



శ్రీ వేపచేదు విద్యా పీఠము

VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

Chief Editor: Sreenivasarao Vepachedu, MS, JD, PhD, LLM

Issue 76 Contents:

Abuse of Medications
Artificial Lung
Improving the Functioning of the PCT System
Alzheimer's Disease
AIDS and Poverty in the US
Capturing CO₂
Waning American Innovation
Biotech Patents in EU
Bilski and Business Method Patents
Ayurveda, Unani, Siddha and Homeopathy Medicines
Animal Research Centers in India
Japanese Companies Manufacture in India
Charles River and WiXi Divorce
Octopus Venom and Scorpion Venom
Biomarkers
Dark Side of Research

Abuse of Medications

The top three most abused prescription pain drugs between 2004 and 2008 were:

- * Oxycodone, in which emergency room visits for nonmedical use rose 152 percent to 105,214.
- * Hydrocodone, in which emergency visits rose 123 percent to 89,051.
- * Methadone, in which emergency visits rose 73 percent to 63,629.

Issue 76

1
5112 [Kali Era](#), [Vikruthi](#) Year, Ashadha month
2068 [Vikramarka Era](#), [Vikruthi](#) Year, Ashadha month
1932 [Salivahana Era](#), [Vikruthi](#) Year, Ashadha month
2010 AD, July

Copyright ©1998-2010

[Vepachedu Educational Foundation, Inc](#)



శ్రీ వేపచేదు విద్యా పీఠము

VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

Emergency visits involving the nonmedical use of pain drugs such as oxycodone rose to 305,885 in 2008, from 144,644 in 2004, according to a study by the Substance Abuse and Mental Health Services Administration and the Centers for Disease Control and Prevention.

Abuse of other drugs, such as morphine, fentanyl and hydromorphone, resulted in fewer visits to the emergency room. But they, too, have increased sharply, according to the study published in the CDC's weekly report on death and disease.

Artificial Lung

Two teams of researchers from New England have built living, breathing lung tissue in the laboratory - feats of engineering that could speed up the development of new drugs and bring researchers a step closer to the tantalizing dream of growing replacement lungs for patients.

Both achievements, described in reports published by Harvard and Yale scientists, are part of broader efforts among researchers to build a range of organs, from the heart to the liver. Such research could provide powerful tools to test drugs and identify toxins, and eventually grow new tissue to repair damaged organs.

Harvard scientists re-created a critical area of lung tissue on a silicon rubber chip the size of a quarter, and found that it responded to bacteria and tiny particles carried in the air just like a living lung. Using a different approach, Yale University researchers regenerated lungs and transplanted them into rats, where they functioned successfully for up to two hours. It will still be many years yet before doctors reach the dream of regenerating lungs to help patients.

Improving the Functioning of the PCT System

During the week of 14 to 18 June 2010, PCT Member states considered proposals to improve the PCT potential contribution to higher quality and more efficiently granted patents at the national/regional level. The recommendations that came out of the meeting were based on a WIPO study entitled, "The Need for Improving the Functioning of the PCT System."
http://www.wipo.int/edocs/mdocs/pct/en/pct_wg_3/pct_wg_3_2.pdf



శ్రీ వేపచేదు విద్యా పీఠము

VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

Alzheimer's Disease

Scientists are reporting advances in detecting and predicting Alzheimer's disease at a conference in Honolulu this week, plus more proof that getting enough exercise and vitamin D may lower your risk. There are better brain scans to spot Alzheimer's disease.

Blood and spinal fluid tests that may help tell who will develop the mind-robbing illness and when. But what is needed most -- a treatment that does more than just ease symptoms -- is not at hand. Several promising ones flopped in late-stage tests - most recently, Pfizer Inc.'s Dimebon. Results on several others won't be ready until next year.

Still, there is some progress against Alzheimer's, a dementia that afflicts more than 5 million Americans and more than 26 million people worldwide. Highlights of the research reported:

- **Prevention.** Moderate to heavy exercisers had half the risk of developing dementia compared with less active people, researchers from the long-running Framingham Heart Study reported. Earlier studies also found exercise helps. Another big government-funded study found that vitamin D deficiency can raise the risk of mental impairment up to fourfold. This doesn't mean taking supplements is a good idea, doctors warn. A large study is testing whether that is safe and helps prevent a variety of diseases.
- **Novel treatments.** Tests of an insulin nose spray to improve cognition gave encouraging results. It's based on the theory that Alzheimer's and diabetes are related. Diabetics seem to have a higher risk of developing Alzheimer's, and Alzheimer's patients tend to have insulin resistance. Giving insulin as a nose spray sends it straight to the brain without affecting blood-sugar levels.
- **Improved detection.** Many types of imaging can document dementia, which usually is diagnosed through cognition tests. For several years, scientists have used one such method -- a radioactive dye and PET scans -- to see the sticky brain plaque that is a key feature of Alzheimer's. But the dye is tough to use, and at least four companies are developing better ones. Philadelphia-based Avid Radiopharmaceuticals Inc. reports success with one such dye, and says it may offer an early warning for those on their way to developing Alzheimer's. A PET scan costs \$3,000 to \$5,000 plus whatever Avid would charge for the dye, if it wins federal approval. It may require special training to give the test and interpret it, so it likely will remain mostly a research tool to pick the right patients for clinical trials and monitor a drug's effects. .



శ్రీ వేపచేదు విద్యా పీఠము

VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

Until there are better treatments, there will be little demand for tests that show you have or are destined to get the disease, several experts said. There's little testing now for the first gene strongly tied to Alzheimer's risk, ApoE-4. Scientists also don't know if the plaque is a cause, an effect, or just a sign of Alzheimer's. Two experimental drugs seemed to clear plaque but did not lead to clinical improvement.

AIDS and Poverty in the US

There's no clear biological reason why the infection rate is eight times higher in blacks than whites, and three times higher in Hispanics than whites. Research studies in Tanzania, Kenya and some other African countries actually found that wealthy people were more likely to be infected than the poor. However, in the US, the story is different – poor people are more likely to be infected with HIV than the rich. A CDC report that was released at the international AIDS conference in Vienna, involved a survey in 2006 and 2007 of 9,000 heterosexual adults, ages 18 to 50. They answered questions on a computer about their income, condom use and other details and were given HIV tests. The research was done in high-poverty neighborhoods in 23 U.S. cities. It focused on heterosexuals who don't use intravenous drugs; that group accounts for about 28 percent of Americans living with HIV. It did not involve gay or bisexual men, who have the highest rates of HIV in the United States.

The results: HIV was detected in 2.4 percent of the people who were living below the federal poverty line, which in 2007 was an annual income of roughly \$10,000 or less for an individual. The 2.4 percent translates to roughly 1 in 42 people. In contrast, infections were found in 1.2 percent of people in the same neighborhoods who made more money than the federal poverty guideline. That's 1 in 83 people. Both rates were higher than the national average, which is 0.45 percent, or 1 in 222 people. The results suggest that Americans in low-income neighborhoods are more likely to be infected because they live among more people who are infected.

According to 2006 estimates, more than 1.1 million Americans are living with the AIDS virus. The number of people taking crucial AIDS drugs climbed by a record 1.2 million last year to 5.2 million overall, the World Health Organization said. Between 2003 and 2010, the number of patients receiving lifesaving antiretroviral treatment increased twelve-fold, according to the Geneva-based body.



శ్రీ వేపచేదు విద్యా పీఠము

VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

Capturing CO2

Scientists have come up with a technique using the waste steam that is a common feature of fossil fuel burning plants. Steam-stripping is proving effective at liberating amines that capture CO₂, ready for reuse. Scientists have been working with solid materials that contain amines effective at removing the carbon dioxide from flue gases that are emitted from facilities that burn coal, such as power stations. The research results were published in the ChemSusChem journal.

Waning American Innovation

Patent expiration, sluggish pipelines and mounting job losses have for some time been a concern, but other forces are threatening Big Pharma's bottom line. One major criticism is that innovation in the industry has become idle—and some of that criticism is coming from the industry itself. Last month, Dr. John C. Lechleiter, president and CEO of Eli Lilly & Co., addressed the Detroit Economic Club and warned that America's greatest competitive advantage—its “genius for innovation”—is in jeopardy. Lechleiter cited a 2009 study by the Information Technology and Innovation Foundation which ranked the United States sixth among the top 40 industrialized nations in innovative competitiveness, but 40th of 40 in measures of what industrialized countries are doing to become more innovative in the future. But Lechleiter also suggested that with the right choices—such as improving math and science education, changing to immigration laws to allow top scientists abroad to bring their talents here and funding and tax breaks for research institutions—“what might seem unimaginable today will be commonplace tomorrow.”

The rapid growth of the CRO market also has some worried that Big Pharma will outsource much-needed jobs and services to firms in foreign countries. Dr. Mark Fishman, president of Cambridge, Mass.-based Novartis Institutes for Biomedical Research (NIBR), the global pharmaceutical research organization of Novartis, recently told the Life Science Leader that “there is no question that the economic downturn has affected the scientific enterprise in the United States, and I worry that this may be a problem for future generations of American scientists.”

Due to these various challenges, analysts have noted that pharma has fallen out of favor with Wall Street and now has one of the lowest price/earnings ratios of any major sector of the stock market. <http://www.drugdiscoverynews.com/index.php?newsarticle=4014>



శ్రీ వేపచేదు విద్యా పీఠము

VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

Biotech Patents in EU

A soybean meal exported into Europe was obtained from genetically modified soybean plants tolerant to the herbicide glyphosate due to the presence of a gene encoding a specific enzyme—EPSPS. The DNA sequence of the EPSPS gene is validly patented in several EU Member States. However, no patent protection existed in Argentina, and the genetically engineered soybean plants were cultivated and processed in Argentina without needing a license. Monsanto then tried to enforce its European patent claim on the DNA sequence against the soybean meal products resulting from these soy plants, once it was imported into the EU, as the soybean meal contained the patented DNA sequence originating from the genetically modified plants.

Uncertainties in the applicability and scope of the Biotech Directive of EU, in particular regarding Article 9 of the Directive, led the Dutch court where the Monsanto infringement litigations were pending to refer several questions to the ECJ for a preliminary ruling: 1) whether a DNA sequence must perform its function at the time of the alleged infringement to invoke protection under Article 9 of the Biotech Directive, or whether performance before or potential later performance is sufficient for Article 9 to apply, and 2) the relationship between the Biotech Directive and national patent law. The Dutch court sought clarification from the ECJ regarding the relevance of the patent filing or grant date in relation to adoption of the Biotech Directive, and the impact of international treaties, specifically the TRIPS Agreement, for any interpretation of the Biotech Directive. The ECJ determined that the protection conferred by Article 9 of the Biotech Directive is not available when the genetic information has ceased to perform the specific function it performed and for which patent protection was granted.

http://www.mondaq.com/unitedstates/article.asp?articleid=105190&email_access=on

Bilski and Business Method Patents

The *Bilski* case presented the Supreme Court with an opportunity to eliminate business methods from the scope of patentable subject matter. The specific patent application before the Court was unanimously rejected. However, the boundaries of patent-eligible inventions remain uncertain, as the court declined to eliminate business methods from the scope of patentable subject matter.

Issue 76

6
5112 *Kali Era*, *Vikruthi Year*, *Ashadha month*
2068 *Vikramarka Era*, *Vikruthi Year*, *Ashadha month*
1932 *Salivahana Era*, *Vikruthi Year*, *Ashadha month*
2010 AD, July

Copyright ©1998-2010

[Vepachedu Educational Foundation, Inc](http://www.vepachedu.com)



శ్రీ వేపచేదు విద్యా పీఠము

VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

Bilski et al filed a patent application on a method for hedging against price changes in the energy market, which was rejected by the Patent and Trademark Office. The inventors appealed to the Court of Appeals for the Federal Circuit, which announced *en banc* that the "machine-or-transformation" test would henceforth be the sole test to determine whether a claimed process describes patentable subject matter, according to which a claim to a process can only be patentable if it recites a transformation of matter or is tied to a particular machine. Bilski's claims failed the test, and were thus held unpatentable. The Supreme Court unanimously agreed that the machine-or-transformation test is not the *sole* test for establishing whether a process describes patentable subject matter, and explained that this test does, in many instances, provide "an investigative tool" for determining patentability of certain processes.

Ayurveda, Unani, Siddha and Homeopathy Medicines

India is bringing in good clinical practice (GCP) guidelines mandating scientific evaluation of drug products based on the traditional medicinal systems like ayurveda, siddha and unani (ASU). Through the implementation of GCP for ASU and TM medicines, the government aims to ensure that the studies are scientifically and ethically sound and that the clinical properties of the ASU medicine and other TM under investigation are properly documented.

The Department of Ayurveda, Unani, Siddha and Homoeopathy (Ayush), under the ministry of health, government of India has recently issued a draft gazette notification informing about the guidelines for good clinical trials on Ayurveda, Siddha, Unani (ASU) medicines and other traditional medicines (TM). The new guidelines for good clinical practice are formulated based on GCP guidelines for clinical trials on pharma products.

Traditional medicine is defined as the sum of total of the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures in India, used for the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illnesses, which do not find a mention in First Schedule of Drugs and Cosmetics Act 1940.

If a manufacturer wants to market an existing medicine for a new indication from the ayurvedic classical reference books, which are officially recognized, he would require published data and proof of efficacy as pre-requisites for licensing, as per new guidelines mooted by Department of Ayush (Ayurveda, Unani,



శ్రీ వేపచేదు విద్యా పీఠము

VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

Siddha and Homeopathy) under the health ministry which sets standards for the formulations belonging to these classical medicine streams.

Ayurvedic health supplements & ayurvedic cosmetics would need photocopy of references from official texts to get a license. If the indication is different from those mentioned in the official texts, safety and effectiveness study submissions are needed.

For water extracts of herbs mentioned in the official texts, no special data is required. However, if it is to be marketed for new indication, then proof of effectiveness is to be generated and submitted for issue of a license.

In the case of hydro-alcoholic extracts of herbs mentioned in the official texts safety data, published literature data and proof of effectiveness data are required as a pre-requisite for licensing, in addition to textual references mandates the draft notification by Department of Ayush amending the licensing conditions for ASU medicines and proprietary ASU medicines.

The amendment draft notification also introduces new rules 158(B) to categorize ayurvedic and herbal products. At present, the herbal medicines from ayurveda, siddha and unani streams are included in a single category under the Drugs & Cosmetic Rules.

These herbal formulations will now be put under four new categories while retaining the current definition of ASU medicine which is referred as classical or grantha formulations. All those medicines that use ingredients mentioned in the texts will be categorized as Proprietary Ayurvedic Medicine (PAM).

Supplement formulations from ayurveda or unani or siddha will officially use the term “Balya” – nutrition and strength giver; “Poshak” – health promoter: positive health promoter, formulations and ayurvedic ingredients that are recommended in official books for promotional and preventive health.

The cosmetic products belonging to ayurveda or unani or siddha medicines will be termed “Soundarya Prasadak”. This deals with formulations having ingredients that are recommended in official books. These drugs are recommended to promote ‘Soundarya’ or beauty related to skin, hair & body care.

The department of Ayush has officially allowed a new category for ayurvedic extracts.

Issue 76

8
5112 [Kali Era, Vikruthi Year, Ashadha month](#)
2068 [Vikramarka Era, Vikruthi Year, Ashadha month](#)
1932 [Salivahana Era, Vikruthi Year, Ashadha month](#)
2010 AD, July

Copyright ©1998-2010

[Vepachedu Educational Foundation, Inc](#)



శ్రీ వేపచేదు విద్యా పీఠము

VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

For ayurveda or unani or siddha extracts, the terms officially used in the notification are ‘Aushadh Ghana’ extracts obtained from plants mentioned in the official books including aqueous (water) or hydro-alcohol (water + ethanol).

<http://www.dancewithshadows.com/pillscribe/india-makes-clinical-studies-mandatory-for-ayurveda-siddha-and-unani-medicines/>

Animal Research Centers in India

The government of India is to establish three animal houses, costing upto Rs 5 crore, to assist drug development research in the country, reports said. The Department of Pharmaceuticals (DoP) under the government of India will be funding the facilities. All the facilities will be compliant with Good Laboratory Practices (GLP) norms for preclinical studies in drug products.

These public sector animal experimentation centers will be open to private companies as well. The department has identified the states of Karnataka, Assam and Hyderabad for the proposed public-funded animal experimentation centers in India.

The department will work with the public sector drug firm Karnataka Antibiotics and Pharmaceuticals (KAPL) for the Bangalore facility. The animal house at Assam will be part of a proposed National Centre for Research and Development of Phyto-pharmaceuticals at Guwahati in Assam. The Guwahati phytopharmaceutical research centre will facilitate plant-based medicine research utilizing the advantage of having large variety of species suitable for phyto-pharmaceutical products in the North-East region. The work for the centre, which is going to be the first of the kind in the country, is expected to begin in the next year.

The third animal experimentation facility will come in Hyderabad, in the southern state of Andhra Pradesh. Hyderabad is a hub for bulk drug production in India.

<http://www.dancewithshadows.com/pillscribe/india-to-set-up-public-sector-animal-experimentation-centres-in-bangalore-guwahati-and-hyderabad/>

Japanese Companies Manufacture in India

Issue 76

9
5112 *Kali Era, Vikruthi Year, Ashadha month*
2068 *Vikramarka Era, Vikruthi Year, Ashadha month*
1932 *Salivahana Era, Vikruthi Year, Ashadha month*
2010 AD, July

Copyright ©1998-2010

[Vepachedu Educational Foundation, Inc](http://www.vepachedu.com)



శ్రీ వేపచేదు విద్యా పీఠము

VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

Japanese drugmaker Eisai Co plans to produce some of its drug product including the high profile donepezil (Aricept) for the treatment of Alzheimer's in India, to leverage on the cost-effective manufacturing offered by the country to ward off generic competition. Eisai will begin manufacturing donepezil (Aricept) in India for exports to Japan, the United States and Europe next year. Patents covering donepezil (Aricept) are set to expire in the United States this November and then in Japan and Europe by 2012. Eisai has decided to shift production to India where it will be able to cut production costs roughly in half.

Eisai will be first major Japanese drugmaker to produce a drug in an emerging market. Eisai will start producing the drug at a newly constructed plant in the Indian state of Andhra Pradesh. Currently, Aricept accounts for about 40 percent of Eisai's total sales. Eisai is also expected to begin Indian production of the ulcer treatment Pariet (rabeprazole). Pariet (rabeprazole) is an acid regulator. Pariet (rabeprazole) will go off-patent in the United States in 2013.

In April, another Japanese drug major Astellas Pharma Inc launched its flagship anti-organ rejection drug Prograf (tacrolimus) in India. Prograf is prescribed to prevent organ rejection in patients receiving allogenic liver, kidney, or heart transplants and was first approved and launched in Japan in 1993. To tap the 1.6 billion rupees immunosuppressant market in India, Prograf will be promoted in kidney, liver, heart transplants & marketed in more than 150 hospitals where transplantation facilities are available. Around 4,000 – 4,200 kidney transplants, 350-400 liver transplants & very few heart transplants are done in India every year. Prograf is available in more than 80 countries and the global leader among immunosuppressant. Prograf (tacrolimus) has similar immunosuppressive properties to cyclosporin, the commonly used drug to stop organ rejection. However, studies showed that Prograf (tacrolimus) is much more potent than cyclosporin in equal volumes. Prograf (tacrolimus) was first approved by the Food and Drug Administration (FDA) in 1994 for use in liver transplantation; this has been extended to include kidney, heart, small bowel, pancreas, lung, trachea, skin, cornea, bone marrow, and limb transplants.

<http://www.dancewithshadows.com/pillscribe/eisai-to-export-alzheimers-drug-donepezil-aricept-anti-ulcerant-rabeprazole-pariet-from-india/>



శ్రీ వేపచేదు విద్యా పీఠము

VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

Charles River and WiXi Divorce

Charles River Laboratories International,, a leading global provider of research models and associated services and of preclinical drug development services, announced that it has mutually agreed with WuXi PharmaTech (Cayman) Inc. to terminate their previously announced acquisition agreement. The Company also announced that its Board of Directors has authorized a new \$500 million stock repurchase program. The termination agreement provides for Charles River to pay WuXi a \$30 million breakup fee for full satisfaction of the parties' obligations under the acquisition agreement and includes mutual releases of any claims and liabilities arising out of or relating to the acquisition agreement.

Octopus Venom and Scorpion Venom

Once thought to be only the realm of the blue-ringed octopus, researchers have now shown that all octopuses and cuttlefish, and some squid are venomous. A study, conducted by an international team of researchers from the University of Melbourne, the Norwegian University of Technology and Science and the University of Hamburg, provides the first insight into the properties of Antarctic octopus venom. It has also revealed the existence of four new species of octopus. Venom has long been recognized as a potentially valuable resource for drug development. However, scientists have only recently discovered the largely untapped resource cephalopods such as octopuses, cuttlefish and squid, possess in their unique venom properties -- especially the species that live in sub-zero temperatures. The venom analysis revealed that Antarctic octopus venom harbors a range of toxins, two of which are described never before. An understanding of the structure and mode of action of venom found in all octopuses may help design drugs for conditions like pain management, allergies and cancer. The research team collected 203 octopuses from Antarctic waters. They then genetically profiled each specimen to identify the species and collected venom to analyze in the lab.

Last year, researchers have carried out the first ever venom analysis in Scorpiops jendeki scorpion and discovered and discovered nine novel poison molecules, never before seen in any scorpion species. Transcriptomic tests have uncovered the protein composition of venom from the scorpion. To humans, the sting of scorpions from the Euscorpiidae family tend to be quite mild – about as painful as a mosquito bite. Researchers are investigating new ways for developing a novel painkiller based on natural compounds found in the venom of scorpions.



శ్రీ వేపచేదు విద్యా పీఠము

VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

Biomarkers

Blood tests have been extremely important tools aiding doctors in making medical diagnoses and in guiding the treatment of many diseases. However, psychiatry is one area of medicine where there are few diagnostic blood tests. New scientific fields may someday generate blood tests that can be used for these purposes. Some of the areas under increasingly intensive study are genetics, the study of variations in the genes (DNA) that can be extracted from blood cells, and genomics like proteomics, the measurement of the levels of specific proteins in the blood, and gene expression profiling, which measures the levels of RNA produced from DNA as an indication of the level of the "activity" of particular genes. Using the latter approach, Dutch researchers evaluated blood gene expression profiles in healthy individuals and patients diagnosed with major depressive disorder, or MDD. They identified a set of seven genes in whole blood that was able to distinguish un-medicated MDD patients from healthy controls.

Levels of the protein clusterin (clusterin/apolipoprotein J), thought to be involved in programmed cell death and the clearance of cellular debris, were elevated in the plasma of Alzheimer's patients but not in healthy controls and people with mild cognitive impairment, according to Simon Lovestone, PhD, of King's College London, and colleagues. Plasma clusterin levels were also elevated in people whose dementia progressed rapidly, compared with those whose disease moved more slowly, the researchers reported concluded in the July issue of *Archives of General Psychiatry*.

Dark Side of Research

Oftentimes, medical journals or pharmaceutical companies that sponsor research will report only "positive" results, leaving out the non-findings or negative findings where a new drug or procedure may have proved more harmful than helpful. A new review of research about this problem points to hidden or misleading studies for all sorts of conditions, including depression, Alzheimer's disease, type 2 diabetes, menopausal symptoms and cancer, said researchers at the Institute for Quality and Efficiency in Health Care (IQWiG) in Germany. Much of that problem arises from financial conflicts of interest when pharmaceutical or medical device companies fund the studies, according to Wieseler and her colleagues. They pointed to past research showing an association between industry sponsorship and positive outcomes or conclusions in studies.



శ్రీ వేపచేదు విద్యా పీఠము

VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

One of the most well-known examples of bias involves the selective serotonin reuptake inhibitor (SSRI) paroxetine (Paxil), an anti-anxiety medicine. The pharmaceutical company GlaxoSmithKline suppressed results from four trials for not-approved use of Paxil that not only failed to show treatment effectiveness for off-label use of its SSRI among children and teens, but also showed possible increased risk of suicidal tendencies in this age group for which the drug was not approved by FDA. (Off-label means the drug, while approved by the FDA for some uses, isn't approved for that particular usage.) As part of a legal settlement with New York State, GlaxoSmithKline agreed to establish an online clinical trials registry for the result summaries of all its sponsored studies conducted after a certain date.

The pharmaceutical giant Pfizer sponsored 20 studies on whether gabapentin (Neurontin) could work for off-label treatment of conditions such as bipolar disorder or migraines. But eight of the studies were never published.

[http://www.livescience.com/health/medical-research-drugs-devices-contains-widespread-bias-omissions-100624.html?utm_source=feedburner&utm_medium=feed&utm_campaign=Feed%3A+Livesciencecom+\(LiveScience.com+Science+Headline+Feed\)](http://www.livescience.com/health/medical-research-drugs-devices-contains-widespread-bias-omissions-100624.html?utm_source=feedburner&utm_medium=feed&utm_campaign=Feed%3A+Livesciencecom+(LiveScience.com+Science+Headline+Feed))

Source: *The primary sources cited above, BBC News, New York Times (NYT), Washington Post (WP), Mercury News, Bayarea.com, Chicago Tribune, CNN, USA Today, Intellihealthnews, Deccan Chronicle (DC), the Hindu, Hindustan Times, Times of India, AP, Reuters, AFP, Biospace etc.*

Notice: *The content of the articles is intended to provide general information. Specialist advice should be sought about your specific circumstances.*