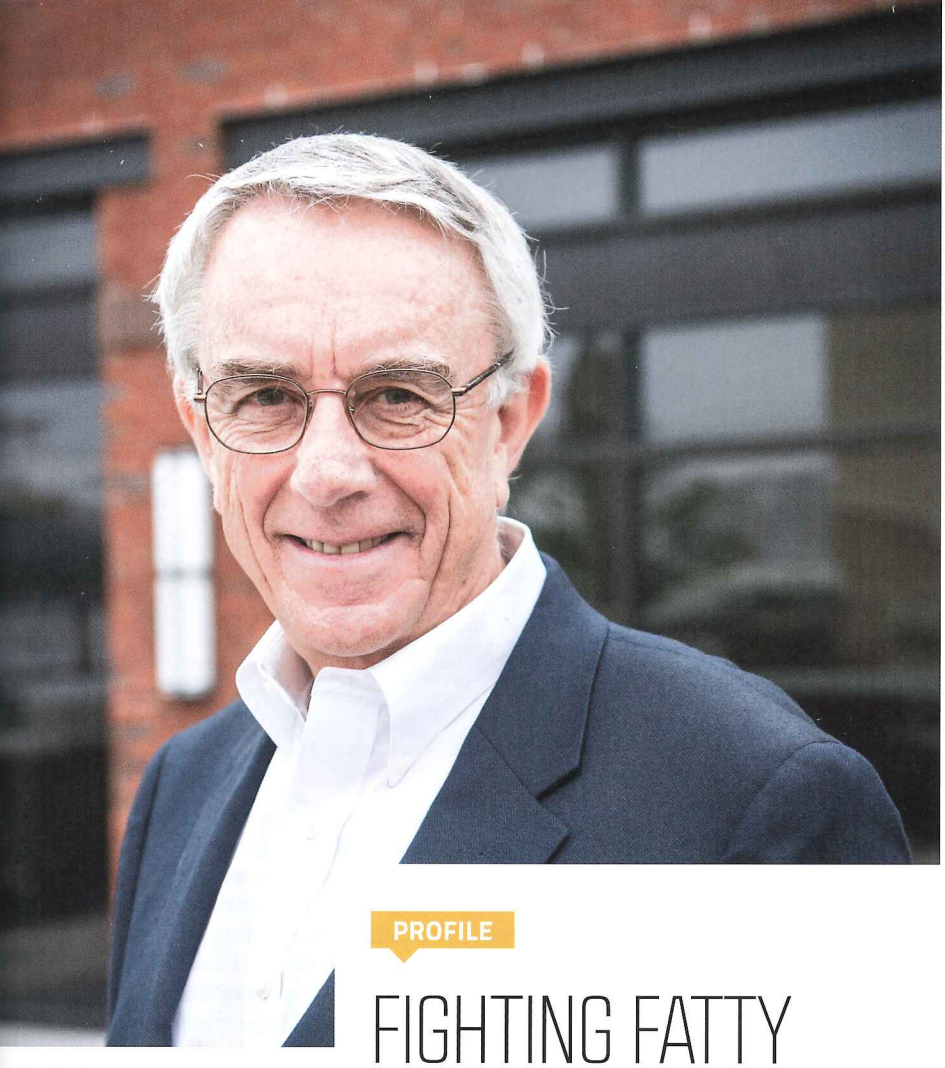

Joe Cook

PROFILE

FIGHTING FATTY LIVER DISEASE

NuSirt's Joe Cook oversees clinical trials for possible breakthrough drug

BY BILL LEWIS

Joe Cook had retired from the pharmaceutical industry, but the promise of developing a treatment for a disease that silently threatens the health of millions of people lured him back into the sector's fold.

"That's a good reason to come to work," says Cook, a pharmaceutical and biotech industry veteran who serves as executive chairman and president of NuSirt Biopharma.

NuSirt, which operates executive offices in Green Hills and research facilities in Knoxville, is conducting clinical trials of a medication to treat non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH).

Byproducts of America's obesity epidemic, the two diseases collectively affect between 85 million and 120 million Americans, Cook estimates.

"It goes hand in hand with fatty belly," says Cook, a founder, director and past chairman of the board of publicly traded Cambridge, Massachusetts-based Ironwood Pharmaceuticals.

NuSirt is conducting clinical trials of a medication that combines several ingredients, including Sildenafil — better known as Viagra — to combat the fatty deposits that cause scarring that can impair liver function or even result in cancer.

Cook says there are few treatments for fatty liver disease. Even discovering its presence is challenging. Patients are faced with a potentially painful and risky large-needle biopsy that may yield an unclear result.

The biopsy procedure "is as unpleasant as it sounds," says Barbara Cannon, NuSirt chief operating officer. Not surprisingly, the disease is often undiagnosed.

NuSirt recently entered a strategic partnership with Derio, Spain-based One Way Liver S.L. (OWL Metabolomics), which has developed diagnostic methods that don't involve a needle.

"No one wants to go to a doctor and have them core out part of your liver," says Cook, who retired in 1993 as a group vice president of global operations at Eli Lilly after more than 28 years of service.

With the new methods, patients could be tested every time they have an annual physical, says Cannon.

If doctors could easily and accurately diagnose fatty liver diseases, NuSirt's medication could be prescribed to treat them in the early stages — assuming the drug wins FDA approval.

The medication works by mimicking the effects of a calorie-restricted diet in which the body has less fat that can wind up in the liver.

"It's as if you ate less," says Cook, who served as chairman of publicly traded Amylin Pharmaceuticals Inc. from 1998 to 2009 and was CEO from 1998 to 2003.

During ongoing clinical trials, NuSirt's medication will be tested and patients' conditions will be evaluated. The outcome of OWL's diagnostic process will be compared with the results of biopsies. During the upcoming third phase of the trials, NuSirt will follow 1,000 patients for 18 months.

The process takes time, but it's much faster than the pace of trials using unproven substances. By using proven drugs, NuSirt is able to avoid years of toxicology testing.

Developing an unknown molecular compound can cost as much as $1 billion. Though development of NuSirt's drug won't require that level of expenditure, the cost is nonetheless a "nine-digit number," says Cook, who is also a principal and co-founder of Mountain Group Capital and a board member of Castle Biosciences, Clinical Products and publicly traded Corcept Therapeutics.

With that expense and the potential size of the market in mind, Cook says it's possible that new partnerships or an acquisition could be in NuSirt's future.

"Most [new drugs] don't make it. It's a very risky business," he says.

And an interesting business at that.

After being introduced to research by Dr. Michael Zemel, a University of Tennessee faculty member who founded NuSirt in 2007, Cook decided to invest in the company in 2010. In May 2013, he joined as an employee.

NuSirt's treatment holds the promise of improving the lives of millions of patients, Cook says. In financial terms, the market for drugs being developed by NuSirt and other pharmas could be as significant as $25 billion in a decade.

"It's not unlike the diabetes market in size," Cook says. "I wouldn't say the entire market is ours," he adds, before noting that if the clinical trials are a success, "NuSirt will have a significant piece of it." NP

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