

Vaccines on horizon for AIDS, Alzheimer's, herpes

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In this undated photo provided by Sanofi Pasteur, technicians perform production operations during a dry run at the company's influenza manufacturing facility in Swiftwater, Pa. Long seen as a sleepy, low-profit niche in the drug industry, this year investment in partnerships and other deals to develop and manufacture in vaccines is on a tear, seen as a crucial new path to growth. (AP Photo/Sanofi Pasteur, David W. Coulter) NO SALES

(AP) -- Malaria. Tuberculosis. Alzheimer's disease. AIDS. Pandemic flu. Genital herpes. Urinary tract infections. Grass allergies. Traveler's diarrhea. You name it, the pharmaceutical industry is working on a vaccine to prevent it.

Many could be on the market in five years or less.

Contrast that with five years ago, when so many companies had

abandoned the [vaccine](#) business that half the U.S. supply of flu shots was lost because of contamination at one of the two manufacturers left.

Vaccines are no longer a sleepy, low-profit niche in a booming drug industry. Today, they're starting to give ailing pharmaceutical makers a shot in the arm.

The lure of big profits, advances in technology and growing government support has been drawing in new companies, from nascent biotechs to Johnson & Johnson. That means recent remarkable strides in overcoming dreaded diseases and annoying afflictions likely will continue.

"Even if a small portion of everything that's going on now is successful in the next 10 years, you put that together with the last 10 years (and) it's going to be characterized as a golden era," says Emilio Emini, Pfizer Inc.'s head of vaccine research.

Vaccines now are viewed as a crucial path to growth, as drugmakers look for ways to bolster slowing prescription medicine sales amid intensifying generic competition and government pressure to cut down prices under the federal health overhaul.

Unlike medicines that treat diseases, vaccines help prevent infections by revving up the body's natural immune defenses against invaders. They are made from viruses, bacteria or parts of them that have been killed or weakened so they generally can't cause an infection.

Investment in partnerships and other deals to develop and manufacture vaccines has been on a tear - and accelerating since the swine flu pandemic began. Billions in government grants are bringing better, faster ways to develop and manufacture vaccines. Rising worldwide emphasis on preventive health care, plus the advent of the first multibillion-dollar vaccines, have further boosted their appeal.

While prescription drug sales are forecast to rise by a third in five years, vaccine sales should double, from \$19 billion last year to \$39 billion in 2013, according to market research firm Kalorama Information. That's five times the \$8 billion in vaccine sales in 2004.

"What was essentially 25 years ago a rounding error now has become real money," says Robin Robertson, director of the U.S. Biomedical Advanced Research Development Authority.

That jump is due to a couple of new blockbuster vaccines and rising use of existing ones. The government's list of recommended vaccines for children since has more than doubled since 1985 to 17. It now also calls for a half-dozen vaccines for everyone over 18 and up to four more for some adults.

The last decade brought breakthrough vaccines against pneumococcal disease and rotavirus - two of the world's top killers - meningitis, cervical cancer and more.

Better technology to create and mass produce vaccines is bringing progress in preventing tropical dengue fever and new threats like superbugs MRSA and *C. difficile*, even ending addiction to cocaine and nicotine. Success on some vaccines in development, particularly for Alzheimer's and AIDS, likely would bring billions a year in sales.

Just this fall and early next year, the swine flu vaccines are expected to bring their makers at least a couple billion extra dollars.

That's despite the five manufacturers for the U.S. not being able to meet an optimistic plan to first make seasonal flu shots and then produce 120 million doses of swine flu vaccine by mid-October - an unprecedented task. But they are steadily catching up with demand.

Unlike most vaccines now "manufactured" in mammal, yeast or other cells - quickly, purely and at high yields - flu vaccines are still grown over many weeks in chicken eggs because it's economical and those newer, faster methods aren't U.S.-approved yet. Because swine flu vaccine grew slower than expected, there have been shortages - and lines of anxious consumers.

But a horde of biotech companies, many using multimillion-dollar government grants, already are testing state-of-the-art technology for the next pandemic.

Scientists - including some at J&J's new vaccine partner, Holland's Crucell NV - even are working to develop the holy grail: a universal flu vaccine targeting a part of the virus that doesn't change year to year.

And some future vaccines will come in patches, pills and nasal sprays, rather than painful shots.

In the last century, vaccines dramatically lengthened lifespans by stopping diseases that killed or disabled millions, from smallpox to polio.

After all those successes, many pharmaceutical companies instead focused on lucrative daily pills for chronic diseases. By the middle of this decade, only a handful were still making vaccines, which are harder to produce than chemical-based pills, making yields unpredictable.

That led to the 2004 fiasco when half the U.S. flu shot supply was lost overnight, plus continuing periodic shortages of some kids' vaccines.

Today, five companies supply flu vaccine: GlaxoSmithKline, Switzerland's Novartis AG, Australia's CSL Biotherapies, MedImmune, part of Britain's AstraZeneca PLC, and France's Sanofi-Aventis SA.

There's been more research on flu vaccines in the last five years than in the previous 20, notes Dr. William Schaffner, Vanderbilt University's head of preventive medicine and a spokesman for the Infectious Diseases Society of America.

Now many drugmakers are rethinking vaccines.

Britain's GlaxoSmithKline is gunning to become the world's top vaccine manufacturer by revenue, unseating pioneer Merck & Co. This spring, Glaxo opened a state-of-the-art vaccine packaging plant in Marietta, Pa., west of Philadelphia, so it can expand in the U.S. market.

Glaxo, which sold only one vaccine in the U.S. 13 years ago, now sells 12 here - and 30 worldwide. It has 20 more in human testing, including ones for meningitis and [malaria](#).

J&J, which previously avoided vaccines, plans to build a full vaccine portfolio, starting with universal flu and Alzheimer's vaccines, says research head Dr. Paul Stoffels.

Even Pfizer Inc.'s \$68 billion acquisition of Wyeth in October was partly about getting its vaccine expertise, now being put to work against Alzheimer's. Wyeth makes the most successful vaccine ever, Prevnar, which protects children from ear infections and potentially deadly pneumonia and blood infections. Prevnar brought in \$2.7 billion in 2008 sales, and with approval of an improved version pending, billions more a year are expected.

Experts call Prevnar the "game changer." It was the first vaccine to exceed \$1 billion in annual sales, followed by Merck's cervical cancer shot Gardasil, with \$2.3 billion in 2008 sales.

"Vaccines are now perhaps seen to be more attractive than drugs," says

Dr. Stanley Plotkin, a former University of Pennsylvania professor and industry researcher who helped develop the German measles and rotavirus vaccines.

Vaccines command higher prices - roughly \$375 for the three-shot Gardasil series - and so are more profitable than in the past. With only one or two makers of most vaccine types, price competition is rare in wealthy countries. Plus, they rarely face generic competition.

For [flu shot](#) makers, the risk of having to throw out millions of unused doses here come spring has plunged as U.S. guidelines have steadily widened to include 83 percent of Americans. Use has jumped from 20 million doses in 1990 to 113 million last year.

And many companies are partnering with promising biotechs, the World Health Organization and global charities, or setting up deals with local drugmakers abroad, to inexpensively manufacture vaccines in developing and middle-tier countries that increasingly want them to prevent much-higher health care costs.

"What you had was, everybody out of the water," says analyst Steve Brozak of WBB Securities. "Now, everybody's back in the water."

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