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Aging: Disease or Business Opportunity?

By DUFF WILSON

FOR four days last December, America's pleasure dome in the desert, Las Vegas, played host to a convention dedicated to the proposition that growing old is "a treatable medical condition."

Booths advertising <u>vitamins</u>, <u>hormones</u> and <u>pharmaceutical drugs</u>, along with an array of oxygenating or detoxifying paraphernalia, filled the exhibition hall of the Venetian Resort Hotel Casino. Lectures and workshops were offered on a bevy of "wellness" topics, including the alluring idea that human growth hormone could be deployed to beat back old age.

Several thousand attendees, mostly physicians, crowded the Venetian, a testament to what analysts say is now an industry that snares \$50 billion a year in sales by catering to Americans' obsession with looking and feeling younger. This spring, though, the anti-aging industry has come under a harsher light. The authorities have indicted 20 people, including four doctors, in three states as part of an investigation into what federal and state prosecutors describe as a booming and illegal trade: Internet trafficking in human growth hormone and anabolic steroids.

More than half of those indicted thus far in the case worked for companies that peddled their wares at the Las Vegas convention or that belonged to the trade group that organized it, the American Academy of Anti-Aging Medicine. Most of the publicity surrounding the investigations has focused on sales to athletes. But experts in government, law enforcement and the industry say human growth hormone, or HGH, is actually used much more often, and increasingly so, to slow aging.

While it has not been accused of any wrongdoing in the investigations, the academy is one of the leading preachers of growth hormone's anti-aging powers and has as its core gospel the idea that HGH can, as its literature states, "produce striking improvements" in patients' "health, energy level and sense of well-being."

Since two osteopathic physicians in Chicago, Ronald M. Klatz and Robert M. Goldman, founded it 15 years ago, the academy has spun its teachings into a lucrative enterprise that claims 20,000 members, runs a Web site (www.worldhealth.net), worldwide conventions and medical education programs that award board certifications in "anti-aging regenerative

medicine." Along the way, the academy has also become a consistent focus of criticism, derided by an establishment that calls anti-aging medicine quackery or hype, says growth hormone is dangerous and labels the academy's promotions as medically and legally specious.

"The whole idea of anti-aging medicine is controversial," said Dr. Robert N. Butler, who was director of the National Institute on Aging, a federal agency, from 1976 to 1982. "On the good side, it encourages healthy behaviors. On the other side, it sells things like human growth hormone, which is harmful."

Medical research has tended to support the view that growth hormone's risks outweigh any potential anti-aging benefits. Under federal law, the substance is illegal to use except for treating childhood growth disorders, <u>AIDS</u> and a rare adult hormone deficiency. But Dr. Klatz and Dr. Goldman have argued that aging is a disease that causes the pituitary gland to gradually produce less growth hormone. Therefore, they say in books, articles and speeches that hormone replacement therapy at low doses is legal and beneficial in "properly diagnosed deficient adults."

Dr. Klatz, who is 51 and the academy's president, and Dr. Goldman, 52, its chairman, declined to be interviewed for this article. But in response to written questions through their lawyer, they said the 1990 federal law making it a felony to prescribe growth hormone for "off label" uses was aimed specifically at athletic abuse and nothing else. Neither of the doctors is mentioned in the recent indictments, and they also have not been accused of any wrongdoing in connection with the investigation.

But many of the individuals and companies cited in the indictments have been involved with the academy and its conventions over the years. Dr. Klatz and Dr. Goldman would not comment on the investigations, saying they barely knew the suspects or the nature of their businesses. They say they neither prescribe nor distribute growth hormone, and advocate doing so only in accordance with state and federal laws and after a proper physical examination, not as an Internet purchase.

They also say that pharmacies and individuals indicted in the investigation will no longer exhibit, sponsor or advertise at academy conventions and have already been removed from the academy's Web site. Pharmacies and individuals had been paying \$150 to \$750 to be listed in the academy's directory and \$3,695 to \$22,000 to buy display booths at its conventions.

Despite the controversy surrounding them, Dr. Klatz and Dr. Goldman have grown wealthy through their stewardship of the academy and as leading anti-aging evangelists, building their business on books like "Grow Young With HGH," disputed science and on people's

perennial — indeed, ageless — fear of growing old. They recently sold an 80 percent stake in their conventions business for as much as \$49 million to the Tarsus Group, a London media concern.

Dr. Klatz and Dr. Goldman are not afraid to take on their critics. In the last few years, they have been embroiled in legal disputes — with the State of Illinois, over offshore medical degrees they received in the late 1990s, and with professional critics whom they sued for giving them a "silver fleece" award in 2004 for promotion of questionable anti-aging products. (That suit was settled last November; its terms are confidential.)

Self-described mavericks, Dr. Klatz and Dr. Goldman dismiss their critics as biased toward "the old-school medical establishment" and say that the medical establishment's current gerontology practices pessimistically promote "a cult of death."

Hormones, including steroids and human-growth treatments, have captured the imaginations and bodies of athletes and others for many decades now, for the all-too-visible reason that they promote rippling, strapping muscular bulk and enhance performance. The hormone movement gained traction after a 1990 article in The New England Journal of Medicine said that a six-month study of 12 men, ages 61 to 81, who took HGH had less body fat and more lean body mass compared with a control group that did not take the hormone.

More recently, however, advocates also have promoted growth hormones as the modern fountain of youth. The expansion of the anti-aging movement is being fed by several factors — among them, graying baby boomers, growing enthusiasm for physical fitness, interest in alternative medical treatments, and, some analysts say, many doctors' efforts to compensate for income lost to managed care. The market for drugs to control and treat diseases of aging and for appearance-related products and services is expected to reach \$71 billion a year by 2009, according to BCC Research, a market research company in Wellesley, Mass.

Government and industry officials estimate that 25,000 to 30,000 Americans take injections of growth hormone for anti-aging purposes, paying up to \$1,000 a month. And investigators say that the hormone, like many pharmaceuticals, is increasingly being bought on the Internet. State and federal law enforcement officials have focused on doctors who may have written prescriptions without seeing patients and on businesses that may have illegally trafficked in HGH.

Some of the legal parameters around promoting and dispensing HGH are nebulous. Steven D. Silverman, an assistant director of compliance at the Center for Drug Evaluation and Research, part of the <u>Food and Drug Administration</u>, says that people advocating growth hormone for anti-aging purposes "may be engaged in protected speech." But, he adds, "if a doctor or pharmacy is actually dispensing this product for anti-aging purposes, that's

different and it may be illegal."

Recent research underscores growth hormone's potential dangers. This year, in the Annals of Internal Medicine, a review of 31 randomized, controlled studies concluded that "risks far outweigh benefits when it is used as an anti-aging treatment in healthy older adults." Side effects, according to the <u>National Institutes of Health</u>, may include <u>diabetes</u>, <u>hypertension</u>, hardening of the arteries and abnormal growth of bones or internal organs.

FOR his part, Dr. Klatz challenges the concerns of the Annals of Internal Medicine about possible risks of HGH, contending that thousands of other studies showed "clear benefits" at lower doses; he compares using the hormone to using insulin for treating diabetics.

He says HGH slows down aging by improving lean muscle mass, reducing body fat and increasing energy. The hormone affects metabolic processes in many ways, according to <u>Genentech</u>, the company that developed the first synthetic growth hormone in 1981. But while Genentech and other pharmaceutical suppliers, on the advice of regulators, emphasize that HGH should be given only for government-approved uses like dwarfism, Dr. Klatz and Dr. Goldman have pushed it onto the frontiers of anti-aging.

"They have led the charge to educate in a realm that pharmaceutical companies won't," said Dr. Mark L. Gordon, a family practitioner in Encino, Calif. Asked how important Dr. Klatz and Dr. Goldman were in the anti-aging world, he responded: "as figureheads, extremely."

But Dr. Stephen Barrett, a senior member of the National Council Against Health Fraud, a nonprofit advocacy group that operates the <u>quackwatch.org</u> Web site, says the academy has misrepresented research on growth hormone and promotes questionable products.

Dr. Barrett dismisses the medicinal value of the academy's work and says its operations are more akin to Fort Knox than anything else. "I think it's basically a money-making machine for Klatz and Goldman," he said.

No mainstream medical association like the American Board of Medical Specialties or the <u>American Medical Association</u> recognizes the academy's board certification — though Dr. Klatz and Dr. Goldman say they are currently asking for A.B.M.S. approval. Doctors seeking certification from the academy must pay \$3,440, study three books partly written or edited by Dr. Klatz and Dr. Goldman, and pass a multiple-choice test, chart review and oral exam.

While the academy has certified hundreds of doctors, some who were once involved with the anti-aging movement have distanced themselves from the work of Dr. Klatz and Dr. Goldman. Dr. L. Stephen Coles, a researcher at the <u>University of California</u>, Los Angeles, recalled the excitement when he first joined the doctors and about 10 other physicians near Cancún, Mexico, in 1992 to talk about hormones and aging. Growth hormone is legal in

Mexico, and some enthusiastic users lived there at the time.

"I remember saying this is really important, this is what medicine will be in the next five years," Dr. Coles recalled. He has changed his mind. Now, he says, "Growth hormone is risky, and I'd like to see long-term studies."

Dr. Klatz and Dr. Goldman are graduates of osteopathic colleges in Iowa and Illinois, respectively. Osteopaths, who represent about 6 percent of the nation's licensed physicians, focus on holistic health treatments and the muscular-skeletal system and also perform functions of medical doctors like prescribing drugs and performing surgery.

Through his lawyer, Dr. Goldman said that he had received two doctoral degrees from "distance learning programs," which he said had required "work with a mentor, textbook reading and testing." A fitness buff, he says in a biography posted on www.worldhealth.net that he has held world records for one-armed push-ups (321) and consecutive sit-ups (13,500).

Dr. Klatz was working at a Wisconsin clinic in 1992 when he was injured in an automobile accident. After diagnosis of a cervical fracture, severe headaches, cognitive problems and a wrist injury, he spent the next six and a half years living in part on about \$500,000 in disability payments, according to court records. During those years, he and Dr. Goldman, whom he first met in 1981, started the academy, working in a quasi-Gothic building in the Lincoln Park neighborhood of Chicago.

Both men received medical degrees in 1998 from the Central American Health Sciences University in Belize, without, they acknowledged, ever having studied in the country. Dr. Klatz and Dr. Goldman say through their lawyer that they earned their medical degrees with transfer credit from previous academic work and a year in clinical rotations in Mexican hospitals.

Licensing authorities in Illinois did not recognize the Belize degrees, and in 2000 fined the doctors \$5,000 each for adding M.D. after their names. They agreed to a cease-and-desist order with an exception: books already printed or being reprinted with the contractual requirement that they be identified as M.D.'s. They were also allowed to continue using the M.D. designation on their résumés.

While the agreement states that they can lose their licenses for violating its terms, the doctors currently identify themselves as M.D.'s in recently published books, correspondence, their Web site and promotional materials for conferences, including one last summer in Chicago. They say through their lawyer that they are not violating the agreement because of a confidential superseding accord, but a spokeswoman for the Illinois Division of Professional Regulation says they are not permitted to designate themselves as

M.D.'s in the state.

Despite having their bona fides questioned in Illinois, the doctors have been able to use the academy and its conventions to promote the anti-aging wonders of human growth hormone. Along the way, many other companies have helped make the conventions successful, and some of them have been charged with illegally trafficking in growth hormone, according to indictments handed down in state and federal investigations of the HGH business.

Among them are an Orlando concern, Signature Compounding Pharmacy, which was a sponsor and exhibitor at the Las Vegas convention; Dr. Robert G. Carlson, the medical director of the Palm Beach Rejuvenation Center, who moderated an anti-aging workshop in Las Vegas; and Dr. Claire D. Godfrey, an obstetrician-gynecologist who runs the Ageless Clinic in Orlando and gave a lecture on female hormones at the convention.

Each of those parties has pleaded not guilty to the charges. Another sponsor and exhibitor in Las Vegas, Applied Pharmacy Services, is named in a sealed indictment in Alabama, according to its lawyer, who denied that the company had engaged in any illegal activity.

IN Las Vegas last December, speakers told doctors how to diagnose mild hormone deficiencies so they could legally prescribe HGH. Dr. Gordon, the California physician, talked about diagnosing pituitary gland damage from brain trauma from slips, falls or sports injuries. A Long Island lawyer, Richard D. Collins, counseled that while growth hormone could not legally be prescribed for completely healthy people, it is permissible for disease symptoms stemming from the aging process.

Mr. Collins is now a defense lawyer for Signature Pharmacy, one of the companies indicted in the recent case. (He did not respond to interview requests.)

It is unclear what impact the investigations will have on the academy or on the careers of Dr. Klatz and Dr. Goldman — or whether it will dent the two men's popularity in the antiaging industry. As recently as two months ago, just before her business was raided and she was charged with illegal distribution of prescription drugs, Naomi Loomis, chief executive of Signature Pharmacy, offered a glowing testimonial saluting the academy on its Web site.

"Since our company aligned with" the academy, she noted, "our success in the age management business has grown exponentially."

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