Subj: THE AGRIBUSINESS EXAMINER #165
Date: 5/30/2002 10:15:55 PM Central Daylight Time
From: avkrebs@earthlink.net

The AGRIBUSINESS EXAMINER
May 31, 2002 #165
Monitoring Corporate Agribusiness From a Public Interest Perspective
EDITOR\PUBLISHER: A.V. Krebs
ADDRESS: PO. Box 2201, Everett, Washington 98203-0201
E-MAIL: avkrebs@earthlink.net
WEB SITE: http://www.ea1.com/CARP/
TO RECEIVE: Name and e-mail address
Contributions Welcome
COMMENTARY:
ABC-TV NEWS "BITTER MEDICINE" SUGGESTS FRIGHTENING PARALLELS WITH FARM CHEMICAL POISON MANUFACTURERS
One can only hope that those family farmers who were fortunate enough to see Peter Jenning's "Bitter Medicine: Pills, Profit and the Public Health" on ABC-TV Thursday night did not let it escape their notice that the same situation the public finds itself in being at the mercy of the pharmaceutical industry when it comes to health care is the same for

farmers when it comes to their reliance on chemical poisons in the production of their crops.

Not only in many cases are the same companies involved, but in matters of who pays for research, patent awards, heavy advertising and defraying costs the predicament is the same as the articles below illustrate.

Ever since the end of World War II the nation's and the world's farmers have been fed a steady diet of "new and improved" chemical poisons, slickly obfuscated by the use of the word "pesticides." As the late brilliant and outspoken University of California entomologist Dr. Robert van den Bosch characterized it:

"Fundamentally, pest control as it is now practiced . . . is essentially not an ecological matter. It is largely a matter of merchandising. In essence, we are using the wrong kinds of material in the wrong places at wrong times in excessive amounts and engendering problems which increase the use of these materials, adds to the pollution problem, adds to the cost of agricultural pest control, and adds to what you might describe as the concern of the general public."

By emphasizing pest eradication rather than pest control the manufacturers of these chemical poisons have managed to keep farmers on a treadmill, promising with each new product that there problems with pests will be solved, which in fact often only generate new problems with both the loss of the pest predators, but also increasing the immune

system of many pests as we have seen with mosquitos and DDT giving rise to whole new generations of super bugs.

Yet in the farm press, which would undoubtedly disappear over night were the chemical poison manufacturers and the farm machinery manufacturers ever to yank their advertising for it pages, continually show farmers pictures of lush green crops and weedless and pest free fields effectively propagandizing and economically seducing them into buying more of the company product.

At the same time the poisons that they can't sell to this nation's farmers because of government restrictions they export abroad which are in turned used on those crops and produce which are increasingly being imported back into the United States with less than one percent, according to the General Accounting Office, being inspected for harmful residues.

At the same time a large measure of the research dollars that go into developing these chemical poisons come out of the tax payer's pockets, just as in the pharmaceutical industry, by way of the efforts of our nation's land grant university's who in many cases not only do the research and development, but through their various extension services, do the actual promoting of these poisons in our fields and orchards.

The time has come for family farmers and grassroots farm organizations to take a long and hard look at these chemical drug dealers who not only care little about despoiling the environment, endangering the health of the men, women and children who work in our

fields, but continue to force consumers to play a game of Russian roulette when it comes to the health and safety of the food they buy for themselves and their family.
Viewing "Bitter Medicine" is most certainly a good starting point in that quest.
"BITTER MEDICINE:
PILLS, PROFIT AND THE PUBLIC HEALTH"
ABC-TV NEWS: Consumers spent $90 billion more on prescription drugs last year than the $64 billion that was spent just six years ago. Are consumers getting their money's worth from the pharmaceutical industry?

First there was aspirin to treat pain and inflammation, then came Advil, Aleve, and 40 other similar drugs. By 1999, Celebrex and Vioxx were on the scene, and they now outsell every other prescription pain reliever on the market. Every year, $4 billion is spent on Celebrex and Vioxx alone.
"There's never been a study showing that they are more effective at relieving symptoms of joint pain and inflammation than all these other medicines that have been available for many, many years and are much more affordable," said Dr. Matt Handley, a physician with Group Health Cooperative, a nonprofit managed-care organization in Seattle.
On top of the $532 million spent every year on over-the-counter drugs, consumers spent $90 billion more on prescription drugs last year than the $64 billion that was spent just six years ago. And yet, there is little evidence that the huge increase in spending is

dramatically improving the health of Americans. Are consumers getting their money's worth?

Why do prescription drugs cost so much money? According to a Tufts University study, on average it costs $802 million to bring one new medicine to market. The high cost of drug development is the industry's justification for the high price of drugs.

"The $802 million figure is used by pharmaceutical firms, I believe, to help explain the enormous challenge involved in bringing a new product to market," said Ken Kaitin, who runs the Tufts Center for the Study of Drug Development. "These are extraordinary costs to bring individual products to market."

While it is not possible to look at a breakdown of research costs --- companies aren't required to make this information public --- their profits are public, and the drug industry is the most profitable industry in the country.

"Their R&D [research and development] costs could be $15 billion, $15 trillion, $15 gazillion, and it wouldn't matter if their profits are double that," said Dr. Marcia Angell, a former editor of the New England Journal of Medicine.

The drug industry claims its high profits are necessary in order to conduct expensive research and development. It spends more on research than any other industry. The federally funded National Institutes of Health may be the drug industry's biggest benefactor. This government agency alone will spend more than $23 billion on research this year. And much of the research benefits the drug industry.

"There's no other industry in which you have so much public investment in the fundamental knowledge that enables the development of the commercial industry itself," said Dr. Bernadine Healy, who used to run the NIH. And how important is this publicly funded research to the industry? The NIH looked at the five top-selling drugs of 1995 in a report. It found that "NIH-funded research played a critical role" in discovering each one of those drugs.

But however much it may actually cost to develop a drug, which drugs are consumers getting for their money? A closer look reveals that much of the profits from prescription sales are not derived from breakthrough drugs, but rather from drugs that are similar to already popular medications.

When a drug company submits a drug to the Food and Drug Administration for approval, the agency tries to determine how important the drug may be. And the FDA divides all drugs into two categories: "priority" drugs --- which are believed to be a "significant improvement" over what already exists, and "standard" drugs --- which are similar to what exists.

But, adding up all the drugs approved over the past six years, 80% of all those drugs were deemed by the FDA to be similar to what already exists. In other words, not a significant improvement.

"I think the level of innovation that we're seeing from the pharmaceutical industry is really mixed," said Nancy Chockley, who runs an institute funded by managed-care

organizations. In a new report, NICHM found the percentage of new, innovative drugs coming from the pharmaceutical industry is actually decreasing.

"What we found is that over the last 12 years that there's really been a shift in the type of new drugs being approved by the FDA," said Chockley. "And we found that most of the growth was really in drugs that did not show any significant clinical improvement."

The patent system gives companies an exclusive monopoly for the length of the patent --- meaning they can make huge profits. That is the incentive drug companies have to continually invent new drugs. Then, when the patents on those drugs expire, other companies can copy the drug, make a generic version, and the new competition in the marketplace lowers the price. The FDA says the generic drugs are just as good as the original drugs.

That's the way the patent system is supposed to work, but that is not the way it always works. The drug industry's lawyers and lobbyists have created or found so many loopholes in the laws that some generic drugs are often delayed or never get to market.

BuSpar is an anti-anxiety drug manufactured by Bristol-Myers Squibb. After the company had had a monopoly on the drug for years, the patent on BuSpar was set to expire on Novmber 21, 2000, which meant a cheaper generic version was supposed to be approved by the FDA and available to consumers the next day.

And then, just hours before its patent on BuSpar expired, Bristol-Myers Squibb got a new patent on what the drug becomes after you swallow it. And the law is written in such a

way that Bristol-Myers was able to then keep the generic drug off the market, claiming that it would violate its new patent. There was no innovation involved --- only an innovative legal strategy.

Dr. Carol Ben-Maimon, who has worked in the drug industry for 15 years and is chairwoman of the Generic Pharmaceutical Association, believes that Bristol-Myers was in this for profit and not public health. "I don't think there's any question," she said. "They didn't do anything to the product to improve it."

Bristol-Myers was sued by the generic companies, which claimed that the last-minute patent filed with the FDA should not keep the generic drug off the market. It took four months for a court to rule in the generic companies' favor.

"During those four months, Bristol-Myers continued to have the exclusive right to sell this product on the market, no generic competition, and I believe this product is about, over a $700 million-a-year revenue product for Bristol-Myers," said Rob Funston, an attorney for a company that produced the generic version, Watson Labs. "So during those four months, they made approximately $200 million." When asked several times to discuss its strategy to extend the patents on BuSpar and on other drugs, Bristol-Myers refused.

Many experts believe the industry, in general, is producing fewer innovative drugs. "If I'm a manufacturer and I can change one molecule and get another 20 years of patent rights, and convince physicians to prescribe and consumers to demand the next form of Prilosec, or weekly Prozac, instead of daily Prozac, just as my patent expires, then why would I be

spending money on a lot less-certain endeavor, which is looking for brand-new drugs," said Dr. Sharon Levine, the associate executive director and a pediatrician for the Kaiser Permanente Medical Group. She is responsible for assessing the best resources for the medical group, including helping decide which drugs are used.

But with so many drugs for each of these conditions, how are consumers supposed to know which drugs are the best? Surprisingly enough, the FDA says a new drug does not have to be any better than what already exists. "All you have to be able to prove is that the drug is better than nothing," said Levine.

The rules by which this hugely profitable industry operates do not always serve customers adequately. The Federal Trade Commission is investigating whether drug makers illegally delay generic competition. Some members of Congress are trying to close the loopholes in the law to make it easier for generic drugs to become available. However, the drug industry has enormous influence in Washington. The pharmaceutical industry has more registered lobbyists than the number of senators and congressmen combined.

STUDY CHALLENGES PHARMACEUTICAL COMPANIES CLAIM NEED OF HIGH PROFITS TO FUND RISKY AND HIGHLY INNOVATIVE RESEARCH

MARC KAUFMAN; WASHINGTON POST: Most drugs approved for use during the 1990s were not innovative new chemicals that treat diseases in novel ways but rather were modified versions of drugs already on the market, according to a new analysis.

The study, by the nonprofit National Institute for Health Care Management (NICHM), challenges a central argument of the nation's pharmaceutical drug industry: that it needs high profits to fund its risky and highly innovative research.

The emphasis on incremental change was especially pronounced in the last six years of the period studied, when the number of popular but less-innovative drugs increased dramatically -- as did the nation's spending on prescription drugs. The report says that while these new drugs may be beneficial to patients, they are not the kind of breakthroughs that consumers have come to expect.

The report concludes instead that drug industry advances are now far more likely to involve relatively minor improvements in how existing drugs are administered, dosed and combined with other existing active ingredients than the discovery of entirely new types of treatments. "The pharmaceutical companies have migrated towards becoming more marketing than research and development organizations," said NICHM President Nancy Chockley. "Highly innovative drugs are rare."

The trade organization representing the drug industry, the Pharmaceutical Research and Manufacturers of America (PhRMA), criticized the study as "fundamentally flawed" and biased because it was done by a group sponsored by the health insurance industry.

PhRMA Vice President Richard I. Smith said that he had not been provided the full report but that he had learned its key points.

"Today's NICHM report appears to be little more than a political and financially motivated cheap shot masquerading as science in the public interest," he said. "It comes as no surprise that its report conveniently ignores many of the basic facts about drug research, not the least of which is that innovation rests in the lives of its beholders."

In particular, he said, the study relied on Food and Drug Administration review categories that are irrelevant to assessing the usefulness of drugs and to how much patients might benefit from them. While some might dismiss the many anti-depression drugs on the market as "copycats," Smith said, studies have shown that half of depression patients try two or three varieties before finding one that works for them.

He also criticized the report for focusing only on the past and not saying anything about the many drugs in the pipeline, especially the products of biotechnology and gene therapy that some believe will transform drug treatments in the future.

The NICHM was founded nine years ago by 11 Blue Cross/Blue Shield companies, and the presidents of those companies constitute most of its board of directors. The group seeks to provide impartial information and has an independent advisory board of prominent health care experts.

The NICHM study looked at whether drugs were accepted by the FDA for "priority" or "standard" review, and whether they included new molecular entities or were

improvements on existing ingredients on the market. The group judged the "priority" drugs that contained new active ingredients as the most innovative and the "standard," "incrementally modified" drug applications as the least innovative.

The study found that of 1,035 drugs approved by the FDA from 1989 to 2000, 46% were in the least innovative category. During that period, only 15%, or 153 approved drugs, were medicines that both used new active ingredients and provided significant clinical improvements, the potential level of benefit needed to achieve a priority FDA review.

During the first six years studied (1989 to 1994), the FDA approved 168 drugs that neither provided significant clinical improvements nor had new active ingredients. In the second six years (from 1995 to 2000), the number in that category increased to 304.

The study also concluded that the doubling of prescription drug spending from 1995 to 2000 --- from $64.7 billion to $132 billion -- was largely attributable to new drugs in the least innovative category. Yesterday's report, and the response to it, are another example of the bare-knuckles brawl that has broken out between the drug industry and the health insurance companies that pay much of the nation's fast-rising prescription drug bill.

Those costs have led to health insurance premium increases and caused the health insurance industry to step up legislative and legal efforts to reduce drug costs, especially through the expanded use of generic drugs. PhRMA and the drug industry have been fighting back fiercely.