

A Nobel laureate geneticist discovers a cure for a rare disease that causes premature aging. He finds that this treatment also slows the aging process in normal people. When he tries to market this treatment, the government intervenes.

The Perfect Problem

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## **The Perfect Problem**

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ISBN 978-1-60145-911-4

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2009

## Chapter 2

The mahogany paneled boardroom of Volarian Pharmaceuticals slowly filled with well-dressed people of obvious distinction. The CEO and Chairman of the Board, Richard Zellar, quietly mingled with the board members as they filled their plates from the buffet at the end of the room. He was dressed in a finely tailored blue pin-striped suit, and his gold cufflinks sparkled as he gestured with his hands when he spoke. His hair was almost white and meticulously combed straight back. The plush leather chairs along the long cherry table were slowly occupied, and everyone picked at their cold shrimp and asparagus as they quietly talked. Zellar decided to call the meeting to order.

“I’d like to welcome you all to the summer board meeting of 2023,” Zellar began enthusiastically, rubbing his hands together. “I’d like to especially welcome our new members, Melinda Bates-Stevens and Andrew Bowen. Would you be kind enough to introduce yourselves to the board?”

“Sure, I guess I’ll go first.” Bates-Stevens stood up, wiped her mouth with her napkin and smiled apologetically. She was an attractive woman in her fifties, conservatively dressed in a black suit. “My name is Melinda Bates-Stevens and I am President and CEO of TechLand, a retail computer, accessories and service company. We have outlets in forty-two states and four countries.”

“Welcome, Melinda. We look forward to your input. Andy?” “Yeah, Dick.” He stood up. “I am Andy Bowen and I am the CEO of ElderCareCo, a nursing home and assisted living company. We have about four hundred units across the country.” Bowen was an enthusiastic forty-five year old man with thinning black hair and a

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waistline befitting someone who was no stranger to an all-you-can-eat buffet.

“Great. We look forward to working with you both. I’d like to call the meeting to order. You have all previously received a copy of the minutes from our last meeting.” He looked from side to side. “Do I hear a motion to accept the minutes as written?”

An anonymous voice muttered, “So moved.”

“Do I hear a second?”

“Second.”

“All in favor please signify by saying ‘aye.’”

“Aye.” The board mumbled in unison. Nobody looked up from their handouts.

“Okay, old business. You all should have received a packet on the genome product. As you know, this has been one of our long term objectives. To get into genetic therapies. Zellar turned to Bob Bender, VP of business development. “Bob, let’s give the new board members some background on this.” Zellar waved his hand over the table. “The agenda is light, so we can spend some time on this. Is that okay with everyone?”

“Sure, Dick. Let me give you a brief summary of where we are on this. Stop me at any time with questions.” Bob was an eager young man, well-dressed and obviously anxious to impress. He paused for a few seconds and looked at his notes. “We’ve been looking into a genetic engineering approach to an anti-aging product.” He looked around the room and smiled, waiting for any response.

“What do genetics have to do with the aging process?” Bowen asked, glancing around to see if anyone might have thought it a ridiculous question.

“As it turns out, quite a bit,” Bender replied, still smiling. “As you know, genes are made of DNA. When cells in our body divide, the DNA in the cells divide. At the ends of the DNA strands are pieces of genetic material called telomeres. Here, let me draw it.”

He walked to the flip chart in the corner of the room and picked up a marker. He drew a DNA strand in blue, and then drew telomeres on the ends in red. “These telomeres, shown in red, help the DNA to reproduce itself. Unfortunately for all of us, each time the

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DNA divides, a piece of this telomere breaks off.” He turned and crossed off the ends of the red telomeres. “So, as we age, the telomeres on the DNA get shorter and shorter. There was a scientist named Leonard Hayflick who determined that in human cells, there is a limit to the number times a cell can divide – only about fifty times. This limit was due to the progressive shortening of these telomeres. After this limit is reached, now called the Hayflick limit, the cells stop dividing and get old and die. So the first thing we looked into was a way to repair these telomeres with an enzyme called telomerase.”

“So, what is this telomerase, Bob? Does this reverse this Hayflick limit?” Bowen asked.

“Well, not exactly. You see, all cells possess this telomerase gene, which produces the enzyme telomerase. Telomerase adds the pieces of DNA lost at the telomeres during cell division. So, when this gene is turned on, the cells don’t grow old. They become immortal. But, unfortunately, early in our development, almost all of our cells turn this gene off. And this starts the clock ticking.”

“So, are we trying to develop a way to turn this gene back on? Or can we deliver this telomerase enzyme directly to the cells?” Bowen pursued.

“Getting a drug to every cell in the body is a daunting task. When you take a pill, it is first broken up by the digestive acids and enzymes. What’s left is absorbed by the intestines and sent to the liver, which filters out everything it deems to be a toxin. After all of this, the medication has to get to the cell, get into the cell, and then exert an effect. Even if we were successful up to this point, there’s the problem of unregulated telomerase.”

“Bob, explain what you mean by unregulated,” Zellar said as he half stood.

“In normal cells, there are regulatory mechanisms that prevent the unchecked growth of cells,” Bender continued. “If we just introduce telomerase into the cell, these regulatory mechanisms are bypassed. That is what cancer cells do. Cancer cells are immortal because they produce telomerase. We’d have a huge problem getting such a drug past the FDA. As you know, the cost of taking a single

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drug through the Food and Drug Administration approval process is three hundred to eight hundred million dollars. We would have to have some assurance that we'd recover our development and FDA approval costs before we got too far into it."

"So could a genetic engineering approach work? It seems, to say the least, problematic," Bates-Stevens added. The other board members nodded in agreement.

"If we were able to genetically engineer an anti-aging treatment, how much longer could people live? Is immortality possible?" Another board member asked.

"I doubt it, really. The longest anyone has ever lived is about one hundred and twenty years. What we would be shooting for is maybe another twenty years or so to our current life expectancy. From our research, that is the number we need to hit to be attractive in the market," Bob added, drawing a '20' on the flip chart and circling it.

"The twenty year life extension is conservative, mind you. The market potential is tremendous, even if it proved to be only mildly effective," the CEO added. "Look at the vitamin and herb market. Billions of dollars. And what sells those products is the hope of benefit and the attraction of self-directed preventive medication. There's very little formal science there. In fact, science almost always ruins their marketing schemes. The more data there are, the less hocus-pocus they can put out. They would much rather that their marketing be based on faith and word of mouth."

"All we would have to do," Bob continued, "is to present the argument we've just presented here around this table to the public concerning this anti-aging product, and then show the data from the independent experiments where nematodes, fruit flies and mice have had their lifespans doubled with this kind of genetic engineering. There are lots of those experiments, by the way. We would have our pick. And that's it. End of marketing plan. It would be a multi-billion dollar product."

"Aging, my friends," Zellar said confidently as he stood, "is the perfect problem. Everyone gets it, and nobody wants it. The market for anti-aging products is growing faster than the science.

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Americans spend more than a billion dollars a year on so called anti-aging cosmetics.”

“So where are we then? More research on telomerase?” Bowen asked.

“Well, we went down that road for a while. But we didn’t get very far. We had some success in our fruit fly experiments, but in our mouse work we had considerable difficulty with gene penetrance. You know, getting the treatment to the target cells.

“We soon realized that researchers in the private sector were way ahead of us. One of these centers is private and mostly self-funded. The Genetic Research Institute. It was founded by Dr. Noah Brantner, a Nobel laureate.”

“Isn’t he some kind of relative of yours, Melinda?” Zellar asked.

“Yes, he’s my son-in-law’s uncle. I’ve met him briefly a few times. I wasn’t aware that he was working on an anti-aging treatment.”

“He has some funding from the Progeria Foundation, as well as from the NIH,” Bender continued. “Progeria is a genetic disease that leads to premature aging.

“As you can see in your handouts, Dr. Brantner’s Progeria treatment, Gerinex, has had some very promising Phase One clinical trials. He has applied for Phase Two trials, and, with our help, he will likely get approval.”

“But what does this disease treatment have to do with Volarian? I’ve never even heard of it.”

“Well,” Bender replied, “in the course of their extensive research into the genetic defects of Progeria patients, they discovered many genetic degradations that occur over time in all of us and eventually lead to what we call the aging process. Repairs for these defects have been bundled into Gerinex. Sort of a shotgun approach when it comes to treating Progeria, but exactly the approach needed to address the many genetic changes associated with the aging process in everybody else.”

“How do we know it will work on people who don’t have Progeria?”



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“The only way to know. Human trials. But with the high cost and incredibly slow pace of getting FDA approval, we had to start our trials outside of this country. As you may know, there is a booming industry in India for doing human clinical trials. There is no shortage of willing subjects. We’ve had a trial going there now for about two years.”

“How many people are in this trial?”

“About five hundred. It’s a small trial. We wanted to make sure there weren’t any bad side effects. And there weren’t. The treatment is very well tolerated. So we are looking to expand our trials.”

“Any results yet?”

“Well, the problem with doing human clinicals is that our lifespan is so long that you have to wait a long time to see a change. With worms and even mice we can see a change in the span of months. But we’ve been measuring things like exercise tolerance, cardiac output, visual acuity and skin elasticity. We’re beginning to see a difference between the treated group and the control group. We’re very confident that this is going to be a very successful treatment. Based on the safety data with Progeria patients and our own experience in India, we are going to file for Phase Three trials to treat the aging process. Probably next spring.”

“How do you think that will be viewed by the FDA?”

“We hope they’ll be receptive, but we have to be prepared for a negative outcome,” Zellar responded.

“What would a negative outcome be?” Bowen asked.

“Government pressure in the form of oversight hearings, investigations and maybe even harassment. We don’t know. But I want you all to be very careful about who you talk to or what you say on the phone or by e-mail.”

“If this is going to be such a big deal, I think we need to know more about this treatment,” Bates-Stevens said.

“I agree. I’d like to have Dr. Brantner come and speak to us about his work. Maybe we could set up a dinner. He can certainly explain it better than Bob or I,” Zellar said. “Melinda and Andy, you

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might want to tour the Genetic Research Institute. We've all been there a couple of times. It's very interesting."

"Yes. I'd like that," Melinda replied. "I'll give Noah a call." She and Andy nodded to each other.

"Good," Zellar said as Bender took his seat. "Any other old business? Okay. Before we go on to new business, does anyone need anything from the buffet?"

## Chapter 3

Brandon Conley kicked at the Yoshino cherry petals on the sidewalk as he walked from his car to the office. The three hundred acres of the National Institutes of Health campus were ablaze with the light pink-laden trees. It was always a welcome statement of spring after the last vestiges of winter had melted away.

As he turned to enter his building, one of seventy-five in the complex, he saw Kyle Thomas ahead of him in the lobby.

“Kyle!” he called out as he quickened his pace to catch up.

“Oh! Hi, Brandon.” He smiled with recognition. “How are you?”

“Good. Great time of year, you know?” He shook some petals off of his shoes. “I’m glad I ran into you. I’ve been meaning to call you.”

“Oh, yeah? What’s up?”

“I’ve got this application I’d like you to look at. It’s pretty interesting and I’m not really sure where to go with it.”

“Okay. Well, are you free for lunch?”

“Yeah. I’m pretty sure. Want to meet in the deli about 12:30?”

“Sure. See you then.” Kyle turned and took the elevator to his floor. Brandon headed for the stairs.

Brandon and Kyle both worked at the National Human Genome Research Institute, or the NHGRI, one of the twenty-seven components of the National Institutes of Health in Bethesda. The NHGRI developed and implemented technology for understanding, diagnosing and treating genetic diseases. It was Brandon’s responsibility to sift through some of the thousands of grant applications that came through the institute every year and decide

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which ones might merit further attention. Kyle was a liaison to the Administration on Aging, under the Department of Health and Human Services in Washington.

Later, Brandon and Kyle carried their trays to an empty table at the deli in their building.

"I had the minestrone last week," Brandon said as he nodded toward Kyle's tray. "It was decent."

"Yeah, it looked pretty good." They set their trays down. "So what's going on?"

Brandon hunched forward over his food. "Ever hear of the disease Progeria?"

Kyle thought for a moment as he blew on a teaspoonful of soup. "Nope."

"Exactly. Few people have. It's a rare genetic disease that causes kids to age rapidly and die of old age by the time they are teenagers."

"So?"

"Well, several years ago we gave a grant to Dr. Noah Brantner to research a genetic therapy for this disease. Have you heard of him?"

"No, can't say as I have."

"He's a Nobel laureate. Cured Muscular Dystrophy. Anyway, his group also got some money from a private donor that had a kid with this disease."

"A rich donor?"

"Big time. So they had a lot of bucks and our blessing."

"And?"

"And, they came up with a treatment. And, it apparently works."

"Great story, Brandon. Chalk up another victory for modern science. Are you going to get any dessert?"

"Wait. Listen. There's more. This guy Brantner has patented this treatment. The drug, if you can call it a drug, is called Gerinex. It has been approved for use in humans with Progeria. But since there are only about a hundred cases of Progeria in the world, it's basically an orphan treatment. So who cares if gets approved, right?"

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“You’d have to put me in the not caring column at this point.”

“Well, listen to this. I got this application the other day from Volarian. You know, the drug company?”

“Yes. I know them.”

“They are asking for us to give them a grant to use this same treatment, this Gerinex, to treat the aging process.”

“But isn’t that what it is already approved for?”

“Yeah, but they’re not talking about Progeria kids here. They’re talking about Phase Three trials in the general population. Get it? A cure for aging!”

Kyle stared into his empty soup bowl, processing what he had just heard. “Oh, my God,” he whispered.

“See what I mean?”

“But you said Volarian. What happened to Dr. Brantner?”

“He must be working with them,” Brandon surmised.

“You mean he must have sold out,” Kyle replied cynically. “How did he get the drug approved in the first place?”

“Initially, he filed an IND.”

“A what? I know I should know this, but...”

“An Investigational New Drug application. This gets submitted to the FDA to provide preliminary research data to see if it will be reasonable to test the drug in humans. In the case of Progeria, he submitted what’s called a compassionate IND, which means the drug will be treating a rare disease.”

“I presume that makes it easier to get approved?”

“Sure. Why not, right? There’s no other treatment. So he easily gets Phase One approval to treat a few of these kids. And apparently he gets some positive results. So he applied for Phase Two, which allows him to treat every kid with Progeria.”

“Did he get it?”

“Yeah. The lobbyists for Volarian pushed real hard for it. This just happened.”

“Enter Volarian,” Kyle interrupted.

“Exactly. It was an easy favor to grant.”

“In return for what?”

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“Volarian probably gave in somewhere. Something important politically to the FDA.”

“So where’s the big problem?”

“The problem is Phase Three.”

“Expanded trials? The last step before approval.”

“Right. Phase Three authorizes treatment of several hundred to several thousand people.”

“But I thought there weren’t that many Progeria patients?”

“That’s the problem. Think about it. Volarian is backing him. I’m guessing they’re going to go after a broader indication.”

Kyle shrugged. “Like what?”

“Like aging in general. You know, stopping aging.”

“Wow. So this guy develops this gene therapy for a rare genetic disease that nobody cares about and nobody notices. I’ll bet this one never even got to the director level. So then he realizes the potential of this treatment and hooks up with a big drug company that’s looking for the next big thing. They’ve got the marketing and the distribution. It’s a pretty clever back door approach.”

“Back door?” Brandon asked.

“Yeah. Drug companies do this all the time. They go for the easy approval for some minor indication, then after it’s been used in people for awhile they go for the more lucrative indication.”

“So, what do we do with this?”

“This isn’t just a medical issue, Brandon. We’re not talking about another treatment for diabetes or anything. This has really big political implications. If this gets out, it could even be an issue in the November election.”

“I didn’t even think about that aspect. You’re right.”

“Let me run this by some of my contacts on the hill. The Administration on Aging needs to know about this. Keep this quiet until I get back to you, okay?”

“Sure. But what if Volarian starts pressing?”

“I don’t think they will. They don’t want the attention at this point.”

“I suppose. Okay. I’ll wait to hear from you,” Brandon said as they got up from their table.

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Kyle Thomas walked away, mumbling under his breath. "Jesus, this is bad!" He pounded on the elevator button. "Goddamn!"

The woman next to Kyle smiled sympathetically, "Oh I know, these elevators are so slow." Kyle looked at her blankly.

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