A drug to treat the chronic condition, like many the industry is now tackling, would require lengthy and especially expensive clinical studies because its effects might be subtle and take months or years to understand. To make sure that an experimental drug deserves such a sizable investment. Pfizer blends marketing with R&D early on. A marketing specialist works with each drug team to ascertain commercial merit. In particular, will the drug meet a compelling unmet medical need and will Pfizer be able to differentiate its medicines from those of its competitors?

For the frailty drug, researchers believed they would have to show that it could do more than boost hormone levels or even muscle growth. Early talks with the Food and Drug Administration confirmed the higher standard. Insurers, too, would need evidence that the frailty drug would be worth their expense.

to persuade regulators and insurers to embrace the drug, the Pfizer team aimed to prove beyond a doubt that elderly people who took it could walk faster and longer and avoid the kinds of falls that force many of them into nursing homes.

Such a drug also could appeal to a younger, healthier but worried market, people who might use the medicine as a lifestyle enhancer, like Viagra, decades before they faced a real danger of frailty. For Pfizer, a medicine to stave off the ravages of old age, unlike an antibiotic taken for a week, could provide a long-term revenue stream: ''People will take it for 20 or 30 years—it'll be like a vitamin,'' predicted John LaMattina, a senior research executive, early last year.

In late 1996, the frailty drug hit its first setback when an otherwise healthy man participating in a small safety study in the Netherlands developed a mysterious, mild rash. The test was halted while the team investigated. The cause was never found, though the leading theory remains that he had a reaction to laundry detergent or hand soap. After a few months, the team concluded that the drug was safe enough to continue.

Pfizer recognized the growth-hormone workers as the best research team of 1996 for their trail-blazing accomplishments. And they continued on the fast track, initiating in late 1997 a larger clinical test of the drug, involving 114 people who randomly received one of four different doses or a placebo for a month. At this stage, the researchers sought to substantiate the safety of the drug and to pinpoint the best dose to use in subsequent tests of effectiveness.

To their happy surprise, the scientists found that even a one-month regimen with the experimental drug produced measurable growth of muscle. ''it was great,'' Dr. Gruetzmacher recalls, ''We didn't expect an increase in less than six months.''

Though encouraging, the results didn't prove the drug was working. The test could have been a fluke. Besides, increases in muscle mass, even if they were real, wouldn't convince regulators to approve the drug, everyone had previously agreed. After lengthy discussion, the team decided to propose a six-month trial of the drug to Dr. Clark and his committee for approval and funding.

But the scientists realized that showing that the drug halted or reversed aging would take months or even years. Dr. Clark pushed the research team to reconsider its time frame and ''go for the home run'' by pursuing a longer and much more expensive test that could detect subtle improvements in patients' ability to function.

The team took six months to design a trial that would provide a definitive answer on whether the drug worked. They eventually proposed a two-year study in elderly patients that would measure muscle and some biochemical markers in the bloodstream. They also would test the subjects' walking speed and endurance and their ability to get in and out of a chair.

Dr. Clark's management committee agreed to fund the study in about 350 patients, much larger than usual for such an early stage. To hedge the outsize bet and ensure that the project was on track, the study included interim analyses at six and 12 months.

Last summer, three senior managers unconnected to the project, including a statistician, were chosen to review the data after six months. As outsiders, they were expected to be unbiased, and they would share their findings with only a few senior managers.

In less than a week, they had reached their conclusion and called Dr. Clark. He decided to break the secrecy and inform the research team of the news.

The patients taking the frailty drug had gained some muscle mass—but less than 3% more than the placebo group, which had also experienced muscle increases. There were no safety problems with the drug. But the study was stopped within a month because the drug appeared ineffective.

Nobody is quite sure why. One theory is that the patients selected for the study may have been too healthy, so there was less room for improvement in the treated group. Another idea is that the drug caused the pituitary gland to release growth hormone in a way that was out of tune with the body's system for using it.

In the end, Dr. Clark's committee ''took pity on us,'' Dr. Landshulz says, and allowed the team one last chance to salvage the medicine. They were permitted to collect and analyze data on the group of early patients in the study who had taken the drug for a year—just in case its effectiveness emerged later than six months.

That was a long shot, everyone agreed, but worth the modest incremental expense. The final analysis was completed this spring, and the results were the same.

Later this month, Dr. Clark's committee will review the file one last time and officially lay to rest the frailty drug, which Pfizer says cost the company $71 million to research and develop.

THE CLOCK IS TICKING

Half of Pfizer's top-earning drugs face patent-expiration pressure.

Drug and Purpose	Expiration of basic U.S. patents	2001 revenue, in billions
Lipitor: Cholesterol	2010	$6.45
Norvasc: Blood Pressure	2006	3.58
Zoloft: Depression	2006	2.37
Neurontin:[1] Epilepsy	1994, 2000	1.75
Viagra: Impotence	2011	1.52
Zithromax: Antibiotic	2005	1.51
Celebrex:[2] Arthritis	2013	[3] 1.16
Diflucan: Antifungal	2004	1.07

[1] Pfizer claims a separate patent concerning chemical stability of Neurontin protects drug until 2017

[2] Pfizer co-promotes Celebrex for Pharmacia Corp.

[3] Estimate.•

APPRECIATION FOR THE SONG, ''WE UNITE,'' BY MS. BECKY COLE

• Mr. INOUYE. Mr. President, I am pleased to share with my colleagues in the Senate and the American people the song, ''We Unite,'' by Becky Cole. The strength and patriotism of Americans following the September 11 attacks inspired her to write and record this song. It captures our citizens' love for their country, its ideals, and its liberties. For me, this song is a reminder of those who are working to rebuild the buildings that were destroyed and reverse the economic consequences of that terrible day. It reminds me of the victims and their families' courage to carry on and live. This song also reminds me of our service men and women around the world who are defending our Nation.

I ask to print in the RECORD the lyrics to Ms. Cole's song.

The material follows:

A NATIONAL ANTHEM ''WE UNITE''

(Words and Music by Becky Cole)

From the depths of the graves we come now as one,
Yielding our lives to an unselfish love.
To expose that which is evil, to remove that which is dark,
To lift up our flag as others burn and tear it apart.

We will fight for justice,
We will risk our lives for love,
We'll rebuild America, with hope we'll stand as one.
To the mighty God above us, we salute and pray,
As one nation under God, we unite our lives today.

Though the winds and the waves have swept across our land,
Causing us to question the beliefs on which we stand.
But now, we're a new nation, under the red, white and blue,
A flag that stands for freedom and waves for me and you.•

TEACHER MAURICE LARUE RETIRES FROM STURGIS HIGH SCHOOL

• Mr. JOHNSON. Mr. President, I rise today to recognize and honor Maurice (Maury) LaRue on the occasion of his retirement as a teacher in the Meade County School District in South Dakota.

By the end of May, Maury LaRue will have completed 33 years in the teaching profession, all at Sturgis High School. Upon graduation with a bachelor of science degree in education from the University of North Dakota, LaRue accepted a position as teacher and debate coach at Sturgis in 1969.

His teaching career has ranged from social studies and literature to vocational broadcasting and forensics. There has always been a strong emphasis on communication skills for LaRue. For 20 years, he was one of South Dakota's most respected and successful debate coaches. His debaters won numerous local, state, regional and national forensic honors. And while his students performed well in competition, the true measure of Maury's ability to build and improve the communication skills of his students, came in the number who went on to become successful community leaders, business leaders, attorneys, senior political staff as well as students who were able to think and communicate in their daily lives as adults, thanks to Maury's dedicated teaching style.

In addition to his many years as teacher and debate coach, Maury also coached cross-country and track for