RED HERRING

Vanity sells

Biotech jumps on the youth bandwagon, and steers clear of the FDA.

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In the sixteenth century, Ponce de Leon searched the Americas in vain for the legendary fountain of youth. Nearly 500 years later, the biotech industry is picking up where the Spanish explorer left off, by trying to create its own magic youth potion: an anti-aging drug to replace the thousands of products fueling today's multi-billion dollar anti-aging market.

Consumers will dish out dollars for anything that claims to smooth a wrinkle or darken a hair, and the biotech industry is paying attention. A new generation of companies is combing the human genome in hopes of developing a drug to capture even a portion of the anti-aging market – worth $42.7 billion in 2003, according to research firm Find/SVP.

While de Leon battled America's indigenous population, malaria, and unexplored wilderness, today's explorers are up against their own obstacles – namely, the U.S. Food and Drug Administration (FDA). The agency does not regard aging as a disease, and will not review drugs to treat it, or allow them to bring drugs, and advertising for those drugs, to market. But many biotech firms are devising new strategies to sidestep FDA regulations and bring their so-called "longevity drugs" to market.

For now, the cosmetics industry – which includes cosmetic treatments, surgery, health clubs, home health equipment, spas, functional foods and beverages, vitamins, minerals, supplements, cosmetics and "cosmeceuticals" – is reaping profits from a huge demand. Find/SVP estimates that sales of all anti-aging products and services will reach $56.7 billion in 2007.

If consumers are willing to spend billions on time-consuming treatments, including creams that require daily applications, and even facial injections of botulism poison, the potential of a convenient pill to replace all of these is staggering. Spotting the opportunity, an influx of new, appropriately named, biotech companies – like Longenity, LifeGen Technologies, Rejuvenon Chronogen, GeroTech, and Juvenon – are treating aging as a genetically controlled process. By isolating the right genes, they hope to pinpoint the causes of aging, and potentially develop a drug that slows, or even stops, its effects. Cambridge, Massachusetts-based Elixir Pharmaceuticals recently published its discovery of a gene that regulates the amount of "bad" cholesterol, or LDL, and plays a role in longevity.

"People that live longer have a form of the gene that produces less of the LDL than us lesser mortals," says Elixir CEO Edward Cannon, who helped found the company in 1999. His team of scientists is now developing compounds that mimic the effects of the mutated gene, called CXG1, with the help of $40.5 million from two Series B closings this year. Investors in Elixir's first round included MPM Capital, Oxford BioScience Partners, and Arch Venture Partners.
The second round was led by Oracle CEO Larry Ellison, the Teachers Insurance and Annuity Association College Retirement Equities Fund (TIAA-CREF), and several individual investors. Mr. Cannon says the $40.5 million should carry them for two years, and another round of fundraising may be considered.

It takes a lot more than money to get any kind of drug to market, and obtaining FDA approval requires proof of efficacy. That's especially tricky for a product that claims to prolong life. Scientists would have to monitor subjects for up to 50 years or more to measure their life spans. If it works, the patients taking the drug could outlive the scientists who study them. And if an anti-aging drug were to somehow win FDA approval, the company's 17 years of legal patent protection would expire, and generic drug makers could easily take over the market. As it stands, the process of bringing a longevity drug to market all but eliminates the possibility of profit.

"Getting a drug on the market is a time-consuming, expensive, and risky process," says Mr. Cannon. He says that Elixir could feasibly complete this process within the next 8 to 10 years – but not for a "cure-all" miracle pill for anti-aging, because of the FDA's stance against aging as a disease.

Several biotech companies have found a way to potentially sidestep FDA regulations, by developing drugs for specific "symptoms" of aging that are related to longevity, including cancer, heart disease, and Alzheimer's. "People who live past 100 got that old because they didn't incur any of the diseases associated with aging," says Mr. Cannon.

If these disease-specific drugs show potential for fighting the signs of aging, then at least money can be made while trying to find out for sure. “These [diseases] are all important markets, huge markets,” says Mr. Cannon. Until the FDA changes its policy, companies can’t market any drugs as anti-aging, but that doesn’t stop doctors from prescribing them for longevity. Mr. Cannon says that so-called “off-label” prescription sales, in which a drug is prescribed for a purpose other than its approved use, sometimes exceed sales for on-label sales.

If an FDA-approved drug demonstrates anti-aging properties, word gets around. A disease-free patient could ask a doctor for an Alzheimer’s drug that could potentially slow the signs of aging – and the physician could prescribe it legally. Some companies are using off-label sales as their primary business model, says Xi Zhao-Wilson, CEO of Campbell, California-based BioMarker Pharmaceuticals, a company seeking compounds with potential to increase longevity.

Last year, BioMarker found the only FDA-approved drug on the market with age-fighting promise: decades-old diabetes drug metformin, sold as Glucophage by Bristol-Myers Squibb. BioMarker discovered that metformin produces the same effect achieved by caloric restriction – a life-long diet – an experimental process that extends life span in mice. Ms. Zhao-Wilson says her company is raising money to fully explore metformin’s anti-aging properties, and to find more compounds that can do the same. Sales of Glucophage and its variants increased 28 percent to $225 million in the fourth quarter of 2002 – there is no way to tell how much of that was from off-label prescriptions.

“I hope later that we can develop the pill or cocktail that covers everything,” says Ms. Zhao-Wilson. Though the prospect may be distant, the successful creation of a miracle anti-aging drug would impact more than just physical appearances.

“It’s scary to think about,” says Howard Waxman, a consultant at Find/SVP who wrote a report on the anti-aging industry. “We’re already facing a healthcare crisis. And if people live longer, are they going to live healthier?”

Mr. Cannon of Elixir says that by targeting specific diseases, these drugs would increase both the length and the quality of life. The healthcare-dependent stages near the end of life would merely be postponed, not prolonged. These people would “live longer because they would keep younger and healthier for a greater amount of time, ultimately lowering the cost for our health system,” he says.

Ms. Zhao-Wilson agrees. “I’m not interested in how long people live,” she says. “I’m interested in the quality of people’s lives. I want people to be able to contribute socially, economically, and politically when they turn 100, or 120.”

A lot to gain Anti-aging products brought in close $43 billion in 2003, according to a report by FIND/SVP. Cosmetic treatments – including Botox, collagen injections, laser treatments, and chemical peels – sold the most, and are estimated to pull in $11 billion in revenues by 2007. Last year, sales of so-called cosmeceuticals, or products that claim to improve physical appearance from the inside out, neared $3 billion, according to market researcher Frost and Sullivan.

Among skin treatments, Botox and collagen alone are reported to be worth more than $200 million per year in sales, and Frost and Sullivan estimates that the skin care market as a whole will grow by 8 to 10 percent annually.

According to Howard Waxman, who wrote Find/SVP’s report on the anti-aging market, the growth is a result of two factors: baby boomers getting older, and Generation X growing up. Baby boomers make up the largest majority among the adult population worldwide, 78 million of which are in the United States. Well into their fifties, the boomers controlled 43 percent of the nation’s disposable income last year, according to FIND/SVP, making them a perfect target for anti-aging marketers and advertisers.

“It’s not just the boomers,” says Mr. Waxman. “It’s clearly affecting people who are in their 30s, and even in their 20s.” The report predicts that the market will continue to get younger, and bring in more men of all ages. If a cure-all anti-aging pill is ever invented, it will have a lot of takers.