HEALTH AND STRESS

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WHY DRUG COMPANIES ARE THE MOST PROFITABLE U.S. INDUSTRY

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According to figures released last Spring, despite a drop in employment rates, a plunging stock market and general economic disaster, pharmaceutical companies continued their supremacy as the most profitable industry in the 2001 Fortune 500 list. **While the overall profits of Fortune 500 companies declined by 53%, the second steepest dive since the list started almost 50 years ago, the top 10 U.S. drug makers increased their profits by 33 percent!**

They also had the greatest return on revenues at 18.5 cents for every $1 of sales, eight times the median for all Fortune 500 companies. Only commercial banking came close with a 13.5 percent return on revenue. Drug companies had a 16.5% on return of assets (compared to a median of 2.5% for all industries) and their more than 33% return on shareholders' equity was over three times the 9.8% median posted by all the Fortune 500 industries. How this Triple Crown of profitability was obtained is a complex story of salesmanship, cunning and deceit.

People are living much longer and the elderly require more medications so demand has risen, but this is hardly the driving factor. Drug companies are once again far ahead of the pack because they have been able to hike prices due to deceptive media blitzes and **their powerful clout on Congress and the FDA. This has allowed them to defeat legislative efforts to curtail rising drug prices, obtain lucrative extensions on monopoly patents and expedite the approval of new drugs despite safety concerns that were disregarded.**

The 10 Fortune 500 drug companies earned $37.2 billion in profits in 2001, up from the $28 billion reported in 2000. That's great for those who work and invest in the industry but consumers, employers and insurers have become frustrated by constantly rising drug costs. Americans spent $154.5 billion on prescription drugs in 2001, a rise of more than 17 percent over the previous year. Spending on drugs increased because more prescriptions were written but that's not the main reason.

ALSO INCLUDED IN THIS ISSUE

What the public does not realize is that prescriptions were shifted to newer, more expensive medications. Prescription prices jumped an average of 10% for everything from drugs aimed at high cholesterol to low libido. That's six times greater than the general inflation rate of 1.6 percent reported by the government. Furthermore, it seems unlikely that anything can be done to stop or slow this "druggernaut".

A Few Facts to Put Things In Perspective

- The drug companies would like you to believe that the high cost of prescriptions is due to large expenditures required for research and development of new drugs. The fact is that they spend much more on advertising and administration. Since 1995, R&D staffs of U.S. brand name drug companies have decreased by 2% while marketing staffs increased by 59%. Currently, 22% of staff are employed in R&D compared to 39% in marketing.
- The top selling drug in 2001 was Lipitor. Increased Lipitor sales contributed more than any other drug to the rise in drug costs that year. Cardiovascular benefits can be achieved with less costly drugs. Furthermore, there can be serious side effects, many of which have been suppressed.
- According to industry estimates, drug companies spent $15.7 billion dollars on promotion in 2000 and gave out $7.2 billion dollars worth of free samples.
- The AMA generates $20 million in annual income by selling detailed personal and professional information on all doctors practicing in the United States to the pharmaceutical industry.
- Two and one-half billion dollars were spent on advertising to consumers in 2000. Increases in the sales of the 50 products most heavily advertised to consumers were responsible for almost half of the $20.8 billion increase in drug spending for 2000.
- In 2000, Merck spent $161 million on advertising for Vioxx, more than Pepsico spent on Pepsi and Anheuser-Busch spent on Budweiser. Vioxx accounted for 5.7% of the total 2000 increase in drug spending.
- If you don't think that advertising and samples bring in big bucks, consider this: one study found that **in treating patients with hypertension, over 90% of physicians actually dispensed a sample that differed from their preferred drug choice!**
- In the early 1990's, about 75% of clinical research dollars went to universities where strict supervision was enforced. This fell to 34% in 2000, when 66% went to investigators working for a pharmaceutical company or a private research firm a company controlled because of partial ownership.
- **Pfizer** led U.S. pharmaceutical companies with **$7.8 billion in profits** in 2001. That's **more than the profits of all Fortune 500 homebuilding, apparel, railroad and publishing industry companies combined!**
- Pfizer earned 24 cents on each dollar of sale largely because of sales of its four blockbuster drugs: Lipitor ($4.5 billion), Zoloft ($2.1 billion), Norvasc ($1.7 billion) and Neurontin ($1.4 billion). Most of you are already aware of the problems with Lipitor and the deceptive practices associated with the unapproved prescribing of Neurontin are now the subject of a civil suit and criminal investigation, as detailed on pages 4–6 of this Newsletter. Pfizer raised the average prices of these drugs by 4.9%, three times the rate of inflation.
- **Merck netted $7.3 billion, or more than the profits of all the Fortune 500 semiconductor, pipeline, food production, crude oil production, and hotel, casino and resort industries combined!**
- A U.S. month's supply of tamoxifen is $180 but a 3-months supply costs $38 in Canada!

Generics, The Purple Pill Saga And OTC's

Most people believed that generic drugs would help to reduce rising drug costs but that's not always true because of drug company pressures and guile. Almost everyone who watches television knows about Nexium, the "New Purple Pill" for heartburn. Like most TV ads for prescription drugs, it urges you to "Ask Your Doctor", who will have a hard time explaining why you shouldn't take it. Most patients had done very well on Prilosec, the previous "Purple Pill" that had been the world's best-selling prescription drug, raking in $6 billion annually at $4.00 a capsule. The main patent on Prilosec expired in October 2001, which would normally have opened the door to less expensive generics. However, Astra-Zeneca was able to delay this with a series of law suits that allowed them to unleash a half-a-billion dollar marketing blitz to move patients off of Prilosec and onto Nexium, their costly, patent-protected "New Purple Pill", which even their own studies showed to be barely more effective than its predecessor.

Prilosec got its big boost in 1997, when the FDA relaxed its rules on direct advertising to the public so that adverse side effects did not have to be mentioned in detail as long as an 800 number or web site was available to get complete information. Heartburn sufferers previously relied on antacids (Maalox, Tums) or H2 blockers (Tagamet, Zantac, Pepcid) that can now be obtained without a prescription. Prilosec was the first of a group of drugs known as proton pump inhibitors that provided more consistent relief. It was initially approved in 1989 for two rather limited indications but subsequent clinical trials extended this to eight disorders, including heartburn. Purple Pill promotions were everywhere from the floor of New York bus terminals to Hall of Fame pitcher Jim Palmer raving about how it had saved his broadcasting career. In 1998, it became the first drug to top $5 billion in sales and continued to rise after that.

Nobody denied that Prilosec was a significant improvement and other companies soon came out with similar products (Prevacid, Protonex, Aciphex) that were less expensive but not as well known.

Astra-Zeneca was able to block generic versions of Prilosec by claiming infringement, not on the main patent, but secondary ones, like inserting a "subcoating" between the main Prilosec molecule and its purple shell, that doesn't expire until 2007. **The company spent $478 million in 2001 on its Nexium promotional campaign and hired an additional 1300 sales reps just for its new Purple Pill. It has paid off since some 42% of Prilosec prescriptions have been converted to Nexium.** Hospitals are particularly concerned about rising prescription drug costs and all sorts of deals are being made. In return for a fantastic discount, Massachusetts General agreed to make Nexium its primary proton inhibitor drug, which will save it over $300,000 a year. It's an even better deal for the company since residents will be trained on Nexium, patients will be discharged on Nexium, and doctors across the country will be told that Nexium is the first choice of this world-famous hospital.

The same tactics are being used by just about all the big pharmaceutical companies, which are under intense shareholder pressure to maintain their best-in-business profits as the patents on about 20 blockbuster drugs expire over the next couple of years. Two thirds of the prescription drugs approved by the FDA over the past decade were modifications or derivative versions of existing medications rather than exciting new pharmaceuticals. That explains the ads for Clarinex that are everywhere on TV and even on CVS prescription bags. Schering-Plough has been offering free seven-day trials to switch allergy sufferers to Clarinex, although it is not much different than Claritin, which brought in $2.3 billion in 2001. Claritin was approved for OTC use last November and the company went along with this because Claritin's patent expired in December, so they could corner both markets.

Many consumers won't benefit since most patients on Claritin currently receive a 90-day supply for a co-payment of $15 to $20 and the OTC cost will be four times as much. As indicated in a previous Newsletter, generic drug manufacturers have also been paid not to introduce competitive products in return for a share of the profits.

A Drug Company's' Deceptive Dealings

Sales of Neurontin exceeded $2 billion in 2001 and more prescriptions were written for Neurontin last year than for Coumadin, Lanoxin and other best sellers. This seems surprising since the drug was approved in 1994 as a supplementary treatment for an uncommon type of epilepsy known as partial seizure disorder and then only after maximum tolerated doses of standard drugs had proven ineffective. So why is Neurontin so popular?

The answer is that once a drug receives official approval for one condition, physicians are free to prescribe it for anything they choose. The FDA prohibits drug companies from promoting such off-label prescriptions but does allow them to "educate" physicians about other possible benefits if they adhere to very strict guidelines. This includes encouraging double blind studies to demonstrate efficacy and safety for other indications to obtain additional approval. However, instead of this, Parke-Davis executives decided to pay for off-label trials to encourage physicians to write more Neurontin prescriptions. Company documents stated results would be "publicized" and published if "favorable" or "positive."

As part of its plan to publish studies, Parke-Davis contracted with Medical Education Systems, Inc., a Philadelphia firm that provides education material and training for medical professionals. The contract was termed "an educational grant" to develop a "scientific article series in support of epilepsy." However, many of the proposed articles focused on the off-label uses of the drug. Medical Education Systems also gave Parke-Davis the right to select the authors of the articles, receive prepublication copies of the articles and suggest changes to them. Some 47 states and the District of Columbia have now launched criminal probes into the marketing of Neurontin. There is also a grand jury investigation by the U.S. Attorney's office in Boston as a result of a civil suit filed by Dr. David Franklin, a former Parke-Davis medical liaison physician. It charges that the illegal promotion of Neurontin defrauded the government out of hundreds of millions of dollars in Medicaid payments alone.

Dr. Franklin quit after 5 months on the job alleging that he was forced to participate in a national marketing campaign in which he and others made exaggerated or false claims about the safety and efficacy of the drug. The suit documented the following specific usages as being illegally and heavily promoted:

Bipolar Disorder - Psychiatrists were told that early results from trials in the treatment of bipolar disorder indicated a 90% response rate when the drug was increased to 4,800 milligrams/day. The daily FDA-approved dosage is 900 to 1,800 milligrams. No such results existed and the only type of clinical trial that had been done was a pilot study showing no benefit with increased dosage. Most of the published reports on the use of Neurontin in bipolar disorder had been written and sponsored by Parke-Davis, a fact that was also hidden. **Personnel were trained to tell physicians that there were no reports of adverse reactions when used in psychiatric illness. In fact, such reports had been given to Parke-Davis by health care professionals but the company consistently concealed this information** from those who asked about safety.

Pain Syndromes, Peripheral Neuropathy And Diabetic Neuropathy - Parke-Davis medical personnel were trained and instructed to report that "leaks" from clinical trials demonstrated that Neurontin was highly effective in the treatment of a number of pain syndromes. Indeed, a 90 percent response rate in the management of pain was being reported! No such evidence existed. Employees were trained to claim support for these findings as a result of inside information despite the fact that no such data existed. The only basis for these claims was anecdotal evidence of minimal, if any, scientific value. Many of the published case reports, according to the court papers, had been created and sponsored by Parke-Davis in articles that frequently hid the company's involvement in the creation of the article. The company's payment for the creation of these case reports was also concealed.

Restless Leg Syndrome (RLS) - Company personnel promoted Neurontin for RLS with no scientific support but only

anecdotal reports sponsored or created by Parke-Davis.

Reflex Sympathetic Dystrophy (RSD) - Physicians were told of extensive evidence demonstrating efficacy in this condition characterized by persistent pain and tenderness following trauma to a limb. Again, the only evidence was from anecdotal reports of dubious scientific value. Parke-Davis medical liaisons were trained to imply that case reports, most of which had been created or sponsored by the company, were actually studies.

Monotherapy For Epilepsy - Medical liaisons were strongly encouraged to push neurologists to prescribe Neurontin as the only drug to treat epilepsy, in spite of the fact that studies found it safe and effective only when used in combination with other seizure drugs. **Although the FDA had rejected the company's 1997 application for approval as monotherapy for seizures, neurologists were told that substantial evidence supported the company's claim that the drug was effective when used alone. In fact, at the time the court papers were filed, Parke-Davis knew that clinical trials using Neurontin alone in seizure were inconclusive and one of these clearly showed that using it alone was not effective.** The vast majority of patients in the study could not continue with the drug alone and there was no significant difference between doses of 600, 1,200 or 2,400 milligrams. Nevertheless, Parke-Davis continued to urge doctors to use higher doses than those approved by the FDA.

Attention Deficit Disorder (ADD) - Pediatricians were told that Neurontin had proven very effective for the treatment of ADD although nothing existed to support this statement except for company generated anecdotal claims. Parke-Davis personnel were trained to report that large numbers of physicians had success in treating ADD despite being unable to produce any case reports to confirm this.

Trigeminal Neuralgia - The Company represented Neurontin as a treatment for trigeminal neuralgia. This is a syndrome of bursts of facial pain that can be so severe that patients have been known to commit suicide. There was no scientific data to support this claim and no evidence that it was as effective as readily available and less expensive painkillers.

Post-Hepatic Neuralgia (PHN) This is another syndrome of severe pain that can persist or recur following a herpes virus infection. Although notoriously resistant to treatment, physicians were told that 75 to 80 percent of all PHN sufferers responded successfully to Neurontin, raising false hopes in thousands of desperate patients. Again, there was no clinical trial or other data to support this claim.

Essential Tremor And Periodic Limb Movement - There was no scientific data to back up Parke-Davis' claim that Neurontin was effective for these difficult to treat disorders, only self-serving anecdotal reports.

Seizures Resulting From Alcohol And Drug Withdrawal - It was suggested by the company that Neurontin was also effective for treating drug and alcohol withdrawal seizures despite the lack of any evidence supporting its use for these disorders.

Migraine - This is where Parke-Davis really raked it in. Claims that Neurontin was effective for treating or preventing migraine headaches made by company medical liaisons were allegedly based on early results from clinical trials. While pilot studies had been undertaken, no early results existed to support these claims and internal documents revealed that one study showed it to be ineffective.

Court papers also quoted a senior marketing executive's teleconference remarks to medical personnel as follows "Pain management, now that's money. Monotherapy, that's money. We don't want to share these patients with everybody, we want them on Neurontin only. We want their whole drug budget, not a quarter, not half, the whole thing. ... That's where we need to be holding their hand and whispering in their ear: 'Neurontin for pain, Neurontin for monotherapy, Neurontin for everything' ... I don't want to hear that safety crap either. ... every one of you should take one just to see that the drug is safe; it's a great drug."

Neurontin was also promoted for multiple sclerosis, Lou Gherigs' disease, radiation myelopathy, tinnitus, interstitial

cystitis and pain due to cancer or anything else. **There is nothing to prohibit doctors from continuing to prescribe Neurontin for any disorder.**

More Pharmaceutical Finagling

It's not clear how the Neurontin story will play out. The court documents clearly prove that former top executives at Parke-Davis sat on a committee that authorized plans to promote prescribing the drug for unapproved indications in an attempt to avoid seeking FDA approval for such uses. In addition, **the company engaged in an illegal marketing campaign that rewarded physicians who prescribed higher levels of Neurontin with cash and other gifts, including trips to resorts, dinners at expensive restaurants, and tickets to sporting events and the theater**.

At the time, Parke-Davis was a unit of Warner-Lambert, which was acquired by Pfizer in 2000. A Pfizer spokesperson indicated that the company could not comment on activities at Warner-Lambert before it was acquired. Internal Parke-Davis documents confirm that Anthony Wild, former president of Warner-Lambert's Pharmaceutical Sector, and Lodewijk J.R. de Vink, the president of Warner-Lambert, were both members of a 1996 "New Product Committee" that developed a "marketing assessment" to prescribe Neurontin for migraine and psychiatric disorders based only on hearsay and in clear violation of FDA guidelines. Neither of these individuals returned calls from investigative reporters and the extent of Pfizer's liability is not clear.

The stakes are huge. Medicaid spending in Massachusetts on Neurontin increased from $1 million in 1996 to $14 million in 2000. Washington's Attorney General, who is spearheading the suit being brought by 47 states and the District of Columbia, reported that his state's Medicaid expenses for the drug also increased more than tenfold during this period. It may be higher in other states and that's just for Medicaid. Since pharmacists don't know whether a drug is being prescribed for approved indications, the suit charges that Parke-Davis was causing false claims to be unknowingly submitted by pharmacists for off label use. Under the False Claims Act, whistle blowers can share up to 25% of the civil damages recovered so Dr. Franklin's motives may not be entirely altruistic.

Finagling is defined as (1) to practice deception or fraud or (2) to trick or cheat a person; to get something by guile or trickery. The origin of the term is obscure but it is often used to describe a card shark who "cheats or reneges". The 1850 English dialect dictionary suggests that it may have derived from the German mesmerist von Feinagle, who was apparently notorious for his trickery. However, it is doubtful that he surpassed some drug companies in that regard.

The AMA's ethical guidelines prohibit physicians from taking gifts of substantial value that do not directly benefit patients. Unethical behavior becomes illegal when gifts are accepted in exchange for prescribing medications that the physician knows will cause false billing to payers. In one recent case, TAP Pharmaceutical Products, agreed to pay $875 million and plead guilty to a criminal charge of conspiring with doctors to overcharge Medicare and Medicaid for its prostate cancer drug Lupron. Six TAP managers and a Massachusetts urologist were indicted by a federal grand jury with conspiring to pay kickbacks to physicians and four other doctors had earlier pleaded guilty to charges of health care fraud by billing for free samples.

Pfizer also recently agreed to pay $49 million to settle allegations it cheated the Louisiana Medicaid program by giving improper discounts to Ochsner Health Plan, the state's largest HMO. The Justice Department did not implicate Ochsner because it helped federal investigators crack the case. As part of the settlement, the government also agreed not to pursue similar allegations involving payments to five other health plans and two pharmacy benefits managers. The whistle blower in this instance was John David Foster, another employee of Parke-Davis before Pfizer acquired the company. Foster's lawsuit alleged that educational grants from Parke-Davis in 1999 were really a rebate that lowered the price of its cholesterol-lowering drug Lipitor for Ochsner. Such an

arrangement violates federal rules requiring a drugmaker to offer the Medicaid program either its lowest price or one that can be shown to be 15% below its average charge, whichever is less expensive.

How Can Such Abuses Be Curtailed?

Last October, the Department of Health and Human Services ruled that many gifts, gratuities and other rewards to physicians and health plans represented illegal kickbacks. The Bush administration wants to impose certain restrictions because aggressive marketing practices have driven up costs for Medicare and Medicaid to astronomic levels. Some consumer groups such as AARP have been supportive but they have been drowned out by pharmaceutical companies, health maintenance organizations as well as doctors who have flooded the government with letters criticizing the proposal. **Interestingly enough, nobody denies these unethical practices.**

A coalition of 19 pharmaceutical companies, including Pfizer, Eli Lilly and Schering-Plough even stated, "The payments and incentives to which the government objects are standard in the drug industry." Merck & Company admitted it routinely gave discounts and payments to health plans to reward "shifts in market share" favoring its products. The AMA complained that without such financial support medical societies would have to stop offering important educational activities. The government focused on disguised gifts from drug companies to doctors and the discounts that middlemen, called pharmacy-benefit managers, receive from manufacturers for pushing their products. Specifically targeted were:

- Payments to doctors and other health care providers for being "consultants" or "researchers" when the only service provided was to use their influence to increase sales.
- The more than 83,000 drug sales representatives who convince doctors, hospitals, pharmacy and drug benefit managers to switch to the most expensive drugs or profitable drugs by providing kickbacks.
- The use of free samples not as advertisements but as income for doctors who charge for giving them to patients.
- Gifts of expensive travel, scholarships, entertainment and other gratuities to health care workers, or, in some cases, their designated individuals, for promoting certain drugs.

Last July, Vermont passed the first law in the country requiring drug-sales representatives to report any gifts to physicians or their staffs in excess of $25.00. While drug companies and the AMA claim that giveaway items like pens, notepads, coffee mugs and other items of nominal value are "harmless", the Massachusetts Medical Society suggested that these "would not be so readily produced if they were not an effective form of advertising. Is the physician who writes a prescription with a company's logo on the pen more likely to write a prescription for that advertiser? Are patients more likely to request a certain drug because they see the notepad on the doctor's desk?" The industry spends well over $19 billion annually on marketing and this will probably rise as increasing generic competition threatens certain blockbuster drugs.

Last June, the Pharmaceutical Research and Manufacturers of America (PhRMA), the chief lobby for brand-name drug companies, issued its own code to govern industry relations with physicians. It prohibited the kind of entertainment, travel, meals, and gifts that were being routinely lavished on doctors by companies pitching their products. However, PhRMA has no regulatory power and all they can do is to ask salespeople to stick to these guidelines on a voluntary basis. According to very recent reports, it's not working, as drug companies continue to sponsor cocktail hours and dining at very expensive restaurants to promote their products under the guise of an "educational program." Several said the biggest backlash from its voluntary code curtailing entertainment came from doctors who were incensed that they couldn't bring spouses and significant others to lavish drug-company dinners anymore. The AMA published similar guidelines ten years ago that nobody heeded.

These new government guidelines are also not laws that must be obeyed but simply recommendations and it is not clear if they will have any teeth. Most believe that abuses can only be avoided if physicians and others refuse these bribes. "No Free Lunch", a grass-roots organization started by a New York internist represents one such growing effort.

Costs Are Soaring Due To Chicanery, Cheating, Deception And Dishonesty

That's just the tip of the iceberg. Industry is struggling to increase sales as generic competition to many blockbuster products is intensifying. **Last year, the industry spent well over $19 billion on marketing, which is one of the reasons that some drugs cost 80% less in Canada.** Generics may not be the answer since their prices have been rising almost twice as rapidly as brand-name drugs. A generic Prilosec is now available but is less than a dollar cheaper. As far as playing by the rules, last August, Forest Laboratories invited some two dozen psychiatrists to sup on tournedos of beef and fine wines at Daniel, one of Manhattan's most expensive restaurants, to coincide with approval of their new antidepressant, Lexapro. In addition, each was paid $500 as a "consultant for the night", although no consulting was done. It paid off since two weeks later, J.P. Morgan's analysts described Lexapro as an "instant success" based on the number of prescriptions written since its introduction. An October survey revealed that Lexapro was the subject of 63% of all drug sponsored meetings doctors attended. Lexapro is simply a refined version of Celexa, an antidepressant that accounts for 70% of the company's sales but whose patent expires next year. There is only one report suggesting that Lexapro might work a little faster but the company paid for this to be published and impartial experts who reviewed this found no benefits for Lexapro compared to Celexa or any other antidepressant. **Forest then concentrated on senior medical students who will start writing prescriptions next year. Forest paid to fly one from each medical school in the U.S. to attend a conference in New York to include meals and accommodations at the Plaza Hotel and Broadway show tickets.**

Companies also pay doctors to let sales reps in their office posing as someone else. A California breast cancer patient sued Alza Corp and her oncologist after one watched as the doctor examined her. The Doctor, who received $500, never revealed the man was a sales rep. In the Neurontin suit, a sales rep boasted in a voice mail "While the patient was dressing, the doctor and I one-on-one would discuss the patient and therapeutic options. I felt I had influenced her." Other internal company documents show this was not an uncommon practice.

In another whistle blowing case, Dr. Paul Stolley, a senior FDA consultant, warned in July 2000 that Lotronex for treating irritable bowel syndrome should be withdrawn because of serious side effects and deaths. It had been approved the year before over the objections of some reviewers who had predicted such problems. Glaxo withdrew the drug in November 2000, but was able to get it reinstated with warnings last June. **Dr. Stolley said the FDA has become a servant of drug companies who pay "product review" fees to gain speedy approval. In the last ten years, eight drugs have been recalled for safety reasons.** The editor of the *British Medical Journal* also believes that there is "a serious erosion of integrity within the FDA." — Stay tuned!

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