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State Board of Healing Arts

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Kathleen Selzler Lippert, Executive Director

Laura Kelly, Governor

To: House Health and Human Services Chairperson Representative Landwehr:

From: Kathleen Selzler Lippert, JD, Executive Director
Tucker Poling, JD General Counsel
Kansas State Board of Healing Arts (KSBHA)

Date: March 20, 2019

Subject: HB 2404

Position: Neutral (Verbal and Written)

The Kansas State Board of Healing Arts (KSBHA) appreciates the opportunity to provide neutral testimony on HB 2402. KSBHA licenses and regulates multiple health care professions. The mission of KSBHA is to safeguard the public and strengthen those who practice the healing arts.

HB 2404 provides legislative authority to expand corporate practice of medicine in Kansas. This is a policy decision for the legislative process. KSBHA acts pursuant to the direction of legislation; it is the legislature who determines state policy.

Recently, Kansas was ranked by a national organization as one of the best states to practice medicine. Kansas was ranked 5th overall and for medical environment; and ranked 6th best for opportunity and competition. Importantly, Kansas ranked in the 3rd best state for least expensive annual malpractice liability insurance. [See attached Best and Worst States article]

Introduction of corporate practice of medicine represents a major policy change for medical practice in Kansas and impacts medical professionals licensed by KSBHA. KSBHA needs clear legislative direction on important issues to facilitate implementing legislative intent.

- There is no language defining the license type who can practice in the proposed legislation. There are many different license types that provide limitations on practice to specific locations or scope; for instance, a training, limited or temporary license.
    - A variety of Kansas statutes provide that a person must hold a valid full active license as a prerequisite.
    - The legislature may want to consider providing clarification on license type.
- The proposed legislation may create conflicts and confusion with existing authorized medical practice structure in K.S.A. 17—2706 through 17-2720.
    - The legislature may need to carefully evaluate how new legislation intersects with pre-existing medical practice business structures to avoid confusion.

- The proposed legislation does not provide statutory authority to support meaningful regulation. It purports to create standards; however, it fails to provide clear authority to support creation of regulations to enforce those standards.
    - Example: subsection (e) creates standard that the corporate entity "shall not impose or substitute its judgment for that of the physician"
        - However, the statute is unclear about the authority of the KSBHA to enforce that standard.
        - Options to clarify enforcement authority included:
            - Defining the "business entity" as a "licensee" as defined in K.S.A. 65-2837. This would clarify that the Board's enforcement authority described in K.S.A. 65-2836 applies to an entity found to be in violation of the standard described in subsection (e). It would also trigger the requirement to report any violations of the Healing Arts Act.
            - Adding language giving the KSBHA authority to enforce the provisions of this statute by revoking the entity's certification, issuing fines against the entity and/or its principal officers, etc.
    - Regulations must be based on clear statutory authority; failure to provide the statutory authority puts the agency at risk of litigation for unlawful delegation of authority.
    - Usually, statutory structure provides requirements for regulated entities; such as:
        - Requirements to report violations of the practice act to the regulatory body.
        - Requirements to review adverse events and report adverse outcomes
        - Requirements to have policy and practices in place to review care that may be substandard
        - Requirement to adhere to medical record requirements

- To allow the KSBHA to effectively promulgate regulations to enforce this statute, the scope defined in subsection (f) should be clarified.
    - "Business entity" is defined as an employer/insurance carrier that offers medical care to its employees/enrollees, but it does not limit providing care to employees/enrollees.
        - Could a business entity provide care to its employees/enrollees and members of the public, or only its enrollees?
- Subsection (d) should be clarified to effectuate the intent (assuming we are correct as to the committee's intent) to include these entities in the vicarious liability protections provided in the Fund statutes (K.S.A. 40-3401 et. seq). The current language could be perceived as in conflict with the vicarious liability protection intended by including these entities as a "health care provider" under the Fund statutes.
    - Compliance with this statute would qualify the entity as a "health care provider" and trigger the Fund's protection from vicarious liability. However, subpart (d) indicates compliance with this section cannot relieve the entity from vicarious liability. This could trigger litigation.

- The nature and extent of appropriate regulation reflects policy set thorough the legislative process. Examples that illustrate decisions that may not hold patient safety and public protection to legislative standards, and can be made by corporations, business entities, or licensees are seen in a variety of headlines; and include:

- "A JoCo man got sick during a vitamin IV at Kansas City Spa. Four days later he died"; March 5, 2019 KC Star headline. [See attached article]
- Horton and Oswego hospitals closed due to foreign corporation decisions. [See attached article]
- "State, federal lawsuits accuse fonder of Denver area clinic of fraud"; September 2015. [See attached article]
- "Labia Lipstick" new product launched by Mensez company is example of unapproved / untested treatment, product, or devise that business entity have medical providers implement. [See attached article]
- Corporate scandals are not isolated or unique. [See attached article listing corporate scandals]

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2017's Best & Worst States for Doctors

Mar 27, 2017 | John S Kiernan, Senior Writer & Editor

Doctors are among the highest-paid and most educated professionals in the U.S. Just consider the fact that "physician" is the most popular profession within the top 1 percent of earners. Doctors are deserving, after all, given the importance of their life-saving work and the struggles associated with life in the medical profession.

Not only did the average medical-school graduate leave campus with more than $189,000 of debt in 2016, but the medical profession has also been undergoing intense transformation in recent years. Health-care reform, the rise of branded hospital networks and the retirement of Baby Boomers are all complicating the lives of doctors and warranting pause from potential whitecoats.

It's therefore fair to expect a certain measure of difference in terms of the working environments faced by doctors across the nation. So in order to help doctors make the most informed decisions regarding where to practice, WalletHub's analysts compared the 50 states and the District of Columbia across 14 key metrics. Our data set ranges from average annual wage of physicians to hospitals per capita to quality of public hospital system. Check out the complete ranking, additional expert commentary to help local governments identify policy initiatives and our detailed methodology below.

Main Findings

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2016's Best & Worst Cities to Start a Career
2017's Best & Worst Cities for Jobs
2017's Hardest-Working Cities in America
2016's States with the Best & Worst Health Care

Best Offers
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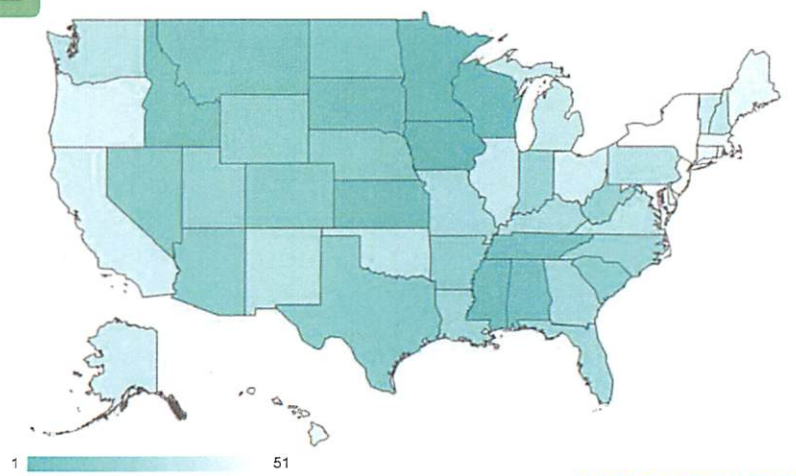

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Best States to Practice Medicine

Overall Rank	State	Total Score	'Opportunity & Competition' Rank	'Medical Environment' Rank
1	Iowa	68.67	2	6
2	Minnesota	66.40	8	1
3	Idaho	66.31	3	11
4	Wisconsin	65.66	10	2
5	Kansas	65.15	6	5
6	South Dakota	63.24	1	42
7	Montana	63.13	4	22
8	Mississippi	62.40	5	23
9	Alabama	61.05	11	9
10	Tennessee	59.56	15	14
11	North Dakota	59.19	14	13
12	Nevada	57.44	17	19
13	Colorado	57.12	16	24
14	Arizona	56.96	13	32
15	Nebraska	56.91	12	34
16	Texas	56.53	23	4
17	Wyoming	55.88	7	47
18	South Carolina	55.60	26	3
19	Utah	54.90	19	11
20	Arkansas	54.75	24	7
21	West Virginia	54.75	9	43
22	Indiana	53.05	25	16
23	North Carolina	52.18	32	10
24	Florida	52.01	22	26
25	Louisiana	51.56	20	35
26	Georgia	51.47	29	21

Best Cash-Back Credit Cards
Best Business Credit Cards
Best Airline Credit Card
Best Balance Transfer Credit Cards

Free Credit Data

Free Credit Score
Free Credit Report
Free Credit Monitoring

Popular Content

Credit Cards for Bad Credit
Student Credit Cards
0% APR Credit Cards
No Foreign Transaction Fee Credit Cards
Business Credit Cards
Chase Sapphire Preferred
Capital One Venture
Citi Double Cash
Capital One Quicksilver
American Express Blue Cash

Contact us to interview one of our experts

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Overall Rank	State	Score	Competition' Rank	Environment' Rank
27	Missouri	50.88	33	20
28	Kentucky	50.01	30	27
29	Washington	49.92	31	25
30	New Mexico	49.89	21	40
31	Pennsylvania	49.08	18	44
32	Virginia	48.81	37	18
33	Oklahoma	47.72	34	33
34	New Hampshire	47.37	28	39
35	Michigan	46.91	36	30
36	Illinois	45.89	27	45
37	Alaska	44.92	40	29
38	Vermont	44.87	39	15
39	Ohio	44.61	38	38
40	California	44.48	46	8
41	Oregon	44.14	45	17
42	Delaware	42.95	35	48
43	Hawaii	41.99	41	31
44	Maine	40.60	42	36
45	Connecticut	38.33	49	28
46	Massachusetts	37.85	47	37
47	Rhode Island	36.84	43	49
48	Maryland	36.45	44	50
49	New Jersey	34.48	48	46
50	District of Columbia	33.72	51	41
51	New York	28.49	50	51

Highest Avg. Annual Wage for Physicians (Adjusted for Cost of Living)

1. Indiana
2. Mississippi
3. Georgia
4. Iowa
5. Wyoming

Lowest Avg. Annual Wage for Physicians (Adjusted for Cost of Living)

47. Connecticut
48. Rhode Island
49. New York
50. Hawaii
51. District of Columbia

Lowest Projected Competition by 2024

1. Idaho
2. Nevada
3. Alaska
4. Mississippi

Highest Projected Competition by 2024

45. Massachusetts
46. New York
T-47. Connecticut
T-47. District of Columbia

Best State vs

16x Difference

Least Punitive State Medical Boards

1. South Carolina
2. District of Columbia
3. Minnesota
4. Massachusetts
5. Connecticut

Best State
vs
Worst State

5x Difference

Most Punitive State Medical Boards

47. New Mexico
48. Delaware
49. Ohio
50. Louisiana
51. Wyoming

Lowest Malpractice Award Payout Amount per Capita

1. North Dakota
2. Minnesota
3. Wisconsin
4. Texas
5. North Carolina

Best State
vs
Worst State

35x Difference

Highest Malpractice Award Payout Amount per Capita

47. Rhode Island
48. Massachusetts
49. Pennsylvania
50. New Jersey
51. New York

Least Expensive Annual Malpractice Liability Insurance

1. Wisconsin
2. Minnesota
3. Kansas
4. Indiana
5. Iowa

Best State
vs
Worst State

6x Difference

Most Expensive Annual Malpractice Liability Insurance

35. West Virginia
36. District of Columbia
37. Michigan
38. Illinois
39. New York

Ask the Experts: The Future of the Medical Profession

Medicine is changing rapidly, and the manner in which it is taught and practiced must adapt accordingly. The industry not only faces an aging population as well as new regulations, but it also must keep pace with technological breakthroughs and make sense of hospital reorganization and rebranding. With that in mind, we sought insight from medical professionals, business experts and public-policy researchers into the future of the medical profession. You can check out our panel as well as the questions we asked them below.

1. How will the various proposals for dismantling the Affordable Care Act, or ACA, affect doctors?
2. What are the biggest issues facing doctors today?
3. How do state and local policies influence the lives of doctors and other medical professionals?
4. What tips can you offer current medical students about what specialty to pursue and where to practice?

5. To what extent does the threat of a malpractice lawsuit affect doctors ability to do their job?
6. In evaluating the best states for doctors, what are the top five indicators?
7. Taken altogether, has the ACA proven to be a net positive or net negative for physicians?

Timothy Hoff
Professor of Management, Healthcare Systems, and Health Policy and Patrick & Helen Walsh Research Professor in the D'Amore-McKim School of Business at Northeastern University

Michael D. Frakes
Professor of Law in the School of Law at Duke University

R. Gregory Cochran
Lecturer in Law and Associate Director of the UCSF/UC Hastings Consortium on Law, Science & Health Policy at UC Hastings College of the Law

Dana Goldman
Leonard D. Schaeffer Director's Chair of the Schaeffer Center and Distinguished Professor of Public Policy, Pharmacy & Economics at University of Southern California

Christopher Plein
Eberly Family Professor for Outstanding Public Service and Professor of Public Administration in the John D. Rockefeller IV School of Policy and Politics at West Virginia University

Christine Nero Coughlin
Director and Professor of Legal Analysis, Writing and Research in the School of Law at Wake Forest University

Bill Freeman
Director and Chair of the Master of Public Health Program at The Chicago School of Professional Psychology

Ann Marie Marciarille
Professor of Law at UMKC School of Law

David Orentlicher
Samuel R. Rosen Professor of Law and Co-director of the William S. and Christine S. Hall Center for Law and Health at Indiana University – Purdue University Indianapolis

Denise M. Hill
Director of Health Law Programs at Drake Law School and Of-Counsel Attorney/Mediator at Whitfield & Eddy Law Firm

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Timothy Hoff

Professor of Management, Healthcare Sys
Helen Walsh Research Professor in the D'
Northeastern University

What are the

The biggest is somewhat by growing chall reimbursed; in the need to tu and health car workdays to carry them out. The doctor these developments, and that is somet surveys show that relationship is a key

Reimbursement increasingly is tied to o physicians may not feel they can contro care doctors must deal with more patie be seen. Another big issue is the high l seen across the profession as a whole. most physicians remains a top priority.

What tips can you offer current medic pursue and where to practice?

Having studied the primary care system reward can come to students who choo Highly technical specialties may pay m associated with them, but I have come family physicians, and pediatricians in m cutting edge world of high-tech medici specialties like neurology or orthopedic

But right now, there is a great need nat and salaries in those fields are going u depends somewhat on the specialty. T doctor is what type of place and emplo preferences for how you see yourself p guiding factor in figuring where to hang

How will the various proposals for dis

Doctors have been asked to adapt to a past decade. The impending changes t change to their everyday worlds. These relationships that have become more e

Methodology

In order to identify the best states for doctors, WalletHub's analysts compared the 50 is states and the District of Columbia across two key dimensions, namely "Opportunity & Competition" and "Medical Environment."

s We evaluated those dimensions using 14 relevant metrics, which are listed below with their corresponding weights. Each metric was graded on a 100-point scale, with a score ver of 100 representing the most favorable conditions for practicing doctors.

ce, We then calculated the overall score for each state and the District based on its to weighted average across all metrics and used the resulting scores to construct our final ranking.

Opportunity & Competition – Total Points: 70

- Physicians' Average Annual Wage: Double Weight (~12.72 Points)
  Note: Data for this metric were adjusted for the cost of living.
- Physicians' Average Monthly Starting Salary: Full Weight (~6.36 Points)
  Note: Data for this metric were adjusted for the cost of living.
- Hospitals per Capita: Full Weight (~6.36 Points)
- Insured Population Rate: Full Weight (~6.36 Points)
  Note: "Population" includes noninstitutionalized civilians aged 16 and older.
- Primary-Care Provider Shortage: Full Weight (~6.36 Points)
  Note: This metric measures the percentage of the population living in a primary-care HPSA, or Health Professional Shortage Area. HPSAs, as defined by the Health Resources & Services Administration, "are designations that indicate health care provider shortages in: Primary care; Dental health; or Mental Health" and "may be geographic-, population-, or facility-based.".
- Projected Share of Elderly Population: Full Weight (~6.36 Points)
  Note: This metric measures the projected percentage of the population aged 65 and older by 2030.
- Current Competition: Full Weight (~6.36 Points)
  Note: This metric measures the number of physicians per 1,000 Residents.
- Projected Competition: Full Weight (~6.36 Points)
  Note: This metric measures the projected number of physicians per 1,000 Residents by 2024.
- Number of CME Credits Required: Full Weight (~6.36 Points)
  Note: "CME" stands for Continuing Medical Education, credits for which the state may require medical professionals to earn in order to maintain their licenses.
- Presence of Interstate Medical Licensure Compact Law: Full Weight (~6.36 Points)
  Note: This metric is based on data from the Interstate Medical Licensure Compact and considers whether compact legislation has been enacted, introduced or not been introduced.

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Medical Environment – Total Points: 30

- Quality of Public Hospital System: Full Weight (~7.50 Points)
  Note: This metric is based on data from the Centers for Medicare & Medicaid Services.
- Punitiveness of State Medical Board: Full Weight (~7.50 Points)
  Note: This metric measures the number of serious disciplinary actions (per 1,000 physicians) taken by the state medical board.
- Malpractice Award Payout Amount per Capita: Full Weight (~7.50 Points)
- Annual Malpractice Liability Insurance Rate: Full Weight (~7.50 Points)

Sources: Data used to create this ranking were collected from the U.S. Census Bureau, Bureau of Labor Statistics, Council for Community and Economic Research, Health Resources & Services Administration, Projections Central's

more individuals had gained insurance
able to see a regular doctor over time. I
these changes to the ACA, which is like
more out-of-pocket for their health care
less, as people wait longer to access ca

Physicians will also begin to feel more p
understand how their insurances work;
been met yet; and which types of healtl
important to get in the short-term, and
involved. In short, physicians more than
for their patients.

Taken altogether, has the Affordable
positive or net negative for physicians

The Affordable Care Act was largely m
more individuals in our country. That w
successful in that regard as upwards of
insured. The ACA did not necessarily d
some of the dysfunctional aspects of th
a physician's work life quality. It has inc
all doctors, without giving them additio
demand.

The ACA has also promoted what I wou
oriented view on health care delivery, w
negatively than positively received by i
stressed and overloaded with administr
demands, and having to prove constan
meeting efficiency and quality goals se
doctors specifically have not seen the
primary care medicine that the ACA wa
physicians continue to work under adv
reimbursement and workload perspecti
do not seem likely to alleviate any of th

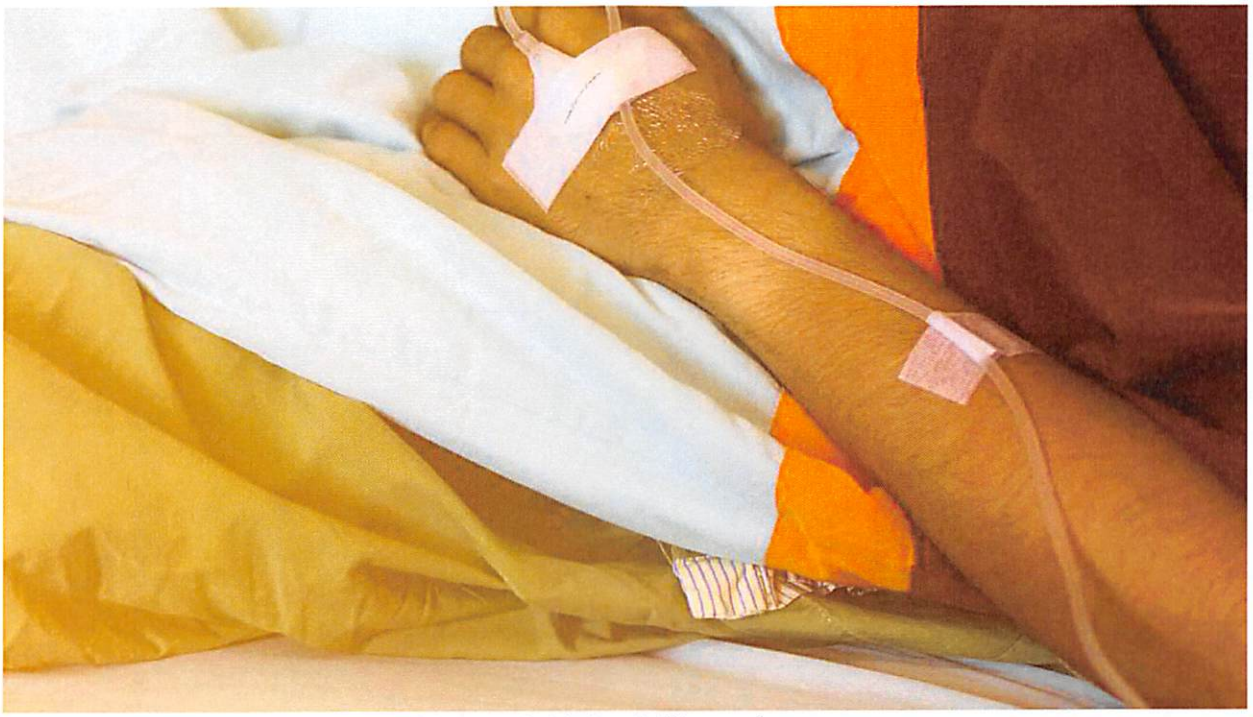
A JoCo man got sick during a vitamin IV at Kansas City spa. Four days later he died

The Kansas City Star

BY ANDY MARSO

MARCH 05, 2019 05:30 AM,

UPDATED MARCH 05, 2019 08:18 PM



File photo of a man lying on a bed with an IV in his hand. *Bigstock*

A 64-year-old Johnson County man went to a Brookside spa for an intravenous infusion of vitamins — a holistic treatment that's becoming trendy despite skepticism from the medical establishment.

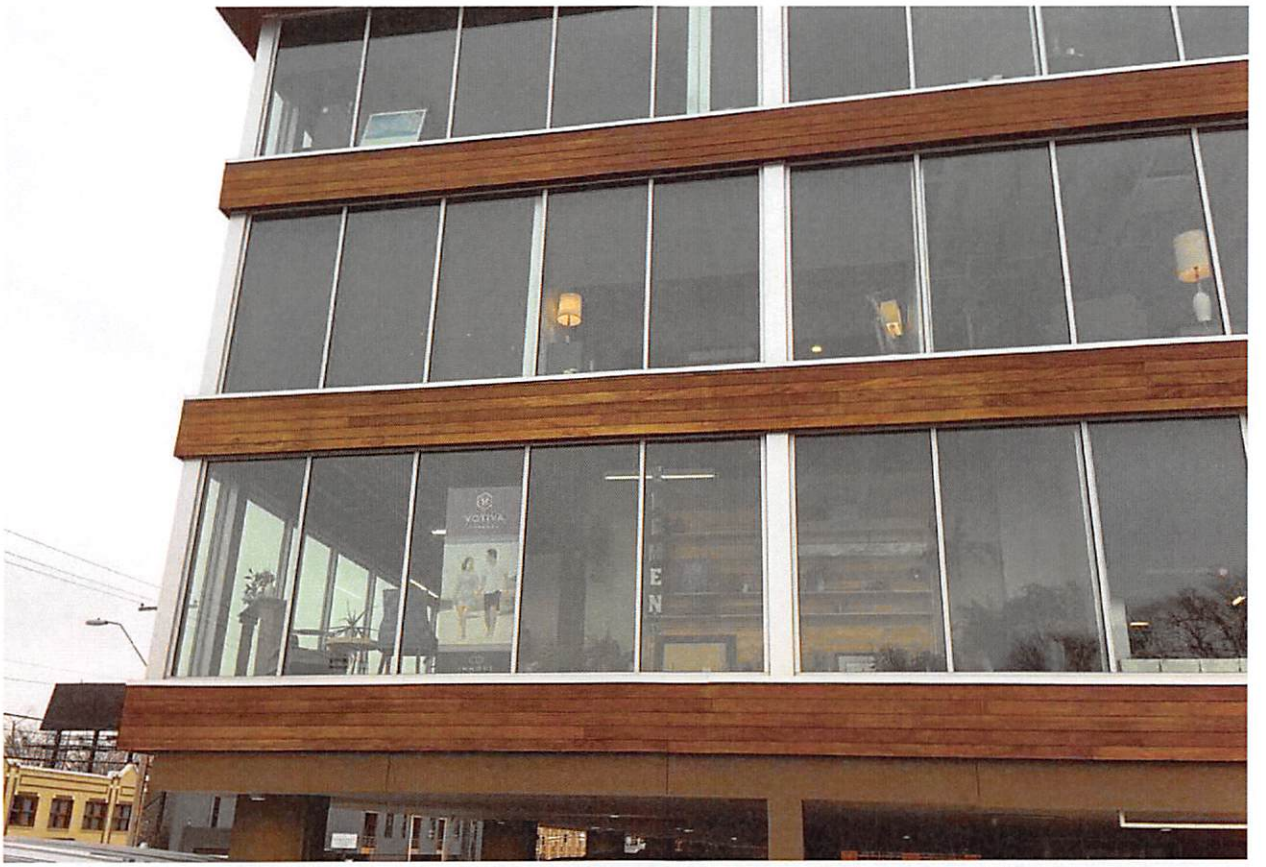
It was the 12th infusion he'd had in the previous three months. But this time was different.

About 10 minutes after the IV started the man felt like his skin was crawling. He started throwing up. The IV was stopped and he went home, where the vomiting continued and he spiked a fever of 103 degrees. The next morning he was admitted to the University of Kansas Hospital with symptoms of organ failure.

Three days later he died.

Authorities have not linked his death to the IV he received at Element Wellness Spa Studio on Nov. 30. But the case has medical professionals questioning whether evidence at the spa was thrown away. And they question whether the growing non-medical IV industry needs more oversight.

The spa's physician, Kelly Logan, didn't respond to multiple requests for comment.



A Johnson County man became ill during an IV vitamin infusion at Element Wellness Spa Studio and died five days later. Element Wellness is on the second floor of an office building at 601 E. 63rd St. in Brookside.

The Star is not identifying the man who died by name because his family has asked for privacy.

His autopsy report, compiled by the Jackson County medical examiner's office, says he died because of underlying medical conditions. But the report said those conditions raise questions about whether he should have been given the IV infusion in the first place.

"It is important to assess the overall health of individuals seeking intravenous vitamin infusion therapy, including laboratory studies to assess kidney and liver function prior to the initiation of therapy," the report says.

The autopsy says that extensive blood tests performed at KU for bacterial, viral and fungal infections came back negative. The man's official cause of death was organ failure due mainly to cirrhosis of the liver, with contributing factors of high blood pressure and obesity.

But Stanley Goldfarb, a kidney specialist at the University of Pennsylvania Hospital who has been critical of the elective IV industry, said it would have been impossible to rule out an infection from the IV without examining the materials that were used at Element Wellness.

"It certainly sounds like something happened in the infusion," Goldfarb said. "Unless the authorities obtained some cultures or chemical analysis of what was infused, it is impossible to know for sure. Toxins can be in the infused material, even bacteria, and not show up on culture or assessment of the patient."

Goldfarb said that if the man had taken ill during an IV at a hospital, all of the materials would have been tested for signs of contamination.

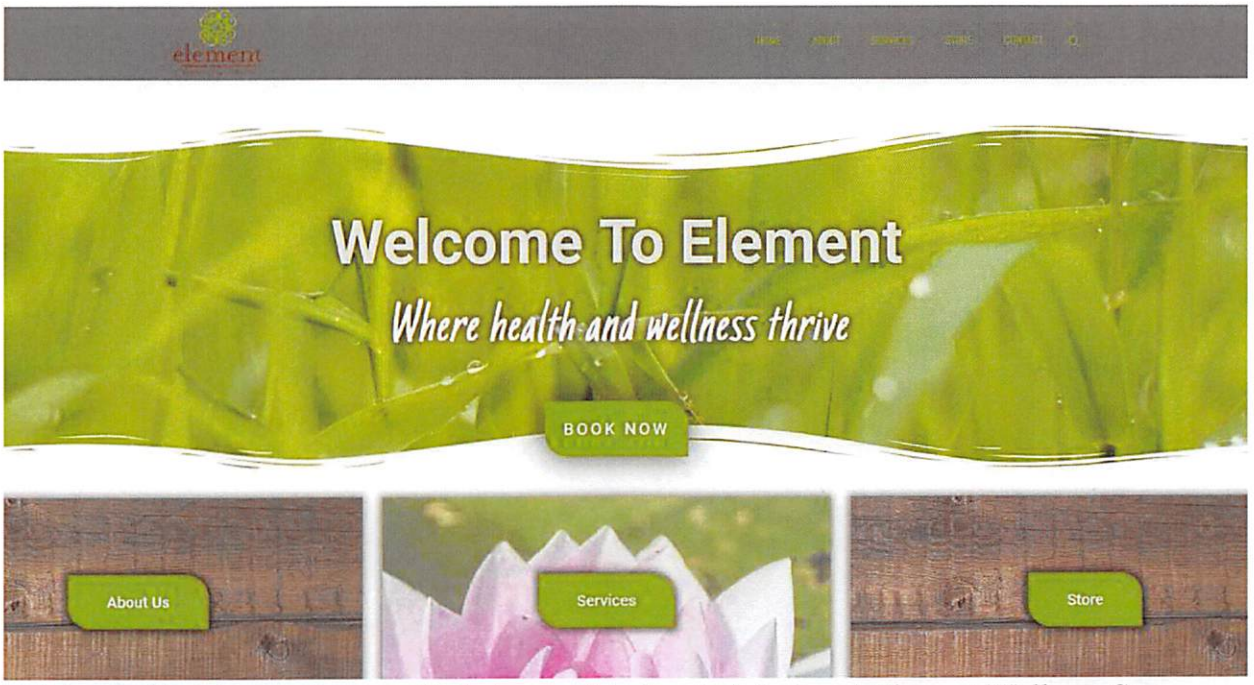
But the Jackson County medical examiner wasn't able to do that in this case.

"According to KU (Hospital), the infusion center told KU that the materials had been discarded," medical examiner spokeswoman Marshanna Hester said via email. "As such, there were no materials for the M.E.'s office to examine."

Randall Williams, director of the Missouri Department of Health and Senior Services, said wellness spas aren't among the medical facilities regulated by his department. But in the wake of the Johnson County man's death, he said, it may be time to update those regulations.

He also said the state medical board should scrutinize whether physicians at wellness spas are providing substandard care that puts people at risk.

"That is an appropriate thing for the Missouri Board of Healing Arts to consider and it's an appropriate thing for us to look into — do we have a gap in our regulations?" Williams said.



A Johnson County man became ill during an IV vitamin infusion at Element Wellness Spa Studio and died four days later.

Elective infusions of vitamins began in Las Vegas, where they were touted both as a treatment for hangovers and a way to maintain health. They've since spread nationwide, thanks in part to testimonials from celebrities like the singer Adele. There are now several companies in Kansas City that provide elective IVs, at wellness spas and sometimes in clients' homes.

The medical establishment has expressed skepticism, though, saying most Americans get all the vitamins they need by mouth and there are real risks every time a needle is inserted into a vein to put a substance directly into someone's bloodstream, even by a medical professional. A 2013 study in England found that as many as 20 percent of hospital patients who got an IV suffered complications because it wasn't done correctly.

Other Kansas City-area physicians have faced scrutiny from the Kansas medical board for elective IVs.

The board suspended a doctor and a chiropractor last year from working at IV Nutrition in Overland Park, saying that the site didn't have proper controls over dosages of potentially harmful substances like magnesium and that a customer who came into the clinic with nausea and vomiting didn't get properly examined before being given an IV.

The two have since had their licenses reinstated after they agreed to change the way they practice. Their lawyer, Brian Niceswanger, said they had agreed to have the doctor review potential clients' electronic medical histories before they're given IVs.

When Meredith Leach Snyder applied for a Kansas physicians' license to expand her mobile IV business across the state line last year, the Kansas Board of Healing Arts said her company didn't meet its standards for medical record-keeping or having plans in place for patients who have allergic reactions.

Snyder was granted a license after she changed her practices, but was also required to take a medical record-keeping seminar and have her charts monitored for six months to ensure her company stays in compliance.

By the time the Johnson County man got to KU Hospital, there was probably little anyone could have done to save him, Goldfarb said after reading the autopsy report. He said the death merits more investigation.

"Certainly patients can develop such a clinical picture without having an infusion," Goldfarb said via email, "but the acuity of the reaction and the proximity to the infusion make one very concerned that there may have been a causal link."

ANDY MARSO

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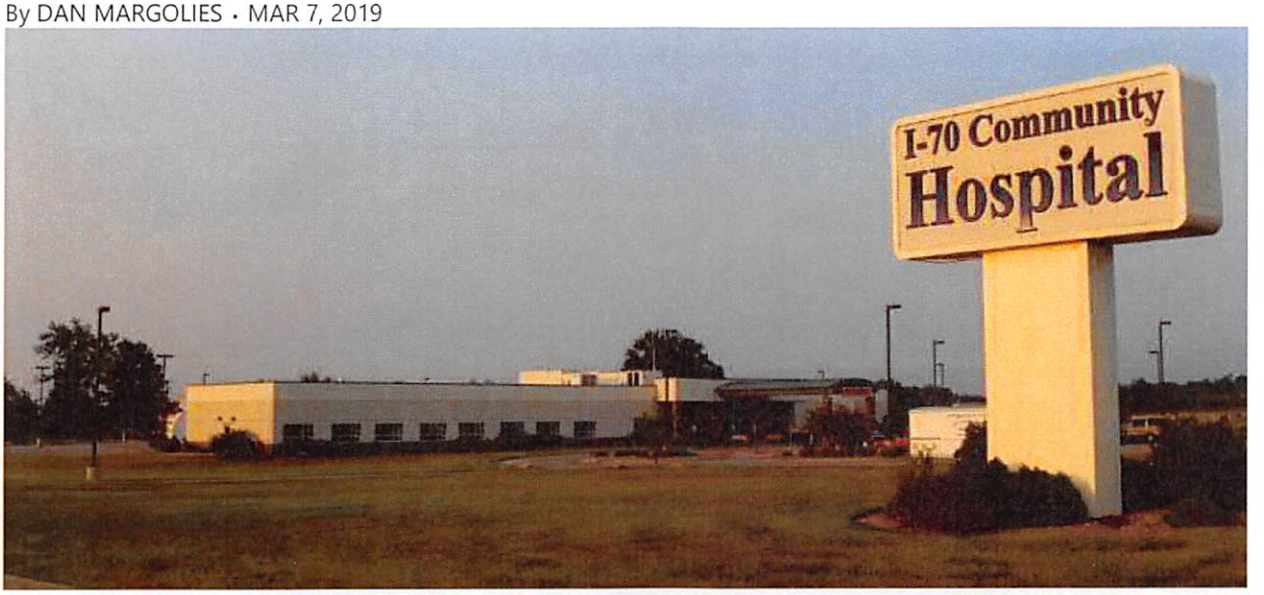
Kansas City Star health reporter Andy Marso was part of a Pulitzer Prize-finalist team at The Star and previously won state and regional awards at the Topeka Capital-Journal and Kansas Health Institute News Service. He has written two books, including one about his near-fatal bout with meningitis.

Another Rural Hospital Once Owned By North Kansas City Company Is In Dire Straits

By DAN MARGOLIES · MAR 7, 2019



The federal government has terminated I-70 Community Hospital's Medicare contract, citing deficiencies that jeopardized patients' safety.

In mid-February, I-70 Community Hospital in Sweet Springs, Missouri, took the unusual step of voluntarily suspending its own license after state regulators said it was "out of regulatory compliance."

The 15-bed critical access hospital said it planned to reopen in 90 days. But now the path forward has become steeper.

On Thursday, the Centers for Medicare & Medicaid Services cut off the hospital's participation in the Medicare program. CMS cited deficiencies that are "so serious they constitute an immediate threat to patient health and safety."

The rural facility, about 65 miles east of Kansas City, is the latest hospital once run by EmpowerHMS, which used to be based in North Kansas City, to find itself in regulatory and financial trouble.

Empower is no longer in charge at I-70 Community Hospital. A court-appointed receiver, Cohesive Healthcare Management & Consulting of Shawnee, Oklahoma, is now running the show, and it says it plans to contest CMS's decision.

"We're in the process of developing an appeal to that," said the hospital's interim CEO, Roland Gee. "Our corporate staff and legal staff are beginning to work on that."

The hospital opened more than a dozen years ago and employed about 50 people.

The hospital and an adjoining clinic remain closed, but Gee said the hospital is working on a plan to address the deficiencies that would allow the hospital and clinic to reopen. He declined to go into specifics other than saying it's "based on the reports that were furnished to us by CMS from their investigations."

"There are just a lot of moving parts right now," he said.

Sweet Springs has a population of around 1,400. The closest hospitals to town are in Clinton, Marshall, Sedalia and Warrensburg, Missouri.

I-70 Community Hospital's closure last month roughly coincided with the closure of another EmpowerHMS-run hospital, Oswego Community Hospital in Oswego, Kansas, about 160 miles south of Kansas City. The 12-bed facility closed abruptly after saying it was unable to cover its operating expenses.

Two other hospitals once run by EmpowerHMS – Hillsboro Community Hospital in Hillsboro, Kansas, and Fulton Medical Center in Fulton, Missouri – have been placed under new management after they struggled to make payroll and meet other financial obligations, and ran short on supplies.

Adding to Hillsboro Community Hospital's woes, CMS recently cited it for serious deficiencies, including a failure to follow its chest-pain procedures for three patients with cardiac complaints and two patients for suicidal thoughts. CMS also said the hospital had failed to provide laboratory services "for medical management of emergency conditions."

The hospital's CEO did not return a call seeking comment.

Other hospitals run by EmpowerHMS have experienced similar financial problems recently. Last week, an Oklahoma judge ruled that Fairfax Community Hospital in Fairfax, Oklahoma, was insolvent and named a receiver to take over its operations. And as of last week, employees of Horton Community Hospital in Horton, Kansas, had not been paid since Feb. 15.

In January, Florida-based iHealthcare entered into agreements with Jorge A. Perez, the Florida resident who led EmpowerHMS, to provide hospital management services to Empower's hospitals. In exchange, Perez was eligible for about $2.5 million in "success fees" if certain conditions were met.

The hospitals covered by the agreements included I-70, Oswego, Hillsboro, Fulton, Fairfax and Horton. Other hospitals covered by the agreements are:

- De Queen Hospital in De Queen, Arkansas
- Drumright Community Hospital in Drumright, Oklahoma
- Haskell County Community Hospital in Stigler, Oklahoma

- Lauderdale Community Hospital in Ripley, Tennessee
- Prague Community Hospital in Prague, Oklahoma
- Regional General in Williston, Florida
- Washington County Hospital in Plymouth, North Carolina

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NEWS > HEALTH

State, federal lawsuits accuse founder of Denver-area clinic of fraud

By **KIRK MITCHELL** | kmitchell@denverpost.com | The Denver Post
September 5, 2015 at 2:06 pm

The founder of a Denver-area addiction clinic claims she and her staff have cured up to 90 percent of her 6,000 drug-addicted clients by repairing damaged brain synapses with a patented genetic formula she invented.

"Give us 3 days and we'll get you clean ... give us 10 days and we'll repair the damaged neurotransmitters & receptors in your brain ... give us 30 days and we'll give you your joy back ... give us 60 days and we'll give you a new lease on life," Aminokit Labs advertises online.

But some question whether the treatments — which typically cost thousands of dollars — are effective, and a series of Colorado and federal lawsuits have accused Aminokit's founder, Tamea Rae Sisco, of fraud, racketeering and practicing medicine without a license.

In addition, the Colorado Medical Board is investigating whether Sisco violated a 2007 federal court injunction that prohibited her from practicing medicine, said Cory Everett, chief of staff of the Division of Professions and Occupations in the state Department of Regulatory Agencies.

Five civil lawsuits have been filed against Sisco's businesses in the past six years. One, a settled federal case, accused Lone Tree-based Aminokit of causing a client to become very ill.

Four other civil lawsuits, which are still winding through state and federal courts, accuse Aminokit of allegations including that an employee sexually assaulted a female client and another employee showed a client where to get heroin.

Sisco had her Kansas chiropractic license revoked in 1997 for fraud after she claimed she was a medical doctor and for having unlicensed people performing chiropractic procedures, according to the revocation order. Her Colorado chiropractic license was revoked in 2005 for practicing outside her area of expertise.

Sisco continues to operate, often under different company names, drawing clients from around the country, according to the lawsuits.

"The reason I brought these suits was to protect the public because the government has not done its job in regulating Sisco," said Denver attorney J. M. Reinan, who filed four of the cases against Aminokit on behalf of five of Sisco's former clients.

Sisco then sued Reinan, accusing him of libeling her business. Sisco declined to comment further, and her attorney declined to comment. Denver District Judge Ronald Mullins dismissed Sisco's lawsuit against Reinan on May 27, court records show.

Run afoul of regulations

A Denver Post review of records from Colorado and Kansas, as well as state and federal court filings, shows that Sisco and her employees have run afoul of regulations while running a series of seemingly unrelated health care businesses for years.

She opened her first drug treatment business in Colorado, called Excel Treatment, in 1999, two years after the Kansas State Board of Healing Arts revoked her chiropractic license. It cited nine violations, including fraud and abetting an "unlicensed, incompetent or impaired person."

Sisco has been associated with multiple physicians whose medical licenses were sanctioned and one employee who was criminally charged.

Albert Celio, a former emergency room physician, was one of the first physicians Sisco contracted to work with at Excel.

After he began working with Sisco, Celio was indicted in 2001 for prescribing medicine without medical necessity in an unrelated clinic. In 2002, a federal prosecutor called his work at Excel "highly inappropriate" given the pending charges. Celio was convicted and sentenced to 27 months in prison in 2005.

At the time of Celio's conviction, Sisco told a Denver Post reporter that she fired Celio, saying, "we don't even want to be associated with him."

Contacted by phone, Celio said he worked with Sisco from about 2001 to 2003. He relinquished his medical license in 2006 but is now seeking reinstatement, he said.

Former Aminokit clients have claimed they not only weren't cured, but that the treatments left them with adverse effects.

In 2005, Dennis Maes, one of Sisco's addiction clients, was taken to Exempla Lutheran Hospital with pneumonia following treatments at Excel.

Maes' pulmonologist, Dr. Jeffrey Sippel, learned that Maes received IV treatments containing L-tryptophan, an amino acid, from Excel for treatment of alcoholism, according to a lawsuit. After Maes was on a respirator for 15 days, Sippel, in consultation with fellow pulmonologists, concluded that Maes' illness was "an adverse reaction to the L-tryptophan."

In an affidavit, Sippel questioned Sisco's product, saying it "has no recognized medical utility either by the FDA or peer-reviewed medical journals." He added: "This use does not meet community accepted standards of care."

Thornton attorney Manuel Solano filed a federal lawsuit against Sisco and her company Excel in 2009. She later settled the lawsuit out of court.

In 2012, Sisco was doing business under the Aminokit name. She had an agreement with Fairfield Inn, 1680 S. Colorado Blvd., to house patients on one floor, Rei nan's lawsuits claim. Aminokit's online ads claim drug addiction clients were cured in 10 days, the lawsuits says.

A lawsuit filed by Reinan on behalf of a woman identified only as Jane Doe in August 2014 accuses an Aminokit counselor, with no professional license, of fondling her breasts in the Fairfield Inn hotel room where she was treated.

Denver District Judge Catherine Lemon in August denied Sisco's motions to dismiss the case.

"Plaintiff has produced sufficient credible evidence of facts in support of the allegations of racketeering—namely wire fraud, computer crimes and criminal impersonation—to preclude summary judgment in favor of any of the named Defendants," Lemon said.

Overcharging patients

The types of care Sisco's businesses offer are far-ranging.

A lawsuit Reinan filed last year on behalf of Cameron George and his father, John, accuses Aminokit of charging their credit cards $7,000 for services including astrology, star chart readings, "bizarre" shock treatments and chiropractic treatments. In all, the family was charged $60,000 for genetic treatments and other services, their lawsuit in Denver District Court says.

Brandon Lassley and his mother, Julia Walker, filed a federal lawsuit in August against Aminokit, Sisco and others. Walker's primary interest in putting her son in the residential center was the promise that he would be monitored 24 hours a day, seven days a week. Lassley was paying $700 a day for acupuncture, foot massages, individual counseling and constant supervision, court records say.

But Lassley rarely was watched or treated. Lassley started hanging out at a Mexican restaurant. Brandon Flowers, an Aminokit employee assigned to be Lassley's "sober companion," helped him find a heroin dealer when he was at the residential treatment center in 2012, according to the lawsuit filed by Lassley. The following year, in 2013, Flowers was arrested in Montgomery, Ala., charged with three counts of methamphetamine distribution and possession of methamphetamine.

Lassley's lawsuit also names former Aminokit medical director Dr. Jonathan Lee as a defendant.

In 2012, when Lassley was in the program, Lee, who runs a laser tattoo, hair removal and Botox clinic, was an interim medical director, Lee said. The Colorado Medical Board suspended Lee's medical license in February of this year, finding him "guilty of a deliberate and willful violation of the Medical Practice Act" after he allegedly failed to properly treat yet another Aminokit patient.

"(Lee) provided care and treatment to 'Patient A' on an outpatient basis, attending to her severe withdrawal symptoms in a hotel room," the suspension order says.

Lee's suspension was in effect until June, when the medical board and Lee entered into a stipulation that restricts certain parts of his practice, Everett said.

Lee denies the allegations, saying that the woman never required hospitalization and was not in severe drug withdrawal.

Another former client, Kristen Ortiz, enrolled in the detoxification center in December for two weeks. At first she was told it would cost $5,000. But her credit card was charged $18,000, according to a lawsuit she filed against Sisco and Aminokit in February.

Aminokit employees called her parents and told her mother that she had a "wet" brain and that she would die within a week unless she was treated, the lawsuit says.

"Based on this extortive high-pressure sales tactic, (Ortiz's) mother gave Aminokit her credit card information and authorized a $1,900 charge for additional IV bags," the lawsuit says.

When her parents traveled from New Mexico, Sisco spoke as though she was Ortiz's physician, the lawsuit says. Defendants in the case have not yet filed a response.

When Ortiz and her parents refused to pay Aminokit any more, Sisco threatened to sue "because of your fraudulent activity ... "

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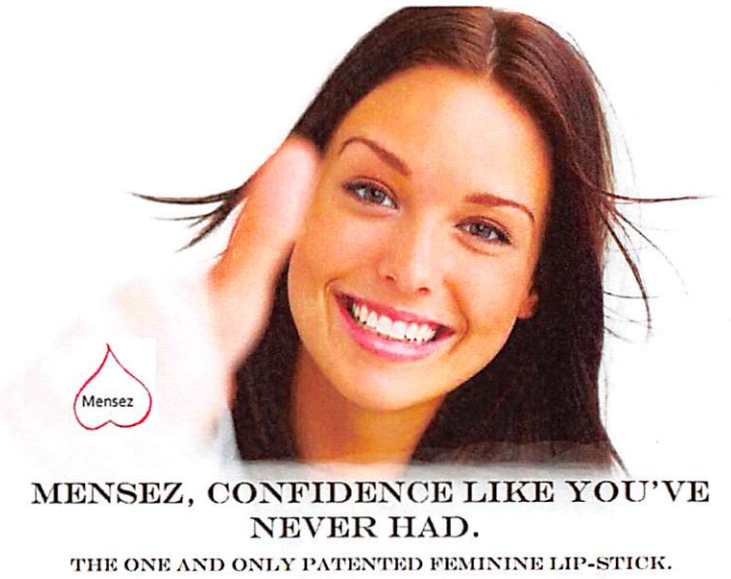


Wichita Chiropractor Dan Dopps' menstrual lipstick company 'Mensez' is a total PR nightmare

Posted by: Meko Haze in Stranger Things February 19, 2017

Wichita Chiropractor Daniel Dopps looks to launch new company Mensez that provides "Feminine Mensez Lipstick"

- The lipstick is an adhesive used to seal the vagina during menstruation until the woman goes to urinate
- Dopps owns the patent on the bizarre menstrual lipstick along with several other patents
- The Mensez Facebook page has received an overwhelming negative response despite no products being available from the company yet

UPDATE: Since the release of this article, Mensez has removed their Facebook page without warning. There is no telling if Dr. Dopps has abandoned this ridiculous idea, or if the company is simply trying to save themselves from any further embarrassment on social media. TDH will be reaching out to Mensez for comment during business hours. As of now Mensez.com is still up and running.

For centuries, women all over the world have prayed for a way to prevent menstrual leakage. If only there were a product they could trust to prevent embarrassing menstrual leaking. Thanks to a chiropractor in Wichita, Kansas, their prayers are about to be answered.

Dr. Daniel Dopps, the CEO and President at Mensez Technologies, has patented a way for women to finally stop menstrual leaking. The longer version reads as follows, according to Dopps' patent.

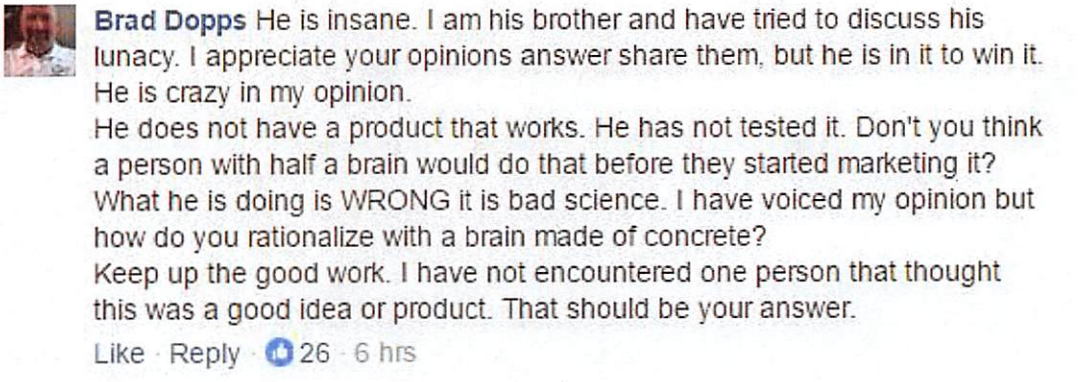
"A method for controlling menstrual flow including sphincterally contracting and expanding labia minora having left and right labium minuses, such anatomical structures moving to a closed position upon each sphincteral contraction or to an opened position upon each sphincteral expansion; adhering and disjoining the labia minora, each adhesion securing the labia minora at the closed position, the disjunctions freeing the labia minora for opening movement; and resisting and permitting menstrual flow, the resistance occurring on sphincteral contraction and adhesion, and the permission occurring upon sphincteral expansion, each adhering step disposing a hydrophobic and bio-compatible adhesive selected from acrylic adhesives, polyisobutylene adhesives, and silicone adhesives, and each disposition step utilizing an applicator selected from brushes, swabs, rub-on sticks, roll-on applicators, pump sprayers, aerosol sprayers, squeeze tube applicators, bottle applicators, and finger applicators."

Feminine Mensez Lipstick

The short version is that Dopps believes that women should glue the lips of their vagina shut with *"Feminine Mensez Lipstick."* The adhesive apparently seals the vagina and keeps in menstruation until the woman goes to urinate, ensuring the *"blood stays secure inside where it should be."*

If you think this has to be a joke, you are not alone. The Mensez Facebook page has gained some popularity, but not in a good way. The comment sections on the Mensez Facebook page has become an excellent source for entertainment.

Mensez seems only to be receiving negative feedback, and they still have yet to release a product. Aside from the concept being completely ridiculous, some are angry about how the page describes the product and the female body; such as referring to a vagina using Mensez as a *"self-cleaning shower drain."*



Included in the comments is one from Dopps own brother, Brad Dopps. In the comment on a Mensez post, a Facebook account that appears to belong to Brad Dopps refers to his brother Dan as *"insane."* Brad goes on to claim that there has been no testing of the product and that he has tried to discuss his brother's *"lunacy."*

"He is insane. I am his brother and have tried to discuss his lunacy. I appreciate your opinions answer share them, but he is in it to win it. He is crazy in my opinion.
He does not have a product that works. He has not tested it. Don't you think a person with half a brain would do that before they started marketing it? What he is doing is WRONG it is bad science. I have voiced my opinion but how do you rationalize with a brain made of concrete?

Keep up the good work. I have not encountered one person that thought this was a good idea or product. That should be your answer."

While both brothers are involved with Dopps Chiropractic, Dan is listed on the website Dopps.com, while his brother Brad is listed on DoppsChiropracticClinic.com. Both businesses are connected to two different addresses.

Is This A Joke

Many appear to be hoping that Mensez is some type of intricate trolling. A bad joke being taken too far. Surely a respected chiropractor could not honestly think this product is a good idea? After doing some research, it does not appear this is a joke at all.

On Dopps' Linkedin, the chiropractor claims to have been the CEO, President of Mensez since January 2014. In the description for Mensez, Dopps writes, *"Mensez LipStick when applied to the labia minora, creates a seal that is perspiration and blood proof but it breaks down instantly with urine, retaining menstrual fluid in the vagina until urination. Upon urinating the seal releases and allows the urine along with the menstrual fluid to exit into the toilet. Think of it as potty training the period, cleaner, healthier, more secure, less risk of infections."*

US9539077 B1

To take things to the next level, Dopps filed a patent on December 5, 2011. According to a patent search, patent US9539077 B1 has a publication date of January 10, 2017, and it is owned by Daniel A. Dopps. Dopps also has multiple patent variants for bottle capping assembly, and a resealable snack bag that has a *"set of snaps"* that are *"fixed directly onto the bag."*

According to Dopps' Linkedin, he is also the CEO, President of Wave-Cap Closures, which holds the patent for *"'On-The-Go' Beverage Caps!"* He is also the CEO, President of ClearNeon Inc, a company that sells *"UV reactive color, developed exclusively from invisible rare earth elements to create maximum color intensity when exposed to black lights."*

A PR Nightmare

The Facebook page for Mensez is a PR nightmare. Whoever is handling the social media page sounds hauntingly reminiscent of male GOP speakers who have made insensitive and uneducated comments towards the female anatomy.

According to the website, Mensez's products are still in development, which gives a clearer idea of how bad things are going with the new company. Normally it is a bad sign if you are getting a significant amount of negative feedback, and your primary product is still in development.

Comments

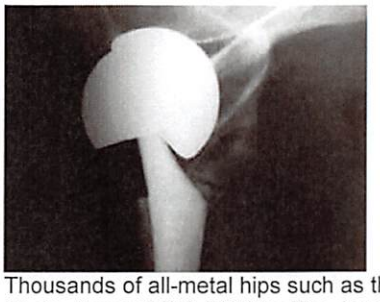
20 comments

http://thedailyhaze.com/wichita-chiropractor-dan-dopps-mensez/

Dangerous medical implants and devices

Most medical implants have never been tested for safety

Consumer Reports magazine: May 2012



Thousands of all-metal hips such as this one have been recalled.
Photo: Tower SS/© 2010 by The Journal of Bone and Joint Surgery, Inc.

Tens of millions of Americans live with medical devices implanted in their bodies—artificial joints, heart defibrillators, surgical mesh. And it's a safe bet that most of them assume that someone, somewhere, tested the devices for safety and effectiveness.

But that is rarely the case. For most implants and other high-risk devices brought to market, manufacturers do nothing more than file some paperwork and pay the Food and Drug Administration a user fee of roughly $4,000 to start selling a product that can rack up many millions of dollars in revenue. Often, the only safety "testing" that occurs is in the bodies of unsuspecting patients—including two of the three people whose stories are told in this report.

As for the smaller number of high-risk products for which advance safety studies are required, government rules allow them to be sold based on studies that are smaller and less rigorous than those required for prescription drugs.

"Standards for devices exist, they just don't make sense," says Diana Zuckerman, Ph.D., a vocal critic of the current system and president of the National Research Center for Women & Families, a nonprofit advocacy organization.

In 2011, a panel from the prestigious Institute of Medicine said the FDA should overhaul its device regulatory system because it fails to ensure patient safety before and after products go on the market. Instead, Congress is now debating a new law that would keep the present system virtually intact and ratify an agreement between the FDA and industry to get devices on the market even faster.

The FDA believes "the program has served American patients well," says Jeffrey Shuren, M.D., director of the agency's Center for Devices and Radiological Health. "As a responsible guardian of public health, the FDA believes it's a challenge to eliminate a program without having a better alternative."

But an investigation by Consumer Reports, which included interviews with doctors and patients and an analysis of medical research and a device-safety database maintained by the FDA, shows the following areas of concern:

- Medical devices often aren't tested before they come on the market. "What they're doing is conducting clinical trials on the American public," says Dan Walter, a political consultant from Maryland. His wife was left with heart and cognitive damage from a specialty catheter, cleared without testing, that malfunctioned during a procedure to treat an abnormal heartbeat.
- There's no systematic way for the government, researchers, or patients to spot or learn about problems with devices. "A coffeemaker or toaster oven has a unique serial number so if a problem is found, the company can contact you to warn you. Your artificial hip or heart valve doesn't," Zuckerman says. "Your doctor is supposed to notify you of a problem but may not be able to if he has retired or passed away."
- Without major changes in the system, there's not much that patients can do to protect themselves.

Below are stories from three people, injured by three very different devices, that highlight the dangers consumers face in the current marketplace.

Surgical mesh: No testing

Janet Holt was "in such pain I couldn't sit, I couldn't stand, and I could hardly walk."
Photo: Alexander Aleman

In 2007, Janet Holt of Floresville, Texas, felt swelling in her pelvic area. She went to her gynecologist, who told her that her bladder and uterus had prolapsed—dropped out of their normal position within her pelvis. The doctor recommended a hysterectomy and bladder lift.

"He talked about building a little bird's nest to hold my bladder up," Holt recalls. "He said I'd be back at work in two weeks." She has yet to return to work full-time on the cattle ranch and small chain of restaurants she runs with her husband.

The "bird's nest" turned out to be a sheet of synthetic mesh that was implanted by instruments inserted through the walls of her vagina. In the weeks and months after surgery, she says, "I was in such pain I couldn't sit, I couldn't stand, and I could hardly walk." Over time, the mesh shrank and shifted, eventually working its way back out of the vaginal wall, an experience Holt likens to "open cigarette burns with each step you take. It's complete torture."

Today, after eight surgeries to adjust and remove the mesh, Holt, who is suing the device manufacturer, says she has been left with painful nerve damage in one leg. "I'm 54 years old and it has totally ruined my life," she says.

Holt is one of hundreds of thousands of women implanted with transvaginal mesh for prolapse repair and bladder support since the first such products came on the market in the early 2000s. Manufacturers marketed the mesh packaged in a "kit" with tools for insertion and marketed them to doctors as an easier way to do a surgery that had traditionally required special additional training.

"The companies were saying, 'The salesman will show you how to do it,' " said Lewis Wall, M.D., professor of obstetrics and gynecology at Washington University in St. Louis. Despite thousands of reports of adverse events, repeated alarms by women's-health and consumer-health advocates, and multiple lawsuits, these products are still being sold—and are still classified as "moderate risk" devices.

In an August 2011 petition asking the FDA to take transvaginal mesh off the market, the consumer advocacy group Public Citizen called it "a 'poster-child' example of the fundamental failure ... to protect the public's health and welfare."

How did it happen? The mesh manufacturers took advantage of a loophole in the law that allowed them to grandfather their products onto the market without any advance safety testing.

Here's how it works: Before 1976, a manufacturer could sell virtually any medical device at will. That year, a new law for the first time classified medical devices into three risk categories, with clinical data required only for devices in the highest-risk category, Class III.

The FDA has yet to fully enforce even that minimal testing requirement. The agency routinely clears new devices in all three risk classes without clinical testing as long as manufacturers can show they are "substantially equivalent" to a device that has already been on the market.

And that's exactly what the makers of transvaginal mesh did. The mesh kits were cleared based on their "substantial equivalence" to an earlier mesh used to repair abdominal hernias that was sold as long ago as the 1950s, even though the kits were designed to be used in a different part of the body and inserted laparoscopically, not through open surgery.

"You're putting a foreign object into the pelvis through a contaminated space, so there's a very high potential risk of infection," Wall says. "But there weren't any clinical trials done with these products before they hit the market."

"The paradox is that companies go to the FDA and claim that a device is 'substantially equivalent,' but when they market it, they claim it's 'new and better,' " says Rita Redberg, M.D., a professor of medicine at the University of California, San Francisco, and editor of the Archives of Internal Medicine. The clearance process costs manufacturers next to nothing; they pay the FDA a user fee of $4,049.

It was only in January 2012, about 10 years after the first kits hit the market, that the FDA took action. It ordered 33 companies to conduct the first-ever post-market safety studies of the products. The agency is thinking of reclassifying those mesh kits to the highest-risk Class III.

But Shuren, at the FDA, notes that with the government's rule-making process, "from the time the FDA decides to upclassify a device to the time it can actually do it can take years."

Lap-Band: Minimal testing

Lisa Wilson's weight-loss device had to be removed after it cut into her stomach.
Photo: Inti St. Clair

In 2009, after many unsuccessful diets, Lisa Wilson, then 46, a pharmacy technician from Seattle, received the Lap-Band adjustable gastric band.

The implanted band constricts the size of the stomach to make it difficult to eat large quantities of food. In fact, the opening left to Wilson's stomach was so small that she had difficulty eating even small amounts of food. It also caused her to throw up almost every day.

But she stuck with it, losing 70 pounds, until a routine endoscopy in December 2010 revealed that the band had cut into her stomach lining and would have to be removed immediately. She developed a post-surgical infection that resulted in a partially collapsed lung and an eight-day hospital stay. Wilson says she has regained half of the weight she lost.

More than 650,000 Lap-Bands have been sold worldwide, according to the 2010 annual report from its manufacturer, Allergan. It's among the minority of devices so novel that manufacturers can't find an older product for grandfathering.

Those products usually have to undergo advance testing for safety and effectiveness to get the FDA's approval for marketing. But the tests aren't nearly as rigorous as those required for prescription drugs, even though, as Redberg notes, "if you have a problem with a drug, you can just stop taking it, but you can't do that for a device implanted in your body."

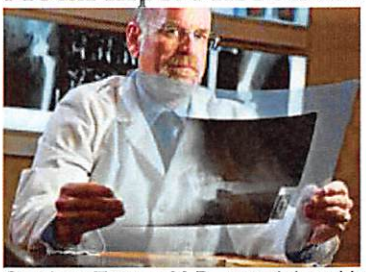
And the FDA charges device manufacturers only $220,050 to review a new device, compared with the $1.84 million it charges to review a new drug application.

If Lisa Wilson had seen the lone study on which the approval was based, she might not have been surprised by her problems. Of the 299 people in the study, 51 percent reported nausea, vomiting, or both, and 25 percent had their bands removed before the end of the three-year study because of complications or failure to lose enough weight.

"Imagine if a car had a recall rate that high," says John Santa, M.D., director of the Consumer Reports Health Ratings Center. "Consumers and regulators would be up in arms. But in the world of medical devices, these things often stay hidden."

The Lap-Band clinical trial was fairly typical of such pre-marketing studies. Redberg and colleagues looked at 123 studies done on high-risk cardiovascular devices that received FDA approval between 2000 and 2007. Only 27 percent met the gold standard of being randomized clinical trials, according to the report, published in December 2009 in the Journal of the American Medical Association.

Metal hips: Missed alarms



Stephen Tower, M.D., was injured by the same artificial hip he implanted in patients.
Photo: Clark James Mishler

If any patient should have gone into a hip replacement fully informed, it was Stephen Tower, M.D., 55, an orthopedic surgeon from Anchorage, Alaska. Instead, he became the victim of another device that was grandfathered onto the market without clinical testing.

In this case, it was an artificial hip introduced in 2005 by DePuy, the orthopedic division of Johnson & Johnson. Called the ASR XL (shown at the top of this page), it was distinctive because both components—the ball at the top of the femur and the socket liner inside the pelvis—were made of chrome-cobalt metal.

The FDA cleared it without clinical testing based on "substantial equivalence" to earlier devices, though such metal-on-metal hips had long been on the agency's high-priority list for requiring advance clinical trials.

The all-metal hips were supposedly a great advance over hips with the traditional plastic socket liner, Tower recalls. "The main reason hips traditionally failed was because of plastic wear," he says. "The metal-on-metal hip was being promoted not only commercially but in the medical literature as being a solution for patients like me, who wanted to return to no-holds-barred physical activity."

By 2006, Tower's arthritic hip had forced him to give up practically all the outdoor pursuits he had moved to Alaska to enjoy. He had a DePuy ASR XL implanted in May of that year, and "within six weeks I did a double century bike race," he says. He was so enthusiastic that within 10 months he had put various models of metal-on-metal hips in six of his patients.

But by the time a year had passed, it became clear that something was wrong. His hip was "pretty much constantly painful" and the chromium and cobalt levels in his blood "were notably high," he says.Then he started noticing other problems, such as disturbed sleep, mood swings and anxiety, hearing loss, visual problems, and tinnitus.

Throughout that period, he says, he repeatedly questioned DePuy engineers, design surgeons, and sales representatives, "and they'd say, 'Geez, Steve, we haven't heard of this.' "

Tower's symptoms became so severe at times that he was unable to work. Meanwhile, his research, some of which he has since published in medical journals, was uncovering evidence that metal debris from joint implants can cause what he describes as "profound poisoning."

After having the hip removed in 2009 and replaced with a new one made of ceramic and plastic, his symptoms have markedly improved.

In August of 2010, DePuy recalled all 93,000 ASR XL hips worldwide after it became clear that the device was failing far more often than average and producing serious injuries. While it's unclear how many people actually have had to have their artificial hip removed, an article in the British Medical Journal called it "one of the biggest disasters in orthopaedic history."

Although the hip was invented and manufactured by an American company, the recall occurred because as early as three years previously—even as DePuy's engineers were assuring Tower that the hip had no problems—regulators in Australia, England, and Wales were noticing serious problems.

They were able to do so because they have national joint registries—a list of every joint implanted—and the ability to track how patients fare with various models. There is no such national registry in the U.S., although Kaiser Permanente has a large private one.

The FDA has a voluntary system whereby doctors, manufacturers, and patients can report problems with medical devices. And though experts estimate that only a fraction of device problems ever get reported, from 2009 through 2011, the agency received 20,518 reports of injuries from metal-on-metal total hip replacements. Of those, 15,137 concerned the now recalled DePuy hip. Many of the remaining complaints concerned several other brands and models that are still on the market in the U.S.

The 2011 Institute of Medicine panel concluded that the FDA's ability to spot problems is so inadequate that it's "impossible to confidently draw broad conclusions about the safety and effectiveness of products that are on the market."

How to fix the system

Consumers Union, the advocacy arm of Consumer Reports, agrees with the Institute of Medicine that the current system of medical-device regulation doesn't protect patients from harm. Consumers Union recommends that the FDA:

- Require that implants and other "life-sustaining" devices be tested at least as rigorously as drugs.
- End the practice of "grandfathering" high-risk new implants and life-sustaining devices.
- Create a "unique identifier system," or IDs for implants, so that patients can be quickly notified about recalls and safety problems.

- Create national registries so that problems can be spotted quickly and patients notified.
- Increase the user fees paid by manufacturers for regulatory review so that the FDA has enough money to do its job.

Have you had a problem? Tell us about it now. If you've had a problem with an implant or a medical device, please tell Consumer Reports about your experience. Your information is kept confidential (unless you indicate otherwise) and your story helps us monitor medical problems, research future articles, and push for reform.
To help, go to SafePatientProject.org and click on "Share Your Story" or click on "Act Now" to help us work for change.

Protect yourself against risks

Here are a few steps you can take to guard against the risks posed by dangerous medical devices.
Consider alternatives. Ask your doctor what will happen if you don't get the implant. Many women who received transvaginal mesh for prolapse repair, for example, probably never even needed surgery.

"Pelvic organ prolapse is almost never a life-threatening condition. It's a quality-of- life issue," explains Daniel S. Elliott, M.D., assistant professor of urology at the Mayo Clinic College of Medicine. "The overwhelming majority of women do not need to have surgery. If you're not bothered by it, then don't do anything. I think many patients weren't adequately informed about that."

You may also have non-mesh alternatives. Elliott says he and other well-trained pelvic surgeons routinely repair prolapses with techniques that don't require any mesh at all. On the other hand, people ill enough to need an implantable defibrillator for their heart may not have another choice.

Research the device. The Food and Drug Administration's website, FDA.gov, has a wealth of information about device safety warnings, complaints, and recalls, easily accessible by typing the name of the device into the site's search box. It's also worth searching Google. If the results include a lot of law firms looking for clients injured by the device, that's a sign to ask your doctor some hard questions.

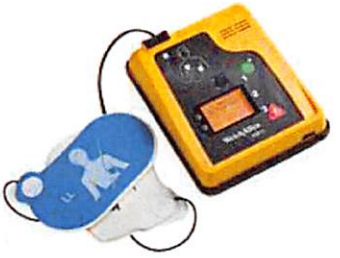
For an optional device like a Lap-Band or breast implant, look around the Internet for patient forums. Though the information there isn't validated, you'll get a sense of whether patients are reporting trouble with the device.
Write down what you got. If your doctor doesn't give you information about the brand name, model, and serial number (if it exists) of your device, ask for it. If you learn of a warning or safety recall, from the FDA or elsewhere, you'll know whether yours is one of the problem models.

Stay alert—but don't panic. If you learn that there are problems with your device, contact your doctor and ask what warning signs to watch for. Also go to the FDA website to read up on official warnings and find out whether it's safe to keep the device in your body.

For example, if you have a metal-on-metal hip, call your doctor if you have pain or other unusual new symptoms, such as heart, vision, hearing, emotional, or neurological problems, because all of those might be signs of a reaction to the device. You might also want to get your blood tested for high cobalt levels, a sign that the hip is deteriorating.

But don't assume that all problematic devices have to be removed. For example, pelvic surgeons say they often get calls from worried women who have had mesh repairs. "If the mesh is not causing any problem, don't do anything because getting mesh out is very difficult and dangerous," Elliott says.

Cardiac devices are risky, too



Automatic external defibrillators have been recalled 90 times in seven years.

Cardiac devices dominate the list of reports to the Food and Drug Administration of deaths and injuries. Here are three devices that have had significant problems in recent years:

Implantable cardioverter-defibrillators. Since 2009, the FDA has received reports of close to 29,000 deaths or injuries from these devices, by far the most for any device type, according to our analysis of the FDA's database of adverse events. Implanted in more than a half-million Americans with serious heart disorders, the defibrillators detect abnormal rhythms and administer shocks to correct them.

The most troublesome aspect of the devices are the leads—wires that connect them to the heart. There have been two major recalls, in 2007 and 2011, of defective leads, the Medtronic Sprint Fidelis and the St. Jude Riata, after they had already been implanted in almost 350,000 patients. Patients with the device leads require close monitoring and face the prospect of having to have them surgically removed.

In congressional testimony in 2009, Boston cardiologist William Maisel, M.D., described what happened to a patient of his: "The simple act of removing his shirt over his head caused his ... lead to fracture. [He] suffered a cardiac arrest in front of his wife." The patient survived but never fully recovered.

Vena cava filters. These devices are placed in the vessel that returns blood from the lower body to the heart to prevent pulmonary embolism, a life-threatening condition caused by blood clots breaking loose from the leg and traveling to the lungs. Some 200,000 people get such filters each year.

Many should be removed once the danger of clots has passed, but often aren't. In a November 2010 study in the Archives of Internal Medicine, Pennsylvania researchers found that pieces of the Bard Recovery filter had broken off and migrated elsewhere in the body in one of four study patients. One patient needed open-heart surgery.

"Remarkably," wrote cardiologist Rita Redberg, M.D., of the University of California, San Francisco, in an editorial accompanying the report, these filters "were considered Class II by the FDA—the same risk category of mercury thermometers—and received approval without any clinical data of safety and effectiveness."

"The devices were being used inconsistent with their FDA clearance," says Jeffrey Shuren, M.D., director of the agency's Center for Devices and Radiological Health. "We don't have authority to do something about that." If you've received the device, ask your doctor whether it has been removed.

Automated external defibrillators. Found in airports and other public buildings, these devices are designed so that bystanders can operate them. AEDs automatically diagnose abnormal heart rhythms and deliver shocks to people in cardiac arrest.

The problem is, they don't always work. The industry has conducted about 90 recalls over the past several years, affecting hundreds of thousands of devices. Between 2009 and 2011, the FDA received reports of 72 injuries, 686 deaths, and 20,667 malfunctions connected with the devices. Arizona researchers found that in most cases the machines weren't able to diagnose the abnormal rhythms properly or failed to deliver the recommended shock.

The FDA is considering whether to downgrade AEDs from the highest-risk category to moderate-risk. recalled Defibrillators have been recalled 90 times in seven years.

Editor's Note:
A version of this article appeared in the May 2012 issue of *Consumer Reports* magazine with the headline "Dangerous Devices."

THE 10 WORST

Corporate Accounting Scandals of All Time

Corporate malfeasance has earned a place among the defining themes of the last decade-and-a-half, helping give birth to the present global recession and the Occupy Wall Street movement. Here's a look back at the who, what, when and how of some of the worst corporate accounting scandals.

WASTE MANAGEMENT SCANDAL (1998)

COMPANY

Houston-based, publicly traded waste management company

WHAT HAPPENED

Reported **$1.7 billion** in fake earnings.

MAIN PLAYERS

Founder/CEO/Chairman Dean L. Buntrock and top executives

&

Arthur Andersen Company (auditors)

HOW THEY DID IT

The company allegedly falsely increased the depreciation time length for their property, plant and equipment on the balance sheets.

HOW THEY GOT CAUGHT

A new CEO and management team went through the books.

PENALTIES

Settled a shareholder class-action suit for **$457 million;** SEC fined Arthur Andersen **$7 million.**

FUN FACT

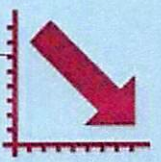
After the scandal, the new CEO A. Maurice Meyers set up an anonymous company hotline where employees could report dishonest or improper behavior.

ENRON SCANDAL (2001)

COMPANY

Houston-based commodities, energy and service corporation

WHAT HAPPENED



Shareholders lost $74 billion, thousands of employees and investors lost their retirement accounts, and many employees lost their jobs.

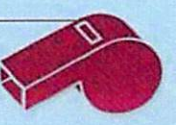
MAIN PLAYERS

CEO Jeff Skilling and former CEO Ken Lay

HOW THEY DID IT

Kept huge debts off the balance sheets.

HOW THEY GOT CAUGHT



Turned in by internal whistle-blower Sherron Watkins; high stock prices fueled suspicions.

FUN FACT

Fortune Magazine named Enron "America's Most Innovative Company" for six years in a row prior to the scandal.

PENALTIES

Lay died before serving time; Skilling got **24 years in prison.** The company filed for bankruptcy. Arthur Andersen was found

WORLDCOM SCANDAL
(2002)

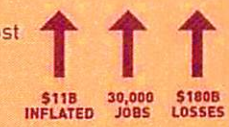
COMPANY

WORLDCOM

Telecommunications company; now MCI, Inc.

WHAT HAPPENED

Inflated assets by as much as $11 billion, leading to 30,000 lost jobs and $180 billion in losses for investors.



MAIN PLAYER

CEO Bernie Ebbers

HOW HE DID IT

Underreported line costs by capitalizing rather than expensing, and inflated revenues with fake accounting entries.

HOW HE GOT CAUGHT

WorldCom's internal auditing department uncovered **$3.8 billion** in fraud.

PENALTIES

CFO was fired, controller resigned, and the company filed for bankruptcy. Ebbers **sentenced to 25 years for fraud,** conspiracy and filing false documents with regulators.

FUN FACT

Following the scandal, Congress passed the Sarbanes-Oxley Act, introducing the most sweeping set of new business regulations since the 1930s.

TYCO SCANDAL
(2002)

COMPANY

tyco

New Jersey-based blue-chip Swiss security systems company

WHAT HAPPENED

CEO & CFO stole $150 million and inflated company income by $500 million.

MAIN PLAYERS

CEO Dennis Kozlowski and former CFO Mark Swartz

HOW THEY DID IT

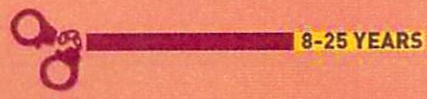
Siphoned money through unapproved loans and fraudulent stock sales. Money was smuggled out of the company disguised as executive bonuses or benefits.

HOW THEY GOT CAUGHT

SEC and Manhattan D.A. investigations uncovered questionable accounting practices, including large loans made to Kozlowski that were then forgiven.

PENALTIES

Kozlowski and Swartz were sentenced to **8-25 years in prison.** A class-action lawsuit forced Tyco to pay **$2.92 billion** to investors.



FUN FACT

At the height of the scandal Kozlowski threw a **$2 million birthday party** for his wife on an island, complete with a Jimmy Buffett performance.

HEALTHSOUTH SCANDAL
(2003)

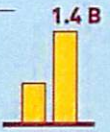
COMPANY

HEALTHSOUTH

Largest publicly traded health care company in the U.S.

WHAT HAPPENED

Earnings numbers were allegedly **inflated $1.4 billion** to meet stockholder expectations.



MAIN PLAYER

CEO Richard Scrushy

HOW HE DID IT

Allegedly told underlings to make up numbers and transactions from 1996-2003.

HOW HE GOT CAUGHT

Sold $75 million in stock a day before the company posted a huge loss, triggering SEC suspicions.

PENALTIES

Scrushy was acquitted of all 36 counts of accounting fraud, but convicted of bribing the governor of Alabama, leading to a 7-year prison sentence.

FUN FACT

Scrushy now works as a motivational speaker and maintains his innocence.

NOT GUILTY?

FREDDIE MAC SCANDAL (2003)

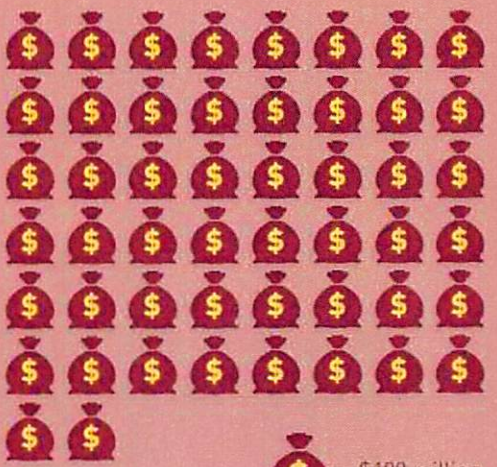
COMPANY

Freddie Mac

Federally backed mortgage-financing giant

WHAT HAPPENED

$5 billion in earnings were misstated.



= $100 million

MAIN PLAYERS

President/COO David Glenn, Chairman/CEO Leland Brendsel, ex-CFO Vaughn Clarke, former Sr. VPs Robert Dean and Nazir Dossani

HOW THEY DID IT

Intentionally misstated and understated earnings.

HOW THEY GOT CAUGHT

An SEC investigation.

PENALTIES

$125 million in fines and the firing of Glenn, Clarke and Brendsel.

FUN FACT

1 year later, Fannie Mae, the other federally backed mortgage financing company, was caught in an equally stunning scandal.

Fannie Mae

AMERICAN INSURANCE GROUP SCANDAL (2005)

COMPANY

AIG

Multinational insurance corporation

WHAT HAPPENED

Massive accounting fraud to the tune of $3.9 billion was

HOW HE GOT CAUGHT

SEC regulator investigations, possibly tipped off by a whistle-blower.

PENALTIES

Settled with the SEC for $10 million

alleged, along with bid-rigging and stock price manipulation.

MAIN PLAYERS

CEO Hank Greenberg

HOW HE DID IT

Allegedly booked loans as revenue, steered clients to insurers with whom AIG had payoff agreements, and told traders to inflate stock prices.

in 2003 and $1.64 billion in 2006, with a Louisiana pension fund for $115 million, and with 3 Ohio pension funds for $725 million. Greenberg was fired, but has faced no criminal charges.

FUN FACT

After posting the largest quarterly corporate loss in history in 2008 ($61.7 billion) and getting bailed out with taxpayer dollars, AIG execs rewarded themselves with over $165 million in bonuses.

LEHMAN BROTHERS SCANDAL (2008)

COMPANY

LEHMAN BROTHERS

Global financial services firm

WHAT HAPPENED

Hid over **$50 billion** in loans disguised as sales.

MAIN PLAYERS

Lehman executives & the company's auditors, Ernst & Young

HOW THEY DID IT

Allegedly sold toxic assets to Cayman Island banks with the understanding that they would be bought back eventually. Created the impression Lehman had $50 billion more cash and $50 billion less in toxic assets than it really did.

HOW THEY GOT CAUGHT

Went bankrupt.

PENALTIES

Forced into the largest bankruptcy in U.S. history. SEC didn't prosecute due to lack of evidence.

FUN FACT

In 2007 Lehman Brothers was ranked the #1 "Most Admired Securities Firm" by Fortune Magazine.

BERNIE MADOFF SCANDAL (2008)

COMPANY

Bernard L. Madoff Investment Securities LLC, a Wall Street investment firm founded by Madoff

WHAT HAPPENED

Tricked investors out of **$64.8 billion** through the largest Ponzi scheme ever.

MAIN PLAYERS

Bernie Madoff, his accountant, David Friehling, and Frank DiPascalli

HOW THEY GOT CAUGHT

Madoff told his sons about his scheme; they reported him to the SEC. He was arrested the next day.

PENALTIES

150 years in prison for Madoff + $170 billion restitution. Prison time for Friehling and DiPascalli.

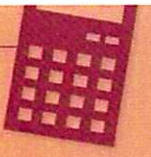
FUN FACT

Madoff's fraud was revealed just months

after the 2008 U.S. financial collapse.

HOW THEY DID IT

Investors were paid returns out of their own money or that of other investors rather than profits.



SAYTAM SCANDAL (2009)

COMPANY

Indian IT services and back-office accounting firm

Satyam

WHAT HAPPENED

Falsely boosted revenue by **$1.5 billion.**

MAIN PLAYER

Founder/Chairman Ramalinga Raju

HOW HE DID IT

Falsified revenues, margins and cash balances to the tune of 50 billion rupees.

HOW HE GOT CAUGHT

Admitted the fraud in a letter to the company's board of directors.

PENALTIES

Raju and his brother charged with breach of trust, conspiracy, cheating and falsification of records. Released after the Central Bureau of Investigation failed to file charges on time.

FUN FACT

In 2011 Ramalinga Raju's wife published a book of his existentialist, free-verse poetry.

PROVIDED BY: ACCOUNTING-DEGREE.ORG

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