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Back-pain treatment scrutinized

LEGAL, MEDICAL TUSSLE OVER CLAIMS OF MACHINES' VALUE

By **Barbara Feder Ostrov**
Mercury News
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Dale John Dorjath was willing to try just about anything to ease the debilitating back pain he had suffered for years - even a machine recommended by his chiropractor that required strapping on Velcro girdles and being pulled in two directions.

"It sounded like it was well worth the money," Dorjath said. "But it didn't work. I had so much pain afterwards, I literally couldn't walk."

Dorjath, a retired 64-year-old accountant from San Jose, said he was treated on a DRX 9000, one of the "spinal decompression" machines touted by some chiropractors as an alternative to surgery for patients with herniated discs or other lower back problems.

While some patients report near-miraculous relief from the machines, the companies that make them and the chiropractors who buy them are coming under increasing scrutiny from local district attorneys and federal officials for fraudulent advertising and unproven claims of effectiveness.

Insurers won't cover the expensive treatment, also known as motorized traction, and mainstream medical experts say it isn't effective.

Last month, FBI agents raided Axiom Worldwide, the Tampa, Fla., maker of the DRX 9000. Also in March, a federal judge in Atlanta ordered Axiom to stop making false marketing claims.

In California, a number of district attorneys, including those in Santa Clara, Santa Cruz and Monterey counties, are jointly investigating chiropractors' marketing of spinal decompression

machines including the DRX 9000. They expect to complete the investigation this summer. Penalties for local chiropractors could be harsh: Two Monterey County chiropractors were fined \$25,000 each last year for deceptive advertising of the machines, although their fines were later reduced.

Company officials did not return repeated phone calls from the Mercury News. A Santa Cruz attorney for Axiom Worldwide, Paul Meltzer, said the issues were "under investigation" and declined to comment further.

At least three South Bay chiropractors regularly

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advertise treatments on the machines in the Mercury News.

Intense competition

The spinal decompression industry is intensely competitive, with major players suing each other and their contractors over marketing claims and breaches of contract. The various machines look different but all purport to work by stretching the spine to increase the space between the spinal discs that act as shock absorbers between vertebrae.

At least 1,000 machines are in use in the United States under brand names such as DRX 9000, VAX-D, Accu-Spina and DRS, according to a trade publication called the Anesthesia & Pain Coders Pink Sheet, which has closely followed the industry. New machines can cost more than \$140,000 while used machines - and \$595 advertising kits - are easily found on eBay. Chiropractors have aggressively marketed treatment with the machines through newspaper ads and infomercials.

Some claims have gotten manufacturers and chiropractors in trouble.

Ruling on a lawsuit filed by a competitor, the federal judge in Atlanta told Axiom to cease claims that the machine is based on NASA space research (it isn't) and that it's approved by the U.S. Food and Drug Administration (the machine was never evaluated for effectiveness, but grandfathered in because it's similar to existing medical devices).

Around the country, chiropractors also have been held accountable for making false claims and fraudulently billing Medicare and other insurers for the treatment.

Last year, two Georgia chiropractors received near-three-year prison terms for fraudulently billing Blue Cross and Blue Shield of Georgia nearly \$2 million for spinal decompression treatments on a VAX-D machine. Most insurers, including Medicare, do not cover the treatment. The chiropractors were accused of falsifying the treatment provided to ensure payment.

Five months after his first spinal decompression treatment, Dorjath said, he still experiences random pain and tingling from his toes to his thighs. His rehabilitation physician believes the machine irritated the nerves around his spine and caused a disc to protrude from his spine, Dorjath said.

When Dorjath was considering the treatment in November, the \$6,000 cost for 20 sessions on the machine seemed expensive, but he was desperate. His already bad back worsened after an encounter with a flying golf ball. Dorjath had received steroid injections from his family doctor, but they weren't working anymore. And his toes were starting to tingle uncomfortably.

Dorjath liked his chiropractor's bedside manner and the fact that he really seemed to care about his pain. Brad Pluckhan, who has offices in Campbell and Gilroy, told Dorjath that the worst that could happen was that he wouldn't get better, Dorjath said.

When he felt pain after two weeks of sessions on the machine, he stopped treatment and Pluckhan refunded his money, Dorjath said.

But for weeks afterward, Dorjath said, he found it difficult to walk, play golf, get out of a chair and turn over in bed. The two are now in arbitration over whether Pluckhan should make other reparations.

'Great addition'

Pluckhan told the Mercury News that the machines have been a "great addition" to his practice. The chiropractor declined to comment on Dorjath's experience, citing patient confidentiality. But he said that clients who have experienced problems with the treatment have not followed strict recommendations such as avoiding exercise, bending, twisting or pushing during the first two weeks of treatment.

That said, Pluckhan acknowledged, "We absolutely agree that this is not a one-hit wonder. It's not going to work on every patient."

Other patients of Pluckhan's, however, sing the machine's praises.

"After the third treatment, I could see a big difference," said Debbie Cino, 54, of San Jose. Cino said an extra vertebra in her back made it difficult for her to sit or stand for long periods, and the treatment helped. "I think it's wonderful," she said.

Doctors say that patients like Cino may have been helped by the machine, but it's also possible that the treatment provides a powerful placebo effect that relieves pain, they say. Some patients' back pain also resolves on its own, but patients may credit their spinal decompression instead, doctors say.

Ideally, medical studies would help answer those questions, but solid research on spinal decompression machines is skimpy at best.

Axiom's marketing materials have claimed that scientific studies proved the machines work to relieve back pain by up to 86 percent. But any studies showing a positive effect were either sponsored by other machines' manufacturers or were poorly designed. There is no published research on the DRX 9000.



Even a literature review co-written by Dr. Alex Macario, a Stanford University anesthesiologist and researcher, and funded by Axiom Worldwide, concluded that the effectiveness of these types of machines for chronic low-back pain is "unproven."

Dr. Harley Goldberg, a Kaiser Permanente physician who oversees the health-maintenance organization's spine care services in Northern California, goes further and condemns the machines. Spinal decompression machines merely offer a new, mechanized twist on old-fashioned traction for back pain - which rigorous medical studies have shown doesn't work, he said.

"My skin crawls when I see the ads, because they take advantage of people in pain," he said. "If spinal decompression actually worked, we would all use it."

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