

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: <sup>1</sup> Epilepsy	1994, 2000	1.75
Viagra: Impotence	2011	1.52
Zithromax: Antibiotic	2005	1.51
Celebrex: Arthritis	2013	1.16
Diflucan: Antifungal	2004	1.07

<sup>1</sup>Pfizer claims a separate patent concerning chemical stability of Neurontin protects drug until 2017

<sup>2</sup>Pfizer co-promotes Celebrex for Pharmacia Corp.

<sup>3</sup>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

several years and is retiring as the director of the social studies department at Brown High School in Sturgis. He has served as a city council member for the City of Sturgis and has maintained a strong interest in community affairs and city, county and state government. He has performed technical direction for the South Dakota State Junior Miss program since 1970, and currently serves as the technical advisor for the Sturgis Community Center Theater. He is a member of the Sturgis Chamber of Commerce, serving on several committees, and is a member of the Fort Meade Museum Board, the Sturgis Area Arts Council and is very active as an elder, choir member and leader with the Presbyterian Church. For the past dozen years, he has also owned and operated a successful photographic studio and gallery in Sturgis and most recently, he has become a volunteer fireman and earned the credentials as information officer. If there were any time left in the day, he would find time to fill it and provide counsel to his students or provide service to his community.

I have met Maury several times during my visits to Sturgis High School and the community of Sturgis. He is definitely a mover and shaker in the community of Sturgis and is very well-respected by both current students and alumni for his skills and abilities as an instructor and for the way he has shaped the lives and futures of those he has tutored over three decades. He is very focused and knowledgeable of local, state and federal politics and issues.

On the occasion of his retirement as a public school educator, I want to congratulate Maurice LaRue for his tireless dedication to his students, his commitment to finding the best in his students and for helping his students to 'communicate' with the world. I also want to commend him for his valuable service to his community over the years. Instead of hiding behind a textbook or staying at the chalkboard, Maurice LaRue has provided his many students over the years with his own example of being active in school and community. He has motivated the lives of many students and many of them would point to Maury as playing a pivotal role in their lives. Can there be any better reward for 33 years of dedicated teaching and community service!

I wish Maurice LaRue the best on his retirement.●

#### IN HONOR OF ENTERTAINER AND COMMUNITY LEADER PAT BOONE

• Mr. FRIST. Mr. President, the name Pat Boone rings synonymous with musical success. Pat has registered 60 songs on the musical charts with eighteen reaching the Top Ten and six reaching Number One. His recording career has spanned five decades—from the 1950s to the 1990s—and compilation albums are reaching a new generation of fans in the 21st century. Indeed, few

entertainers can claim a more sustained career of success than Pat Boone.

Pat's success has even extended beyond music. He starred in fifteen films for 20th Century Fox. He hosted two weekly television variety shows—the Pat Boone Chevy Showroom and the Pat Boone Show. He has been a constant presence on radio both as a musician and as a show host. He has also found time to write several books about teenage life and, more recently, religion and family.

Pat donated all proceeds from his first book—Twixt Twelve and Twenty—to the Northeastern Institute of Christian Education. This was a sign of good things to come. Throughout his career, Pat Boone has generously given his support to countless charitable organizations. Perhaps most notably, he has served as spokesman, national chairman, and host of the Easter Seal Society Telethon for almost two decades.

Though Pat has attained worldwide fame, he has never forgotten his Tennessee roots. This is especially true for his charity work on behalf of Bethel Bible Village. For the last 25 years, Pat has been the celebrity host of the Bethel Bible Village Spectacular Golf Tournament. He has helped raise more than \$1.3 billion for Bethel and bring it national recognition as a premier facility for the care of troubled and at-risk children.

Pat Boone is one of the most successful entertainers of our time; he's also one of the most caring and compassionate community leaders in America today. Pat has always put community first—whether it's the close-knit community of his family or the broader community of charitable organizations. I offer this statement to Pat Boone in recognition of a career of success and gratitude for a life of giving.●

#### RECOGNIZING ASIAN PACIFIC AMERICAN HERITAGE MONTH

• Mr. DAYTON. Mr. President, I rise today in honor of Asian Pacific American Heritage Month. In recent years, Americans have experienced an energizing infusion of Asian-based culture, which resonates in diverse folkways, cuisine, art forms, and religious beliefs and practices. In all these areas, I believe Minnesota is especially privileged, thanks to Asian American citizens who present a unique, vigorous dimension, both established and emerging. Therefore, I would like to highlight the ways that Asian Pacific Americans in particular have enriched our state.

We who make Minnesota our home truly comprise an international community. The Asian Pacific American presence in my state dates from the late nineteenth century, when Chinese, Japanese, and Filipino settlers first arrived. Today, many more groups, such as the Koreans, Asian Indians, Tibetans, Hmong, Vietnamese, and Cambodians, have augmented Minnesota's

Asian Pacific community. This growth is ongoing, and I am pleased to say that in my state, the Asian Pacific American population increased over 100 percent in the last decade. Furthermore, the City of Saint Paul is distinguished by the largest Hmong population in the nation.

The Asian Pacific population has significantly contributed to the economic, social, and political fabric of Minnesota. In the Twin Cities of Saint Paul and Minneapolis, Asian entrepreneurs have succeeded in re-establishing key business districts in areas once dormant, leading to the revitalization of entire neighborhoods. These Americans have further invested in Minnesota through unprecedented rates of home ownership. In greater Minnesota, Asian Pacific Americans are also being welcomed. For example, Warroad, Minnesota, always a notable breeding ground for great hockey players, is now also home to a small but vibrant Lao population. Moreover, I am very proud to say that Minnesota has elected our nation's first Hmong legislator, State Senator Mee Moua.

The State Council on Asian-Pacific Minnesotans has chosen five individuals or groups who have made especially worthy contributions, and I would like to acknowledge these remarkable award winners.

Joseph Hui, who has resided in Minnesota for 30 years, has built a successful business career, but, more importantly, he has given back generously through community service and philanthropy. He was one of the founders of the Asian Pacific Endowment for Community Development, a fund directed and operated by Asian Americans. The fund encourages different Asian Pacific communities to work together in providing social, health, educational, economic, and cultural services. Thus far, the fund has given approximately \$300,000 in grant money to more than 60 organizations.

Rita Mitra Mustaphi, a renowned choreographer, dancer, and educator, introduced the classical Indian dance form, Kathak, to Minnesota. She uses this 2000-year-old form of storytelling, essentially dance-poems, to explore bold, contemporary themes. She is the founder and Artistic Director of the Kathak Dance Theatre, which is the only professional dance theater of its kind in the Midwest. The theater received a grant from the National Endowment for the Arts to create and perform a new dance theater piece.

Another artistic innovator, Rick Shiomi, is a leading Asian American artist. He is the founder of Mu Daiko, a taiko drumming troop, and the Artistic Director of Theater Mu, a group primarily cultivating new Minnesota playwrights and Asian American actors. Blending ancient artistic forms, traditions, and stories with contemporary ones, these performers are dedicated to the ideal of theater as a total sensory experience. Their unique work reaches new audiences through Theater