Big Pharma Cashes in on HGH Abuse

DAVID B. CARUSO & JEFF DONN, Associated Press

Whether for athletics or age, Americans from teenagers to baby boomers are trying to get an edge by illegally using anabolic steroids and human growth hormone, despite well-documented risks. This is the second of a two-part series.

A federal crackdown on illicit foreign supplies of human growth hormone has failed to stop rampant misuse, and instead has driven record sales of the drug by some of the world's biggest pharmaceutical companies, an Associated Press investigation shows.

The crackdown, which began in 2006, reduced the illegal flow of unregulated supplies from China, India and Mexico.

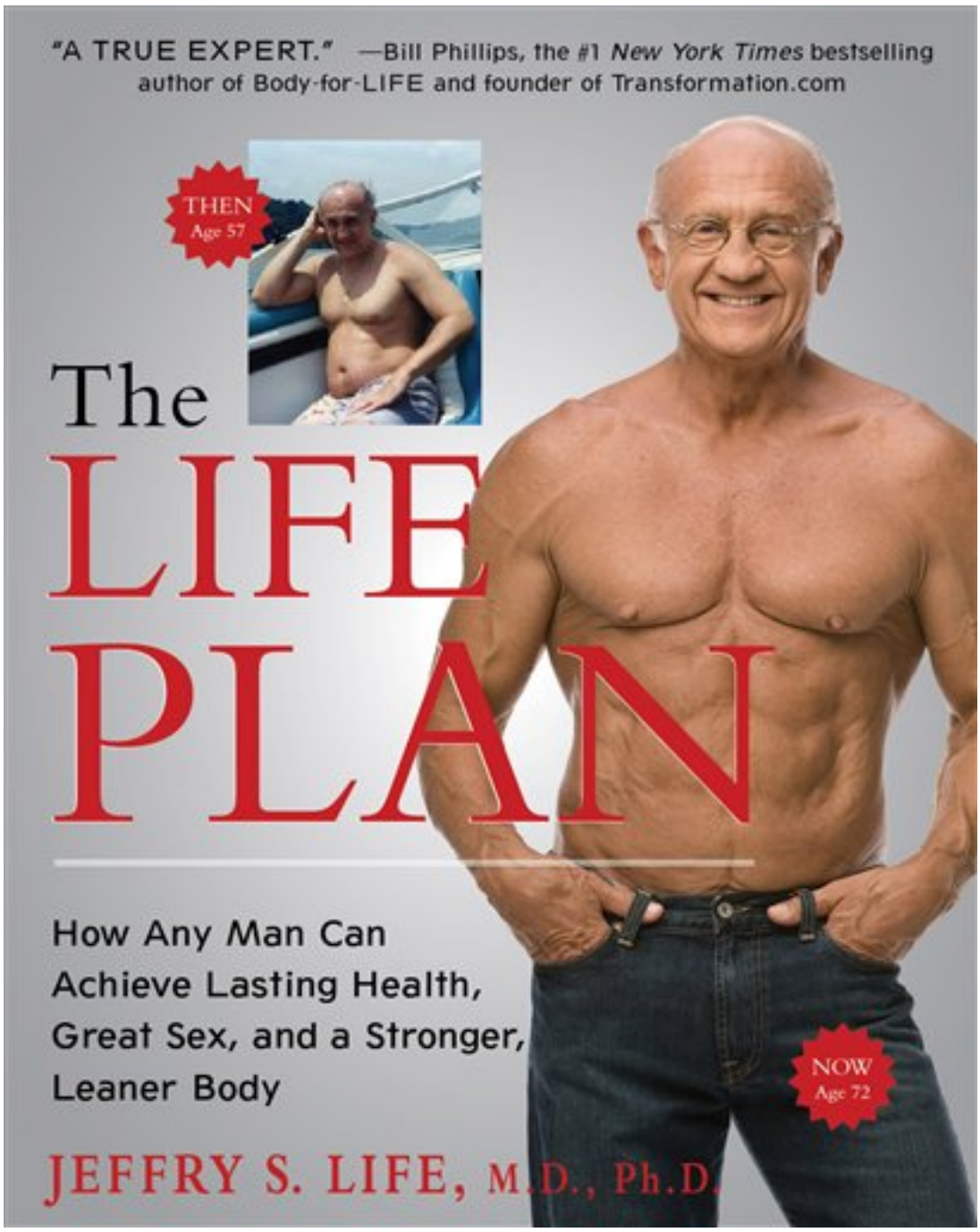
But since then, Big Pharma has been satisfying the steady desires of U.S. users and abusers, including many who take the drug in the false hope of delaying the effects of aging.

From 2005 to 2011, inflation-adjusted sales of HGH were up 69 percent, according to an AP analysis of pharmaceutical company data collected by the research firm IMS Health. Sales of the average prescription drug rose just 12 percent in that same period.

Unlike other prescription drugs, HGH may be prescribed only for specific uses. U.S. sales are limited by law to treat a rare growth defect in children and a handful of uncommon conditions like short bowel syndrome or Prader-Willi syndrome, a congenital disease that causes reduced muscle tone and a lack of hormones in sex glands.

The AP analysis, supplemented by interviews with experts, shows too many sales and too many prescriptions for the number of people known to be suffering from those ailments. At least half of last year's sales likely went to patients not legally allowed to get the drug. And U.S. pharmacies processed nearly double the expected number of prescriptions.

Peddled as an elixir of life capable of turning middle-aged bodies into lean machines, HGH — a synthesized form of the growth hormone made naturally by the human pituitary gland — winds up in the eager hands of affluent, aging users who hope to slow or even reverse the aging process.



Experts say these folks don't need the drug, and may be harmed by it. The supposed fountain-of-youth medicine can cause enlargement of breast tissue, carpal tunnel syndrome and swelling of hands and feet. Ironically, it also can contribute to aging ailments like heart disease and Type 2 diabetes.

Others in the medical establishment also are taking a fat piece of the profits — doctors who fudge prescriptions, as well as pharmacists and distributors who are content to look the other way. HGH also is sold directly without prescriptions, as new-age snake oil, to patients at anti-aging clinics that operate more like automated drug mills.

Years of raids, sports scandals and media attention haven't stopped major drugmakers from selling a whopping $1.4 billion worth of HGH in the U.S. last year. That's more than industry-wide annual gross sales for penicillin or prescription

allergy medicine. Anti-aging HGH regimens vary greatly, with a yearly cost typically ranging from $6,000 to $12,000 for three to six self-injections per week.

Across the U.S., the medication is often dispensed through prescriptions based on improper diagnoses, carefully crafted to exploit wiggle room in the law restricting use of HGH, the AP found.

HGH is often promoted on the Internet with the same kind of before-and-after photos found in miracle diet ads, along with wildly hyped claims of rapid muscle growth, loss of fat, greater vigor, and other exaggerated benefits to adults far beyond their physical prime. Sales also are driven by the personal endorsement of celebrities such as actress Suzanne Somers.

Pharmacies that once risked prosecution for using unauthorized, foreign HGH — improperly labeled as raw pharmaceutical ingredients and smuggled across the border — now simply dispense name brands, often for the same banned uses. And usually with impunity.

Eight companies have been granted permission to market HGH by the U.S. Food and Drug Administration, which reviews the benefits and risks of new drug products. By contrast, three companies are approved for the diabetes drug insulin.

The No. 1 maker, Roche subsidiary Genentech, had nearly $400 million in HGH sales in the U.S. last year, up an inflation-adjusted two-thirds from 2005. Pfizer and Eli Lilly were second and third with $300 million and $220 million in sales, respectively, according to IMS Health. Pfizer now gets more revenue from its HGH brand, Genotropin, than from Zoloft, its well-known depression medicine that lost patent protection.

On their face, the numbers make no sense to the recognized hormone doctors known as endocrinologists who provide legitimate HGH treatment to a small number of patients.

Endocrinologists estimate there are fewer than 45,000 U.S. patients who might legitimately take HGH. They would be expected to use roughly 180,000 prescriptions or refills each year, given that typical patients get three months' worth of HGH at a time, according to doctors and distributors.

Yet U.S. pharmacies last year supplied almost twice that much HGH — 340,000 orders — according to AP's analysis of IMS Health data.

While doctors say more than 90 percent of legitimate patients are children with stunted growth, 40 percent of 442 U.S. side-effect cases tied to HGH over the last year involved people age 18 or older, according to an AP analysis of FDA data. The average adult's age in those cases was 53, far beyond the prime age for sports. The oldest patients were in their 80s.

Some of these medical records even give explicit hints of use to combat aging, justifying treatment with reasons like fatigue, bone thinning and "off-label," which means treatment of an unapproved condition. In other cases, the drug was used "for an unknown indication," meaning that the reason for treatment wasn't clear.

Even Medicare, the government health program for older Americans, allowed 22,169 HGH prescriptions in 2010, a five-year increase of 78 percent, according to data released by the Centers for Medicare and Medicaid Services in response to an AP public records request. And nearly half the increase came in one year: 2007.

"There's no question: a lot gets out," said hormone specialist Dr. Mark Molitch of Northwestern University, who helped write medical standards meant to limit HGH treatment to legitimate patients.

And those figures don't include HGH sold directly by doctors without prescriptions at scores of anti-aging medical practices and clinics around the country. Those numbers could only be tallied by drug makers, who have declined to say how many patients they supply and for what conditions.

The AP approached every U.S.-authorized manufacturer to ask what efforts they make to market responsibly and prevent abuse. Only one HGH supplier, Novo

Nordisk, agreed to an interview.

"We're doing our level best to make sure that the right patients are getting the right medicine at the right time," said company spokesman Ken Inchausti.

He said the company is aware of the abuse issue. He said if patients apply for assistance from the company's patient-support hub, prescriptions will be flagged for review if they are missing the most rigorous test or an endocrinologist's signature. He said the company won't sell HGH directly to doctors accused of bad practices and does not deal with anti-aging clinics.

Representatives of other FDA-approved HGH makers insist they do not encourage use by bodybuilders or athletes or wealthy baby boomers trying to recapture their youth. But some said they are largely powerless to control who uses their medications or why.

"Lilly cannot restrict the actions of distributors, pharmacies or doctors," Eli Lilly spokeswoman Kelley Murphy said in a written statement.

That argument doesn't fly for critics like Dr. Peter Rost, a retired Pfizer executive who filed a whistleblower lawsuit over the HGH marketing practices of Pharmacia, which later merged with Pfizer. He said drug companies are simply looking the other way and betting that their profits will eclipse the cost of any fines.

They view it as "good business," he said.

PEDDLED ON INTERNET

Type "human growth hormone" into any Internet search engine, and it will spit back countless websites with overblown promises of smoother skin, better sex, weight loss and even renewed body organs.

Any doctor who actually prescribes the drug for those purposes is taking a legal risk.

FDA regulations ban the sale of HGH as an anti-aging drug. In fact, since 1990, prescribing it for things like weight loss and strength conditioning has been punishable by 5 to 10 years in prison.

Such marketing claims are routinely made at hormone clinics like Palm Beach Life

Extension, whose owners are among 13 people now awaiting trial on federal charges in Florida in a steroids and HGH distribution case brought last year.

"Grow YOUNG with Us!" screamed a banner on the company's now-defunct website, which advertised that HGH can reduce body fat, improve vision, strengthen the immune system, aid kidney function, lower blood pressure and enhance memory and mood.

The clinic arranged to have its clients' prescriptions filled at Treasure Coast Pharmacy, in Jensen Beach, Fla.

In 2009, the FBI recorded a phone call between the pharmacy's owner, Peter Del Toro, and a doctor in Elkton, Md., who was cooperating with agents after being implicated in a related steroid-distribution case.

Their talk, documented in a court filing, illustrates how things often work in the networks of pharmacies and clinics that drive HGH sales.

Patients submitted a medical history form by mail and took a blood test. But in most instances, the indictment said, the evaluation was a sham: One doctor was charged with giving a clinic a pad of blank, signed prescriptions to save him the chore of signing off on each diagnosis. He got $50 for every drug order bearing his name, the indictment said.

Dr. Rodney Baltazar, the Maryland physician cooperating with the FBI, sometimes consulted briefly with patients via webcam. But he made it clear in the call that those evaluations were perfunctory at best.

Baltazar was a gynecologist, not an endocrinologist. He said he knew "a little bit" about HGH and testosterone, which are often prescribed in tandem, but he relied largely on clinic salespeople to set doses.

The pharmacist coached the doctor: Keep detailed medical charts documenting that patients are taking the drug for at least some kind of health problem, just in case the U.S. Drug Enforcement Administration ever came calling.

"Because somebody questions you, you want to be able to say, 'Here, look at his chart. You know, he's got fatigue. He's got, you know, a decreased sex drive. He's got increased body fat. He has some -- some slight depression, probably.' Whatever his signs and symptoms are."

None of these conditions is a legal reason to prescribe HGH. But the pharmacist said that most investigators will be satisfied and move on "because there's guys that are just selling stuff basically like a boiler room."

Del Toro was arrested along with 12 other people in September 2011 on charges that they distributed steroids and human growth hormone to people who had no legitimate medical need. He is awaiting trial. His lawyer declined to comment. Baltazar was sentenced to six months in prison for involvement in steroid distribution schemes.

At the height of the crackdown in 2007, the federal government went after Pfizer in a case involving anti-aging clinics. The company paid $34.7 million in fines to settle the case — 11 percent of the company's annual revenue from the drug.

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TROUBLED HISTORY

Blockbuster U.S. sales of HGH represent the latest frustration in 25 years of government efforts to control abuse of the growth drug made infamous by sports scandals.

First marketed in 1985 for children with stunted growth, HGH was soon misappropriated by adults intent on exploiting its modest muscle- and bone-building qualities. Congress limited HGH distribution to the handful of rare conditions in an extraordinary 1990 law, overriding the generally unrestricted right of doctors to prescribe medicines as they see fit.

Despite the law, illicit HGH spread around the sports world in the 1990s, making deep inroads into bodybuilding, college athletics, and professional leagues from baseball to cycling. The even larger banned market among older adults has flourished more recently.

For years, cheaper supplies from unauthorized foreign factories, particularly in China, fed the market via direct and Internet sales that sidestepped the medical establishment.

Though such shipments were banned under other law, the imports initially attracted little attention because they were usually labeled as raw pharmaceutical ingredients, which compounding pharmacies are allowed to bring into the country.

That flow began to be curtailed in 2006, when U.S. drug authorities stepped up efforts to block shipments at the border.

A handful of pharmacies across the country were hit with criminal charges over their handling of HGH. Federal prosecutors charged China's biggest HGH maker, GeneScience Pharmaceutical, with illegally distributing its Jintropin brand in the U.S. The company's CEO pleaded guilty in 2010.

With illicit supplies crimped, many pharmacies stopped selling unauthorized HGH. But tens of thousands of adult abusers began buying pricey U.S.-approved HGH that remained available in abundant supply, the AP found in its analysis of sales data.

Thus, pushed by a powerful demand, sales of U.S.-approved brands have swelled far beyond expected levels for a drug approved in just a handful of rare conditions.

Dr. Robert Marcus, a retired hormone specialist who left HGH manufacturer Eli Lilly and Co. in 2008, said that company was bent on stopping foreign counterfeits, not on cutting off abusers. "That's where their major level of frustration was — pharmaceutical fraud — rather than focusing on people who were using growth hormone illegitimately," he said.

Dr. Jim Meehan, of Tulsa, Okla., who has used HGH to treat aging problems and sports injuries, said the federal clampdown "never seemed to affect my patients and their ability to get Omnitrope, Tev-Tropin" and other government-approved brands.

The big drug companies have applauded the foreign crackdown and urged the government to do even more to combat sales of fake or fraudulently labeled HGH. In 2004, Bruce Kuhlik, speaking for the Pharmaceutical Research and Manufacturers of America, told a federal task force that unauthorized drug importation "is inherently unsafe" and industry representatives used Chinese HGH imports as their poster child.

In 2007, as the HGH embargo gained momentum, authorized makers picked up 41 percent more HGH orders, raising their annual total from 245,000 to 345,000, according to the analysis of the IMS Health data. Similarly, most of the drug's sales boom happened in the first two years of the crackdown, with 46 percent inflation-adjusted growth in yearly sales to $1.1 billion.

Steve Kleppe, of Scottsdale, Ariz., a restaurant entrepreneur who has taken HGH for almost 15 years to keep feeling young, said he noticed a price jump of about 25 percent after the block on imports. He now buys HGH directly from a doctor at an annual cost of about $8,000 for himself and the same amount for his wife.

Despite higher prices, the business has expanded in recent years largely on the strength of sales to healthy adults who can afford to indulge their hope of retaining youthful vigor.

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GROWING OLD

Many older patients go for HGH treatment to scores of anti-aging practices and clinics heavily concentrated in retirement states like Florida, Nevada, Arizona and California.

These sites are affiliated with hundreds of doctors who are rarely endocrinologists. Instead, many tout certification by the American Board of Anti-Aging and Regenerative Medicine, though the medical establishment does not recognize the group's bona fides.

The clinics offer personalized programs of "age management" to business executives, affluent retirees, and other patients of means, sometimes coupled with the amenities of a vacation resort.

The clinics insist there are few, if any, side effects from HGH. Mainstream medical authorities say otherwise.

A 2007 review of 31 medical studies showed swelling in half of HGH patients, with joint pain or diabetes in more than a fifth. A French study of about 7,000 people who took HGH as children found a 30 percent higher risk of death from causes like bone tumors and stroke, stirring a health advisory from U.S. authorities.

For proof that the drug works, marketers turn to images like the memorable one of pot-bellied septuagenarian Dr. Jeffry Life, supposedly transformed into a ripped hulk

of himself by his own program available at the upscale Las Vegas-based Cenegenics Elite Health. (He declined to be interviewed.)

These promoters of HGH say there is a connection between the drop-off in growth hormone levels through adulthood and the physical decline that begins in late middle age. Replace the hormone, they say, and the aging process slows.

"It's an easy ruse. People equate hormones with youth," said Dr. Tom Perls, a leading industry critic who does aging research at Boston University. "It's a marketing dream come true."

Some scientific studies of HGH have found modest benefits: some muscle and bone building, as well as limited fat loss, but nothing like the claims of the anti-aging industry. And some of the value credited to HGH may instead come from testosterone, which is routinely provided with HGH by anti-aging doctors and sports suppliers.

Endocrinologists say it's natural for the body to produce less growth hormone as people age beyond their early 20s, because they aren't growing anymore. Only a tiny number of adults with extraordinarily low HGH levels — perhaps several thousand of them — are believed to suffer real deficiencies that can properly be treated with the hormone.

Still, anti-aging doctors routinely diagnose otherwise healthy middle-aged people with an HGH deficiency, simply because their levels are lower than in young adults. "Basically anyone going through midlife," can benefit from the drug, declared one prescriber, Dr. Howard Elkin, of Whittier, Calif., who has himself competed as a bodybuilder.

Dr. Kenneth Knott, of Marietta, Ga., said HGH helps his older patients feel "more vibrant" and look "more alive."

Like many anti-aging doctors, he diagnoses patients by testing for a blood component called insulin growth factor, which is indirectly tied to HGH. Endocrinologists use a more authoritative test that stimulates the pituitary gland to make HGH itself. Nearly all insurers insist on this stimulation testing, and that's why clinic patients almost always pay for HGH out of their own pockets.

Bob Vitols, a 50-year-old lab assistant at a veterinary medicine company in Lincoln, Neb., is a rare exception. His unusually generous health plan isn't allowed to challenge a doctor's prescription.

Four years ago, Vitols began feeling run down. So he Googled his symptoms on the Internet, decided he had a hormone deficiency, and sought out a clinic.

One doctor put him on testosterone replacement therapy. A second clinic added HGH after diagnosing him with osteopenia, a mild bone thinning common in aging adults. It is not, however, a condition that can properly be treated with HGH.

Despite the diagnosis, the treatments — which can cost $10,000 per year — have been covered by his health insurance, he said. He takes Genotropin, the HGH made by Pfizer. His prescriptions are filled via mail order by CVS Caremark Corp., one of the largest dispensers of prescription drugs in the U.S.

Vitols said the drug changed his life: his mood is better, and he isn't burning out every day at 2 p.m. "I feel like I could walk outside and just walk through a fence — and come out fine on the other side," he said.

His experiences with the drug haven't all been positive, though. Vitols said he initially developed elevated liver enzymes and went to a specialist, who told him to stop taking hormones immediately.

Instead, Vitols said, he adjusted his dosage, and the problem disappeared.

He also dumped the specialist:

"I could tell he was against hormones right at the start," Vitols said.

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Associated Press Writer David Caruso reported from New York and AP National Writer Jeff Donn reported from Plymouth, Mass. AP Writer Troy Thibodeaux provided data analysis assistance from New Orleans.

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AP's interactive on the HGH investigation:
http://hosted.ap.org/interactives/2012/hgh *[1]*

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The AP National Investigative Team can be reached at investigate(at)ap.org

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