Are Pharmaceutical Companies Curing Us, Killing Us or Both?

James Unland
President, The Health Capital Group
Editor, Journal of Health Care Finance
Adjunct Professor, Loyola University, Chicago
Many thanks for Thacher’s hospitality. Special thanks to Mr. Mulligan and to Chris Mazzola, Claire Kendrick and faculty Ms. Grant and Mr. Sawyer
I will present some concerns, but…
the human race will always need medications
and pharmaceutical companies are important not just to the USA but, increasingly, to the world.

For example…
In the context of ‘infectious diseases’ bacteria and viruses just LOVE how we’re multiplying!
Population growth exacerbates human vulnerability.
Trade, travel, communication, interdependent economies all increase opportunities for ‘pathogens’
It’s no longer good enough for the USA to be relatively ‘clean’ when it comes to viral/bacterial control.
SARS: Cumulative Number of Reported Probable* Cases
Total number of cases: 4288 as of 23 April 2003, 16:00 GMT+2
<table>
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<th>INTERACTIVE</th>
<th>OUTBREAKS</th>
<th>HUMAN CASES</th>
<th>HUMAN DEATHS</th>
<th>FLIGHT PATTERN</th>
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**Bird Flu: Spread of the H5N1 Strain**

*Updated: April 30, 2008*
Heparin Find May Point to Chinese Counterfeiting

By WALT BOGDANICH
Published: March 20, 2008

Federal drug regulators, in announcing Wednesday that the mystery contaminant in heparin was an inexpensive, unapproved ingredient altered to mimic the real thing, moved closer to concluding that Americans might be the latest victims of lethal Chinese drug counterfeiting.

The finding by the Food and Drug Administration culminated a worldwide race to identify the substance discovered early this month in certain batches of heparin, the blood-thinning drug that had been linked to 19 deaths in the United States and hundreds of allergic reactions.

The contaminant, the regulators said, is a chemically altered form of chondroitin sulfate, a dietary supplement made from animal cartilage that is widely used to treat joint pain. The agency's announcement followed a report Wednesday in The New York Times that was the first publicly to identify the modified substance as the likely contaminant. That report was based on nearly two dozen interviews with researchers and scientists in China, the United States and Canada.
MOSCOW, September 25 (RIA Novosti) - India, Iran, France and South Korea are the latest countries to ban dairy products from China, where four children have died and thousands have been affected by melamine-tainted milk since early September.

So far, over 20 countries have either banned or restricted imports of Chinese dairy products, including Australia, New Zealand, Indonesia, and Japan. At the same time, safety checks of Chinese products are continuing around the world.

The Directorate General of Foreign Trade of India said in a statement that it had introduced a three-month ban on all Chinese dairy products. India, the world’s largest milk producer and Asia’s third-largest economy, does not however import milk products from China, and the ban is intended as a preventive measure.

South Korea announced the ban after discovering that two brands of Chinese biscuits on sale in the country were contaminated with melamine.

Meanwhile, Iran has banned all Chinese products containing milk, Deputy Health Minister Rasoul Dinavand told Fars News.
Post USFDA ban, Ranbaxy readies plan B for drugs

20 Sep, 2008, 0820 hrs IST, Khomba Singh, ET Bureau

NEW DELHI: Ranbaxy may shift production of the $1.5-billion drug Valacyclovir to its other FDA-approved facilities, according to some analyst reports. Valacyclovir is slated to be launched in late 2009. Last year, Ranbaxy had reached an out-of-court settlement with GSK—the innovator company—and estimates are that Ranbaxy could earn around $90-$100 million during the one-time six-month marketing exclusivity period for the product. Most analysts are of the opinion that there is enough time for the company to secure approvals to launch from other units. Valacyclovir is one of the 30 drugs whose import into US from Ranbaxy's manufacturing facilities in Poanta Sahib and Dewas has been banned by the FDA.
Like many subjects in life…

…this is truly ‘multidisciplinary’ in nature involving fundamental science, applied science, medicine, health insurance and reimbursement, government policy, government regulation (federal and states), medical law, statistics and risk analysis, economics, writing and publishing, marketing and advertising, consumer behavior analytics, stocks and bonds, securities law, class action law, devices as well as medications, genetics, foreign policy, trade policy and related regulation, demographics, male/female differentiation, zoology…

And I’m sure I’ve left out a few!
Three essential qualities to try to take with you into this type of subject…

-- Willingness to ‘learn without fear’
-- Open-mindedness and self-questioning
-- Willingness to ‘look at the whole forest’ and how multifaceted big issues are
Let’s start with the pharmaceuticals ‘curing us’ part of this discussion...
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<td>Under 5 years</td>
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Life Expectancy

- All Low- and Middle-income countries
- Low-income countries
- Middle-income countries
- High-income countries
- United States
Some ‘diseases’ have grown in prevalence
British surgeon Joseph Lister
Introduces ‘antiseptics’ in 1860s
The First Miracle Drugs
How the Sulfa Drugs Transformed Medicine
Penicillin: the first miracle drug

Many of you are here only because penicillin saved your life, or the life of one of your parents or grandparents. Penicillin's ability to cure people of many once-fatal bacterial infections has saved so many lives that it is easy to understand why it was once called a "miracle drug".

Antibiotics are chemicals, effective at very low concentrations, created as part of the life process of one organism, which can kill or stop the growth of a disease-causing microbe—a germ. In 1929, Alexander Fleming, a doctor and researcher at St. Mary's Hospital in London, England, published a paper on a chemical he called "penicillin", which he had isolated from from a mold, *Penicillium notatum*. Penicillin, Fleming wrote, had prevented the growth of a neighboring colony of germs in the same petri dish. Dr. Fleming was never able to purify his samples of penicillin, but he became the first person to publish the news of its germ-killing power. Howard Florey, Ernst Chain and Norman Heatley expanded on Fleming's work in 1938, at Oxford University. They and their staff developed methods for growing, extracting and purifying enough penicillin to prove its value as a drug.
Penicillin cures gonorrhea in 4 hours. See your doctor today.
Many parents wonder why doctors don’t give as many penicillin shots as in the past. A shot of penicillin was once the treatment of choice for streptococcal pharyngitis (strep throat). Now it is rarely used, and for good reason.

A course of oral penicillin, if taken properly, is as effective as a shot of the same drug. The main reason not to give a shot is the possibility of a life-threatening allergic reaction.

The chances are one in 2,000 that a person will have a serious reaction after their first injection of penicillin, and one in 50,000 the reaction will be fatal. Every year there are 250-500 deaths from reactions to penicillin. There have been only eight reported fatal reactions ever reported to oral penicillin.
Curbing Antibiotic Use
In War on 'Superbugs'
September 3, 2008; Page D1

Hospitals are turning to a new breed of antibiotic SWAT team to win the war against "superbugs" -- the bacteria that are outmaneuvering nearly every weapon in the arsenal of drugs long used to fight them.

The efforts, known as antimicrobial stewardship programs, team top pharmacists, infectious-disease specialists and microbiologists. The groups monitor the use of a hospital's antibiotics and restrict prescriptions of specific drugs when they become less effective at fighting infections. The heightened vigilance comes as the federal Medicare program plans to begin refusing to pay hospitals to treat preventable infections that patients contract while under the facilities' care.

Stopping Superbugs
How consumers can help in the fight against drug-resistant bacteria.

- Do not take antibiotics to treat viral illnesses like colds and sore throat (except strep throat).
- Only use antibiotics prescribed to you by a health-care provider.
- Follow instructions on the label: finish the prescription even if you feel better.
Another factor that may contribute to the spread of C-diff in hospitals is the widespread use of alcohol hand gels as a part of hand hygiene programs. These hand gels do kill bacteria, but they do not kill the C-diff spores, thereby allowing the spores to be transferred between patients. Only hand-washing with soap and water will kill the spores.

Both the JCAHO and CMS are taking notice of the rising incidence of C-diff. Hospital acquired C. difficile infection is one of the nine new proposed "never events" for which Medicare will no longer pay at a higher rate if it is acquired during a hospital stay. JCAHO's 2009
Trick or Treatment: The Undeniable Facts about Alternative Medicine (Hardcover)

by Simon Singh (Author), Edzard Ernst (Author)

⭐⭐⭐⭐⭐ (6 customer reviews)

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Let’s talk a case regarding a controversial drug situation....
Trial Intensifies Concerns About Safety of Vytorin

A clinical trial found the cholesterol drug Vytorin did not help heart patients, but seemed to raise their cancer risks.

By ALEX BERENSON
Published: July 22, 2008

In a clinical trial, the cholesterol-lowering drug Vytorin did not help people with heart-valve disease avoid further heart problems but did appear to increase their risk of cancer, scientists reported Monday.
For Widely Used Drug, Question of Usefulness Is Still Lingering

By ALEX BERENSON
Published: September 1, 2008

When the Food and Drug Administration approved a new type of cholesterol-lowering medicine in 2002, it did so on the basis of a handful of clinical trials covering a total of 3,900 patients. None of the patients took the medicine for more than 12 weeks, and the trials offered no evidence that it had reduced heart attacks or cardiovascular disease, the goal of any cholesterol drug.

The lack of evidence has not stopped doctors from heavily prescribing that drug, whether in a stand-alone form sold as Zetia or as a combination medicine called Vytorin. Aided by extensive consumer advertising, sales of the medicines reached $5.2 billion last year, making them among the best-selling drugs in the world. More than three million people worldwide take either drug every day.

But there is still no proof that the drugs help patients live longer or avoid heart attacks. This year Vytorin has failed two clinical trials meant to show its benefits. Worse, scientists are debating whether there is a link between the drugs and cancer.
EDITORIAL

Many Questions About Vytorin

The risks and benefits of a best-selling anti-cholesterol drug remain thoroughly muddled despite a new analysis that purports to exonerate it from the worst safety concerns. For now, patients and doctors are best advised to use Vytorin only as a last resort when other treatments have failed.

Vytorin, which is sold jointly by Merck and Schering-Plough, combines two cholesterol-lowering drugs. One is a traditional statin, the other a newer drug known as Zetia. As described by Alex Berenson in The Times, the Food and Drug Administration approved Zetia (and later Vytorin) on the basis of a handful of short-term clinical trials that showed they could lower cholesterol but shed no light on whether they could reduce heart attacks and cardiovascular disease, the main goal of a cholesterol-lowering drug.

A huge marketing effort propelled Vytorin and Zetia to blockbuster status. Then the bad news started coming in. A small clinical trial indicated that while Vytorin reduced cholesterol levels, it failed to slow the growth of fatty plaques in the arteries. A second trial showed that Vytorin did not help people with heart-valve disease avoid further heart problems. Worse yet, that trial suggested that Vytorin increased the risk of developing and dying from cancer, an unexpected and frightening finding that seemed implausible to many scientists.
April 1, 2008

Accusations of Delays in Releasing Drug Results

By ALEX BERENSON

CHICAGO — The lead outside investigator on a crucial trial of two widely used heart drugs said in an e-mail message last July that Merck and Schering-Plough, the companies that make the drugs, were deliberately delaying the release of the trial results “to hide something.”

The companies did not release the preliminary results of the trial, called Enhance, until January, almost two years after the trial was finished. When they were finally released, the trial’s results showed that the drugs, Vytorin and Zetia, did not work to reduce plaque in arteries. The results led a panel of cardiologists to recommend on Sunday that the drugs be used only as a last resort.

The new information was contained in e-mail messages to executives at Schering-Plough that were released Monday by Senator Charles E. Grassley of Iowa, the ranking Republican on the Senate Finance Committee. The committee has been investigating the delay in the release of the Enhance trial results.
Boehringer Inhaler Might Pose Higher Stroke Risk, FDA Says

By JENNIFER CORBETT DOOREN
March 18, 2008 4:48 p.m.

WASHINGTON -- The Food and Drug Administration said Tuesday it is opening a safety review of Boehringer Ingelheim GMBH's respiratory drug Spiriva after the company reported a possible higher risk of stroke to the agency.

In an "early communication" posted on the FDA's Web site, the agency said Boehringer Ingelheim submitted the results of 29 studies involving Spiriva, an inhaler that treats patients with chronic obstructive pulmonary disease, which showed a slightly higher rate of stroke among patients treated with Spiriva compared to those not receiving the drug. Most of the studies looked at Spiriva's HandiHaler, which is co-marketed with Pfizer Inc.

"Additional information is needed to further evaluate this preliminary information about stroke in patients who take Spiriva HandiHaler," the FDA said. The agency said it has requested additional information from the company and is reviewing post-marketing adverse events reported to FDA involving Spiriva.

The FDA said that, based on data from the studies submitted by Boehringer Ingelheim, the preliminary estimates of the risk of stroke are eight patients per 1,000 patients treated for one year with Spiriva and six patients per 1,000 patients treated for one year with placebo, meaning the estimated excess risk of a stroke possibly associated with Spiriva is two patients for each 1,000 patients over one year.
Hospital fined for Quaid babies drug mix-up

From the Associated Press
March 21, 2008

A Los Angeles hospital was fined $25,000 by state health regulators on Thursday for giving overdoses of a blood thinner to three infants including the newborn twins of actor Dennis Quaid.

The California Department of Public Health cited Cedars-Sinai Medical Center and 10 other hospitals for violations that caused or were "likely to cause, serious injury or death to patients."

Cedars spokesman Richard Elbaum said the hospital has cooperated with state investigators and intends to pay the fine.

The fine against Cedars-Sinai comes two months after the state issued a 20-page report blaming the hospital for giving Quaid's premature twins and another unidentified baby 1,000 times the intended dosage of heparin in November. All three children recovered, but two needed a drug that

More Related:

- Dennis Quaid files suit over drug mishap
- The Quaid newborns
- What recourse do victims of medication errors have?
September 2, 2008

Doubts Grow Over Flu Vaccine in Elderly

By BREnda GOODMAN

The influenza vaccine, which has been strongly recommended for people over 65 for more than four decades, is losing its reputation as an effective way to ward off the virus in the elderly.

A growing number of immunologists and epidemiologists say the vaccine probably does not work very well for people over 70, the group that accounts for three-fourths of all flu deaths.

The latest blow was a study in The Lancet last month that called into question much of the statistical evidence for the vaccine’s effectiveness.

The authors said previous studies had measured the wrong thing: not any actual protection against the flu virus but a fundamental difference between the kinds of people who get vaccines and those who do not.
April 16, 2008

Merck Wrote Drug Studies for Doctors

By STEPHANIE SAUL

The drug maker Merck drafted dozens of research studies for a best-selling drug, then lined up prestigious doctors to put their names on the reports before publication, according to an article to be published Wednesday in a leading medical journal.

The article, based on documents unearthed in lawsuits over the pain drug Vioxx, provides a rare, detailed look in the industry practice of ghostwriting medical research studies that are then published in academic journals.
Aug. 19 (Bloomberg) -- A Merck & Co. study of Vioxx that the company said showed whether the painkiller was easier on the stomach than an older drug was actually a marketing tool to boost sales, according to researchers.

Their conclusions are based on 100 internal company memos and reports about the study known as Advantage obtained from lawsuits against Whitehouse Station, New Jersey-based Merck over heart risks tied to Vioxx, now withdrawn. The trial of 5,557 patients started in 1999, just as Vioxx was cleared for sale, according to the Annals of Internal Medicine report.

The study, which recruited 600 doctors, was crafted by Merck's marketing department to get physicians to prescribe Vioxx, the researchers wrote. The report provides some of the first evidence of what is thought to be a widespread practice: enlisting doctors for a study to boost their confidence in a new drug and get them to promote it to colleagues, they said.

The Advantage study ``was marketing masquerading as science,'' said lead author Kevin Hill, of Harvard Medical School in Boston, in an Aug. 15 telephone interview. They went about this in a very analytic way, picking doctors who would be most influential, who will talk to other doctors and recommend Vioxx to them, and thus increase prescriptions in the area, planting the seeds of additional Vioxx use."
Putting sales over safety
Friday, September 12, 2008
In the early days of its wonder drug, Vioxx, Merck scored a trifecta, getting research reports reviewed and accepted by three of the most important scientific journals in the country — the New England Journal of Medicine, the Journal of the American Medical Association and the Annals of Internal Medicine.
Merck isn't the journals' darling any longer. Last month, even as Merck wrapped up a $4.5 billion settlement to end most of the lawsuits related to Vioxx's withdrawal because of cardiovascular risks, the Annals of Internal Medicine joined the other two journals in denouncing the Vioxx studies they had published.

Annals of Internal Medicine
19 August 2008 | Volume 149 Issue 4 | Pages 251-258

The ADVANTAGE Seeding Trial: A Review of Internal Documents

...Purpose: To describe a known seeding trial, ADVANTAGE (Assessment of Differences between Vioxx and Naproxen To Ascertain Gastrointestinal Tolerability and Effectiveness), through documents of the trial sponsor, Merck & Co. (Whitehouse Station, New Jersey).

...Data Sources: Merck internal and external correspondence, reports, and presentations elicited to inform legal proceedings of Cona v Merck and Co., Inc., and McDarby v Merck and Co., Inc. The documents were created between 1998 and 2006.

...Conclusion: Documentary evidence shows that ADVANTAGE is an example of marketing framed as science. The documents indicate that ADVANTAGE was a seeding trial developed by Merck's marketing division to promote prescription of Vioxx (rofecoxib) when it became available on the market in 1999.
Former Pharma Pitchman: Beware of New Drugs

An insider speaks up on the Vioxx scandal—and reveals common tactics that dupe patients and doctors alike

By Sarah Baldauf
Posted September 18, 2008

Tom Nesi, author of the new book *Poison Pills: The Untold Story of the Vioxx Drug Scandal*, wants you to know what you're getting into when you pop a newly approved, heavily marketed prescription drug. A longtime director of public affairs at the pharmaceutical company Bristol-Myers Squibb, Nesi has more than 30 years' experience in medical communications and strategy. Now a writer and consultant, he comes off as no shill for the industry he once served.

His book focuses on the cautionary tale of Vioxx, the prescription painkiller that was pulled from the market after doctors belatedly realized that it caused heart, blood, and kidney problems—including some that were fatal. His broader objective, though, is to help consumers take advantage of good medicines while sidestepping the harm some can cause.

You say the most expensive drug you can take is a free sample. How is that?
They're very seductive—they're free. Merck distributed 17 million samples to 25,000 physicians and 375,000 patients. The problem is that if you've been doing fine on a 20-cent pill, you get the free sample for a month or two, then you have to go to the drugstore to fill the prescription and then it costs you $3 a pill.
Big Pharma and Health Care: Unsolvable Conflict of Interests Between Private Enterprise and Public Health/Commentary/Author's Response

By Brezis, Mayer Belmaker, R H

Mayer Brezis, MD, MPH Center for Clinical Quality & Safety, Hadassah Medical Center & School of Public Health, The Hebrew University of Jerusalem, Israel
During a trial on duloxetine (an SSRI tested for use in stress incontinence), a young volunteer with no depression committed suicide. The FDA investigation of the death was reported as a "trade secret" (protected even under the Freedom of Information Act). After medical investigative journalist Jeanne Lenzer published the story (12), the FDA revealed that the rate of suicide attempts with duloxetine in trials of stress urinary incontinence was double that of a placebo. Lenzer concluded: "The use of trade-secret laws to conceal deaths and serious side effects linked to drugs has the obvious flaw of putting profits before public health." It appears as if the interests
Advertising Drugs and Selling Sickness

Public advertising gets increasingly powerful using aggressive direct-to-consumer marketing, payments to celebrities for appearing on TV shows and telling about their illnesses and cures, and sophisticated targeting of consumer groups that will then effectively lobby insurers and regulators for the industry's causes (23, 24).
A most remarkable tactic for expanding drug markets is "disease mongering," i.e., trying to convince essentially well people that they are sick by medicalization of trivial conditions: for instance, defining abdominal discomfort as irritable bowel syndrome or normal aging as menopause and osteoporosis, inducing people to believe they need treatment (29). Psychosocial conditions are especially susceptible to framing by experts as medical conditions: attention deficit hyperactivity disorder (ADHD), depression, social anxiety disorder, sexual dysfunction, and premenstrual "dysphoria." Pharmaceutical companies use the Internet to access teachers and to influence their brokerage role to increase ADHD diagnosis and Ritalin usage (30). For concerned parents, a suggested response by Novartis to teachers is: "Make it clear to them that it is important for them - and their child - to understand and follow the doctor's medical advice about medication and other therapies for ADHD. ADHD is a serious condition that may require the child to be on medication and undergo counseling for a long duration" (30). Big Pharma has taken an aggressive marketing interest in sex, using public relations, advertising, and a variety of tactics to create a sense of widespread sexual inadequacy and interest in drug treatments, both for women and men. People are often
James Unland
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