The Seattle Times
Winner of Eight Pulitzer Prizes
Local News

Originally published November 19, 2007 at 12:00 AM | Page modified November 19, 2007 at 11:16 AM

Public never warned about dangerous device

A young mother in Los Angeles was desperate. A rare form of cancer was ravaging her 5-month-old son. Their doctor said chemotherapy offered...

By Christine Willmsen and Michael J. Berens
Seattle Times staff reporters

ALAN BERNER / THE SEATTLE TIMES
The man and his machine Panos Pappas demonstrates the power of his PAP-IMI by using a chain on his head to cause current to leap from the coil. He calls it "modern scientific alchemy" and "micro-lightning." Others call it "a piece of junk" and "the worst of the newest technologies."

A young mother in Los Angeles was desperate. A rare form of cancer was ravaging her 5-month-old son. Their doctor said chemotherapy offered the best hope for survival, a 1-in-4 chance.

Natalia Campos watched as her baby, Antonio, struggled in pain through the first few treatments. Then she learned of an alternative-therapy clinic that promised a cure, without pain, using a machine called a PAP-IMI.

Twice a day at the Bio-Energy Services clinic, Campos held Antonio while the 260-pound machine pulsed powerful electromagnetic waves into the tumor bulging from his neck. The treatments failed, and Antonio died — the victim not only of his cancer, but of

what one health official later called a "major national health fraud."

The man behind that fraud is Panos Pappas, a math professor from Athens, Greece, who invented the PAP-IMI. He sold the machines to scores of practitioners in the United States who used them to exploit patients. They avoided detection by taking advantage of federal regulations that allow them to operate on an honor system in clinical studies. Although the U.S. Food and Drug Administration has linked Pappas' machine to patient injuries and death, it has never warned the public about the dangers.

And while the FDA in 2005 prohibited the use of the machine, The Seattle Times found PAP-IMIs in use in at least five states, including Washington. Among those offering treatments were a psychologist in State College, Pa.; a physician in Bellflower, Calif., and a former chiropractor in Issaquah.

FDA spokeswoman Karen Riley said the agency will "follow up on" the PAP-IMI, based on The Times' findings. Pappas, meanwhile, continues to insist the machine "is absolutely safe," and that it "can cure cancer and AIDS."

From his Athens office, Pappas said: "I'm not sure the world is ready to understand the PAP-IMI. It goes beyond known human knowledge."

Scientist and salesman

One had the brains for invention, the other was always ready to close a deal. Pappas, 60, a Greek scientist, invented the Pap-Ion Magnetic Inductor, or the PAP-IMI, a medical device he describes as a rapid healing machine. It pulses the body with electromagnetic waves that he says repair damaged cells.

Charles "Chuck" Wallach made a living for 20 years selling insurance, private club memberships, even T-shirts.

While in California, Pappas met Wallach and treated his chronic back pain with the PAPIMI. Both claimed the treatment a success, and a partnership was born. Neither had a medical degree, but together they dreamed of building an international health-care empire by selling the PAP-IMI.

In 1995, they asked the FDA, which regulates medical devices, for clearance to sell the machines in the United States. The agency turned them down, citing a lack of scientific data. The National Institutes of Health says machines like the PAP-IMI have not been scientifically validated.

The two men devised a ploy to keep the PAP-IMI alive. Pappas and his employees constructed the machines in Athens. Before being shipped, machines were mislabeled as seed germinators, passing through U.S. Customs without steep import fees and FDA scrutiny, customs documents show.

Wallach set up a treatment clinic in Los Angeles, Bio-Energy Services. It also became the national sales and marketing hub.

Exploiting a loophole
Next, Pappas and Wallach exploited a regulatory hole that would make their scheme legal: They launched a clinical study.

For that, they didn't need the FDA. They hired their own private regulator. The FDA routinely cedes its oversight of clinical studies to committees of medical professionals called institutional review boards, or IRBs. Review boards are required to oversee the design and safety of clinical studies, from drugs to devices.

IRBs traditionally have been centered at medical and academic institutions. But today, based on mounting commercial demand, scores of private companies sell IRB services, which include quick study approval and oversight for as little as a few thousand dollars. In May 2001, Wallach solicited a private review board in San Diego, Biomedical Research Institute of America, also called BioMed IRB.

Wallach proposed a study to see if the PAP-IMI could reduce pain, saying the device posed little risk to test subjects. BioMed IRB approved the study. BioMed would not comment to The Times on the study.

BioMed established safety rules. For example, patients with pacemakers should not receive the electromagnetic treatments.

Essentially, Wallach and PAP-IMI operators were on an honor system. They agreed to notify the review board of any injuries or deaths linked to treatment.

The FDA didn't know about the PAP-IMI study; the agency does not collect any information on studies involving devices that are considered low-risk. The FDA doesn't even know some devices exist.

The FDA prohibits anyone who is conducting a study from profiting by selling a device or treatments. But some companies try to get around the rule.

"Some device manufacturers use the IRB system to essentially market their device under the guise of a study," said Phil Phillips, former deputy director in the FDA's medical device center. Sheila McCarthy, a former office manager of Bio-Energy Services, said Pappas and Wallach were fixated on profits.

"The approval of the IRB study was a means to sell more machines," she said. "The deal became more important than the treatment."

"A bunch of cowboys"
Pappas and Wallach were free to market the unproven treatments under the banner of a

government-approved clinical study.

Wallach and his sales crew pitched the PAP-IMI at health-care expos in Las Vegas, Orlando and other cities, selling them for up to $55,000 to physicians, chiropractors, acupuncturists, naturopaths and massage therapists. They also sold machines to people with no medical background as well as to those who were desperately ill.

Whenever anyone at Bio-Energy Services sold a PAP-IMI, a staffer rang a bell to let everyone know.

Wallach and the sales crew displayed a chart that showed operators how they could generate up to $150,000 in the first year. And if they sold a PAP-IMI, they would receive a $3,000 commission.

"They had free rein," McCarthy said. "It was a bunch of cowboys. It was the Wild West. It was the worst of the newest technologies — completely out of control."

Before long, PAP-IMI operators, under the guise of the study, offered treatments across the country at 37 locations. Dozens of other operators broke the rules by treating people without IRB oversight, said FDA investigator Jim Fleckenstein, who later opened a case against Bio-Energy Services.

Among the operators were at least 10 licensed health-care professionals who previously had been disciplined. Bio-Energy Services' promotional materials quoted physicians, cited unsubstantiated cancer studies and shared testimonials of people claiming they were free of pain after PAP-IMI treatments.

Johnny Heurung, former general manager of Bio-Energy Services, became troubled by how the PAP-IMI was being marketed. "They would tell people on the phone or Internet or in the meeting it would cure," he said. " 'Cure' is a big word in life, and it's wrong. "When people are very ill, people will fall into the trap. They were coming into the clinic looking for a magic bullet or cure, but it wasn't."

Employees lured people of all ages into the Los Angeles clinic. They offered gift certificates and discount packages, like 20 sessions for $880.

The company touted the device's cures to support groups for people suffering from chronic fatigue, immune dysfunction and allergies.

To try to generate goodwill, Bio-Energy Services gave free PAP-IMI treatments on weekends to people at nursing homes and at a homeless shelter.

After Heurung and McCarthy complained to Wallach about the lack of patient safety and the aggressive selling tactics, they said, he fired them.

Not all operators were happy with the machine, either. Bob Green, a former massage therapist and forester in Post Falls, Idaho, bought a PAP-IMI in December 2001 as a way to make money while helping people.

The moment he plugged it in, sparks flew and its plug melted. Green fixed it, but from then on doubted its safety.

"The way they built it and put it together, you could get electrocuted," he said. "It was a piece of junk." He asked for a refund, but Wallach refused.

Wallach also warned him not to complain to the FDA. "If you make up stories to tell them, I will sue you and take your house," he wrote to Green in July 2002. "Start saving your pennies."

Green's wife, Ellen, later used the machine to try to cure her breast cancer. Despite his warnings to stay off the device, he said, she was convinced it would save her. She died in January 2005.

Delayed reports of deaths

In April 2002, the review board found out that Wallach was improperly selling the machines to people outside the pain study. The board alerted the FDA of the violation. Weeks later, BioMed IRB discovered a more serious problem at a study site, Lifeworks Wellness Center in Clearwater, Fla.

During a review of clinic records, the IRB learned about two patients whose deaths had not been promptly reported. A woman with cancer and a man with heart disease and chronic renal failure had died several days after receiving PAP-IMI treatments.

The review board determined that LifeWorks' president, physician David Minkoff, had failed to properly report the deaths.

The delays — one of them five weeks — made it difficult to determine if the treatments had caused or contributed to the deaths. The review board, as required, alerted the FDA about the lapse.

In a letter to the review board, Minkoff wrote that the "treatments had nothing to do with their demises."

During the study, Florida health officials suspended Minkoff's medical license. They determined that he had prescribed medications inappropriately to a woman in 1995, according to the FDA and the Florida Board of Medicine. Minkoff didn't return phone calls or e-mails seeking comment.

By now, BioMed IRB had found other problems with PAP-IMI operators, such as making misleading claims. In June 2002, the review board ordered Wallach and other

operators to stop using the machines at all the study sites.

Some ignored the order, including Wallach. He chose to run a renegade clinic.

"Having them tell us we had to take back all the devices was based on the assumption that they were God, I guess," Wallach wrote in a letter to PAP-IMI practitioners. "Please remember that IRBs are hired by us; we are the customer."

"Quickly stop them"

The same month that little Antonio Campos began treatments at Bio-Energy Services in Los Angeles, the FDA received a four-page fax alleging flagrant misconduct by Wallach and others at the clinic. The whistleblower, an employee, urged the FDA to "quickly stop them as they flaunt and ignore the law."

When FDA investigator Fleckenstein inspected the clinic, he was horrified by what he saw: a baby being pulsed by the PAP-IMI.

"We went through the roof. We knew we had to pursue this," he said. The PAP-IMI was one of the most egregious cases in his 30-year career, he said.

Natalia Campos, having little money but determined to save her son, was working part time at the clinic to pay off the $60 treatment sessions. She had rejected pleas from a doctor and a nurse at Childrens Hospital Los Angeles to continue Antonio's chemotherapy treatment.

"We were adamant he would not survive without chemotherapy," said Margaret Bottcher, a nurse. "Who wouldn't do anything for their 5-month-old son? I can understand the desire for something better or easy. But not everyone can be trusted."

Campos did not return calls seeking comment for this story.

After the FDA saw what was happening at Bio-Energy Services, it decided that rather than shut down the clinic, it would widen the investigation. It teamed up with California health regulators and the Los Angeles County District Attorney's Office.

But that meant that in the meantime, patients would continue to be treated with the PAPIMI. Christopher Wogee, a California Food and Drug Branch section chief, wrote in an e-mail to other state health officials: "Looks like major national health fraud ... regard this assignment as extremely important."

Meanwhile, Wallach was determined to keep the PAP-IMI network going in the U.S. His solution: shop for another private institutional review board. He found Texas Applied Biomedical Services, or TABS, of Houston. Its motto: "Let Us Keep TABS For You." Fleckenstein said he informed company President Joyce Heinrich about the problems with Wallach and the PAP-IMI.

TABS approved Wallach's study. His network was back in business.

Bio-Energy Services "assured me things had been corrected and we moved forward," Heinrich said. "I don't feel TABS did anything inappropriate."

Major endorsements
Wallach and his sales staff even persuaded an NFL team to lend its credibility to promote the miracle device.

Impressed by Wallach's sales pitch, the San Francisco 49ers agreed to let Pappas and Bio-Energy Services use the team logo and player testimonials in exchange for free use of the PAP-IMI, former 49ers head trainer Todd Lazenby said.

In 2002 and 2003, more than 20 players, including wide receiver Terrell Owens, were given PAP-IMI treatments.

Lazenby said some players were treated five times a week. He didn't recall any of them signing consent forms that explained the risks of treatment. But the players did give written permission for their names to be used to market the machine, he said.

The team doesn't endorse the PAP-IMI today, 49ers spokesman Aaron Salkin said. Pappas still uses the 49ers' name to promote his invention.

Even the star of the 1970s TV show "The Life and Times of Grizzly Adams" promoted the PAP-IMI in a commercial. In exchange, the actor, Dan Haggerty, received free pain treatments at the Los Angeles clinic.

Before he was treated, Haggerty said, he showed his X-rays to Wallach. Haggerty had nearly died from a motorcycle accident and had a steel rod in his left leg and steel plates in his right ankle.

But the PAP-IMI, according to study rules, must not be used on anyone with large metal implants. Its electromagnetic pulse can cause metal to overheat and burn surrounding tissue.

Haggerty said he had no idea he had been at risk until he was informed by a reporter. He was upset that he hadn't been warned. "Maybe it was my ignorance, but I didn't think it would fry me like a piece of bacon," he said.

He no longer endorses the device.

Another death
When a 68-year-old woman died of a heart attack during treatment, Pappas and Wallach feared that the FDA would shut down the study.

Maria Silva, her daughter and daughter-in-law started PAP-IMI sessions at the Los Angeles clinic in February 2003, each for different ailments. They each received treatment packages — 10 visits for $480.

Silva previously had suffered a heart attack. She also had lupus, hypertension, arthritis and diabetes, an autopsy later showed. According to rules of the study, she never should have been pulsed because she had chronic heart disease.

On March 29, near the end of Silva's 30-minute treatment, she appeared to be napping, but an employee couldn't wake her. Silva had stopped breathing and had no pulse. An employee called 911. Silva died of cardiac arrest.

An autopsy by the Los Angeles County coroner didn't find evidence that the PAP-IMI treatment caused her death. But the autopsy doesn't indicate that the PAP-IMI was inspected or that the coroner knew Silva wasn't supposed to be treated because of her heart disease.

Bio-Energy Services contacted Nelson Marquina, a medical-device consultant who had put Wallach in touch with TABS.

In an e-mail to Wallach and other employees, Marquina said to send him a copy of Silva's file and statements made by the medics and her daughter.

"DO NOT contact the TABS IRB! By law, we have 10 days to inform the IRB," Marquina wrote. "Let me see the data and determine the best way of presenting the facts so that we do not create another reason for additional scrutiny by the FDA or requirements by the IRB."

Marquina later said the e-mail reflected his attempt to help his client. He said Silva never should have been treated because of her chronic heart condition.

Heinrich, the TABS president, said she properly reported the death to FDA officials.
A Los Angeles County deputy district attorney, Mary Ann Keyfauver, and state health investigators started to build a criminal case against Wallach. But the case moved slowly, in part because of too few staff and reluctant witnesses.

Ten months after discovering the illegal use of the PAP-IMI, California Department of Health Services seized four machines from Bio-Energy Services in June 2003, essentially shutting down the clinic.

When a California Food and Drug Branch research scientist disassembled the device, he determined that it "poses significant hazard" to both operator and patient. The device delivered a "substantial and dangerous electrical current to the loop or probe that cannot be regulated by the person."

California health officials declined a request for an interview about the case. They also refused to give reporters access to their 2003 search warrant of Bio-Energy Services, even though the case was closed. The Seattle Times filed motions in a Los Angeles court and got the record released earlier this year.

Few FDA inspections

During the investigation, FDA investigators learned that at least 100 PAP-IMI devices had been sold to operators, many of them pulsing patients without enrolling in the clinical study.

The FDA inspected only three clinics — Bio-Energy Services, LifeWorks in Florida and the Center for Holistic Medicine in Washington, D.C. Checking a sample of patient records, the FDA found 26 cases in which people were not told of the risks before being treated by the PAP-IMI.

The agency discovered numerous patients who, under the rules of the pain study, shouldn't have been treated because the PAP-IMI might injure them: people with heart disease, ulcers, pacemakers and other conditions.

The Times also found patients who said they were harmed. An Illinois woman said that after being pulsed, a fibroid tumor in her uterus burst, causing bleeding and pain. A Los Angeles man said he suffered blurred vision, headaches and a life-threatening aneurysm. The agency lacked the staff and resources to inspect the dozens of other PAP-IMI clinics, Fleckenstein said.

He said he's still concerned about what the FDA might have found if it had inspected the other PAP-IMI clinics.

In November 2004, just as a Los Angeles County district attorney prepared fraud and theft charges against Wallach, he died of a heart attack. As a result, the criminal case was abandoned.

In the end, the District Attorney's Office sued Bio-Energy Services national sales manager Jerry Anderson for making misleading claims. Anderson paid a $9,750 fine. "I was the scapegoat," he told The Times.

One other PAP-IMI operator was shut down and fined $9,350. For its part, the FDA sent a warning letter to LifeWorks Wellness Center in Florida, ordering it to correct numerous violations.

The agency notified Pappas in June 2005 that he must shut down the pain study at all sites. Keyfauver, no longer a district attorney, said she could only go after local operators in the health-care fraud case. She wishes federal authorities had expanded it. "It concerns me it's still out there," Keyfauver said. "I think it's a dangerous machine."

Devices keep coming

From Athens, Pappas stills makes and sells the PAP-IMI. The device can be found in more than a dozen countries, he said. And a technician continues to fix the devices in the U.S.

Before shipping out new machines, Pappas gives them a quality check, testing them on people who come in for free treatment, he said. Some people reported they felt less pain after being pulsed.

He is unbowed. "We are going to the rest of the world until they speak out," he said. "Then the FDA has no choice."

With the PAP-IMI prohibited from import into the U.S., makers of similar devices have seized its market.

Mike Davis, president of PEMF Systems in Las Vegas, designed a smaller, similar version of the PAP-IMI. His $20,000 device, the size of a small suitcase, is sold under a variety of names, including Magnapulse, Davis said. PEMF is not registered with the FDA. Davis said he plans to get approval to use the machines in a clinical study.
He talked to Times reporters at the Rife International Health Conference in Seattle last year. More than 300 attended the annual conference, a mecca for people buying and selling energy-medicine devices.

Davis said he sold three Magnapulses during the event, including one to a physician and one to an alternative-therapy cancer clinic.

He said he has sold 300 devices worldwide, about half in the United States. One of his Magnapulse distributors is the former national sales manager for Bio-Energy Services, Jerry Anderson.

After regulators shut down the PAP-IMI operation, they prohibited Anderson from selling or distributing any unapproved medical devices in California.

He can get around that: Anderson now lives in Hawaii.

Staff reporter Sonia Krishnan and researchers David Turim and Gene Balk contributed to this report.Christine Willmsen: 206-464-3261 or cwillmsen@seattletimes.com; Michael J. Berens:
206-464-2288 or mberens@seattletimes.com

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