

Medicare's Costliest and Most Dangerous Drug: Prolia

Built on a manufactured diagnosis, modest benefits, and catastrophic harms
[Dr Bharat Desai, M.D.](#)

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Disclaimer

This essay is for educational purposes only and is not intended as personal medical advice. Patients should consult their own physician before making any medical decisions.

Prologue – The Fracture That Changed My Perspective

It began with a friend seeking advice after a fracture that should never have happened.

She hadn't fallen — she merely turned, and her femur snapped.

Her orthopedic surgeon recommended inserting a prophylactic rod in the other femur because the X-ray showed it was “thick.”

That didn't make intuitive sense. Thick bones are supposed to be strong — so why was hers at such high risk of breaking?

Then came the missing clue: she'd been on **Prolia**, a drug prescribed to prevent fractures, for five years.

She had no pathological fractures or high-risk factors beyond a low T-score.

That “thick” femur wasn't healthy at all — it was brittle to the core, the direct result of the very drug meant to protect it.

A treatment designed to prevent fractures had caused one of the most catastrophic fractures imaginable.

What began as a simple consultation turned into a deep investigation into bone biology, the pathophysiology of osteoporosis, and the clinical trials behind its treatments.

What I uncovered was shocking — and profoundly disturbing.

Act I – The Birth of a Manufactured Disease

The diagnosis of osteoporosis was *manufactured* in 1994, when a small ad-hoc committee at the World Health Organization decided that anyone whose bone density was 2.5 standard deviations below the average of a healthy 30-year-old woman would henceforth be labeled “osteoporotic.”

It was a label applied to what is, for most women, a normal biological transition — the gradual bone loss that accompanies aging and accelerates during the first decade after menopause.

True osteoporosis, in the biological sense, means abnormally brittle bone caused by identifiable pathology — nutritional deficiency, hormonal imbalance, toxic exposure, or prolonged immobility — where structure and strength diverge sharply from age-expected norms.

The chosen cutoff, a **T-score of -2.5**, didn't arise from biology or fracture data — it was **reverse-engineered**.

Researchers observed that about 15 percent of older women experience a hip fracture in their lifetime, then asked:

“At what T-score do about 15 percent of women fall below?”

The answer was -2.5.

So they declared: “T-score below -2.5 means osteoporosis.”

Overnight, tens of millions of healthy postmenopausal women were reclassified as patients — and an ICD code (**M81.0, “age-related osteoporosis”**) transformed a normal stage of aging into a billable disease.

That circular logic created a billion-dollar industry — and, eventually, Medicare’s costliest drug.

Even at the time, leading researchers such as **Steven Cummings** and **L. Joseph Melton** warned that the threshold was arbitrary and detached from real fracture risk.

They urged the WHO to use the **Z-score**, which compares bone density

to age- and sex-matched peers — the same way we interpret blood pressure or muscle mass.

But the T-score was chosen instead — guaranteeing that nearly every postmenopausal woman would eventually fall below the line.

It expanded the market for osteoporosis drugs exponentially.

By the late 1990s, critics such as **Ioannidis & Lau (BMJ, 1997)** and editorials in *Osteoporosis International* warned that the definition had “medicalized normal aging.”

But by then, the narrative was locked in — reinforced by marketing that portrayed fragility as inevitable and medication as salvation.

A woman who felt perfectly healthy could now be told she had a disease simply because her scan crossed a number.

Suddenly she — and her doctor, following the algorithm — believed her bones might “snap any moment” and that she needed lifelong medication.

Why did the T-score prevail despite clear warnings?

The truth remains opaque. The WHO panel kept no public minutes, and conflicts of interest were never disclosed.

Many members later became leaders of the **International Osteoporosis Foundation**, which soon received major funding from **Merck, Lilly, and Amgen**.

Act II – The Promise of a Miraculous Cure

Then came the so-called miracle.

Denosumab (Prolia), a monoclonal antibody, blocks RANKL — the signal that tells osteoclasts to remove old bone.

The idea sounded brilliant: if bone loss causes fractures, stop bone loss.

And on scans, it seemed to work. DEXA scores rose, doctors saw “stronger bones,” and patients felt reassured.

But it was a dangerous illusion.

Bone density is not bone strength.

What Prolia builds isn't new bone — it's *old bone that never dies*.

Remodeling stops, micro-cracks accumulate, and bone becomes stiffer and more brittle — like aged wood that snaps instead of bending.

The pivotal **FREEDOM trial (Cummings et al., NEJM 2009)** made headlines with a 68 percent reduction in vertebral fractures and a 40 percent reduction in hip fractures.

Those numbers, repeated endlessly in marketing slides, sound dramatic — but they're **relative reductions**, not absolute outcomes.

In absolute terms:

- **Vertebral fractures:** 7.2% → 2.3% over 3 years (ARR = 4.9%; ≈ 1.6% per year) ≈ 16 fractures prevented per 1,000 women per year — most seen only on X-ray.
- **Hip fractures:** 1.2% → 0.7% over 3 years (ARR = 0.5%; ≈ 0.17% per year) ≈ 1–2 hip fractures prevented per 1,000 women per year.

The disease itself was defined by hip-fracture risk — yet the pivotal trial barely showed a signal for hip protection.

The apparent miracle was, in truth, a mirage — an improvement on paper, not in life.

Act III – The Rebound Trap: Prolia, the Opioid of Bones

When Prolia is discontinued, bone turnover surges.

Within months, many women experience rapid bone loss and clusters of spontaneous vertebral fractures.

To avoid this rebound, patients are told to stay on the drug indefinitely.

And when bone-density scores drop after stopping, both doctor and patient panic — reinforcing the fear that they can never safely quit.

A drug sold as protection becomes a **biological trap** — a form of physiological dependency, not unlike an opioid.

Act IV – When the Net Benefit Is Zero

Prolia prevents about 1–2 hip fractures per 1,000 women each year, yet causes roughly 1 atypical femur fracture per 1,000 women each year.

When the likelihood of harm approaches the likelihood of benefit, the net clinical gain falls to zero.

At that point, treatment stops being prevention — it becomes an **annuity for the drug company.**

Act V – The Profit Machine

Despite modest benefit and real danger, Prolia is now **Medicare's costliest outpatient drug.**

Under Medicare's "buy-and-bill" system, physicians are reimbursed at the drug's average sales price plus 6 percent, while manufacturers add rebates and volume discounts.

It's a structure where nearly everyone profits — pharma, distributors, sales reps, even prescribers — except the patient.

In 2023, taxpayers spent **over \$3 billion** on denosumab — more than on any cancer or cardiac medication under Part B (*CMS 2023*).

By 2024, more than **two million American women** were already receiving Prolia.

The “eligible” pool is vastly larger: roughly **nine to ten million women over 50** meet the T-score definition.

Under current guidelines — and with Prolia marketed as the convenient, twice-yearly “bone-protective” injection — most will remain on therapy for life.

If that trajectory continues, Medicare’s annual spending will climb from **\$3 billion in 2023 to nearly \$20 billion per year by 2030**.

That is not a public-health strategy — it is a **financial time bomb disguised as prevention**.

And if drug companies succeed in expanding similar “treat-the-risk” models to **GLP-1 drugs for obesity**, Medicare’s collapse will no longer be hypothetical.

The system will buckle under the weight of chronic, lifelong prescriptions masquerading as prevention.

It's the perfect business model — a **perpetual-dependency machine** engineered for the benefit of a pharmaceutical cartel.

The same playbook that fueled the opioid epidemic now drives a quieter addiction — one that turns healthy individuals into lifelong customers.

Act VI – The Physiology We Forgot

True bone strength comes from stressing and nourishing the skeleton — not from silencing its biology.

- **Protein** builds the collagen matrix that minerals harden.
- **Micronutrients** — vitamins D3, K2, magnesium, zinc, and B-complex — direct calcium into bone, not arteries.
- **Healthy fats** — natural saturated, monounsaturated, and omega-3 — support hormones and absorption of fat-soluble vitamins, not industrial omega-6 seed oils that drive oxidation and inflammation.
- **Resistance and impact training** trigger renewal and improve balance and fall resilience.

- **Hormonal balance**, especially adequate estrogen, preserves bone architecture.
- **Sunlight, movement, and sleep** align circadian and metabolic rhythms.
- **Fix insulin resistance. Metabolic health is bone health.**

For fifty years, fat-phobic, lipid-centric medicine left millions deficient in the very nutrients bones require — protein, D3, K2, natural fats, and minerals — while steering them toward refined carbohydrates and seed oils, fueling today's epidemic of metabolic dysfunction.

A Personal Note to My Colleagues

I'm not a rheumatologist, nor a research scientist who has spent thousands of hours dissecting trial data.

What I've presented here is drawn entirely from publicly available evidence, guided by applying human biology and physiology — and by asking *how, why, and why not* with common-sense reasoning.

If anyone believes my interpretation is inaccurate — whether in the data, the framing, or the conclusions — I welcome critique.

My goal is not to lecture, but to invite dialogue.

Challenge it. Rebut it. Examine the numbers, read the studies, and decide for yourself.

If the data I've presented are factually correct — and if you reach the same conclusion that I did — then ask yourself a simple question:

Would you take this drug yourself?

Would you give it to your spouse, your sister, or your patient — based solely on a T-score?

For me, the answer is **no**.

Knowing what I know now, I could not in good conscience prescribe Prolia for routine “age-related osteoporosis, strictly based on T score”
There are safer, stronger, and far more physiological ways to protect

bone — through muscle, movement, nutrition, hormones, and metabolic health.

Epilogue – The Moral Fracture

Prolia isn't just a drug story — it's a symbol of medicine's moral fracture: how good intentions harden into dogma, and dogma into harm.

The abject failure of the American medical-industrial complex is etched in the data — and in the lives it was meant to protect.

U.S. life expectancy is now **78.4 years (2023)** — down from 78.8 in 2019 — while we spend about **\$13,400 per person** on healthcare, more than any other nation.

In Japan, life expectancy is around **84.5 years**, with spending of just **\$5,300 per person**.

We outspend. We underperform.

The verdict for the physician is sobering.

We've stopped thinking critically — stopped asking *how, why, and why not* — and in doing so, betrayed our duty as true patient advocates.

But we don't have to accept this status quo.

We can — and must — be the catalyst for change.

What medicine needs now is not just a **paradigm shift**, but a **paradigm mindshift** —

a transformation in how we think, question, and care.

It begins with respect for human biology, with curiosity over complacency, courage to challenge, and the humility to be wrong.

Until that happens, stories like Prolia — and statins — will keep repeating.

About the Author

Dr. Bharat Desai is a board-certified internist who practiced for nearly four decades before devoting his work to exploring and teaching physiology-based medicine — a return to curiosity, context, and common sense in healthcare.

Suggested References

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