



Cornell University
ILR School

Cornell University ILR School
DigitalCommons@ILR

Book Samples

ILR Press

2014

Watch Your Back! How the Back Pain Industry is Costing Us More and Giving Us Less - And What You Can Do to Inform and Empower Yourself in Seeking Treatment

Richard A. Deyo MD
Oregon Health & Science University

Follow this and additional works at: <https://digitalcommons.ilr.cornell.edu/books>



Part of the [Analytical, Diagnostic and Therapeutic Techniques and Equipment Commons](#), and the [Labor Relations Commons](#)

Thank you for downloading an article from DigitalCommons@ILR.

Support this valuable resource today!

This Article is brought to you for free and open access by the ILR Press at DigitalCommons@ILR. It has been accepted for inclusion in Book Samples by an authorized administrator of DigitalCommons@ILR. For more information, please contact catherwood-dig@cornell.edu.

If you have a disability and are having trouble accessing information on this website or need materials in an alternate format, contact web-accessibility@cornell.edu for assistance.

Watch Your Back! How the Back Pain Industry is Costing Us More and Giving Us Less - And What You Can Do to Inform and Empower Yourself in Seeking Treatment

Abstract

[Excerpt] This book considers what we know about treatments for back pain and asks a number of critical questions.

Are some of the most popular treatments really effective? Do they “cure” or even improve the problems they claim to address? If some back pain treatments are ineffective or even harmful, why do patients clamor for them and doctors provide them?

Who benefits from the vast back pain industry that’s developed over the past thirty years? Is it patients? Or the doctors, hospitals, and manufacturers that produce the technology of back pain therapy?

What does all this say about our medical system? Or our efforts to enhance quality, improve safety, and reduce health care costs?

How can patients maneuver to help themselves rather than help the medical industry? Will efforts to measure patient satisfaction help deliver safer and more effective treatments or encourage the opposite?

In answering these questions, this book does more than describe and analyze the back business. It also explores the complex ways that doctors interact with patients, drug companies, and medical device makers. The results can inadvertently lead to treatments that are ineffective or even harmful.

Keywords

back pain, treatment, therapy, patient satisfaction, medical industry

Disciplines

Analytical, Diagnostic and Therapeutic Techniques and Equipment | Labor Relations

Comments

The abstract, table of contents, and first twenty-five pages are published with permission from the Cornell University Press. For ordering information, please visit the [Cornell University Press](https://digitalcommons.ilr.cornell.edu/books/99).

WATCH YOUR BACK!

How the Back Pain Industry Is Costing Us
More and Giving Us Less—and What You
Can Do to Inform and Empower Yourself in
Seeking Treatment

RICHARD A. DEYO, MD

ILR Press
an imprint of
Cornell University Press
Ithaca and London

The views expressed by the author of this book are not intended as a substitute for medical advice, diagnosis, or treatment provided by the reader's personal physician.

Copyright © 2014 by Cornell University

All rights reserved. Except for brief quotations in a review, this book, or parts thereof, must not be reproduced in any form without permission in writing from the publisher. For information, address Cornell University Press, Sage House, 512 East State Street, Ithaca, New York 14850.

First published 2014 by Cornell University Press
Printed in the United States of America

Library of Congress Cataloging-in-Publication Data

Deyo, Richard A., author.

Watch your back! : how the back pain industry is costing us more and giving us less—and what you can do to inform and empower yourself in seeking treatment / Richard A. Deyo MD.

pages cm — (Culture and politics of health care work)

Includes bibliographical references and index.

ISBN 978-0-8014-5324-3 (cloth : alk. paper)

1. Backache—Treatment. 2. Back—Diseases—Treatment. I. Title.
II. Series: Culture and politics of health care work.

RD768.D44 2014

617.5'6406—dc23 2014006972

Cornell University Press strives to use environmentally responsible suppliers and materials to the fullest extent possible in the publishing of its books. Such materials include vegetable-based, low-VOC inks and acid-free papers that are recycled, totally chlorine-free, or partly composed of nonwood fibers. For further information, visit our website at www.cornellpress.cornell.edu.

Cloth printing 10 9 8 7 6 5 4 3 2 1

CONTENTS

Preface	ix
Acknowledgments	xiii
1. Back Pain Nation	1
2. Even the Best and Brightest	19
3. What's Wrong? What's Not? Can We Tell the Difference?	31
4. Painkillers: Easy Solutions Sometimes Aren't	41
5. Painkillers and the Marketing of Pain	51
6. Pain Management, Now That's Money	59
7. Stabbed in the Back	69
8. Surgical Gadgets and the Explosion of Fusion Surgery	81
9. The Pointed Search for Relief: Injections, Ablations, and Blocks, Oh My!	93
10. Why Would You Get Better after Useless Therapy?	103
11. Manipulating the Pain: Chiropractic and Other "Alternative" Treatments	113
12. Nobody Takes It Seriously!	121
13. Boot Camp	131

CONTENTS

14. Amplifying Your Voice	143
15. Some Policy Implications	153
Notes	173
Index	203

Chapter 1

BACK PAIN NATION

Since nearly all of us get back pain, you may be one of the sufferers. If you're not, you probably will be. Two-thirds of adults report back pain at some time in their lives. Think of it as a frustrating part of a normal, healthy life.

Yet back pain is distracting, debilitating, or disabling for some people. It's among the leading causes of work disability, and it restricts many people's activities. Compared with cancer, diabetes, or heart disease, back pain may seem trivial to some, but it's costing our society nearly as much as these life-threatening conditions.

If you have back pain, you're confronted with a growing menu of treatments that are rapidly increasing in use. When our research team at the University of Washington scrutinized the growth in treatments for back pain, the numbers were startling. Over roughly a decade, from 1994 to 2005, there was a 300 percent increase in MRI scans of the low back for Medicare patients. There was over a 100 percent increase in the use of narcotic painkillers for back pain and over a 200 percent increase in spinal fusion surgery. Expenditures for epidural steroid injections in the Medicare population—thanks to increasing use and rising prices—increased over 600 percent. We'll explain and examine these treatments later.

These numbers mean that someone was making plenty of money from back pain. But as we'll see, there's no sign that, on average, patients were getting better results over this time. These changes reflected a booming back business.

How much do we spend on back pain? Coming up with realistic cost estimates is a challenge. One approach is to ask how much more people who have back pain spend for medical care than similar people who don't. Our research group's best estimate, based on national surveys: \$86 billion in 2005. That was 9 percent of *all* health care costs, comparable to the costs of cancer or diabetes. And that figure didn't even consider the costs of work loss or disability compensation.

Our team also found that costs for back pain were increasing faster than costs for medical care overall. And, of course, overall medical costs have increased faster than general inflation for many years.

Market watchers estimate that spinal implants alone—the plates, screws, and gadgets often used in spinal fusion surgery—cost \$3.8 billion in 2009. That's not counting the hospital charges or doctors' bills. The national hospital bill for those operations—which includes the gadgets—was around \$38 billion, although hospitals collect less. Drug market analysts estimated the market for narcotic painkillers at \$8.4 billion in 2011, and more than half the people who regularly take painkillers have back pain.

The cost of treating back pain appears to be higher in the United States than in most other developed countries. Our rate of back surgery, for example, is about twice the rate in Australia, New Zealand, most of Europe, and Canada. It's five times higher than in the United Kingdom. And Americans seem to have a unique conviction that high-tech treatments can solve all their medical problems.

Many people, perhaps most, assume that more medical care can only be better. Doctors are paid for doing more, not necessarily for doing better, so they're happy to deliver more care. That means more testing, more doctor visits, more surgery, and more drugs.

But are more of these things really better? This book considers what we know about treatments for back pain and asks a number of critical questions.

Are some of the most popular treatments really effective? Do they “cure” or even improve the problems they claim to address? If some back pain treatments are ineffective or even harmful, why do patients clamor for them and doctors provide them?

Who benefits from the vast back pain industry that’s developed over the past thirty years? Is it patients? Or the doctors, hospitals, and manufacturers that produce the technology of back pain therapy?

What does all this say about our medical system? Or our efforts to enhance quality, improve safety, and reduce health care costs?

How can patients maneuver to help themselves rather than help the medical industry? Will efforts to measure patient satisfaction help deliver safer and more effective treatments or encourage the opposite?

In answering these questions, this book does more than describe and analyze the back business. It also explores the complex ways that doctors interact with patients, drug companies, and medical device makers. The results can inadvertently lead to treatments that are ineffective or even harmful.

These issues aren’t unique to patients and doctors dealing with back pain. Back pain is a microcosm of broader problems in our health care system. As we’ll see, well-meaning and popular solutions—often involving new drugs, devices, or even quality improvement efforts—may aggravate rather than solve the problems.

That’s why so many people have a huge stake in understanding the back business. The first group of stakeholders is obviously back pain sufferers. If you have back pain, this book will help you take more control of the problem, avoid harm, and get your life back—or keep it.

Hope is an important part of getting better, and I want to convince you that even if there’s not a definitive cure, your life is going to improve. Although you’ll read here about many ineffective treatments,

there are treatments that can help, and most require patients to take charge of their care.

So one goal of this book is to encourage more involvement in decisions about your own care. This doesn't mean insisting on a particular test or treatment against medical advice. It doesn't mean that medical advice is always wrong or that you can't trust your doctor. Rather, it means you need to become well informed and deeply involved in making decisions about your care. *Blindly* accepting professional recommendations—even though they're well meaning—may not always be a successful strategy.

David Freedman, a science and business journalist, wrote a book ominously titled *Wrong*. With many medical and business examples, he points out that a large fraction of expert advice is flawed. Regarding medical controversies, he remarks that humans “happen to be complex creatures living in a complex world, so why would we expect answers to *any* interesting question to be simple?”

He goes on to remind us that, given these complexities, any advice that's likely to be right is likely to be complex. It “will come with many qualifications. . . . Because of all the ifs, ands, or buts, it will be difficult to act on.”

Even more frustrating, Freedman argues that we're all attracted to simple solutions and overly optimistic predictions. So genuinely good advice is often incompatible with our expectations. It's likely to be at odds with every aspect of the advice we *want* to believe.

What about the latest and greatest cures for back pain reported in the media? These cures appear on an almost daily basis. Freedman suggests being wary of advice that gets favorable attention from the press, the online crowd, or your friends. The problem is that the popularity of an idea is likely to reflect good promotion, provocativeness, or how well it resonates with the conventional wisdom rather than its likelihood of being right. We should beware of false messiahs.

I encourage avoiding a passive role not only in decision making but in physical activity. Don't treat back pain by going to bed rest, the standard treatment prescription when I was in medical training. Don't

assume the cure will be found by lying in an MRI scanner. Don't assume it will be fixed by lying on an operating table. Don't assume that lying down for injections will be the cure. We'll see the fallacies in each of these assumptions.

In fact, resuming activities, increasing physical activity, and even vigorous exercise are often the keys to improving back pain—things no doctor or practitioner can do for you.

This leads to the second group of readers I hope to reach: the health care professionals who treat back pain. Although some may seem motivated by self-interest as much as by patient need, most are deeply caring and want to help.

That's one reason they continue to “do something,” even when that something may not work. Doctors, physical therapists, and nurse practitioners, like so many Americans, have been socialized not to “just sit there” but to act.

The imperative to act is especially hard to resist when a suffering human being is sitting in your office begging for relief. Unfortunately, as we'll see, many of the things doctors recommend may be useless or worse. So providing those who treat back pain with a better understanding of the research evidence may help them do a better job with their patients.

Finally, I hope to reach policy makers and the media. The media have become an integral part of the medical industrial complex in general and the back business in particular. Miracle cures are a staple of popular health coverage. They attract an eager readership at magazine stands and bookstores and in cyberspace or the blogosphere.

There's nothing particularly sexy about exercise and yoga classes—activities that may be genuinely helpful for back pain. But the constant stream of “miracle cure” stories attracts hits. The problem is that it conveys a message to back pain sufferers that salvation lies in expensive treatments. Typically, treatments that are done to them rather than activities done by them.

If we want to deal effectively with back pain—not to mention our broader health care crisis—it's important that journalists, health

reporters, and bloggers become more critical. They need to understand how to frame the issues, critically analyze the latest treatments, and translate this to a lay audience of patients and their families.

Policy makers also need to learn more about the genesis of the problems they're trying to solve. Back pain is a perfect policy laboratory. Our research into relationships between patients and doctors teaches us that putative silver bullets sometimes only make the problem worse. These silver bullets often include ever more intensive intervention, new technology, pain scales, and patient satisfaction questionnaires.

As we take a tour of the back business, many readers—particularly patients and doctors—may be deeply suspicious of my conclusions. Arguments to decrease use of specific medical services are often received with skepticism because this appears only to reduce quality of care and not improve it. Such a message will alarm readers who are convinced that certain treatments will work. As we'll see, even highly educated and influential people often insist on tests and treatments for back pain that are unlikely to help.

Other readers will question the motives of anyone who argues for less medical intervention, assuming that this reflects insensitivity to suffering, preoccupation with cost cutting, efforts to ration care, or a threat to patient autonomy. On the surface, cost containment seems to be the sole motivation. Insurance company maneuvers to limit their costs only reinforce these suspicions.

Glib pronouncements that “less is more” or that we're practicing “evidence-based medicine” are not reassuring. These phrases lead many people to conclude that something is being withheld—something that might have benefit. How could more testing and more information possibly be harmful? How could treatment that's more intensive possibly lead to worse results?

Answering these questions is part of the challenge of this book. A recurring theme is not to confuse doing more with doing what's best.

Have rapidly rising expenditures for back pain and a raft of new treatments helped? If more care and newer care were better, we might expect falling rates of activity limitation and work disability due to

back pain. If all the surgical innovations of recent years were real improvements, we might see rates of *repeat* surgery going down. That is, we might expect that people would be doing so well after surgery, they wouldn't need more operations.

With heart disease, that seems to be just what's happening. Work disability from heart and blood vessel disease has been falling in recent decades. This is a result of better prevention and better treatment.

But for back pain, just the opposite is occurring. Annual surveys of people with back pain report steadily *worse* functional limitations over the past decade. Work disability due to back pain has been increasing. And rates of repeat surgery have been going up instead of down. This is both counterintuitive and emotionally unsatisfying.

But with back pain—as with many chronic diseases—there's a fundamental flaw in assuming that someone else is going to fix you. Nonetheless, they can get rich trying.

Let's be honest about a couple of things. First, research shows that most people with a recent onset of back pain—even severe back pain—will get better on their own, through natural healing processes. As a result, it's surprisingly hard to prove that treatments help in a new episode of back pain. That's because any treatment comparison has to beat this normal, rapid healing. Furthermore, because most people get better, it's easy to make the mistake of assuming that the improvement was the result of a particular treatment.

A fraction of people with back pain develop ongoing, unrelenting problems. Even more develop grumbling, low-level pain that flares up from time to time. For people with persistent or “chronic” pain, there are no magic bullets. I don't have a cure. To paraphrase a Frank Cotham cartoon in the *New Yorker*, I don't even have a race for the cure.

Most books and magazine articles on back pain offer *The Cure*. But notice . . . the cures are all different. And disabling back pain is increasing in the United States, despite the proliferation of cures.

The overabundance of cures, and variations in clinical practice from one doctor to the next, prompted my longtime colleague Dan Cherkin to subtitle an article we once wrote, “Who You See Is What

You Get.” A New York pain specialist, Dr. Seth Waldman, put it slightly differently. “Each approach to diagnosis and treatment is essentially a franchise, and there are too many franchises battling for control.”

Dr. Scott Haldeman is a medical neurologist *and* a chiropractor. As if that’s not enough, he has a PhD in neurophysiology. His roots in South Africa are still audible when he speaks, and his education spans South Africa, Canada, and the United States. In a recent review, he and his colleagues counted more than two hundred available treatment options for chronic low back pain, without even considering surgery.

Now, if you have pernicious anemia, there’s one treatment: vitamin B12. If you have thyroid deficiency, there’s one treatment: thyroid hormone replacement. If you have appendicitis, there’s generally one treatment: an appendectomy. But for back pain, there are more than two hundred options, plus dozens of different surgical procedures. If one treatment were overwhelmingly effective or clearly superior, this situation wouldn’t exist.

Throughout this book, I’ll be talking about lower back pain, which is more frequent than neck pain. And I’ll be talking about the most common type of back pain—the type that’s not caused by cancer, infection, or serious underlying disease. The type that’s not associated with serious nerve injury that might cause foot or leg weakness, for example.

You may assume that you need an MRI to rule out these more serious conditions, but a careful office examination is usually all that’s necessary. In fact, we’ll look at some hazards of getting fancy tests when they aren’t needed.

Overtesting and overtreatment turn out to be rampant in the back pain world. This partly explains why costs are skyrocketing while results are plunging. Again, this is hard to understand.

Hasn’t medical research improved length and quality of life for people with AIDS? Isn’t it true that kidney transplants do the same for people with end-stage kidney failure? Don’t people with hip replacements get to play tennis again? Why aren’t the results of care for back pain similarly improving?

Peter Pronovost is an intensive care doctor at Johns Hopkins Medical School in Baltimore. Clean-shaven and with a full head of light brown hair, he looks like a handsome athlete. He's famous for reducing complications in intensive care units by simply using checklists, as pilots do before flying, to avoid overlooking simple steps.

Pronovost argues that we have two American health care systems: "one that leads the world in discoveries and the other that often harms rather than heals." He also reminds us of consistent best estimates that the U.S. health care system wastes one-third of all spending—about \$900 billion a year—on errors, waste, and inefficient care.

I argue that care for back pain is part of Pronovost's second health care system. Care for back pain is low-hanging fruit, where we could easily improve care and cut costs at the same time. In fact, it's the poster child for medical waste. Much of this is the result of an entire industry built around pain, taking advantage of vulnerable people who are often desperate for explanations and relief.

So over the next chapters we'll look closely at research on the efficacy of most popular back pain treatments. We'll examine what we know about them and then, at the end of the book, turn to what really works. In the course of this exploration, we'll learn why people may be "helped" by ineffective treatments, why doctors continue to prescribe them, and what we can do to break this cycle. I'll conclude with recommendations designed to promote better treatment, less pain and suffering, and lower health care costs.

I've had the opportunity to treat many patients with back pain and to conduct some key back pain research. Our studies have challenged and changed the standard of back care in the United States and around the world. Most of these studies have passed the test of time and helped patients and health care providers alike.

Yet even the best scientific studies draw opposition by threatening the status quo and the lucrative back pain industry. As a medical editor reminds us, once an industry builds up around an idea, research evidence gets politicized. Good research may get lost in a blizzard of opinion pieces.

So I've taken my share of flak at major spine conferences. This can happen when you challenge outmoded thinking and dare to suggest that some popular treatments aren't safe and effective. I quickly learned that dealing with disagreement and controversy is part and parcel of being a scientist. Let me offer some stories of my baptism in the back pain business and how I came to be convinced that some treatments are overused.

Going to Bed for Back Pain

When I started my medical career in the 1980s, the standard treatment for back pain was bed rest. Strict bed rest. You were not to get out of bed for meals. You were not to sit up in bed. We debated whether it was okay to go to the bathroom or whether a bedside commode was necessary. No one questioned the value of bed rest. We argued instead whether it had to be for two weeks or whether one week could suffice. But we prescribed some kind of bed rest for everyone with back pain.

Have you ever tried staying in bed for two weeks without sitting up? It's hard even to imagine. Even watching TV would require having it bolted to the ceiling. It was a prescription destined to drive people mad. And two weeks of bed rest is enough to cause muscle weakness and deconditioning of the heart and lungs. Fortunately, I doubt that anyone actually followed our instructions, and many admitted that they didn't.

We'd see those patients back in the office a few weeks later for follow-up. I'd often ask if they'd finished the bed rest as prescribed. The usual response was a chagrined, "Well, I tried it for a couple of days but really couldn't do it any longer than that." Or, "Well, I couldn't afford to miss work that long, so I had to cut it short."

"Well, is your back feeling better?" I'd ask. "Oh yeah, it's quite a bit better now" was the usual response.

Here was an odd disconnect. Most patients weren't following our instructions at all, but most were getting better anyway. What if the conventional wisdom was just wrong?

When I looked for scientific studies on the effectiveness of bed rest, I couldn't find any. This seemed to be a treatment based on theory, lore, and authoritarian pronouncement rather than actual data.

The theory was that lying down minimized pressure in the discs of the spine, the cushions between the vertebrae. And there was research using large-bore needles positioned in the disc and attached to pressure transducers showing that was true. But no one had proven that disc pressure was a key source of pain or that bed rest made pain get better faster.

The decision seemed to matter. Even though bed rest wasn't a treatment we billed for, the stakes for a patient were high. A week or two of work absenteeism had financial risks, and for some might even jeopardize the job. Physical deconditioning was inevitable. Being immobile thins bones, weakens muscles, and increases the risk of blood clots in the legs.

So in the 1980s, having just finished a research fellowship, I wanted to test whether bed rest actually made any difference. In the face of some skepticism and anxiety, my colleagues and I designed a study to test the theory.

We would take patients from a walk-in clinic with a complaint of back pain and—with their consent—randomly assign them to a full week of bed rest or just two days. We had to persuade the human research ethics committee that it was reasonable to withhold a full week of bed rest. That was the standard of care, after all. We chose two days of bed rest as a comparison strategy because it just seemed too radical to recommend none at all.

We recruited more than two hundred patients, most with back pain for less than a month. Then we followed them up over three months. We found no difference at all between the two-day strategy and the seven-day strategy in terms of pain relief or return to normal activities.

The only difference in the results was in work absenteeism. Those who spent two days in bed missed an average of three days of work, compared with six days for those assigned to a week in bed. In essence, by prescribing bed rest, we were prescribing work absenteeism without any

medical benefit. Some people might not be able to return to physically demanding jobs after just two days, but they didn't need to stay in bed.

Since that time, nine more randomized trials have come to essentially the same conclusion. And of course, several of those studies tested a strategy of no bed rest at all. The results of these studies hint that staying out of bed isn't merely as good but might be *better* than resting in bed. And the lack of benefit for bed rest seems to be true for people with sciatica as well as back pain alone. That's the electric shock-like pain in the leg that some people with back pain get.

Happily, doctors no longer prescribe bed rest for back pain.

A few years after our study, one of my colleagues, a neurologist with a wry sense of humor, kidded me about the consequences. Tongue firmly in cheek, he reminded me that our research had eliminated one of doctors' favorite excuses. "If someone with back pain didn't get better," he said, "we could always ask, 'Well, did you stay at strict bed rest for a week?'" When the answer was inevitably "no," we could always say, "Well, no wonder you didn't get better! You didn't follow my instructions!"

Of course, he was describing a classic strategy of blaming the victim. We had a good laugh and were both pleased that clinical practice was evolving away from this approach.

When the *New England Journal of Medicine* published our bed rest study, it got some attention in the news media because back pain is so common. I got a few angry letters from patients who felt I was taking a valuable treatment away from them. One wished me a lifetime of agonizing chronic back pain as retribution. I also got a few indignant letters from neurosurgeons, who just *knew* bed rest was critical and that patients would be harmed without it.

But overall, doctors accepted the study, and there was only modest controversy. I got invitations to lecture about the results, and they seemed to fit well with a growing sense that bed rest wasn't much use for this condition, or for anything else. No one was making money off bed rest, there was no market for bed rest, there was no industry supported by bed rest. It was an easy sell. Practice changed.

Contrast that with the impact of our next major research effort.

Less than Electrifying Results

Our next project was a study of transcutaneous electrical nerve stimulation, or TENS. TENS is a treatment that delivers mild electrical stimulation through several electrodes stuck to the skin. The stimulation comes from a device about the size of a deck of cards, which attaches easily to a belt and has wires to the electrodes.

Doctors also based this treatment on a theory—that sensation from an outside source could compete with pain signals to the brain, reducing the pain sensation. There was an analogy to rubbing your funny bone when you smack your elbow.

Companies initially developed TENS units as a way to screen for patients who might benefit from surgically implanted electrodes right next to the spinal cord. When some patients seemed to improve with a TENS unit alone, it became a treatment in its own right. But there was little rigorous proof that it worked.

So—again with patient consent—we assigned patients with persistent back pain to get a real TENS unit or a sham TENS unit. The sham units were identical to the real thing, with a flashing “on” light, but they delivered no electrical current.

Patients in both the true TENS and the sham TENS groups improved. In fact, both groups improved the same amount, at the same pace. The benefit of TENS appeared to be mostly a placebo effect.

The *New England Journal of Medicine* also published this study, and it got a lot of attention. This time, the response was more heated.

I found myself debating with the president of a TENS manufacturer on public radio. The company president argued that without the wonders of TENS, patients would be “condemned to the living hell of narcotic addiction,” as if TENS or narcotics were the only treatment choices for back pain. Remember, Scott Haldeman identified two hundred different treatments for back pain described in the medical literature.

I found myself responding to angry letters from physical therapists, who often recommend and manage TENS therapy. Letters to the editors of clinical journals and newsletters attacked our study for years—and

still do even today. It apparently hit a nerve that our study of bed rest didn't.

Sales of TENS units dipped for a while but then recovered. Nonetheless, a recent review of research studies (almost twenty years later) supported our results. It concluded that the highest-quality trials do "not support the use of TENS in the routine management of chronic low back pain." It also encouraged further research, because there are still few high-quality studies. Guidelines from the American Academy of Neurology similarly concluded, "TENS is not recommended for the treatment of chronic low back pain."

In 2012 the controversy led Medicare to encourage research that's more definitive. Medicare officials have taken the stance that they'll pay for TENS therapy only if patients agree to participate in such a study. The results may determine whether Medicare will continue insurance coverage for TENS.

This was my introduction to the influence of entrenched interests in managing back pain. The device manufacturers and therapists who favored TENS therapy had a major investment in the treatment. They vigorously resisted any suggestion that it might be no more than a placebo.

Unfortunately, their response was not to fund more and better research. Once a treatment has approval of the Food and Drug Administration (FDA), manufacturers have little to gain by doing more research.

You may assume that FDA approval of TENS units means they've been well tested and proven effective. But TENS units were introduced shortly before the FDA acquired authority over medical devices in 1976. At that time, devices already on the market were "grandfathered in" for approval. Furthermore, the FDA's early evaluation of medical devices focused on safety more than efficacy. And newer devices are widely approved on the basis of "substantial equivalence" to devices marketed before 1976.

I was beginning to learn about the back business. It's a for-profit business dedicated to selling products and generating return for stockholders.

Any benefit for patients is welcome but secondary. And as we'll see, the market comes close to including every American adult. It's a business that always assumes newer and more is better, despite growing evidence to the contrary.

My immersion in the back Business had begun, but it was far from complete.

Fusing Spines

My real baptism came with research on spinal fusion surgery. This is an operation designed to join two vertebrae with bone grafts, an operation we'll discuss later in more detail. It's most often performed today with screws inserted into the vertebrae, and connecting rods or plates to immobilize the vertebrae while the bone grafts heal. This hardware is expensive and profitable, adding thousands of dollars to the cost of a single back operation. The most popular gadgets are called pedicle screws, which were relatively new at the time we naively embarked on a new research project.

As the TENS project was being published, our research team received funding from the federal Agency for Health Care Policy and Research. Congress gave this new agency responsibility for improving the effectiveness and efficiency of health care rather than making laboratory discoveries.

One part of our research focused on spinal fusion surgery. Our critical review of the available research suggested that there were few scientifically validated indications for this type of surgery. Our research also suggested that this type of surgery resulted in greater costs and complications than simpler forms of back surgery.

At the same time, the agency sponsored a guideline panel to summarize the research literature on back pain, and I was a member of the panel. The chair was an orthopedic surgeon, and the panel included three other orthopedic and neurosurgeons. The entire panel had twenty-three members, representing nearly every profession and specialty with an interest in back pain. The panel limited itself to back pain of recent

onset, or “acute” low back pain, and concluded that nonsurgical treatments were most often appropriate. Regarding fusion surgery, all the studies we found addressed persistent back pain, so there was no evidence that it helped for acute pain.

The research and guideline efforts were simply too much for the North American Spine Society, a group made up mainly of spine surgeons. The society had close ties to the companies that make screws and rods for fusion surgery. The Spine Society argued that our research and the guidelines were biased against their preferred forms of therapy. The group inspired a letter-writing campaign to Congress, and some members formed a lobbying group with the stated goal of eliminating the funding agency.

One screw manufacturer, AcroMed, sought a subpoena of all our research records and communications at the University of Washington. Another company, Sofamor Danek, sought a court injunction to block release of the back pain guidelines. Neither effort was successful, but they exposed the role of device manufacturers in opposing our research and the production of guidelines.

The Agency for Health Care Policy and Research became a political target not only because of lobbying related to back pain but also because a new Congress was eager to cut government spending as part of its “Contract with America.” Further, Republican members of Congress saw the agency and its new head as advocates for the Clinton health plan, which they opposed.

In one budget draft, the House of Representatives eliminated the agency. However, many medical groups and hospital organizations came to the support of the agency, and it survived with endorsement of the Senate—but with a 25 percent budget cut. Political pressure related to the back pain guidelines led the agency to stop sponsoring the production of guidelines, despite a congressional mandate when the agency was established. And despite the fact that guidelines could be useful to thousands or even millions of patients and their doctors.

The North American Spine Society later faced allegations that some of its continuing medical education programs were thinly disguised

promotions for the spinal screws. The plaintiffs, patients alleging bad results from pedicle screws, likened the educational seminars to Tupperware parties.

Courts dismissed suits against the Spine Society for lack of evidence, but suits against the device manufacturers went forward. AcroMed, which had subpoenaed our research records, settled thousands of patient lawsuits alleging bad results, for \$100 million. The company did not acknowledge any liability.

Years later, in 2006, Sofamor Danek's parent company, Medtronic, reached a \$40 million settlement with the federal government over allegations of kickbacks to spine surgeons. The company denied any wrongdoing, but the Justice Department described the kickbacks as "sham consulting agreements, sham royalty agreements and lavish trips."

Also in 2006, the successor to the Agency for Health Care Policy and Research (the Agency for Healthcare Research and Quality, or AHRQ) sponsored a systematic review of the research literature on use of spine fusion surgery for a common diagnosis, degeneration of spinal discs. By that time, there were some strong research studies, all from Europe, that we hadn't had in the mid-1990s. That draft review concluded, "Fusion for degenerative disc disease has no conclusive advantage over nonsurgical treatment, either in the short-term or the long-term."

Despite research findings and allegations against the manufacturers, sales of pedicle screws and similar spinal devices have risen steadily since our research in the 1990s, thanks in part to aggressive marketing. According to government statistics, spinal fusion surgery of all sorts increased 660 percent between 1993 and 2010. The proportion of operations involving pedicle screws or similar hardware has increased as well, so that surgeons now use these devices in the vast majority of fusion operations.

Even some surgeons find the increase alarming. Dr. Edward Benzel, a neurosurgeon at the prestigious Cleveland Clinic, estimated that fewer than half the spinal fusions being performed were appropriate.

“The reality of it is, we all cave in to market and economic forces,” he told the *New York Times* in 2003. In the same article, Yale University neurosurgeon Zohar Ghogawala added, “I see too many patients who are recommended a fusion that absolutely do not need it.”

The *Times* also quoted Stan Mendenhall, the editor and publisher of *Orthopedic Network News*. Mendenhall said, “A lot of technological innovation serves shareholders more than patients. . . . The money is driving a lot of this.” And spine fusion rates have continued to climb steeply since those comments a decade ago.

We might note that none of these investigations has prompted Congress to substantially expand AHRQ’s budget or restore its mandate to sponsor development of clinical guidelines.

In retrospect, each of our research projects inflamed opponents who had strong beliefs or market share in a particular approach to back pain. None welcomed evidence that conflicted with strongly held opinions. And some were big businesses that seemed eager to avoid scrutiny of their products while profiting from patients with back pain. These experiences became the germ of my conviction that we’re overusing many treatments for back pain.

What’s the real evidence that some treatments for back pain are overused? Does research support this conclusion? This book addresses these questions and many more. It’s the first comprehensive look into what has become a vast and lucrative industry purporting to address back pain, a problem that afflicts millions of Americans.

As we look for more evidence of overuse, I’ll introduce a number of back pain sufferers, some of them quite famous. You may figure that you’re smart enough to avoid the pitfalls. But even the best and brightest among us have sometimes stumbled when it comes to getting treated for back pain. We’ll take a look at some of these individuals over the course of this book and see what we can learn from their experiences.

Chapter 2

EVEN THE BEST AND BRIGHTEST

We know a lot about managing back pain, but many patients never get adequate care. Even celebrities and those in prominent positions sometimes encounter quicksand when they seek care for back pain.

David Fridovich is a tough guy. He was a star linebacker in college, then a Green Beret. In fact, he became a three-star general and deputy commander of the nation's elite Special Forces—the Green Berets, Army Rangers, Navy SEALs, and Delta Force.

Cindy McCain is a savvy businesswoman and philanthropist. She chaired one of the largest beer distributors in the United States, became the wife of Senator John McCain, and adopted an orphan from Bangladesh. She took up racecar driving and flying in her spare time.

Jerome Groopman is a famous doctor and author. He's a professor of medicine at Harvard Medical School and a leading researcher in cancer and AIDS. In all his spare time, he pens articles for the *New Yorker* and writes best-selling books.

John F. Kennedy was the king of Camelot. He served all too briefly as the thirty-fifth president of the United States.

What do these four have in common, other than being smart, ambitious, talented, and successful? Like most of us at some time, they

were plagued by back pain. *Unlike* many of us, by virtue of position or wealth, they had access to the best health care in the world. And yet, to make matters worse, all suffered at the hands of medical professionals they consulted.

Consider the experience of President Kennedy. What he thought was the best medical care in the world bought him two failed back operations, life-threatening complications, a raft of fruitless injections, a useless corset, and years of unnecessary pain. He improved only after pursuing a rigorous exercise program created by Dr. Hans Kraus, a pioneer of sports medicine.

Like Kennedy, the others found benefits from proven low-tech treatments after suffering through unproven high-tech treatments. We shouldn't conclude that all novel or high-tech back pain treatments are useless—but many are overused.

Kennedy's instructive medical history illustrates many of the themes of this book. So let's take a closer look at the history of his back pain and the mistakes he and his doctors made. Then we'll consider the lessons that modern patients can glean from his experiences. Even though his story is decades old, and treatments have ostensibly advanced since the 1960s, many modern patients have similar experiences. In fact, you may conclude that little has changed.

We now have details of Kennedy's back problems, thanks to recent work by both historians and doctors. The relevant medical records became accessible only in 2002 because they had been guarded by friends of the Kennedy administration. Most recently, the family of Dr. Hans Kraus donated some of Kennedy's private medical records to the Kennedy Presidential Library in 2006, filling in events from Kennedy's final years. I had a chance to review Kraus's records at the Kennedy Library.

A Presidential Problem

According to military records, Kennedy began having "an occasional pain in his right sacro-iliac joint" as early as age twenty-one. Kennedy himself described sudden back pain after a tennis match during college,

reporting that it felt like “something had slipped.” His mother, Rose Kennedy, cited a football injury as yet another possible cause of Kennedy’s back pain.

With the outbreak of World War II, Kennedy tried to volunteer for both the Army and the Navy, but both rejected him because of back problems. At that point, Kennedy undertook a personal exercise program. A subsequent medical examination in 1941 deemed him fit for duty, though Kennedy sought further evaluation of his back problems shortly thereafter.

A Boston doctor judged that Kennedy did not have a herniated disc, often called a “slipped disc.” The doctor wrote, “I don’t think this is a disc since the pain . . . does not even remotely resemble a disc—no interference with reflexes, nothing pointing to a spinal condition.”

A Navy neurosurgeon agreed that Kennedy’s pain wasn’t consistent with sciatica. Sciatica is the electric shock of pain and tingling that travel down the leg when a herniated disc pinches a spinal nerve. His doctors recommended against surgery.

Kennedy was working in the Secretary of the Navy’s office when the Japanese attacked Pearl Harbor, but he wanted a combat assignment. After training, he took command of a patrol torpedo (PT) boat in the Pacific.

Kennedy’s crew members were aware of his ongoing back problems. He slept with a plywood board under his mattress and wore a “corset-type thing.” A colleague wrote that Kennedy refused to report to sick bay and “feigned being *well*.”

During a nighttime patrol in the Solomon Islands, in pitch-black conditions, a Japanese destroyer rammed Kennedy’s PT 109. Kennedy was at the wheel, but the impact threw him against the rear wall of the boat’s cockpit, where his back slammed against a steel reinforcing brace.

Military records documented Kennedy’s subsequent heroics. Despite his reinjured back, Kennedy towed a badly burned crewman three miles through open ocean with a life-jacket strap clenched in his teeth. This and other actions won Kennedy the Navy and Marine Corps Medal.

But the war took a toll on Kennedy's back problems, which worsened after the sinking of PT 109. It remains unclear if this was a result of the collision, the strenuous rescue effort, or simply the worsening of an ongoing condition.

After Kennedy returned to the United States, doctors reevaluated him for back surgery. Though still in the Navy, in 1944 Kennedy went to the New England Baptist Hospital with his family's financial support. Here neurosurgeon James Poppen operated on Kennedy for a presumed herniated disc. Following surgery, though, Poppen wrote, "There, however, was very little protrusion of the ruptured cartilage."

Ordinarily, successful disc surgery results in prompt relief. Instead, Kennedy had persistent pain, a prolonged hospitalization, and a resulting transfer to the Chelsea Naval Hospital. Poppen attributed the ongoing pain to severe muscle spasms.

At the naval hospital, the neurosurgeon who had seen Kennedy before deployment to the Solomon Islands reassessed the situation. He questioned the need for surgery. While in the hospital, Kennedy wrote to a girlfriend, saying, "In regard to the fascinating subject of my operation I . . . think the doc should have read just one more book before picking up the saw."

After reviewing the records, my orthopedist colleague Robert Hart said of the surgery, "It was probably a misdiagnosis, but the surgeon in that case did what any surgeon would do—he went ahead and removed the disk anyway." Hart also noted that X-rays a few months after surgery were normal, with no signs of wear in the discs or vertebrae and nothing that would make the spine unstable.

Kennedy was from a political family, so it was no surprise that after his Navy discharge, he ran for Congress. He had persistent back problems through a vigorous political campaign. Those close to him described frequent use of steaming hot tub baths and a lumbar corset. The campaign was successful despite the back problems. Kennedy won by a wide margin and served in Congress for six years.

In 1952, Kennedy moved into the Senate after defeating incumbent Republican Henry Cabot Lodge Jr. While campaigning, he often

walked with crutches to relieve his spine. During his first Senate term, Kennedy's back pain progressed, and he became unbearable to work with. His personal secretary of twelve years, Evelyn Lincoln, wrote that she considered finding a new job.

By 1954, X-rays showed that the disc space where Kennedy had surgery had completely collapsed, leaving essentially no cushion between the adjacent vertebrae. Some early bone spurs were beginning to form. My colleague, Bob Hart, reviewed the X-rays and found no sign of osteoporosis or vertebral compression fractures, contradicting some historians.

That year, at age thirty-seven, Kennedy discussed further back surgery at New York's Hospital for Special Surgery. Despite increased risks due to other medical problems, Kennedy and his doctors decided to proceed with a spinal fusion operation at the site of the previous disc surgery. Doctors told Kennedy that a fusion procedure would strengthen his lower spine and that without it he might lose his ability to walk.

His father, Joe Kennedy, tried to dissuade Kennedy from surgery. But Rose Kennedy later said, "Jack was determined to have the operation. He told his father that even if the risks were fifty-fifty, he would rather be dead than spend the rest of his life hobbling on crutches and paralyzed by pain."

Kennedy underwent the spinal fusion procedure, an operation that welds vertebrae together with bone grafts. The operation included placement of a metal implant made of cobalt-chromium. Such implanted plates were relatively new: a high-tech aspect of Kennedy's treatment.

The postoperative course went poorly. Perhaps because of a serious urinary infection, Kennedy at one point lapsed into unconsciousness, and a priest performed last rites. When he finally left the hospital, Kennedy went to recover at a family home in Palm Beach, Florida.

But an infection brewed at the site of his surgery. In 1955, he returned to the hospital for his third spine operation: to remove the metal plates and surgically clean the infected wound.

While recovering from this operation, Kennedy consulted with Dr. Janet Travell. Travell, a specialist in internal medicine and pain

medicine, eventually became his personal doctor. Asked about the cause of Kennedy's back pain, Travell found it impossible "to reconstruct by hindsight what might have happened to him over the years." However, in her opinion, Kennedy "resented" the back operations, which "seemed to only make him worse."

Travell later recommended a rocking chair for Kennedy, believing it helped his back. She also began trigger point injections with procaine, a local anesthetic. Kennedy's diagnosis when he left the hospital was sacroiliac and lumbar pain with continued muscle spasm.

In 1957, Dr. Travell diagnosed a recurrent abscess of the lumbar spine and admitted Kennedy once again to the Hospital for Special Surgery. In Kennedy's fourth spine operation, surgeons drained a staph abscess and removed dead tissue.

In 1960, Kennedy mounted his successful campaign for the presidency. At that point, he was determined to present the picture of health and vigor, declaring himself in "excellent" shape. But in the White House, Kennedy received regular medical care from a phalanx of doctors, among them Travell, Admiral George Burkley, and a doctor who had immigrated from Germany, Max Jacobson. Jacobson had the reputation for treating celebrities with "pep pills" (amphetamines), and patients nicknamed him "Dr. Feelgood."

Jacobson treated Kennedy with injections of a bizarre cocktail of vitamins, hormones, amphetamines, and other ingredients. Kennedy thought these made him less dependent on crutches and once dismissed questions about the injections by saying, "I don't care if it's horse piss. It works."

However, Burkley concluded in 1961 that Kennedy's various passive treatments, including injections, back braces, ultrasound, and hot packs, were doing more harm than good. He observed what Kennedy tried to hide from the press: that the president went up and down helicopter stairs one at a time, rose only with difficulty from sitting, and often relied on crutches. Fearing the president might end up in a wheelchair, he pressed Travell to consult Dr. Hans Kraus.

Kraus was an Austrian immigrant who specialized in rehabilitation medicine. He was an exercise advocate and had worked with President Eisenhower to establish the President's Council on Physical Fitness. A mountaineer and rock climber who married a downhill ski champion, Kraus was well known to athletes. Some describe him as the father of sports medicine in the United States.

A biographer noted, "Dr. Kraus's approach was controversial within the American medical establishment. He relied strongly on strengthening and stretching exercises, common sense, and avoiding surgery at all costs. His treatments were seemingly old-fashioned, time-consuming and relatively unprofitable for a doctor." Nonetheless, he had a celebrity clientele that included Katharine Hepburn, Eleanor Roosevelt, Yul Brynner, and Angela Lansbury.

Records in the Kennedy Library show that Kraus examined JFK in October 1961 and concluded, "Weakness and stiffness of key posture muscles may well account for some of the persistent pain and acute episodes. . . . We should try a program of gradually increasing strengthening exercises for weak muscles, and limbering and stretching exercises for stiff muscles. . . . I would be in favor of injecting as little as possible."

Kennedy began to exercise three times a week in a small White House gym. He followed a regimen of aerobics, strengthening, and flexibility exercises, all to the strains of his favorite country-and-western and show tunes.

Along with massage and heat therapy, this regimen became a respite for Kennedy from his busy schedule. Nonetheless, Kraus's notes repeatedly indicate that, given competing demands, Kennedy was not as adherent to the program as Kraus would have liked.

Even so, the exercise program produced results within weeks. A *New York Times* article in December 1961 noted, "President Kennedy still is swimming and taking muscle-strengthening exercises every day. . . . His bad back apparently is tremendously better. . . . Dr. Kraus still makes the visit once or twice a week, Presidential aides said, and he has done wonders for the President."