Medical Genocide, Part 26

HOPE

The scandalous inside story of the trashing of a drug

HEARTBREAK

that could save the lives of millions of people.

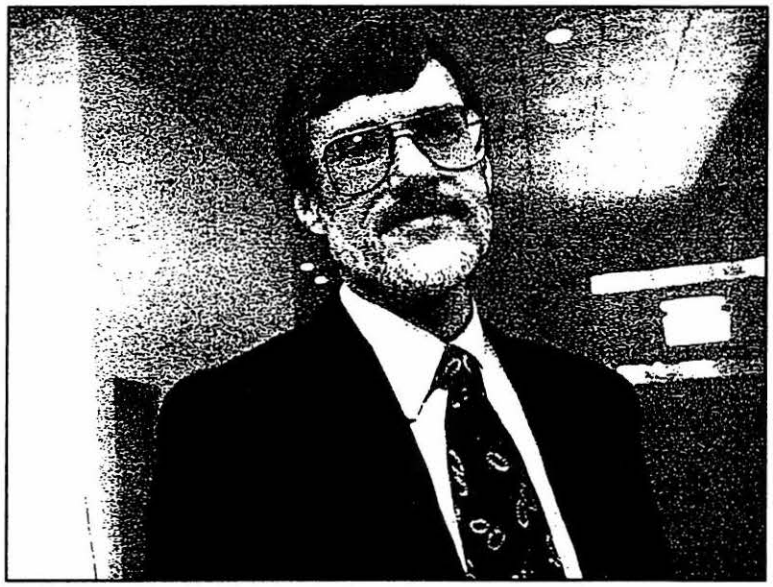
AND HORROR

Text and Photographs by Jeff Kamen. Painting by Kunio Hagio.

If you or someone you love should come down with cancer or AIDS, you will probably be denied the one drug that may offer the best possibility of an effective treatment with the least side effects. It's called hydrazine sulfate. It's cheap, simple to make, and easy to take. It works for roughly half of all the patients who have received it, and it's being deliberately suppressed by some of the most influential doctors in the U.S. cancer establishment. As a result, a million Americans alone are being denied lifesaving benefits each year. What you are about to read is the story of a scandal that has already caused untold human suffering.

This article and supporting research documentation are being presented to appropriate committees in Congress, where a full, public investigation is being considered. Careful reporting over the past 11 years by *Penthouse*, by ABC's "20/20," and by this reporter on Independent Network (TV) News informed millions of Americans about hydrazine sulfate's

THE CANCER ESTABLISHMENT'S RESEARCH BUREAUCRACY IS A LARGELY HIDDEN WORLD, BUT SADLY SIMILAR TO THE REST OF GOVERNMENTAL BUREAUCRACY—SELF-PERPETUATING AND SELF-PROTECTING.



Dr. Michael Kosty (above), the researcher chosen by the N.C.I., deliberately failed to exclude "incompatible substances" from his study of hydrazine sulfate. Dr. Rowan Chlebowski (right) said that at least "half a million Americans each year suffering from cancer cachexia could be helped" if the drug were widely available.

lifesaving powers and pressured the federal government into ordering a much-needed national clinical trial.

But now one-third of that massive test is over, and the net effect is to continue the almost-20-year suppression of this extraordinary drug, which stops the starvation that kills most cancer patients, shrinks some tumors, and, research suggests, may even be a long-sought "magic bullet" against a broad range of cancers. Considering the spread of AIDS and the high probability that cancer will touch you or someone you love, the unending attack on hydrazine sulfate may become very personal in your own life.

By now you are probably asking yourself questions like: How can this be true? When it comes to fighting deadly diseases, aren't we all on the same side? Who would want to stop a good drug from getting to those who are suffering? If it is true that reputable scientists in the United States and in Russia have successfully used hydrazine sulfate, why isn't it available? Where is this drug if someone you care about needs it tomorrow?

We'll answer that last one first: Hydrazine sulfate is meticulously blocked from even your doctor's hands by federal regulations, and strangled by tests that make the drug look like a worthless fake. The drug's developer, Joseph Gold, M.D., director of the nonprofit Syracuse Cancer Research Institute, in Syracuse, New York, is appalled and alarmed because of what it means for cancer victims, as well as for his own efforts. Since he left the U.S. space program, Dr. Gold has devoted his life to unraveling the mysteries of cancer cachexia and its treatment with hydrazine sulfate. As the developer of this drug, he really knows how it works and what gets in the way of its curative qualities.

For over a decade, Dr. Gold has been warning that if you drink or take sleeping pills or

IF YOU ARE A CANCER ESTABLISHMENT INSIDER, YOU HAVE SOME LATITUDE. BUT GOD HELP YOU IF YOU ARE AN OUTSIDER, NO MATTER HOW GOOD YOUR CREDENTIALS, YOUR WORK, OR YOUR IDEAS. OUTSIDERS ARE REGARDED WITH DISTRUST.

Dr. Joseph Gold (above), the developer of hydrazine sulfate, realized that if he could find the key to pick cachexia's lock on cancer patients' ability to process food, many of them would, quite literally, stop starving to death.

tranquilizers, you might as well not bother taking this drug, because it simply doesn't do its thing when alcohol or any of the rest are in your blood.

Simple, right? Well, naturally, Dr. Gold told the National Cancer Institute to keep those incompatible chemicals out of the nationwide clinical trials of hydrazine sulfate, the first of which was finally concluded last year. Don't worry, they told Dr. Gold, we know what we're doing, and hydrazine sulfate will receive a fair test.

Right. The National Cancer Institute participated in compromising this first test by allowing alcohol, sleeping pills, and tranquilizers to be taken by dying lung-cancer patients who were being given hydrazine sulfate in conjunction with chemotherapy. That cynical act denied the 270 desperate patients who were in the group of even a fighting chance at less pain and longer life. The undermining of the first test also guarantees that the overall judgment on hydrazine sulfate will be tainted, even if the last two test groups demonstrate positive results.

The trouble with this story is that the "bad guys" a" wear white coats. Having done pioneering work against cancer in some cases, on the surface they seem to be fulfilling their responsibilities as guardians of the public health. Perhaps this drug and its developer stuck so deeply in their personal and institutional craws that the high priests of cancer found every possible excuse to trash hydrazine sulfate, a drug not invented by any of them or the corporations and research centers that are members of their old-boy network.

Raging egos, self-righteous turf-protection (including thousands of jobs that might be threatened if the drug got a truly fair test), and a subtle but very effective signal to researchers whose work supports hydrazine sulfate—researchers who have been forced to abandon more

than a decade of carefully controlled clinical trials, their work neatly consigned to obscurity—are the apparent reasons why millions of cancer patients in our own country and around the world are presently being denied the benefits of hydrazine sulfate.

In a ballroom of the Omni Shoreham Hotel in Washington, D.C., some of the nation's top AIDS researchers gathered on November 3, 1992, to develop improved strategies for helping the growing number of straight and gay Americans who are being picked off by the only lethal sexually transmitted disease of our time. During a break from the heavy work, Albert Wu, M.D., a young assistant professor of medicine at the renowned Johns Hopkins Hospital in Baltimore, walked from the AIDS conference into the nearest ballroom to check out the much less depressing scene.

It was the election-night headquarters of the Democratic National Committee. As balloons and a huge victory map were being prepared for later use, Wu watched TV monitors as early returns signaled Bill Clinton's electoral-vote landslide. A reporter noticed Wu's AIDS Clinical Conference badge and asked him if he did any work with cachexia, the starvation that seizes many AIDS patients, sending them to an early and painful death. "Yes," said the physician, "I work on cachexia. Why do you ask?" The reporter asked the doctor if he'd ever heard of hydrazine sulfate, the only substance that has demonstrated its ability to arrest and then reverse the terrible wasting away of body and spirit that is cachexia.

Wu said he did not know anything about hydrazine sulfate, and wanted to know lots more after the reporter told him that the drug blocks cachexia in cancer patients. "Why don't I know about this?" asked the AIDS specialist. Why indeed! One reason is the long-standing and continuing hostile climate in which the medical establishment has enveloped the drug, which has resulted in a virtual purging of the medical literature of any reference to hydrazine sulfate's documented curative powers and to its even greater potential.

One of the results of continuing high-level intimidation is its clear signal to the pharmaceutical industry. The principal method for bringing a new drug to the public—the one most often taken—is research and development by drug companies. But those manufacturers rely on the goodwill of the cancer establishment, and, in fact, are integral parts of it, ultimately employing many senior officials of the National Cancer Institute who—in some cases—dip in and out of the private and public sectors. In fact, the high priests in white coats created such a negative environment for hydrazine sulfate that pharmaceutical houses were discouraged from marketing it. So all doors appear to have been closed to this drug, which could be extending the lives of millions of dying people all around the world right now.

CANCER CONFLICTS OF INTEREST?
Now, as to why the big guns in cancer officialdom would oppose any simple, easy-to-administer, effective, inexpensive, and safe therapy for cancer, here's the short list:

- The two-billion-dollar-a-year budget for the National Cancer Institute and its programs could be radically cut; other National Institutes of Health budgets could suffer similar effects.
- Big regional cancer centers like Memorial Sloan-Kettering in New York, M. D. Anderson in Houston, Dana-Farber in Boston, and the Mayo Clinic in Rochester, Minnesota, as well as the monies they receive, would shrink drastically. Thousands of careers could be jeopardized.
- There would be much less need—except for prevention programs—for the American Cancer Society, the Leukemia Society, the American Institute for Cancer Research, or any other national cancer fund-raising society.
- The cancer-related pharmaceutical industry's income would be severely impaired. Such drugmaking giants as Bristol-Myers Squibb would probably suffer significant contraction of income.
- The need for cancer specialists would vanish. Oncologists would become as extinct as syphilologists, whose ineffective treatments for syphilis bled their hapless patients of millions until the advent of the "magic bullet" penicillin.
- Hospital income would be significantly diminished. Hospitals with high cancer-related income could be forced to close.
- Thousands of smaller companies that constitute a cancer cottage industry would vanish.
- Thousands of physicians and researchers in America alone would lose their jobs or have to be retrained.

Those are the main reasons why hydrazine sulfate—or any other potentially broad-based, easy-to-administer treatment against cancer—would draw such terrible fire from those now dining at the trough of cancer cash. Since we are not talking about a violation of law, it probably does not matter if the opponents of hydrazine sulfate have consciously considered the above consequences and acted upon those considerations. Whatever their motivations, their actions, including the apparent sabotaging of federally funded clinical trials of the drug, deny the public access to it.

> "When a senior official at the N.C.I. asked how I'd gotten interested in hydrazine sulfate, I told him it had kept my mother alive. He looked at me as though he'd been punched in the gut."

SETTING THE STAGE FOR CONFLICT
Hydrazine sulfate's most recent modern use was as a military rocket fuel. The developer of its use as a drug was himself a military officer—a U.S. Air Force medical-research physician assigned to help win the space race against the Soviet Union during some of the most frightening days of the Cold War. Joe Gold, M.D., was one of a handful of elite young doctors who devised selection procedures for the first seven Mercury Astronauts from a group of 31 candidates, and helped make the critical judgments as to which U.S. test pilots were sufficiently prepared to become America's first spacemen.

The world had been stunned and alarmed when the U.S.S.R. orbited the sputnik and then flew Major Yuri Gagarin into orbit. President Dwight D. Eisenhower—and later John F. Kennedy—promised that the United States would follow the Russians into space and surpass them. It was up to the rocket riders of the Mercury program to accomplish that mission; it was up to the Mercury doctors to make sure that the astronauts were fit to withstand their body-pounding thunderous rides free of the earth's gravity, and then the fiery reentry of their space capsules into the earth's atmosphere.

So the medical team had to be both brilliant and bold, identifying their goals and charging unswervingly at them, tolerating no interference as they screened and tested the pilots who would dare the cold darkness of space and return. Gold was one of the doctors who certified that a Korean War Marine Corps combat veteran named John Glenn was ready for the challenge.

To match the needs of the Project, Gold and his physician colleagues, like their spacemen patients, became dedicated, tough, and uncompromising—impatient with fools, incompetents, or self-serving careerists whose philosophy was: Stick with the old ways and you won't get into trouble. In short, Gold was the kind of doctor who would not

tolerate anyone standing in the way of the welfare of his patient.

Of course, that is exactly the kind of doctor you'd want on your team if you were sick. But it turns out that a hard-charging, nothing-is-more-important-than-the-patient approach is precisely the wrong personality to have if you want to survive in the world of the cancer establishment's research bureaucracy. It is a largely hidden world, but sadly similar to the rest of governmental bureaucracy—self-perpetuating and self-protecting. Survival within it demands that you become meticulous about not offending those whose goodwill can make or break your access to funding. If you are an insider, you have some latitude, but God help you if you are an outsider, no matter how good your credentials, your work, or your ideas. Outsiders are inherently regarded with suspicion, distrust—and anathema.

Into this spun-glass universe of ever-so-diplomatic medical men came young Joe Gold, fresh out of the Air Force. He was filled with the fervor of the Mercury Program (having received a Presidential Citation from Eisenhower for his work), but his intensity was now directed at finding the answer to a single scientific question that haunted him: Is there some chemical way to block the abnormal process in the body that causes the tumor-triggered starvation called cachexia?

Gold realized that if he could find the key to pick cachexia's lock on cancer patients' ability to process food, many of them would, quite literally, stop starving to death. At the very least, he thought, that would restore considerable quality of life and keep them alive longer, so other treatments might have time to cure their cancers and save them. As the idealistic doctor was developing his concepts and, ultimately, hydrazine sulfate, he had only a theoretical idea that this drug would also be found to stop tumor growth. "That," says a still enthusiastic Gold, "is the expected side effect of stopping cachexia."

In the 1970s Gold published early results of his animal studies, and the prestigious Memorial Sloan-Kettering Cancer Hospital on Manhattan's wealthy East Side summoned him to make a presentation to their top scientists. Gold took another trustee of the Syracuse Cancer Research Institute with him and made a formal presentation. As a result, Sloan-Kettering indicated that it would like to proceed with human studies.

The Sloan-Kettering enthusiasm was unanimous, except from one quarter—the old-guard chemotherapists, who made clear their undisguised antipathy. Gold was nevertheless delighted, and in conjunction with members of the Sloan-Kettering executive staff, wrote a protocol for administering the drug, to which all parties firmly agreed and were committed. What followed were two collisions—of style and substance—that forever poisoned the way Gold and hydrazine sulfate were treated by the reigning medicrats of the U.S. cancer establishment:

EARLY CONFRONTATIONS

• Dr. Gold is invited by telephone to a Memorial Sloan-Kettering Hospital news conference, which will announce a plan for a joint study of hydrazine sulfate with the Syracuse Cancer Research Institute. Gold advises them that he must first consult with his own board of directors. His board advises Gold to inform Sloan-Kettering that it would welcome a news conference, but that it should take place in Syracuse. The news conference never happens. (Years later Gold has a chance encounter with a former senior medical-liaison officer of the hospital, who still remembers the incident. "You cost us 16 million dollars back then," the ex–Sloan-Kettering official says. "We were going to showcase you and your work, invite a lot of wealthy donators who could have made substantial contributions to our general efforts. We may have even shared some of these funds with your institute.")

> "If an inexpensive therapy for cancer was marketed, hospital income would be significantly diminished and there would be less need for organizations such as the American Cancer Society."

• Gold visits Memorial Sloan-Kettering to check on the patients receiving his experimental new drug and cannot believe what he sees. Instead of following the jointly-agreed-on protocol of 60 milligrams of hydrazine sulfate per single dose, the hospital is engaged in underdosing and overdosing. In some cases patients are being given only one, two, three, four, or five milligrams a day. Others who have been started on the correct dose and are beginning to show anti-cachexia improvements are abruptly switched to 90 to 100 milligrams per single dose, wiping out their good responses. Gold is appalled and complains to the Sloan-Kettering physicians that they are not obeying the study protocols. They tell him that "[they] know how to test cancer drugs. [They] know exactly what they are doing," Gold recollects.

Naturally, the results of the Sloan-Kettering study—the first by a major cancer hospital—are dismal. By their measure, hydrazine sulfate was "inactive," the kiss of death for a new drug. The results of the flawed study were published in a major cancer journal, and both Gold and hydrazine sulfate were permanently "marked." Almost 20 years later, that study is the one that most middle-aged physicians recall first, if they have any knowledge of hydrazine sulfate.

TIMING IS EVERYTHING

That test at Sloan-Kettering came at a curious time in the history of the U.S. fight against cancer. Only a few years earlier, a brilliant researcher named Vincent DeVita, M.D., announced to the world that he had developed a combination drug therapy called MOPP, which killed the tumors of Hodgkin's disease in 80 percent of all cases. The oncological community underwent a revolution. Dr. DeVita's work on Hodgkin's gave birth to the boom in tumor-killing, or cytotoxic, chemotherapy. Doctors now had high hopes that chemicals could be developed that would vanquish all cancers.

DeVita became the director of the federal National Cancer Institute—in effect the nation's cancer czar—and through him billions of taxpayer dollars were ultimately spread among research centers from coast to coast. Unfortunately, 23 years after DeVita's meritorious work on Hodgkin's, senior cancer researchers like Professor Jerome Block, M.D., of the University of California at Los Angeles (U.C.L.A.) Medical Center, have come to the conclusion that in most cancers, cytotoxic chemotherapy has failed to seriously improve patient survival, and that the quality of patients' lives has often been made additionally miserable by devastating side effects.

Gold and hydrazine sulfate were going in exactly the opposite direction from cytotoxic chemotherapy. Virtually no important side effects of hydrazine sulfate were produced, and when doctors followed the established protocol, 50 percent of all patients receiving the drug lived longer, higher-quality lives. Gold did not mean to be—but had become—a heretic, an iconoclast, a defiler of the one true faith of cytotoxic chemotherapy. His refusal to capitulate, his continuing publishing of research results, and the drug's clear potential attracted two diverse supporters to him and hydrazine sulfate: a high cancer official in the United States, and one of Russia's most respected senior research physicians. On separate tracks, Dr. Frank J. Rauscher, Jr., a former director of the National Cancer Institute and senior vice-president for re-

search at the American Cancer Society, and Michael L. Gershanovich, M.D., chief of the Departments of Therapy and Clinical Chemotherapy of the famed Petrov Research Institute of Oncology of the Soviet Ministry of Health in Leningrad (now St. Petersburg), moved to further test the drug.

The Russians moved first. They tested hydrazine sulfate against cancer cachexia in dozens of "factually terminal" patients suffering from a broad range of tumors. No matter which specific cancer was the trigger of the starvation, in about 50 percent of all cases, the patients' symptoms improved or disappeared, their cancers stopped growing or regressed, and some patients even went on to long-term survival. In the United States, the Petrov Institute's report by Dr. Gershanovich was read with keen interest.

Rowan Chlebowski, M.D., Ph.D., an insightful and ambitious research physician at the Harbor-U.C.L.A. Medical Center, brought the Gershanovich report to the attention of his boss, Professor Jerome Block, who said he "wanted to check out this Russian thing." Block had been a senior official of the National Cancer Institute when its director was Frank Rauscher, the avuncular and gentle scientist who was a predecessor of DeVita's as the nation's top cancer doctor. Rauscher was now running the research arm of the American Cancer Society. Block sent Rauscher Chlebowski's proposal to do a carefully controlled study to see if the Russian results could be authenticated. If they could, that would mean the American medical establishment would have to fully test hydrazine sulfate's potential as the first anti-cachexia drug.

A peer-review committee of the American Cancer Society gave Chlebowski's proposal high marks and voted to fund it. Then an A.C.S. advisory panel—composed of mostly outside, "old-boy" scientists—reversed this decision. Rauscher disregarded the advisory panel's recommendations and used A.C.S. discretionary money to fund Chlebowski's study. Following the established protocol of drug administration—and making sure that patients did not also take sleeping pills, tranquilizers, or alcohol (known incompatible agents that ruin the drug's effectiveness)—Chlebowski gave hydrazine sulfate to terminally ill lung-cancer patients whose bodies were wasting away because of cachexia.

It would be the first of four successful, double-blind, placebo-controlled trials of the drug at U.C.L.A.'s Harbor Medical Center. With each set of results, Chlebowski published in top medical journals, creating renewed interest in the drug and, apparently, incurring the wrath of the "high priests" who had trashed it from the beginning.

In 1983, following Chlebowski's presentation of a paper on the effectiveness of hydrazine sulfate at the prestigious annual scientific meetings of the American Society of Clinical Oncology, Gold encountered DeVita, who, Gold remembers, "poked me in the chest with a finger and said, 'I'm going to take off my gloves on hydrazine sulfate!' " (At press time DeVita had not responded to repeated calls to comment on this article.)

So it came as a shock but no surprise that in the next edition of DeVita's influential textbook on cancer, hydrazine sulfate was lumped with other treatments in the chapter entitled "Unproven Methods of Cancer Treatment." And that was well after the U.C.L.A. and Soviet teams had reported their successes at medical conventions and in widely read oncology journals.

Some of the more independent-minded physicians who read the journal reports obtained hydrazine sulfate for their patients through the Food and Drug Administration and reported to Dr. Gold that many stopped starving and were once again able to eat, and that some returned to fully functional lives.

> "A nothing-is-more-important-than-the-patient approach like Dr. Gold's is precisely the wrong personality to have if you want to survive in the cancer establishment."

A VERY PERSONAL MATTER

In Sarasota, Florida, in the summer of 1987, 64-year-old Erna Kamen was sent home to die in "three to nine days"—after surgery, radiation, and chemotherapy had failed to prevent her from being eaten alive by metastatic lung cancer. Cachexia was consuming her. But her oncologist had read the journal reports and prescribed and obtained hydrazine sulfate as a last resort.

The patient, who was this reporter's mother, managed to swallow the first 60-milligram capsule and collapse back into her bed, her eyes growing vacant. Only hours later she rebounded, saying she was hungry and eager for some good conversation. Two days before I had flown to Sarasota from Washington, D.C., to help take her home from the hospital, to tell her that I loved her, and, really, to say farewell. Her sudden return to life was especially shocking to me, because the National Cancer Institute's public-information service had told me by phone ([800] 4-CANCER) the day before that hydrazine sulfate had no value. The National Cancer Institute was giving that line to doctors, patients, and families until I broadcast a series of five television news stories on the more than 100 stations that carried Independent Network News.

In those reports my mother spoke about the impact of the drug on her own life, Dr. Chlebowski said that at least "half a million Americans each year suffering from cancer cachexia could be helped" if hydrazine sulfate were widely available, Dr. Rauscher called for nationwide testing of the drug, and Robert Wittes, M.D., a senior official at the National Cancer Institute, said hydrazine sulfate wasn't given a high priority because it "doesn't kill tumors." Of course, almost nothing the N.C.I. spends money on *does* kill tumors for any great length of time. It was the same old song: If it isn't cytotoxic chemotherapy, it just can't be good. After my interview with Wittes, he walked me to the elevator and asked how I'd gotten interested in hydrazine sulfate. As the elevator doors opened, I told him that the drug had kept my mother alive. The high priest of cancer looked at me as though he'd been punched in the gut. I stepped into the elevator and was gone.

Weeks later I received a phone call from Dr. Henry Masur of the National Institutes of Health, the parent institution of the N.C.I. Dr. Masur was the chair of the experimental-AIDS-drug screening committee. After an interview with him on another subject the previous week, I had asked what he knew about hydrazine sulfate. "Nothing. What is it?" He had sounded very interested when I told him the drug works against cachexia—a major killer of AIDS patients as well as cancer victims—and had said he would look into it. But his present phone call wasn't about AIDS. Masur said simply, "The Cancer Information Line has stopped saying hydrazine sulfate doesn't work. Instead, they're referring callers to the results of the U.C.L.A. study." Naturally, I felt terrific. My mother was recovering, and my journalism had helped to clear the name of hydrazine sulfate; thousands of viewers were calling our news desk to find out how to get hydrazine sulfate for their dying mothers and fathers.

My mother had four mostly good months thanks to the drug. If she had continued on it, she might still be with us. Because of her strengthened condition (she had gained back 23 pounds of real weight), however, a decision was made—against Dr. Gold's advice—to take her off hydrazine sulfate to try a new cytotoxic treatment. As Dr. Gold had warned, she was dead five days after the commencement of the new treatment. That was January 1988. But the good news about hydrazine sulfate

had gotten out. She had wanted that very much. Dr. Gold was hopeful that, at long last, the National Cancer Institute would order a large-scale trial of the drug, using patients from coast to coast.

But a few months later, N.C.I. Director DeVita was trashing the drug once again—at least, so he thought. He told Sandy Rovner of *The Washington Post*, "You have to distinguish between good ideas and bad ideas and ho-hum ideas. And hydrazine, I think, is a ho-hum idea." DeVita went on to characterize hydrazine sulfate as a therapy that merely resulted in "plumper people." Yet it is well-known in the medical community that weight gain has been a therapeutic goal for many years and that fully two-thirds of all cancer deaths are traceable to cancer cachexia.

LEFT JAB, RIGHT CROSS

Chlebowski's team at U.C.L.A. submitted a grant application to the N.C.I. for a more advanced test of hydrazine sulfate, a multi-institutional confirmation trial that would have moved the drug further down the road to acceptance and sharply increased the likelihood that, finally, a pharmaceutical house would pick up the rest of the drug's development costs and proceed to marketing. In the world of federal grants, an application is rated on a number system. In this case, a perfect score is "1." The bigger the number, the worse your work is regarded. Chlebowski is not only an extremely bright researcher but is internationally recognized in his field of intermediary metabolism and cancer chemotherapy. (He was one of 13 scientists selected by the U.S. government to help establish a cancer treatment and teaching center in Taipei, Taiwan, in 1990.) So he was surprised, to say the least, when the N.C.I.'s peer-review panel rejected his application and resoundingly insulted him with a very high number. Always careful in his public utterances, Chlebowski says now that "a lack of enthusiasm for the drug . . . and an overall [hostile] climate surrounding it" were responsible for stopping his decade of hydrazine-sulfate research dead in its tracks.

The January 1990 issue of the *Journal of Clinical Oncology* arrived in the offices of the nation's cancer doctors bearing what Dr. Gold calls "a bizarre medical paradox." The lead, peer-reviewed article by Chlebowski and a team of seven other physicians and scientists reported that in their final test of the drug—a prospectively randomized, placebo-controlled, double-blind study—hydrazine sulfate increased the survival of end-stage lung-cancer patients. That's a very significant finding, and signals physicians that they should give greater heed to the possible use of this drug for cancer patients in general. But as the readers of this journal turned the pages, they ran smack into an editorial slamming Chlebowski's rationale, methodology, and conclusions. Entitled "Hazards of Small Clinical Trials" and written by Dr. Steven Piantadosi of the Johns Hopkins Oncology Center in Baltimore, the editorial rips the reliability of "small" groups of patients as indicators of a drug's performance in wide use. The trouble is, the only drug he gives specific mention to is—you guessed it—hydrazine sulfate. What is curious, to say the least, is that Chlebowski's final study drew on 65 patients, an appreciable number for this kind of study. Moreover, in this same journal issue, 12 out of a total of 22 studies reported—or 54.5 percent—employed far *less* patients than the Chlebowski study, some as few as 15 patients. Nevertheless, there was not a word of criticism of these studies or of any conclusions they had reached.

For Dr. Gold, the Piantadosi editorial

> "If reputable scientists in the United States and in Russia have successfully used hydrazine sulfate, why isn't it available?"

"gives an unmistakable signal that any study of hydrazine sulfate bearing positive data will be singled out for special attention." He characterizes this work as a " 'hired-gun' editorial whose effect is not only to demolish legitimately obtained positive results with hydrazine sulfate, but to deter further independent clinical study of this drug."

So the left jab and the right cross landed hard. First Chlebowski's multi-institutional grant application was given an exceedingly poor grade; then his final report to the medical community on hydrazine sulfate was attacked by Piantadosi, who, besides being a senior researcher, also sits on the oncology advisory panel of the F.D.A., which makes recommendations to the F.D.A. on which cancer drugs should and should not be approved.

Chlebowski was stunned by the editorial. As a result, after ten years of studies and coming to the conclusion that hydrazine sulfate could have helped millions over that period, he dropped out of hydrazine-sulfate research. Shortly thereafter, he received an invitation to join the executive board of the prestigious American Society of Clinical Oncology, the publisher of the *Journal of Clinical Oncology* in which he and the drug were pilloried. Chlebowski is enjoying his newly found prestige, but he is still smarting from Piantadosi's lash. Almost three years later, he is still wearing the scars.

Over breakfast at the Sheraton New Orleans, where the ASCO executive board was meeting this past Halloween, Chlebowski labeled Piantadosi's effort "not a helpful editorial, [but one] which could have been written about 20 other papers published in *J.C.O.* [the previous] year. . . . I can tell you that I was shocked by the tone of the editorial. . . . He said my work had not advanced the development of hydrazine sulfate. That is not correct." Understand that for a career organization man like Rowan Chlebowski, those are incendiary words, uttered only because he cannot fully contain his rage at the attack that rained down on him because of his successful studies of hydrazine sulfate.

Like Dr. Gold, Chlebowski said he feared the editorial would scare off potential partners in research that he had still wanted to do on hydrazine sulfate: "It might make other people lots more cautious than I was going to be, and that would make it hard to package the right group of people together to be able to make [an] application strong enough so that it would be more compelling [to win grant approval]."

Chlebowski's final involvement with hydrazine sulfate might well have been his most explosive—an approved (and funded) grant to study the effects of the drug on AIDS patients, who, like so many cancer victims, often succumb because their bodies have lost the ability to process food in any form. If hydrazine sulfate could be shown to stop and reverse cachexia in AIDS patients, they might have the chance to fight on. But no sooner had Chlebowski received his grant to do the work, he says, than he discovered that F.D.A. regulations would tie him up in red tape for months just to get his hands on a reliable supply of the easily manufactured chemical. It was the last straw. He dropped the project.

Burned and disappointed but still needing to continue with his career, Chlebowski moved on to other, much less controversial, less politically loaded, work. For his boss, Dr. Jerry Block, dropping hydrazine-sulfate research was deeply disappointing, since his early decision to buck the politically correct crowd—including N.C.I. Director DeVita—had paid off in what he still regards as good, solid research, which he thought would have included the AIDS study. Block said he had high hopes that hydrazine sulfate would be effective against AIDS cachexia.

During an interview in the Los Angeles suburb of Redondo Beach this past November, Block said that no other drug has ever been subjected to the

"gauntlet of scientific criticism" that hydrazine sulfate has been forced to run. A former senior official of the N.C.I., Block called for the convening of an "international conference" on hydrazine sulfate. "Cachexia isn't a trivial problem. It isn't only cancer, it isn't only AIDS. Cachexia touches our lives in many ways. It is a part of advanced aging as well."

Block was mid-bite on a warm raisin scone at the Redondo Beach Inn and in a genial mood. But when he was told that the first portion of the nationwide testing of hydrazine sulfate paid for by the N.C.I. had deliberately included the incompatibles, his generally warm and smiling face hardened into a mask. Like Chlebowski, he said he too would have excluded the incompatibles. Block clearly believes that hydrazine sulfate and its developer have been the subjects of continuing harassment by the medical establishment.

"Look at how long they've been working on immunotherapy," he says. "There's never been a randomized clinical trial [he laughs], a randomized, controlled clinical trial that shows immunotherapy is good. Yet they're still funding that. They've been investing in that for decades. Possibly Joe [Gold] made a political mistake by not calling hydrazine sulfate 'immunotherapy.' "

In 1985 Dr. Maxwell Gordon was senior vice-president of the Science and Technology Group of Bristol-Myers. After deciding that hydrazine sulfate was going to save a lot of lives, he sent a letter to Dr. Gold to signify the pharmaceutical house's "intention to conclude an exclusive worldwide license agreement with you on hydrazine sulfate" (for which Gold holds the patent). Gordon's letter signaled three important coming events: a comprehensive testing of the drug against all forms of cancer, the marketing of the drug throughout the world, and an enormous intellectual, emotional, and monetary payoff to Gold after 17 years of hard, lonely work during which his pioneering efforts had been greeted with scorn and abuse.

But none of those good things was to be. To learn why, we interviewed Dr. Gordon this past November at Lenti-Chemico Pharmaceutical Laboratory, Inc., in Teaneck, New Jersey, where he is the chairman of the board and the C.E.O. of the U.S. subsidiary of Japan's Ajinomoto Co., Inc. Gordon remembers what happened to the hydrazine-sulfate deal as if it were yesterday, not almost eight years ago. He said his bosses at Bristol suddenly reversed themselves and declared, "Forget it, the deal's off." Gordon said the deal-killer had been "Stephen K. Carter, an N.C.I. alumnus and part of the establishment. [Carter] put himself on the line and said, 'If you do this [take on hydrazine sulfate], I'm quitting.' " Gordon left Bristol; Carter—who denied through a spokesman that he had threatened to quit to kill the deal—stayed on and is now director of the company's Worldwide Clinical Development.

Gordon remains a detached but enthusiastic supporter of Gold's work and of hydrazine sulfate. But "without a positive, multi-institution, clinical trial of the drug," he says, there is little probability that any drugmaker will pick up hydrazine sulfate.

When Gordon learned three years ago that exactly such a trial was about to begin—paid for by taxpayer dollars—he contacted the doctor in charge and urged him to make sure that the test excluded from patients' diets all alcohol, sleeping pills, and tranquilizers. Those substances had been shown in the past to ruin hydrazine sulfate's effectiveness. Gordon has a clear recollection of his conversation with Dr. Michael Kosty, the researcher selected by the N.C.I. to direct the first of three trials at the Scripps Clinic, a cancer center in San Diego.

"I emphasized the importance of those exclusions," Gordon says, "so I'm at a loss why they didn't do it." Gordon also says that Kosty had plenty of time to make sure the test was fair and honest. "He [Kosty] was writing the protocol" when Gordon called. (Gordon sent him a letter dated September 19, 1989, emphasizing in writing the importance of the exclusions.) How did Kosty respond to Gordon's guidance? "He said, 'You're right,' and that he would follow my advice," Gordon says.

Kosty, responding to *Penthouse*'s follow-up, contends, "This is incorrect. We talked with many individuals prior to finalizing the study and made no commitments to include/exclude specific medications."

Not only did Kosty deliberately fail to exclude the incompatible substances from the study (because of this failure, Rauscher terms the results of this study "suspicious"), but he said in an interview with me at his home in San Diego that "we just think that that's a nonissue." Sure. Like mixing gravel in with the gasoline that you put in your Porsche. Not surprisingly, the Kosty study, with its protocol of incompatibles, was reported as negative. Kosty further said that the Russian work—a 740-patient, 15-year study—had been "shoddy," and stated that his own study of hydrazine sulfate proved that the study conducted by Chlebowski and his team at U.C.L.A. was "meaningless."

Kosty even went beyond the portfolio of his assignment. In his report on hydrazine sulfate presented at last spring's ASCO meeting, Kosty stated, "We discourage the general use of hydrazine sulfate in cancer." The word *general* in that context means "all types" of cancer. But Kosty didn't test all types of cancer—his study was restricted to non-small-cell lung cancer. The fact is, his statement is unsupportable. Moreover, since Kosty's assignment was strictly to study hydrazine sulfate in combination with chemotherapy, he could not state what the effects of hydrazine sulfate itself were against non-small-cell lung cancer—no hydrazine sulfate–alone "arm" was tested. And since Kosty failed to exclude the known incompatibles of hydrazine sulfate, no statement can even be drawn as to the effect of hydrazine sulfate in combination with chemotherapy. In effect, the Kosty study demonstrates nothing. No scientifically valid conclusions whatsoever can be drawn. The entire study, which cost the N.C.I. up to a million dollars, can be seen as a total waste of the taxpayers' funds.

A curious counterpoint to Kosty's negative report to ASCO was his statement that was reported in *Oncology Times*, a monthly newspaper for cancer doctors and researchers. On April 24–26, 1991, Kosty and his group from the Cancer and Leukemia Group B, charged with overseeing the N.C.I.-Kosty study, met to consider the preliminary results of this study.

On April 29, 1991—three days after the evaluation of these preliminary results was completed—Naomi Pfeiffer, a science writer for *Oncology Times*, reported that she was told by Kosty in a telephone interview that the results indicated that those patients who received hydrazine sulfate had "far superior" survival than patients in studies where hydrazine sulfate was not used, and, further, that side effects were "negligible." This story was published in the newspaper's June 1991 issue. In her telephone interview with Dr. Kosty, Pfeiffer asked, "Are the definitive data likely to be different?" Kosty replied, "No, they [the data] can only get better."

In November of last year, Kosty insisted that Pfeiffer had misquoted him: "I never said it. I said that as a group, since we hadn't broken the codes on the patients in the study yet [on the double-blind], all the patients were doing better in terms of how long they were living, in terms of other Phase III studies. Both the people receiving placebo and the people receiving hydrazine. I said nothing about one group or the other because I was blinded to the results until the study was virtually completed." If that is so, then why did he and his group meet to discuss and then report on preliminary results in April 1991? Kosty is new to the business of high-profile research. Pfeiffer is an old hand with 30 years' experience. She told me, "I did not misquote him. I remember what he said. For some reason, he's trying to make me out a liar."

Dr. Gold quickly realized that there was no way that he could alter the outcome of the Scripps cancer center–based study, given the inclusion of its

negative bias factor of incompatibles. The two other N.C.I.-sponsored Phase III studies of the drug—against lung cancer and colorectal cancer—were soon to begin at the Mayo Clinic in Rochester, Minnesota, under the supervision of Dr. Charles Loprinzi. In response to appeals from Dr. Gold, Loprinzi said in a letter dated June 15, 1990, "I have made modifications to both of our hydrazine [sulfate] studies to exclude the use of any alcohol and tranquilizers."

When I asked Kosty how he felt about Loprinzi's changing the Mayo protocols to exclude the incompatibles, Kosty said, "They didn't change it. They had excluded it from the very beginning." Who told him that? "Chuck Loprinzi. . . . He sent me a copy of the protocol before it was opened, and it had those things excluded." Did he ask him why he had done it? "No. I guess they decided not to make that an issue. Obviously, by excluding, you remove that as a potential criticism." (!)

But Dr. Gold contends that the doctors at the noted Mayo Clinic appear to have engaged in an unorthodox practice in the design of their hydrazine-sulfate study, which could also compromise the results. A careful reading of Loprinzi's June 15, 1990, letter to Gold shows that Loprinzi started his patients first on chemotherapy, waited for nausea to clear, and then started hydrazine sulfate. "We have written into the protocol," he wrote, "that these pills should not be started for several days until after the first emesis [vomiting] from the first cycle of chemotherapy [has] cleared."

To this Gold responds, "In effect, this means that his team has administered what is called 'prior therapy,' prejudicing the study against hydrazine sulfate in violation of his own protocol. Section 3.18 of the official Mayo protocol No. 89-24-51 reads, 'Patients [admitted to the study group would have to be] previously untreated with chemotherapy for this cancer or other cancers.' Loprinzi thus tips the scales against hydrazine sulfate, since nausea from the first course of chemotherapy can take from a few days to up to a week to clear. He should have started hydrazine sulfate and chemotherapy concurrently. Or, if he wanted to tip the scales in a protocol-justified manner, hydrazine sulfate *before* chemotherapy."

When questioned by *Penthouse,* Dr. Loprinzi replied, "No, we did not bias the outcome. I can't buy that. We wanted to give hydrazine sulfate the best possible shot."

We can only hope that the physicians at Mayo live up to their reputations as good and wise healers and do not succumb to pressures to smear hydrazine sulfate.

Some of you reading this right now have just lost a friend, loved one, or colleague to cancer. Hydrazine sulfate might have spared them, alleviated their pain and suffering, even given them back their normal life. Yet only a minority of doctors—and even fewer ordinary citizens—have even heard of the drug.

And what about the AIDS patients? Like cancer victims, many of them die not of the disease itself, but of the terrible wasting away the disease mechanism creates. Can hydrazine sulfate reverse the cachexia metabolism of AIDS as it does the cachexia of cancer? Preliminary metabolic studies say yes. But clinically, the question remains unanswered. And that is because the U.C.L.A. team has relinquished its AIDS grant, caught in the vise of a 16-year concerted effort to destroy the drug.

Why should an N.C.I. director threaten to "take off [his] gloves on hydrazine sulfate" after the presentation of a positive clinical study of the drug at an important cancer conference by a team of experienced and objective cancer investigators? Why should the U.C.L.A. team give up ten years of escalatingly successful controlled clinical trials of hydrazine sulfate at the zenith of its success? Throw away its AIDS grant? Why should a prestigious mainstream cancer journal print an editorial whose only apparent functions are to selectively attack its lead article and serve notice to the cancer community that positive results on hydrazine sulfate will be singled out for "special attention"? Why should an N.C.I. study group want to retain substances in its protocol that are known to be incompatible with hydrazine sulfate—that could only result in harm to the patients taking the drug (and help guarantee a negative outcome of the clinical trial)—when to exclude those substances would do no harm to the study? Why should a high official of the N.C.I. derisively label hydrazine sulfate a drug that results only in "plumper people" when weight loss is a major factor in cancer death? Why should the principal investigator of an N.C.I. study of hydrazine sulfate recant his original statement of favorable preliminary results? Why should all independent clinical research of this extraordinary drug cease? The consequences of this destructiveness are enormous, not only denying a fighting chance to both the drug and the patients caught in compromised studies, but presenting alarming ramifications for the cancer community at large. In Dr. Gold's words:

"Each year 500,000 Americans die from cancer, and there are over a million new cases annually in this country alone. The U.C.L.A. data indicate that over half of these afflicted patients would be helped by hydrazine sulfate, some achieving significant extensions in survival. The Soviet data, consistent with the U.C.L.A. results, indicate that of every million late-stage cancer patients, 500,000 would receive significant symptomatic improvement, 400,000 would show a halt or regression in tumor growth, and some would go on to long-term survival. If, indeed, any one of the N.C.I. studies has been rigged, or if official intimidation and coercion against further independent clinical studies of hydrazine sulfate are at work, as may well be the case, the result will be increased suffering to these hundreds of thousands of human beings and their families. That the N.C.I. should be part of an effort to snuff out hydrazine sulfate constitutes what is truly one of the most shameful, scandalous medical undertakings in this country's history, depriving vast numbers of people of their health, happiness, and lives."

Author's note: Jeff Kamen is currently at work on a book and a documentary film about hydrazine sulfate. He asks anyone who has had firsthand experience with the drug to write to him at Box 15600, Washington, D.C. 20003.

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