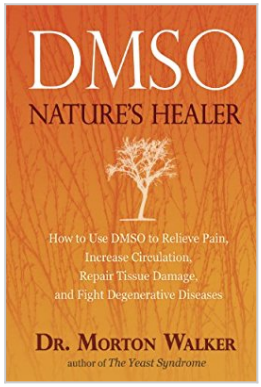

DMSO: Nature's Healer

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An easy-to-understand, up-to-date guide on the highly publicized drug, DMSO

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About the Author
Dr. Morton Walker is an award-winning professional medical writer. He has written more than seventy books, including the bestsellers *Sexual Nutrition* and *The Yeast Syndrome*, as well as thousands of magazine articles.

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My appreciation is extended to the medical consultant for a first edition of this book. Ten years ago, William Campbell Douglass, M.D., then of Sarasota, Florida, put together a three-day medical conference comprised of experts on dimethyl sulfoxide. They came to Sarasota from around the United States and six foreign countries and brought specialty knowledge of DMSO with them. They shared this knowledge with each other, and I was the medical journalist who recorded their information, produced magazine and clinical journal articles, and eventually the first edition of this book. The present second edition is an update and then rewrite of that initial published effort.

Preface

The American Medical Association (AMA) held a leadership conference the weekend of February 14, 1981, and one of its speakers was Otis R. Bowen, M.D. Dr. Bowen is former governor of Indiana, a leader in medicine, management, and politics. In his presentation to the AMA, he shocked the assembly by admitting that he took the law into his own hands and used an illegal drug to ease his wife’s pain while she was dying. Beth Bowen died January 1, 1981, after months of agony from multiple myeloma, a type of bone cancer.

Dr. Bowen, who was preparing to step down from the governorship at the time, turned to dimethyl sulfoxide, or DMSO, to ease his wife’s intense pain. He had obtained the liquid solvent from a veterinarian and found that it relieved his wife’s suffering “in minutes,” he said.

The Food and Drug Administration (FDA) forbids the use of DMSO in humans except in treating a rare urinary bladder condition. Even in the face of the government ban, Dr. Bowen did what he knew was right for his wife by administering intravenous DMSO. “Why can’t dying persons, with severe pain, have easy prescription access to it?” he asked in his speech. “The only excuse I could find was that, after prolonged use and heavy dosage, it caused an occasional cataract in dogs only.”

Before you’ve read very far into this book, you’ll probably be asking questions similar to Dr. Bowen’s. It won’t be difficult to identify with the patients involved here, some of whom have been forced to take treatment into their own hands by turning to DMSO.

In fact, DMSO has *not* been found unsafe for humans. Any side effects are merely minor irritations. DMSO stops bacterial growth. It relieves pain. As a vasodilator, the drug enlarges small blood vessels, increasing the circulation to an area. It softens scar tissue and soothes burns. DMSO’s anti-inflammatory activity relieves the swelling and inflammation of arthritis, bursitis, tendinitis, and other musculoskeletal injuries. And it does many more good things of a therapeutic nature for anyone who is injured or ill.

I recommend that you use DMSO strictly under the supervision of a doctor who is skilled in its application.

Only the pure pharmaceutical grade should be employed, not the crude industrial grade.

DMSO is both a drug and a good solvent. Industry values it for removing paints and varnishes, and dissolving certain plastics such as rayon, polyvinyl chloride, polyurethane, methacrylate, and acrylic. It doesn't affect cotton, wool, nylon, leather, or polyesters.

More important, it benefits human body cells, tissues, and organs in unique ways. DMSO is the twenty-first century's newest healing principle with a very wide range of usefulness. It represents an entirely different means of treating diseases—not as an ordinary drug that works for a given disease, but as a holistic ingredient that brings whole-body cellular function back to normal.

Dimethyl sulfoxide has had a battered thirty-year history. But because of the general public outcry about its ban, DMSO has become a household word and a medical-political cause célèbre. Those of us who have been using the drug for twenty-six to twenty-eight years never dreamed that it would become a focal point in the continuing battle between individual freedom and the power of government.

My colleagues and I have been criticized, ridiculed, and even persecuted in some medical circles for promoting and using DMSO. But I, and others like me, came to the conclusion, having observed establishment medical thinking for forty years, that the only way a truly revolutionary treatment principle can be brought to the patient is by appealing to the general population through the information media. That is the purpose of this book.

Much of my material will appear anecdotal to the scientist, but such language is what the public understands best. And sometimes a hundred patient stories, heard by a sensitive and intelligent physician, are as good as or better than a double-blind research project. Double-blind studies are often just that—everyone involved is blind and stays that way until, many years and thousands of patients later, it is discovered that the particular drug doesn't work or is too toxic to warrant its use.

Good current examples of toxic drugs are the arthritis agents Motrin, Tolectin, Nalfon, and Naprosyn. They all underwent extensive double-blind testing. All are weak organic acids and prostaglandin inhibitors—like aspirin. About as effective as aspirin, these four drugs have two distinct differences: they are more toxic than aspirin and cost ten to thirty times more money. So much for double-blind studies.

Whether you agree or disagree with current claims, it's likely you'll affirm that if a drug has been proven safe, doctors should be free to use this agent when they believe it will help their patients. With all the extremely potent and dangerous drugs on the market, it is absurd to keep such an effective product as DMSO from pharmacy shelves.

Certainly not all of the claims for DMSO will prove to be valid, but in my opinion, many of them have already shown themselves to be true. And the most dramatic use of the medication is likely yet to be discovered.

Another purpose for my book is to point out the myriad applications of this unique substance. Once DMSO is legalized for use in all states and ethically produced for topical, parenteral, and oral administration, people won't have to smuggle the feed-store grade and the crude industrial grade into their homes to paint on their arthritic joints.

DMSO will eventually find its place in the armamentarium of American medicine. We who believe in the substance want to see it happen sooner than later. The clinical evaluation of DMSO began in the United States in 1963 and now, in 1992, the FDA still has not approved the drug for more than one use. This situation gives rise to some underlying questions you may find running throughout this book. How do we get

the FDA to see beyond its blind spot? How can we either bring DMSO to the people or declare the substance useless once and for all?

You will find lots of answers in these pages. DMSO needs even more public pressure than has been leveled at the regulatory process already. We want doctors to be able to prescribe DMSO without fear of censure from the medical world or the hospitals that employ them. If this doesn't happen, it appears that little will be done to ensure that a pure, medical grade of DMSO will be made available for patients.

In writing this book, I have found a distinct reticence by doctors to have their names mentioned in connection with DMSO. Often they provided me with glowing case reports of successes with the drug treatment, but their fear of colleague criticism prevented my revealing their identities. I had to discard such reports, and there were hundreds of them.

DMSO has the largest potential number of uses ever documented for a single chemical. My wish is that this book will bring more of them into the public domain than has been allowed to this point. It should be well understood by everyone at the outset that I don't say the substance is some kind of miracle cure. More properly, DMSO is a very effective and versatile compound that has been successfully adapted for a number of health problems. I want to get it into the hands of more people so that they may be relieved of discomforts and diseases for which DMSO is appropriate. I hope you will agree that mine is a worthy goal.

Morton Walker, D.P.M.

Stamford, Connecticut

CHAPTER 1

The Painkiller With a Problem

In the late spring of 1980, Eva Lee Snead, M.D., then a family practice specialist in San Antonio, Texas, learned that her friend, thirty-two-year-old psychologist Marjorie Saloman, was supposed to undergo a hysterectomy, the removal of her uterus. Mrs. Saloman's genital system problem arose from a stenosis of the cervical os. This condition is a narrowing or stricture at the mouth of the neck-like opening to the uterus where it extends into the vagina.

The psychologist described to Dr. Snead how several unsuccessful attempts at cervical dilatation had been attempted by her gynecologist. He tried to relax the cervix by injecting local anesthesia at its lower quadrant. Such an anesthetic technique usually is simple and effective, but this particular block had been no help to the woman even after many tries. Mrs. Saloman's gynecologist admitted that for her the attempted cervical dilatation was a complete failure.

The pain had been so great for this patient that when the dilatation instrument was inserted she had fainted. Her gynecologist quickly removed the instrument because the anesthetic was not allaying the pain. None of his attempts to relieve the problem worked; surgical removal of the uterus was the next procedure of choice.

Dr. Snead asked her friend to wait a week before having the hysterectomy, if delay was agreeable to the gynecologist. Complying with this request, Marjorie Saloman had her physician telephone Dr. Snead to learn the medical reasoning behind it.

Having some prior experiences with DMSO (dimethyl sulfoxide) treatment, Dr. Snead persuaded him to combine the substance with vitamin E and apply it topically to the patient's cervical area. Dr. Snead wanted to try to reduce the woman's scar tissue and adhesions, which DMSO is able to do.

“I was lucky enough to run into the gynecologist on the day that we were going to apply the DMSO,” Dr. Snead wrote me, “and he inserted the substance himself with the vitamin E. Before five minutes were over, his instrument slipped into the cervix without any sensation felt by the patient.”

A month later, the gynecologist rechecked the woman’s constricted cervix and found it was still overly narrow. He repeated the application of DMSO and vitamin E, and after a few minutes was able to insert the instrument to stretch the opening without any problem. This time it was a highly successful procedure, and the hospital appointment for surgery was cancelled.

The patient wore a device that was inserted to keep the cervical canal’s wall stretched. In the meantime, Dr. Snead placed her friend on megavitamin therapy using high doses of nutrient substances to restore health to surrounding tissues.

One month after the device had been inserted, the woman was again checked by her gynecologist who found the cervical os perfectly expanded. He was able to insert probes without first applying DMSO or anesthesia and without the patient feeling any discomfort. Marjorie Saloman had definitely been saved from having a hysterectomy.

Yet Dr. Eva Lee Snead had her medical license revoked for repeatedly employing DMSO and other forms of complementary medicine—what some have labelled “quackery” but that rightly may be considered alternative methods of healing. The state of Texas is not predisposed to allowing deviations from the medical mainstream. And, as you will see, use of dimethyl sulfoxide by forward-looking physicians is out of the medical mainstream.

* * *

Lorae Avery, Ph.D., director of The Health Center, Inc., an acupuncture and nutrition clinic in Auburndale, Florida, expressed her amazement to me at the effectiveness of DMSO in eliminating pain. She saw excellent results when physicians working for The Health Center applied the substance externally to patients. One of them was sixty-five-year-old Anna Goldeman, who had been suffering for years with bursitis of the right shoulder. She went to The Health Center for relief of the bursitis in November, 1980, and was gratified by the results of DMSO treatment.

More dramatic than the patient’s alleviation of her shoulder pain was the easing of a discomfort that had begun four years previously. Mrs. Goldeman had undergone amputation of the left hip high in the groin, which resulted in “phantom limb pain.” After amputation of a limb, or a portion of it, the amputee may experience strange sensations as though the part were still there. This feeling of phantom pain is generally considered to be a stump hallucination. It arises from various types of nerve stimuli, resulting in burning, tingling, pricking, tickling, or really severe pain. Such sensations are not uncommon for an amputee and are not readily treatable.

With application of DMSO to her right shoulder, phantom limb pain with its constant twitching went out of Mrs. Goldeman’s left groin. She no longer sensed that she still had an extremity. Now she could feel more at peace with her situation.

Dr. Avery said, “We did not attempt to treat the phantom limb pain; our physicians were concerned with the bursitis. Yet, the phantom pain disappeared coincidentally from application of DMSO to the woman’s shoulder. Thus, what happened is, DMSO applied to one part of the body caused phantom pain to go away in another part of the body. And it’s permanently stayed away.”

Checking back with Dr. Avery over ten years later, I learned that Mrs. Goldeman continues in comfort

knowing that DMSO is available to cease her pain whenever needed.

* * *

Murray Franklin, M.D., of Chicago, is a Clinical Associate Professor of Medicine at the University of Illinois College of Medicine, as well as the medical director of the Union Health Service, the largest prepaid medical plan in the state of Illinois. He received a supply of DMSO in the fall of 1980 and decided to try it for the benefit of some patients for whom nothing else had worked. One of the people receiving topical therapeutic applications was Lucas Sheinholtz, fifty-two, who had been troubled with rheumatoid-osteoarthritis of both knees for more than a decade. Mr. Sheinholtz, hobbling with the assistance of two canes, arrived at Dr. Franklin's office complex to visit another physician. The patient had previously received many injections of cortisone, which his regular physician administered routinely. But no appreciable improvement in his arthritis had been observed by either the patient or his doctor.

"I suggested to the man's physician that we might paint some DMSO on both of his painful knees," Dr. Franklin said. "His right knee was swollen; the left knee was not. The right knee was warm to the touch. The patient's doctor agreed to a therapeutic trial, and I applied DMSO in three applications. Since I was not fully acquainted with how to use the solution, I allowed an application to dry and then put it on again and again. Within fifteen to twenty minutes the patient said he felt no pain and was able to walk practically without the use of a cane.

"He returned in one week and described his pain in the left knee as having disappeared completely," said Dr. Franklin. "There just wasn't any. The pain in the swollen right knee had returned just a little. I applied the DMSO again and the man got a similar result within a quarter of an hour. No more pain! I haven't seen him since and presume he is feeling fine."

THE NEW MEDICAL BREAKTHROUGH FOR PAIN

The people have a new medical breakthrough for pain: dimethyl sulfoxide, called DMSO. By itself or in combination with other medical ingredients, dimethyl sulfoxide should be useful in treating almost every disease known to mankind. The substance, a byproduct of pulp and paper manufacturing, has been employed safely and successfully by millions of people around the world to control swelling; reduce discomfort; take away inflammation; slow the growth of, and in many instances kill, bacteria, viruses, and fungi. It heals burns and relieves sprains, strains, and arthritic joints. It has worked effectively against cataracts, sports injuries, scleroderma, myasthenia gravis, tuberculosis, and even lessened mental retardation in people with Down's syndrome.

Cancer seems to respond well to DMSO. At Mount Sinai Hospital in New York City, Charlotte Friend, M.D., has turned cancerous cells into harmless normal ones in the test tube by putting them in touch with the DMSO solutions. Thus, DMSO cancer research is in progress.

Reported in the *Journal of Clinical Oncology*, in November 1988, twenty cancer patients with extravasation of anthracycline (destructive secretions from tissues of the toxic chemotherapeutic agent anthracycline onto the recipient's skin with the potential to form cancerous ulcers) were treated on a single-arm pilot study with topically-applied 99 percent dimethyl sulfoxide and observed for three months with regular examinations and photographs. DMSO was applied to approximately twice the area affected by the extravasation and allowed to air dry. This was repeated every six hours for fourteen days. The initial signs of extravasation included swelling, redness, and pain. The median area of damage on the skin of these patients was 8.25 square centimeters (cm2) and a median of twenty-five minutes elapsed between extravasation and application of DMSO.

In no patient did extravasation progress to ulceration or require surgical intervention, as is usual with this toxic chemotherapeutic agent for cancer. The authors of this report suggest with 95 percent confidence that ulceration was likely to have occurred in at least 17 percent of these patients. They go on to say that at three months there was no sign of residual damage in half the patients, while a pigmented indurated area remained in ten. The only side effects of DMSO included a burning feeling on applications, subsequently associated with itch, redness, and mild scaling. Slight blisters occurred in four patients, and six reported a characteristic breath odor associated with oysters. The oncologists stated that topical DMSO appears to be a safe and effective treatment for the cancer-related condition, anthracycline extravasation.1

DMSO tends to prevent the formation of scar tissue, or to dissolve it once present. The contracture (drawing together) of scar tissue ordinarily left after a burn doesn't take place.

Chilean physicians have published their results of using the substance, which indicate that it reduces the incidence of heart attacks or angina pain. It has been credited with preventing damage to heart muscle when tested in animal experiments. As with its use in stroke, DMSO may be lifesaving if employed early in heart attacks. Investigation is continuing.

Studies in Chile also show DMSO to be a penetrant across the blood-brain barrier. It carries drugs effective against certain forms of mental illness directly into the brain.

Placed into the nostrils, DMSO can open blocked sinuses within a few minutes.

It transports antibiotics right into the middle ear to lessen infections. It does the same against viruses and reduces the symptoms of herpes zoster (shingles) and herpes simplex (fever blisters). The viruses are hit with antiviral drugs by the DMSO transport. Furthermore, the herpes II venereal disease is greatly relieved by application of DMSO directly to the genitalia.

Periodontists in Poland have cleared up gum disease and reduced tooth decay and their associated pain by painting DMSO on the involved areas. Some pioneering dentists are dropping it into empty tooth sockets after extractions, especially those for wisdom teeth. It stops post-extraction swelling.

A 1987 paper coming out of Russia described the treatment of patients having generalized periodontitis with indomethacin in a suspension of dimethyl sulfoxide. Periodontitis is disease of the structures supporting the teeth such as the gums, periodontal membrane, and alveolar bone. The action of bacteria on food debris accumulated around the margins of the gums causes the formation of plaque, which eventually forms a hard deposit, tartar (or calculus). This accumulates in the gingival crevices (the spaces between the gums and the surface of the teeth), which become abnormally enlarged to form gingival pockets. It's an early stage of periodontal disease.

In chronic gingivitis, the gums are marked by chronic inflammation, and they become swollen and bleed easily. Calculus accumulates in the gingival pockets, causing bleeding and ulceration. Untreated, the plaque spreads to the underlying periodontal membrane and alveolar bone, which are destroyed. In this stage of chronic periodontitis, the teeth become loosened and eventually fall out.

Periodontal disease is the major cause of tooth loss in middle-aged and elderly people. It is brought on by poor oral hygiene and also by ill-fitting dentures and badly made artificial crowns and fillings. The early stages of periodontitis are treated by scaling to remove the calculus and polishing to remove the plaque, combined with careful oral hygiene. In advanced disease the gingival pockets are surgically removed by gingivectomy (gum excision).

Now periodontal disease is being treated with indomethacin and DMSO, in combination. Indomethacin is a

drug with anti-inflammatory, antifever, and pain-killing properties, but containing no corticosteroids. Its mode of action, like that of certain other anti-inflammatory drugs, is not known.2

Before this Russian publication, clinical results from the treatment of a hemorrhagic form of periodontosis were reported from Bulgaria. The clinicians used a complex herb extract and 15 percent DMSO to rid their patients of periodontal disease.3

American podiatrists have found DMSO effective for the treatment of painful corns, calluses, ingrown toenails, bunions, hammertoes, heel spurs, and even the inflammation of gouty big toes. DMSO appears to control gout pain after just seven days of application.

Inflammations such as pink eye from viral invasion go away after a few applications of DMSO.

All this happens in a way that medical scientists have yet to fully understand. They don't know how DMSO actually works. For this reason primarily, DMSO is not approved by the United States Food and Drug Administration (FDA) for any other human medicinal use except as a treatment for interstitial cystitis, a condition that causes scarring and gradual shrinkage of the bladder.

Bruce H. Stewart, M.D., of the Cleveland Clinic Foundation, and Sheridan Shirley, M.D., of the University of Alabama, administered DMSO to 213 patients and found it quickly healed the bladder condition despite the fact that the patients had not responded to traditional treatment. Before the success of DMSO, people suffering with interstitial cystitis faced either major surgery of the bladder, or even its complete removal. They suffered from the urge to urinate as frequently as every ten minutes.

Unlike criteria laid down for studying the use of DMSO for other conditions, the study on interstitial cystitis was done following an elementary protocol. The patients were ill, didn't improve spontaneously, and all forms of treatment were ineffective. They then received DMSO and improved markedly. DMSO had eliminated the patients' health problems and won approval by the FDA for use in bladder treatment—but only for interstitial cystitis.

THE FDA OBJECTION TO OTHER DMSO USES

"The fundamental problem from the point of view of the FDA is the quality of the scientific information that is available to support the various claims that are made for DMSO," said J. Richard Crout, M.D., Director of the Bureau of Drugs with the Food and Drug Administration. Dr. Crout made his statement at a hearing before the House Select Committee on Aging, 96th Congress, held March 24, 1980.

Dr. Crout continued, "I want to make it clear that the Food and Drug Administration has approved DMSO for the indication for which there is evidence that meets the statutory standard. We are prepared to approve it for any other indications when the evidence comes along that it does meet that statutory standard."

In brief, the drug can be approved if clinical researchers show substantial evidence of its effectiveness by providing the FDA with well-controlled trials. The "possibility" that DMSO is effective, according to the present statute, is simply not enough. For this reason, the only thing holding up FDA approval of DMSO for any of the substance's indications is the availability of well-controlled trials that meet statutory standards, said Dr. Crout. There is a basic conflict between the quality of the scientific evidence available and the statutory standard for approval.

This fundamental confrontation is best illustrated by a new drug application (NDA) submitted in 1978 by Research Industries Corporation of Salt Lake City, Utah, the major producer of a human medicinal grade of DMSO in 50 percent concentration called Rimso-50. Research Industries Corporation wanted to extend the

use of its product and market it for the symptomatic relief of pain and ulceration in the fingers of patients with scleroderma. Scleroderma is a rare collagen disorder that results in thickening of the skin from the swelling of fibrous tissue. It most often involves the hands, especially causing ulcers on the fingers, and less frequently on other tissues in the body. After detailed review by the FDA's Bureau of Drugs staff and its Arthritis Advisory Committee, the NDA was refused on the grounds that the available clinical trials did not yet demonstrate that DMSO was effective for scleroderma. Medical science's current investigative techniques using double- or single-blind studies seemed inadequate for evaluating the effectiveness of DMSO in this instance.

Research Industries Corporation relied principally on one particular study to demonstrate DMSO's effectiveness against scleroderma. This study had each patient dip only one hand into a solution of DMSO. The untreated hand was observed as a control. Both hands had ulcerations of the skin of the fingers, and investigators thought that DMSO's effectiveness in healing sclerodermatous ulcers would clearly be shown by what happened to the two hands.

Dr. Crout described what happened. "There was a general improvement trend in the healing of ulcers of the fingers in many patients, and in a few this was quite striking. Interestingly, however, this improvement occurred in both hands in these patients with scleroderma; that is, both the treated and untreated hands tended to heal."

Now, DMSO is different from any other known medical substance in that it is easily absorbed into the body. Paint an amount the size of a silver dollar anywhere on your upper body and in thirty seconds you'll taste it on the tip of your tongue. It penetrates the skin and travels through the blood stream that fast.

The officials of the Research Industries Corporation argued that both hands of the affected patients healed because DMSO worked equally well on the hand in touch with the liquid and on the control hand. Simply, DMSO healed the control hand by traveling through the blood stream to the ulcer site. Absorption of the substance into the body from the treated hand was inevitable because of its unique power of penetrability. Current techniques utilizing the scientific method as it is understood today cannot be applied to the study of DMSO.

Dr. Crout said, "Our staff and advisory committee felt, to the contrary, that improvement of the untreated hand raised the strong possibility that the general improvement trend in the whole trial was attributable to a nonspecific effect of DMSO. Everyone agreed that the trial showed that DMSO may be effective, but few felt that the trial proved the point.

"Because the statutory standard for approval of a drug is substantial evidence of effectiveness as shown by well-controlled trials, not simply the possibility of effectiveness," continued the FDA chief, "we are unable to approve DMSO for this indication at this time."

In order for a new drug to be recognized by the FDA it must conform to section 505 of the Food, Drug, and Cosmetic Act, which holds that the standard for effectiveness is "substantial evidence" of effectiveness. This means evidence must come from controlled clinical investigations conducted by experts qualified by scientific training and experience to evaluate the effectiveness of drugs.

Dr. Crout declared that applications for an investigational new drug (IND) submitted for DMSO during the previous eighteen years were faulty. They had not been assembled into scientifically designed studies. They had not followed that certain discipline required by research. All INDs must go through a standard FDA procedure to win approval. The prior investigational new drug applications submitted by three pharmaceutical companies of national repute were poorly prepared, said Dr. Crout, and the companies did not know how to present an IND application to the FDA to show proper evidence of value in the use of

DMSO. He made this statement despite the fact that these same pharmaceutical firms had previously won approval for other drugs.

FLAWS IN FDA PROCEDURE

Of course, the pharmaceutical companies disagreed. The co-discoverer of the therapeutic properties of DMSO, Stanley W. Jacob, M.D., Associate Professor of Surgery at the University of Oregon Medical School, certainly disagreed. He believed the advisory committee that made recommendations against FDA approval of DMSO was biased against DMSO. Dr. Jacob told the House Committee on Aging: “I am not at all satisfied that the FDA is giving DMSO a fair shake.”

The DMSO researchers who worked with patients on a case-by-case basis pointed out that the FDA advisory committee was negatively disposed. The committee members had never themselves used DMSO as a therapeutic tool. And this was admitted by Dr. Crout.

The Honorable Claude Pepper, former Chairman of the House Select Committee on Aging, was inclined to agree with the analysis made by Dr. Jacob. Congressman Pepper told Dr. Crout, “If there is a drug for which there was an enormous amount of prospect of good that was being pressed upon you by three drug companies who apparently thought the drug had enormous potential, in a case like that, I would think that you would be eager to see if the claims that were made could be justified. You would be looking for satisfactory proof that would square with your conscience and your judgment that that product might give relief to a lot of people and could be put on the market.

“Now, the public—and I must say up to now I share the opinion—has the impression that your agency in its desire to be careful and its desire not to let anybody be hurt, has denied perhaps a lot of people relief in fear that if they allowed the thing to be approved as it was presented, that they might be hurt by it; that yours is a negative attitude, that you don’t tell them what is wrong with the application in an informal way so they can attempt to correct it and the like; that you are not eager to see the users of the country that might profit from it get the advantage of it,” said the Congressman.

“You say, ‘It is no skin off my back,’ as the old saying goes, ‘if these folks cannot comply with the technicalities. That is the law, it is none of our responsibility. Let them get a better lawyer or somebody else. We are not running it. We are just sitting up here trying to protect the public interest.’

“Are you sure that there is no justification for the public or even members of Congress having that impression of our regard of your duties?” asked Congressman Pepper. “Are you sure there is no foundation for that fear?”

Dr. Crout discounted such a possibility and implied that DMSO was having difficulties because it was so unorthodox. He said it would be far easier for a new drug to have its application approved if it was closer to something already in the marketplace, such as a new antibiotic or tranquilizer that duplicates an existing one.

DMSO is a substance totally strange to medical science. It has a novel mode of action not understood within the context of our current healing concepts. It is an altogether new principle that will possibly revolutionize therapeutics once it is studied in a more exacting way. For now, however, DMSO is not being studied in accordance with the standard double- or single-blind procedures commonly used in the scientific method. This is the present problem. And it is one that has perplexed the medical community ever since DMSO was first discovered to have therapeutic value to counter human injury and heal human disease.

The existence of this new anti-inflammatory painkiller raises the questions: How can it be established with certainty the degree to which DMSO does or does not work for the numerous and varied conditions reported

in the medical literature by clinicians using it successfully? Are we able to break the logjam that enables a federal agency to keep this drug from general use because its research studies don't conform to the regulations laid down by that same federal government for its citizens' protection? Does DMSO have a history of controversy among pioneering health professionals and bureaucratic medical conservatives alike, because neither group truly comprehends how radically this substance departs from known principles of healing? Must DMSO remain controversial?

CHAPTER 2

DMSO's Controversial History

On November 10, 1980, United States Food and Drug Administration officials entered the office of Dr. Stanley Jacob at the University of Oregon Health Sciences Center. They were looking for research reports on possible damage to human eyes from the use of DMSO. They had an administrative search warrant issued by a federal judge and were prepared to rifle through and seize the files kept by Dr. Jacob.

William Zuber and Dr. Alan B. Lisook of the FDA were refused access to any documents by Jacob even in the face of the federal warrant. Instead, Jacob's attorney, Jay Geller, answered the warrant point-by-point in federal court. Mr. Geller said such reports or documents didn't exist or, if they did, were not in Jacob's possession.

Geller added that certain documents requested were privileged patient information and not available even under court order except in cases where patients give permission. Zuber and Lisook walked away with only one paper that Jacob provided, a two-page memo on DMSO and its legal use in treating interstitial cystitis. Otherwise, they got no response to questions they asked. Zuber admitted he did not have any authority to question the physician, since the Food, Drug, and Cosmetic Act does not give the FDA "access to people, just things."

When Lisook asked Geller whether the reports had ever been in Jacob's possession in the past, Geller assured the investigators that they had not and that no documents had been removed from the doctor's office since the warrant was issued. Zuber and Lisook then terminated the meeting, saying they didn't believe they could obtain any information "central to this warrant."

Geller accused the FDA of harassing Jacob. He said much of the information requested in this federal warrant was on record from previous hearings.

Jacob said there was no evidence of damage to the human eye caused by DMSO. "Allegations of hidden toxicity are false," he stated.1

Such controversy, with legal actions and reactions, has commonly surrounded the puzzling painkiller dimethyl sulfoxide. Its exciting biological and medical uses have made the substance one of the stormiest and most disputed drugs of our day. It lay dormant for nearly one hundred years after its discovery; now it had burst on the medical scene amidst contention, discord, charges and countercharges—literally a war of words intended to convince others of the truth.

The loser in all this intraprofessional argument is the medical consumer. Patient advocacy doesn't seem to exist when it relates to DMSO. Welfare for the people has been abandoned. The facts remain undetermined with certainty; guidance to help victims of illness make the wisest health decisions for themselves has been ignored. Health professionals and medical bureaucrats apparently are failing to fulfill their responsibilities to the public.

THE SOURCE AND ORIGIN OF DIMETHYL SULFOXIDE

DMSO was first synthesized in 1866 by Russian scientist Alexander Saytzeff in Kazan, on the Volga River in Central Russia. He saw that the substance was colorless, had a garlic-like odor, felt oily to the touch, looked like mineral oil when poured from the test tube, and left an aftertaste similar to clams or oysters. It had laboratory curiosity value for Dr. Saytzeff and his fellow chemists because dimethyl sulfoxide combined with almost any chemical he dropped into the liquid. It was an excellent solvent, useful as a degreaser, paint thinner, and antifreeze. For about eighty years, the only publication advising scientists about the stuff was a paper Dr. Saytzeff had submitted to an obscure German chemistry journal that printed his article in 1867.

After World War II, chemists started to show active interest in the substance. A number of papers appeared in chemical literature in 1948, showing DMSO to be an excellent solvent. In 1959, a group in Great Britain demonstrated that the solvent would protect red blood cells and other tissues against freezing conditions.

Dr. H. Harry Szmant, Chairman of the University of Detroit's chemistry department, explained that the liquid has a tremendous capacity to dissolve substances. It is a reagent that can speed up some chemical reactions a "billionfold."

"The unique capability of DMSO to penetrate living tissues without causing significant damage is most probably related to its relatively polar nature, its capacity to accept hydrogen bonds, and its relatively small and compact structure," he said. "This combination of properties results in the ability of DMSO to associate with water, proteins, carbohydrates, nucleic acid, ionic substances, and other constituents of living systems. Of foremost importance to our understanding of the possible functions of DMSO in biological systems is its ability to replace some of the water molecules associated with the cellular constituents, or to affect the structure of the omnipresent water."2

Controversy began to surround DMSO in 1962 when Dr. Jacob first became interested in how to safely freeze human kidneys and considered the solvent for this purpose. He asked Robert Herschler, a chemical applications supervisor at the Crown Zellerbach Paper Company, for some of the chemical. Crown Zellerbach had plenty to spare, since DMSO is a byproduct of its paper-making process. For five dollars a quart it can be produced commercially in crude form for refining into human medicinal application.

At their first meeting, Robert Herschler mentioned that he had difficulty washing the stain off his hands when both DMSO and dye got on them. Dr. Jacob recalls: "We painted DMSO on our skin and within fifteen minutes noticed an oyster and garlic taste. The skin where the chemical had been was dry."

The drying effect of dimethyl sulfoxide set off the DMSO explosion. Dryness of a therapeutic agent makes it valuable in the treatment of burns, since moisture tends to promote infection. Jacob and Herschler tried it on burned rats and found those treated were quieter in behavior than the untreated. The drug relieved burn pain. "From that point on, DMSO usage just spread like wildfire," Dr. Jacob said in an interview.

In the United States DMSO is derived from *lignin*, the cement substance of trees. In Europe and other places it is synthesized from coal, petroleum, or other organic substances.

Collaborative efforts between Jacob's staff representing the University of Oregon Medical School and Herschler representing Crown Zellerbach Corporation demonstrated in laboratory tests that DMSO would not only pass through the skin and mucous membranes, but during passage would carry with it a certain number of other substances. For instance, penicillin can be dissolved in DMSO and be carried through the skin without a needle. Local anesthetic can be carried the same way.

In these early studies, DMSO was shown to relieve pain, reduce swelling, slow the growth of bacteria,

improve blood supply, soften scar tissue, enhance the effectiveness of other pharmacologic agents, act as a diuretic, and function as a muscle relaxant. It eliminated the pain of sprains, strains, and arthritis, and even the pain of broken bones.

Veterinarians used the substance, by prescription, for arthritic conditions or injuries in animals. In arthritic greyhounds, an injection of either DMSO or corticoid (a substance that has an action like a hormone of the adrenal cortex) will enable the animal to race again. In six months 60 percent of the corticoid-treated dogs will have a recurrence, but less than 20 percent of the dogs treated with DMSO show such recurrence.

THE FDA ENTERS THE PICTURE AND CONTROVERSY STARTS

The first report on the use of DMSO as a pharmacologic agent was written by Jacob in 1963 and published February 1, 1964. It caused a flood of trials and wild enthusiasm over the new “miracle” drug that carried other substances through the skin and into all organs of the body. It was soon obvious that the chemical could relieve inflammation and pain in many conditions, some heretofore untreatable any other way.

The first investigational new drug (IND) application for the clinical study of DMSO in humans was submitted to the FDA on October 25, 1963, and subsequently approved. Enormous interest in the drug developed rapidly, to the point where it began to be used very extensively, especially for the treatment of sprains, bruises, and minor burns. The drug was supplied at no charge to great numbers of investigators in general medicine, specialty medicine, and to paramedical professionals, including physiotherapists, a few dentists, nurses, and the author of this book, a former practicing podiatrist.

By 1965 an estimated 100,000 patients had received the medication. Studies were being conducted but the FDA did not consider them to be well enough controlled to document clearly that the observed benefits were actually due to the drug. *The New York Times*, in a lead editorial on April 3, 1965, called DMSO “the closest thing to a wonder drug produced in the 1960s.” An international symposium of medical scientists in Berlin, West Germany, in July 1965, was held to exchange information on the effects of DMSO.

Still, when three new drug applications (NDAs) on DMSO were submitted to the FDA in 1965, all three were turned down. The pharmaceutical companies Merck, Syntex, and Gibb submitted their NDAs with the statement that DMSO was ready to be a prescriptive agent. The FDA denied their statement and applications, and in fact published its own statement in the *Federal Register* terminating all clinical use of DMSO. The agency cited toxicological studies showing that high doses of the drug changed the refractive index of the eye lens in experimental animals. That is, a change occurred in their focusing power and a certain cloudiness came over the lenses.

The agency’s concern was that visual damage might occur in humans exposed to DMSO. Researchers and bureaucrats didn’t know at that time that the eye changes were limited to particular species. Nothing happens to monkeys or, most important, to human beings.

A year later this prohibitive policy was relaxed somewhat. The FDA permitted new investigations for the clinical evaluation of DMSO in serious conditions, such as scleroderma, persistent herpes zoster, and severe rheumatoid arthritis, for which no satisfactory therapy is available.

In September 1968 the FDA published a further revision, a relaxation of its DMSO policy that allowed topical application to the skin for not more than fourteen days for less serious disabilities such as acute musculoskeletal conditions—for example, sprains, bursitis, and tendinitis. This relaxation of rules was based on a toxicological study of people that provided a reassuring result: no evidence of human eye toxicity due to DMSO was present.

Yet, again, another NDA submitted by Gibb Pharmaceutical Company in 1971, stating that DMSO was ready to be prescribed in the United States, was denied.

An NDA, on the use of DMSO for scleroderma, was submitted by Research Industries Corporation in 1978. The study was planned by Arthur L. Scherbel, M.D., then Chief of Rheumatology at the Cleveland Clinic Foundation, under supervision of doctors at the FDA and consultants from the National Academy of Sciences. Dr. Scherbel carried out these studies and saw changes in a treated hand, as compared to an untreated hand. In three months there was a marked improvement that was statistically significant. When Dr. Scherbel came to the FDA for acceptance of his study, it was refused. The NDA was denied.

By 1983, the NDAs tossed aside by the FDA included 1,500 medical studies performed on approximately 120,000 patients with a variety of health problems. Moreover, four more international symposia were held by health scientists to accumulate more information on DMSO. The second symposium conducted was under the auspices of the New York Academy of Sciences, in March 1966 in New York City. The third was sponsored by the University of Vienna, Austria, in November 1966. The fourth and fifth were again in New York, under the sponsorship of the New York Academy of Sciences, in January 1974 and September 1982. All of these symposia reported favorably on the drug.

Because of the ongoing differences among DMSO pioneers and the medical bureaucrats, Charles C. Edwards, M.D., then Commissioner of Food and Drugs, asked the National Academy of Sciences in 1972 to review all available information on the effectiveness and toxicity of DMSO. He wanted the National Academy members to provide the FDA with an independent judgment on these matters.

The Academy appointed a committee of experts, with six subcommittees, to conduct the review. The committee ran an active review until 1974. The Academy was actually a semi-governmental body, not really independent at all. As it received its financing under an FDA contract, it tended to agree with the FDA position on DMSO. Specifically, the report finally presented by the National Academy of Sciences stated that there was inadequate scientific evidence of effectiveness of the drug for the treatment of any disease, that the toxicity potential was sufficiently great that the drug should remain an investigational drug, and that controlled clinical investigations were necessary to demonstrate the effectiveness of DMSO.

In light of continued lack of evidence of eye damage in humans from the time it laid down regulations against DMSO, the FDA has concluded that the regulation is no longer necessary. Thus, finally, on September 21, 1979, the agency published a *Federal Register* proposal to revoke the regulation. Yet, Jere Goyan, Ph.D., former head of the entire FDA, continued to make public statements about the dangers of eye toxicity. It may have been to justify these statements that he sent investigators to grab files wherever they could, searching for reports on DMSO and its relation to the human eye.

Also by 1983, the FDA had sixteen active investigational new drug applications for DMSO on file. Conditions under study included scleroderma, joint injuries, and spinal cord injuries. There were no active INDs for the study of DMSO in the treatment of rheumatoid arthritis or osteoarthritis, which seems unusual as DMSO use for these conditions is the most popular.

THE PUBLIC REBELS AGAINST THE FDA REGULATIONS

Despite the FDA restrictions on the use of DMSO, tens of thousands of Americans still manage to obtain it. Some use a form of the medicine that has been approved for veterinary use. Some resort to the industrial solvent. Others travel to DMSO arthritis clinics in Mexico. The drug is passed from person to person, especially among victims of arthritis.

Even though there is no existing IND arthritis application pending before the FDA, osteoarthritis and

rheumatoid arthritis are the two main health problems being treated by layperson exponents of DMSO. The public is rebelling against the imposition of what it considers nonsensical regulations for limited use of DMSO. People ask, if it is safe enough for internal treatment of interstitial cystitis, why isn't it safe to paint it on the skin for arthritic joints?

An underground market for supplying the substance has developed. Pharmacies sell the pure medical grade on a doctor's prescription at a cost of anywhere from fifteen to twenty dollars for four ounces. Technically, once a drug gets FDA approval for certain uses—such as for interstitial cystitis—it is not illegal in any state for a doctor to prescribe it for other purposes.

The thriving nationwide black market in DMSO is also operating, unfortunately, across the counters of hardware stores, in gasoline stations, at mail-order houses, on the backs of trucks operating near shopping centers or parking lots, and even out of ice cream parlors. For example, according to a published article in the *Chicago Tribune*,3 the industrial grade dimethyl sulfoxide solvent has appeared in such unlikely spots as an ice cream parlor and a locksmith's shop in Chicago. A solvent retailer based in Seattle, Washington, offers a toll free mail-order number and has opened stores in Milwaukee, Chicago, and Evanston, Illinois.

The sales pitch for the substance is careful not to make medical claims about DMSO. "We're selling this to you as a solvent; what you do with it is up to you. It's against the law any other way," one salesperson says.

Billy Williams, president of the solvent retail firm, says that the DMSO he sells is pharmaceutical grade. It's safe, he assures people, though he technically sells it as a solvent.

"We're marketing this stuff because it sells," Williams said. "And we assume people use it. We get orders from doctors, chiropractors, and dentists." He opened a packaging and distribution plant, and buys a pharmaceutical grade DMSO in bulk from an undisclosed medical laboratory, then packages it into smaller bottles in his Seattle plant. "We buy it third-hand from the medical lab," Williams said. "They 'back door' it to us.

"As to the medical usage, we can't help but be aware that people actually are using it to reduce the pain of arthritis. I have read many letters that people are using it, because they imply that they have arthritis or muscle strain or a number of medical disorders.

"I know what we're selling it for: we're selling it for a profit. That sounds crass, but that's what people are in business for. The stuff works! We're not profiteering in the sense that we're going to profit from somebody's misery."

Another typical source of public sale is a hairstyling salon in Chicago. The manager said he stopped selling the solvent because of the controversy over its legality. "I only sold it for a few days," he said. He had purchased a case of industrial DMSO from a Chicago police officer who had also supplied the ice cream parlor.

Research Laboratories, Inc. of Salt Lake City, Utah is often referred to by the United States Food and Drug Administration when inquiries are made by physicians and other health professionals for a source of dimethyl sulfoxide for human therapeutic purposes. Research Laboratories sells a 50 milliliter (ml) ampoule of DMSO to health professionals for injection purposes for $28.00.

Specifically for the consumer, the finest source of acquiring DMSO products is Dr. James Critchlow, proprietor of American Pharmaceutical Enterprises, Inc., P.O. Box 12543, Scottsdale, Arizona 85267; telephone (602) 998-4142 or call toll free (800) 345-3391. American Pharmaceutical Enterprises (APE) provides a deodorized, pharmaceutical grade of DMSO quite suitable for human therapeutic application. A

purified pint by mail order costs $60.00 and Dr. Critchlow's slightly lemon-scented DMSO Solvent Creme in a four-ounce jar is $29.95.

He also furnishes DMSO products for medical doctors, osteopaths, podiatrists, chiropractors, naturopaths, homeopaths, dentists, nurses, physical therapists, and other types of health professionals who utilize DMSO as part of their therapeutic reserves. Under the Critchlow company name, Phyne Pharmaceuticals, Inc., P.O. Box 12543, Scottsdale, Arizona 85261 or 14325 North 79th Street, Scottsdale, Arizona 85260; telephone (602) 998-4142 and toll free (800) 345-3391, health professionals are offered medical grade products for topical or internal application. For instance, the Phyne Pharmaceutical pint quantity of liquid DMSO is so pure that many doctors use it for intravenous infusions of patients. Product prices are considerably less for health professionals when they purchase in quantity.

Federal studies, according to former FDA Commissioner, Jere E. Goyan, indicate that industrial grade DMSO is not suitable for treating humans. It does not have to pass the same quality control as the medical grade. When the solvent is transferred to smaller containers, it increases the chances of impurity. The FDA official warning states that the "risk that may accompany use of the industrial grade . . . is its potential as a carrier chemical capable of delivering harmful substances into the bloodstream if they are present in impure DMSO or on the skin."

"People are taking a risk whenever they use a substance of unknown quality and effect," Commissioner Goyan said. "It's risky business to drink, inject, or apply to the skin any substance not intended for that purpose."

The black market in DMSO, pure grade and industrial grade, continues simply because the FDA keeps the drug off the market for any use except the treatment of interstitial cystitis. Arthur Scherbel, former senior physician at the Cleveland Clinic's Department of Rheumatic Disease and Immunology, declared that the FDA is holding back approval of the drug "for no good reason. People are using it without proper guidance, and that is a mistake. The sooner it is released the better."4

LEGISLATORS ACT ON BEHALF OF THE PEOPLE

No fewer than six resolutions to legalize the public use of DMSO and to override the ruling of the FDA have been introduced into the United States Congress. United States Senator Mark O. Hatfield (R-Ore.) said: "Since I have no scientific expertise, I cannot make an absolute statement that DMSO is indeed the wonder drug of our century, but every bit of evidence I encounter reinforces the premise that it is.

"After over 1,200 scientific publications on the merits of DMSO, after international symposia in Germany, the United States, and Austria—all concluding that DMSO is safe and effective—after three separate pharmaceutical firms have submitted four new drug applications to the FDA, DMSO is still not available to Americans, though it is available in many other countries. I have urged the Senate to support my legislation on behalf of all Americans who are suffering today from diseases untreatable by any other known substance and those who may have need of this drug in the future."

The Honorable Wendell Wyatt (D-Ore.) reintroduced legislation in the United States House of Representatives aimed at getting a fair hearing for DMSO. "Since the FDA action against DMSO has been taken on the flimsiest of evidence," said Wyatt, "we have been unable to get even a hearing for DMSO. The whole issue has been submerged under a bureaucratic cloud."

The Congressman's efforts, and the efforts of other members of the United States legislature, have paid off. Senator Edward M. Kennedy (D-Mass.) held a Senate subcommittee hearing on the drug's status at the FDA on July 31, 1980. Congressman Claude Pepper (D-Fla.) chaired a hearing (under the title "DMSO: New

Hope for Arthritis?") before the House Select Committee on Aging on March 24, 1980.

Since those hearings, the Inspector General of the Department of Health and Human Services has been conducting an investigation into the regulatory procedure DMSO has undergone at the FDA.

Furthermore, some state legislatures have overridden the FDA ruling against dispensing DMSO and altered state laws to allow its use by authorized health professionals. Currently Texas, Washington, Montana, Oklahoma, Florida, Oregon, Louisiana, and Nevada are the eight states in the nation that have authorized prescribing the medication. Legalization of DMSO in Florida is another example of the people rebelling against FDA regulations. The difference here was that the legalization of DMSO in Florida was pushed by a legislator whose wife was forced to travel to Mexico for DMSO treatments.

In 1977, the Florida legislature legalized the drug for intravenous, intramuscular, oral, and topical human therapy. The Florida law reads:

Section 1. No hospital or health facility shall interfere with the physician-patient relationship by restricting or forbidding the use of dimethyl sulfoxide (DMSO) when prescribed or administered by a physician licensed under chapter 458 or 459, Florida Statutes, and requested by a patient unless the substance as prescribed or administered by the physician is found to be harmful by the State Boards of Medical Examiners and Osteopathic Medical Examiners in a hearing conducted under the provisions of the Administrative Procedure Act, Chapter 120, Florida Statutes. Furthermore, no hospital or health facility shall remove the staff privileges of a physician solely because said physician prescribed or administered dimethyl sulfoxide (DMSO) to a patient under the conditions set forth in this act.

Section 2. No physician licensed under chapter 458 or 459, Florida Statutes, shall be subject to disciplinary action by the State Boards of Medical Examiners and Osteopathic Medical Examiners for prescribing or administering dimethyl sulfoxide (DMSO) to a patient under his care who has requested the substance unless the State Boards of Medical Examiners and Osteopathic Medical Examiners, in a hearing conducted under the provisions of the Administrative Procedure Act, Chapter 120, Florida Statutes, has made a formal finding that the substance is harmful.

Section 3. The patient, after being fully informed as to alternative methods of treatment and their potential for cure and upon request for the administration of dimethyl sulfoxide (DMSO) by his physician, shall sign a written release, releasing the physician and, when applicable, the hospital or health facility from any liability therefor.

Section 4. The physician shall inform the patient in writing if dimethyl sulfoxide (DMSO) has not been approved as a treatment or cure by the Food and Drug Administration of the United States Department of Health and Human Services for the disorder for which it is being prescribed.

Section 5. This act shall not apply to conditions for which dimethyl sulfoxide (DMSO) has been approved as a treatment by the Food and Drug Administration of the United States Department of Health and Human Services.

Following passage of this new law, the potential for abusing it, spurred on by paid advertisements of DMSO clinics as well as broad media coverage, prompted the Florida Medical Association (FMA) to issue a statement in the form of a "letter to the editor," in October 1980, to all newspapers throughout Florida. A *60 Minutes* television broadcast had stimulated an almost daily stream of inquiries, both by letter and telephone, to the FMA headquarters in Jacksonville, Florida. Most of the in-state queries were from the press, while the

majority from out of the state were from individuals with a variety of symptoms seeking a physician to provide them with the “miracle cure” called DMSO. The FMA official position is this:

Without an approved new drug application, the drug cannot be marketed or distributed in Florida for indications other than the treatment of interstitial cystitis. However, legally, a doctor may prescribe an approved drug for other indications.

The Florida Legislature passed a law in 1978 which permits a physician to use DMSO after advising the patient of alternative treatment and any potential for cure. The law requires that upon request to the physician for DMSO treatment, the patient shall sign a written release of liability to the physician and, when applicable, the hospital or facility. The physician shall inform the patient if DMSO has been approved by the FDA for the disorder for which it is being prescribed in writing.

The Florida Medical Association does not condone going outside of the approved and responsible mechanism for the introduction of a new drug. As a matter of fact, physicians covered by professional liability insurance under the FMA-sponsored plan have been warned regarding the drug. They will not be covered by the plan if they use DMSO for any symptom other than the relief of interstitial cystitis for which, as previously stated, it is approved by the FDA.

At the same time, FMA does encourage its physician members who are interested to take part in the FDA investigational program in this and other areas. Assistance is available for obtaining from the FDA an Investigational New Drug Application (IND) plus sterile nonpyogenic DMSO solution. In order to participate in this research, the physician must agree to keep the necessary records. The DMSO solution will be supplied free of charge and assistance given to the physician in developing the necessary protocol.

As to the law passed during this year’s legislative session allowing for the manufacture, distribution, and sale of a DMSO ointment in Florida, FMA has no direct knowledge and no participation in any way in this matter. We are informed by officials in The Department of Health and Rehabilitative Services (DHRS) that they are in the process of developing rules and regulations to govern the manufacture of such a product and that at this time one formal application to do so has been submitted.

We are also informed by personnel in the DHRS that there is a serious question in their minds as to what constitutes a “safe” product for human consumption. This question could lead to an Attorney General’s opinion being sought prior to anyone being allowed to manufacture a DMSO product in Florida.

Consumer inquiries concerning DMSO or any other new experimental drug should be directed to the FDA Bureau of Drugs, Advisory Opinion Board HFD 35, 5600 Fishers Lane, Rockville, Maryland 20852. Physicians interested in working in the experimental drug program should contact the FDA Bureau of Drugs, Division of Oncology HFD 150, Radiopharmaceuticals Branch, 5600 Fishers Lane, Rockville, Maryland 20852.

On January 28, 1981, the Public Health Committee of the General Assembly of the State of Connecticut held a committee meeting to consider whether the state should encourage physicians to use DMSO to treat painful and sometimes fatal diseases. A bill submitted by Wolcott, Connecticut Representative Eugene Migliaro would relieve medical doctors of their professional liability if they prescribed DMSO. Migliaro explained that the public may receive DMSO through the mail.

“We know that DMSO is not a cure,” Migliaro said. “And I understand the things that can happen to you if you use it wrong. I’d like to protect it. This will say to doctors, ‘protect your people without fear of being

sued.’”

State Senator Regina Smith, Public Health Committee co-chairperson, noted that doctors are liable for all other drugs they prescribe. She indicated that it would be a dangerous precedent to exempt this experimental drug.5 The Connecticut bill was defeated, but DMSO supporters said that they planned to submit a revised version in the future. They did not.

I agree in principle with Senator Smith, but the FMA has gone to the opposite extreme. Florida medical liability policies won’t cover the use of DMSO for anything other than interstitial cystitis.

Between the time the FMA issued its official statement about DMSO and the State Legislature of Connecticut introduced a bill to get physicians off the hook in the event something went wrong with any patients for whom they had prescribed DMSO, the State of Florida spoke up. James T. Howell, M.D., State Health Officer in the Department of Health and Rehabilitative Services of Florida, felt it necessary to respond on DMSO. Through the press Dr. Howell expressed a grave concern that an industrial solvent-type of DMSO was made available for human consumption. He was also worried about the veterinary product. He said that neither of these had been refined for human consumption and could be extremely harmful.

Two programs with a tremendous viewing audience broadcast over CBS-TV, one in March 1980 and a repeat in July 1980, seem to have caused people to throw caution aside. The public insisted upon getting hold of this painkilling drug whether it’s surrounded with controversy or not. All that people want is relief of pain whatever the cause. Interestingly, some prominent figures in sports, politics, acting, and other occupations are submitting to DMSO treatment, too, without regard to whether its use is legally admissible by the judgments and standards of the FDA.

The various applications of DMSO in clinical practice and for home use as a self-care remedy for such problems as arthritis, shingles, headaches, cataracts, herpes simplex, burns, Down’s syndrome, spinal cord injuries, bursitis, sprains, and many other conditions, make it an ideal product. The various modes of treatment such as skin applications, intravenous therapy, and oral and intramuscular therapy are desperately wanted by the famous and unfamous alike.

THE NEW PAINKILLER BECOMES A MEDIA CELEBRITY

When Governor George Wallace traveled across the country to find pain relief from DMSO administered by Dr. Stanley Jacob, this new painkilling drug got a big boost. He began treatment July 1, 1980, to relieve discomfort associated with paralysis.

Wallace had been confined to a wheelchair since he was wounded in a 1972 assassination attempt while campaigning for the Democratic nomination for President at Laurel, Maryland. Doctors described Wallace’s discomfort as occurring in the “flank,” a medical term referring to the area between the lowest rib and the waist. While his pain was not excruciating, it was persistent and limited Wallace’s everyday activities.6

The governor’s flank discomfort reportedly disappeared, especially by faithfully dabbing DMSO on the painful area from time to time during the course of a month. As Wallace was a well-known public figure, his success in relief from pain has had an impact on the promotion of the drug as a painkiller and anti-inflammatory agent that works.

An even greater booster was the television news show that Wallace watched that featured DMSO as the definitive but controversial product for eliminating pain when all else failed. Wallace was controversial himself at one time and he knew the incongruity of such a label. The TV show stimulated the governor to seek treatment with DMSO.

On March 23, 1980, and again on July 6, 1980, the popular television program *60 Minutes* reported on DMSO. In a broadcast segment titled "The Riddle of DMSO," CBS news correspondent Mike Wallace gave broad national attention to this chemical. On the program, Dr. J. Richard Crout, the chief FDA opponent of DMSO, said that double-blind studies were mandatory before approval would be forthcoming from his agency. Yet, researchers can't conduct double-blinds because of the distinctive odor of the product. Within a few minutes of putting it on your skin, you can taste it on your tongue; it penetrates the skin and runs through the blood stream so effectively.

There is a lot more to the issue of DMSO, however, and on 60 *Minutes* Mike Wallace brought in the human factor in which the relief from pain is of primary importance. He showed Emily Rudich playing the piano in spite of her severely deformed fingers and years of searing, unrelenting pain from arthritis.

Referring to DMSO's effect on her condition, Mrs. Rudich said, "I have some very badly gnarled fingers from arthritis, and the DMSO eases the arthritis right away. It's not a miracle drug, doesn't really cure it, but it eases it . . . I had a fever blister on my lip. I used DMSO three times, and the fever blister went away immediately. I've cut myself in the kitchen, and sometimes quite badly, and have used DMSO on it and the cuts begin to heal right away."

Most dramatic was the case of Sandy Sherrick of Riverside, California, who had suffered severe whiplash and nerve damage in an automobile accident two years before. In November 1979, Mrs. Sherrick writhed in an agony of back, neck, and shoulder pain. "No painkiller, no therapy, no doctor, it seemed, could help," said Mike Wallace.

"Oh, the pain was extremely bad," Sandy Sherrick confirmed. "I was to the point where I cried continuously. I did not cook meals. I did not clean. I barely got myself dressed. . . . They finally got to the point where they just told me, 'You're going to have to live with it. The weather's going to affect you, and you're just simply going to have to live with it.'"

Upon learning about DMSO, Mrs. Sherrick grasped at it as a last resort. Feeling awful pain throughout the trip, she flew to Portland, Oregon, for treatment by Dr. Jacob. By the third day of intravenous and topical application of DMSO, the patient began to feel somewhat better, reported Mike Wallace. *60 Minutes* followed her progress on videotape. Before she left for home, Dr. Jacob showed her where and how to apply DMSO topically to her neck and back.

The television camera then switched to Mrs. Sherrick in her Riverside, California, home. She was feeling comfortable, smiling, and taking no medicine for pain relief. She said, "Oh, the pain's gone. The pain is totally, completely gone from my neck. . . . I'm telling the truth, the honest-to-God truth." She could do her housework, drive a car, lift packages. "I have not found anything I can't do."

Mike Wallace pointed out that a story like Sandy Sherrick's does not take the place of a scientific test, which the FDA requires.

"Well, that's fine. I can understand their feeling," said Mrs. Sherrick. "But they've got to be able to look at the test results and take me as an individual. I have no reason to say it does work or it doesn't. All I can say is what it's done for me personally. It worked for me."

This powerful presentation reached 70,000,000 TV viewers. Dr. Jacob's office was immediately swamped, with up to 10,000 people figuratively crying, "Save me, save me from pain!"

Pain victims also came to other physicians around the United States, Canada, and Mexico who were known to utilize DMSO. They arrived in droves. Telephones in the offices of doctors and pharmacies in Florida,

Oregon, Louisiana, and Nevada rang busily for several days following the Sunday evening broadcast of *60 Minutes.*

A subsequent wire service report about the FDA's refusal to approve the drug appeared around the country in Tuesday's newspapers.

In his program footnote, Mike Wallace stated: "Tomorrow morning in Washington, the House Committee on Aging begins an inquiry into why DMSO is not available to all Americans for any appropriate ailment, including plain and simple pain." The numbers of letters and telephone calls that came into congressional offices inquiring about the cause of DMSO unavailability were massive. A sampling of the letters sent to just one congressman, Claude Pepper of Florida, are found in Chapter 4.

The disclosures that came out of this and other Congressional investigations were shocking to an already embarrassed scientific medical community. The apparatus by which the Food and Drug Administration studies the efficacy of a new drug was turned upside down. As fully discussed in Chapter 13, revelations about ignorance of the scientific method or fraudulent tests in relation to the drug's effectiveness caused not only DMSO opponents to discontinue clinical trials but even made its proponents back off. And this disconnection to the product's therapeutic effects also included its chief proponent, Dr. Stanley Jacob.

As you will read in more detail later on, FDA investigator Dr. K.C. Pani allegedly took money from Dr. Jacob to pay off his wife's exceedingly high medical bills for cancer treatment. Dr. Pani lost his standing and his job with the FDA. Dr. Jacob was indicted by the Federal Grand Jury on three counts of improper payments to an FDA official and one count of criminal conspiracy. In May 1982, mistrial was the result of these courtroom trials.

Then the government went after Dr. Pani and Dr. Jacob again. This time, Dr. Pani plea-bargained and accepted conviction of a misdemeanor as his crime. Dr. Jacob not only was let off, but the FDA, on October 29, 1982, offered him an apology for their incorrectly bringing the charges against the pioneering surgeon.

More than that, it was learned by Congress that poor or fraudulent investigative techniques employed during the trials of DMSO for interstitial cystitis, the only condition for which it is approved in the United States, almost had the FDA recall such approval. Not this or any other internal or external condition would have been allowed as acceptable in the United States for DMSO application. Research Industries Corporation (RIC), the manufacturer of Rimso-50, a major retail-selling brand of DMSO, apparently played a big role in causing the FDA to have its breach of confidence in the drug. In a semi-confession to U.S. Senator Edward Kennedy, the president of RIC admitted his company's complicity in the mismanaged interstitial cystitis clinical trials.

And there were more adverse findings, which will be revealed near to my book's ending. However, almost all of the fallout during these Congressional investigations occurred from human foibles, greed, and/or inappropriate behavior and not from physical, chemical, or biological faults of dimethyl sulfoxide. The drug remains as efficacious as ever—a true medicinal from nature that continues to astound both holistic and conventional medical scientists as a new and powerful healing principle.

Still, the result from exposure of these scandals of ten years ago is that very few clinical studies on DMSO have been carried out and published since that 1982–83 period. Compared to prior decades, the relatively few journal papers—perhaps 100 of them, which are cited throughout these pages—are all that remain of the tremendous effort originating at the University of Oregon Medical School. If DMSO experiences a resurgence of interest among researchers, it will happen more from prompting of doctors by medical consumers who are reading magazine articles and books such as this one. Because of its dramatic remedial properties, dimethyl sulfoxide deserves more respectful attention than mere public interest. Scientists must

be the ones to take up the challenges presented. The public should have access to the remarkable therapeutic principle of DMSO about which I report in the next amazing chapter.

CHAPTER 3

The Therapeutic Principle of DMSO

A married couple arrived in Sarasota, Florida, directly after the *60 Minutes* television broadcast. They had driven all night from Hamilton, Ohio, to keep a 9:00 A.M. emergency appointment to receive the new wonder drug for pain at The Douglass Center for Nutrition and Preventive Medicine (no longer open). They considered their quest for DMSO to be a last-ditch try after a full year and $10,000 worth of unsuccessful treatments with other remedies.

Mrs. Fred Dabbelt explained that her husband's left hand had become stiff and claw-like after surgeons operated to remove a blood clot in his arm. The hand was unusable. Nothing helped the muscles regain their normal capacity, and, after a series of unsuccessful procedures, the doctors began to suggest that the problem was psychological.

After three intravenous injections of DMSO, Fred Dabbelt was able to open and close his hand—something he had found impossible to do before.

Altogether, the patient had five days of treatment. When contacted nine months later he said, "The pain has completely disappeared. My hand is still numb but usable. Before DMSO, the hand looked like a claw; it now looks normal."

"We'd tried everything. This was the last resort," said Mrs. Dabbelt. "It's just amazing. Before this, nothing worked."

How *does* dimethyl sulfoxide work? It may best be summed up in the words of Dr. Stanley W. Jacob, co-discoverer of the therapeutic properties of the drug: "We've barely scratched the surface, for this is a new principle in medicine. We've had only three new principles in our century—the antibiotic principle, the cortisone principle, and now the DMSO principle—and the DMSO principle is the only new one of our generation. Despite all the controversy, my guess is that history will record it this way!"

This chapter explores the *modus operandi* of DMSO and discusses its penetration power and the rationale for its use. We will be taking a highly technical biochemical science and simplifying it as much as possible without changing the hypotheses upon which DMSO actions are based.

Students of biophysics and biochemistry will find the following information useful for their purposes. Others may wish to skip to here for a summary.

STRUCTURE AND PHYSICAL PROPERTIES OF THE MOLECULE

The dimethyl sulfoxide molecule is ten-sided with a center occupied by a sulfur atom. Two methyl groups, an oxygen atom, and a nonbinding electron pair are located at the points of the tetrahedron. See Figure 3.1 for a depiction of the molecular formula.

DMSO's molecular weight is 78.15. The drug is capable of entering into a chemical reaction characterized by the development of heat, and it releases 60 calories (cal) per gram (g) of DMSO when mixed with water. The boiling point at 760 millimeters (mm) mercury (Hg), degrees Celsius (°C) is 189.0; vapor pressure at 20°C, mm Hg is 0.37; specific gravity at 25°C, grams per milliliter (g/ml) is 1.0958; melting point, °C is

18.55; heat of combustion, cal/g is 6,050; flash point in an open vessel, °C is 95; viscosity at 20°C, centipoise (cP) is 2.473; surface tension at 20°C, dyne/centimeter (cm) is 46.2.1,2,3,4

Because DMSO has a freezing point of 68°F, one is able to tell its approximate concentration, if a bottle of the liquid solvent is acquired from an unknown source. Put the unopened bottle into the refrigerator (not the freezer). Within two hours the liquid will turn solid, like ice. You now have 99.5 percent DMSO, the purest and highest concentration made. Leaving the bottle cap on will prevent hydrolyzation (decomposition) so that the liquid will freeze at 68°F or less.

Figure 3.1 Molecular formula of dimethyl sulfoxide.

If, when the frozen bottle is turned upside down, little rivulets of water flow through the ice, you probably possess the veterinary grade DMSO. This is a 90 percent concentration. Ten percent is distilled water.

If the DMSO doesn't freeze while standing in the refrigerator, put it into the freezer compartment. If it does *not* turn solid even after standing at below 32°F, it probably indicates a 50 percent mix of DMSO and water. If it *does* turn solid in the freezer, this liquid is not DMSO, or is almost all water with just a small bit of the solvent mixed in. Fifty percent DMSO is an antifreeze; it will work well in automobiles for winter driving.

To reliquify DMSO that has turned to a block of ice in the bottle, merely put it into a pan of warm water. In pure form, the life of the solvent is indefinite. DMSO may be used for years.

Many other physical properties of DMSO could be discussed, but those given here provide enough of a representative sampling, since this is not a text exclusively on the chemical and physical characteristics of the solvent. Almost all the known chemical and physical properties of DMSO are found in Crown Zellerbach's *Dimethyl Sulfoxide Technical Bulletin.*

The crystalline structure of this solvent indicates the presence of a weak hydrogen bond that contributes to the molecular forces in DMSO.5 In liquid state DMSO seems to assume a chainlike structure held together by the alignment of the two sulfur-oxygen poles.6,7 This structure is believed to suffer a partial breakdown between 40°C and 60°C since certain properties of the liquid, such as the refractive index, density, and viscosity, exhibit distinct changes in their temperature coefficients in this temperature range.8

Users Review

From reader reviews:

David Tillery:

Now a day people who Living in the era wherever everything reachable by interact with the internet and the resources in it can be true or not call for people to be aware of each info they get. How people have to be smart in getting any information nowadays? Of course the answer then is reading a book. Looking at a book can help men and women out of this uncertainty Information specially this DMSO: Nature's Healer book as this book offers you rich information and knowledge. Of course the information in this book hundred percent guarantees there is no doubt in it you may already know.

Alfred Hoover:

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