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WALDHOLZ ON HEALTH
By MICHAEL WALDHOLZ

Drug Makers Need New Tactics To Keep Up With the Competition

The blockbuster drug will always be the formula of choice for big pharma. But these days it's becoming much tougher to achieve.

The sluggish flow of new breakthrough drugs is now widely accepted as a major cause of the industry's recent earnings slump and stock swoon. As an unprecedented line up of winners, such as **Eli Lilly**'s Prozac and **Schering-Plough**'s Claritin, go off patent there are few new big winners to replace them.

For more health coverage, visit the Online Journal's Health Industry Edition[1]

The current drug development drought isn't a short-term blip, expert say. Instead, it results from entrenched research styles that must change rapidly for the drug industry to thrive.

Some strategies that many pharma managers have resisted but are now expected increasingly to consider include:

• Splitting mega-research bureaucracies into smaller, more nimble operations;

• Increasing success rates by going after lower-revenue products;

• Developing injectable drugs rather than just pursuing those taken in pill form;

• Out-sourcing, rather than building in-house, emerging drug-hunting technologies;

• Aggressively shelving potentially promising but high-risk projects;

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Michael Waldholz is news editor for health and science for The Wall Street Journal. Mr. Waldholz joined the Journal in 1980 as a reporter covering medicine and the health-care and pharmaceutical industries. He was named a senior special writer in March 1994, became a news editor for the science, technology and health group in May 1995 and was named deputy editor for health and science in January 1996, and editor for science and health in 2000.

In 1997, Mr. Waldholz led a team of Wall Street Journal reporters that was awarded a Pulitzer Prize for chronicling the development and effects of new AIDS therapies. He's been nominated for and won many other awards, including a Pulitzer nomination as part of a team of writers for a series on genetics. Mr. Waldholz is the author of "Curing Cancer," published by Simon & Schuster in 1997. He is a co-author of "Genome," about the hunt for human genes, published by Simon & Schuster in 1990. Mr. Waldholz writes a bimonthly column for the Journal's Personal Journal section called "Prescriptions." He also appears each Monday on CNBC's "Power Lunch" and also throughout the week reporting about health and biotechnology.

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• Employing new lab techniques that can swiftly identify drugs with a high likelihood of success before firms enter expensive and lengthy human trials, where most projects fail.

"The companies have to increase the amount they are spending on R&D as a percentage of sales," says Richard Evans, an analyst at Sanford C. Bernstein. But "they have to find new ways to make that research spending much, much more productive."

The Challenge of Innovation

Drug makers' research pipelines have long been inefficient. But many big drug makers made up for high rate of failure by merging (see article on Pfizer's acquisition of Pharmacia[2]), relying on one or more blockbusters for the bulk of their profits, increasing prices, employing aggressive marketing, or all of the above. Now the power of those tactics is waning.

There is acute competition among drug makers selling "me-too" products -- take antidepressants Prozac, Paxol and Zoloft -- or arthritis treatments such as Celebrex, Bextra and Vioxx. And many of these drugs must also vie with similar-acting inexpensive generic copies.

All this competition is compounded by emerging pressure from states and managed-care plans to hold down their booming drug expenses (see related article[3]). Aggressive marketing is suffering its own backlash from consumer groups and pols (see related article[4]).

In this environment, it's no longer good enough to produce drugs that are simply incremental improvements. New products have to represent genuine medical advances -- drugs that can sprint far ahead of potential copycats and that treat infirmities so crucial they can command top prices despite cost-control pressures.

But that kind of innovation is tougher and tougher to achieve. Drug makers are partly a victim of their own success. The drugs that exist now for chronic ailments, such as **Merck**'s Cozaar for high blood pressure or **Pfizer**'s Lipitor for high cholesterol, are already so advanced that inventing truly significant new therapies that can garner premium prices is a reach.

Drugs for diseases still hungering for a cure, such as Alzheimer's, would be a manufacturer's home run. An Alzheimer's cure is especially tantalizing because of the disease's demographic. A function of old age, Alzheimer's has the entire baby boom generation as a potential market. But with a disease like Alzheimer's, where we don't even know the cause, research entails enormous investments for the slimmest chance of success.

Get Smart

So big pharma is left playing a risk/reward game that demands smarter deployment of research resources.

GlaxoSmithKline took one step earlier this year, when it carved its giant drug discovery operations into six separate centers, each competing within corporation for resources and acclaim.

ARE DRUG MAKERS IN FOR IT?

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"The scientists are going to be very accountable here," CEO Jean-Pierre Garnier said then. "They can't hide. They have to produce drugs. And if they produce drugs, they will be rewarded."

GlaxoSmithKline is also using genetic advances to identify which patients will benefit most from experimental drugs. This tact is likely to lead to drugs that serve smaller populations and generate less revenue. But the approach is certain to help avoid side effects that kill so many promising drugs in research, thereby increasing the number of drugs that make it through the pipeline.

Roland Andersson, a consultant at Strategic Decisions Group, a Menlo Park, Calif. consulting firm, sees more companies, such as Pfizer and Pharmacia, going after cancer medicines. Traditionally, cancer drugs haven't achieved blockbuster status. But Mr. Andersson points out that progress in understanding the biology of cancer is generating a host of new ways to attack the disease. A company with a basket of small-revenue cancer drugs, he suggests, will have as robust a bottom line as one with a mega-hit against a chronic disease such as diabetes.

Why Drug Makers Are Failing in Quest for New Blockbusters[6]
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Others expect drug makers to swallow their research pride and follow the success of some biotechs that have turned proteins produced in the body into medicines. For years, drug companies such as Merck have said they favor drugs in pill form, since those are the easiest to use and most likely to generate the largest sales. But even Merck researchers now say they have been swayed of late by the overwhelming success of so-called protein drugs that must be regularly injected, such as Enbrel and Remicaide for treating rheumatoid arthritis.

The success of these drugs shows that patients are open to using a needle if the medicine represents a significant advance. (Immunex makes Enbrel and Centocor, a biotech firm, developed Remiacaide. **Johnson & Johnson** acquired Centocor several years ago.)

"The big drug makers are finally realizing that [injectable] proteins can be a very big business," says William Haseltine, CEO of Human Genome Sciences, a biotech firm specializing in turning new gene discoveries into protein medicines.

Despite these shifts in the drug-maker mindset, the ever-powerful lure of hitting pay dirt with a drug for a poorly treated ill such as Alzheimer's will keep big pharma from undergoing wholesale makeovers. But the wise firms will find ways to hedge their bets along the way.

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