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VEPACHEDU EDUCATIONAL FOUNDATION

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Issue 131

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Jury and J & J

A 20-year-old Alabama man won a lawsuit against Janssen Pharmaceuticals (a Johnson & Johnson subsidiary) after an antipsychotic drug caused weight gain. He was awarded $ 2.5 million in damages in a Philadelphia court. Austin Pledger reportedly took an antipsychotic drug known as Risperdal as a child and wasn't "adequately warned." The drug's label warned of the risk of gynecomastia, the condition of men growing breasts, "Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported in patients receiving prolactin-elevating compounds.[1]" In 2013, the FDA announced that Janssen Pharmaceuticals pled guilty to a charge of misbranding the drug as a treatment for dementia without it being approved by the FDA to do so. The company had to pay a $400 million criminal fine for introducing a misbranded drug, as well as $1.25 billion for another civil settlement. In addition, there are over 1,200 cases filed in Philadelphia over Risperdal waiting to be settled.

Johnson & Johnson[2] was recently asked by a jury in the state of California to pay $5.7 million in damages to settle a lawsuit pertaining to transvaginal meshes. Less than a month ago, it was announced that Boston Scientific will pay $600 million to J&J to settle a lawsuit related to the acquisition of Guidant Corp. At the end of 2013, a court ruled that J&J will have to pay $2.5 billion in damages to settle hip implant lawsuits. While in some cases the company has won, its financial statements suggest that the net outflow of cash pertaining to litigation expenses is significant.

J&J's litigation expenses have averaged roughly $1.28 billion annually, and there is a clear pattern in the lawsuits filed against the company. Most of them seem to be related its medical devices & diagnostics

subsidiaries. However, J&J has been divesting its medical devices & diagnostics assets. Last year, the company sold its diagnostics unit, Ortho-Clinical Diagnostics, to the Carlyle group for around $4 billion.

Biosimilars

Zarxio, which is biosimilar to Neupogen, is a medication that boosts the production of white blood cells and helps to ward off infection in patients receiving strong chemotherapy for some tumors. The most common expected side effects of Zarxio are aching in the bones or muscles and redness, swelling or itching at injection site. Serious side effects include spleen rupture; serious allergic reactions and acute respiratory distress. Neupogen raked in $1.2 billion for Amgen last year, a lucrative market that Novartis, and its Sandoz unit that makes Zarxio, are now eyeing eagerly. The FDA said in January that an internal panel seemed inclined to give Zarxio the green light to treat the same five conditions Neupogen does. Sandoz declined to issue a price target for Zarxio.

Biosimilars have been widely available in Europe since 2006, but the FDA was only granted the right to review and approve them when the Patient Protection and Affordable Care Act (PPAC Act), signed into law by President Obama on March 23, 2010, amended the Public Health Service Act (PHS Act) to create an abbreviated approval pathway for biological products that are demonstrated to be “highly similar” (biosimilar) to or “interchangeable” with an FDA-approved biological product. These new statutory provisions also may be referred to as the Biologics Price Competition and Innovation Act of 2009 (BPCI Act).

A biosimilar product is a biological product that is approved based on a showing that it is highly similar to an FDA-approved biological product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products. The biosimilar must have the same strength and dosage form (injectable, for example) and route of administration as the reference product. The biosimilar must be manufactured following Current Good Manufacturing Practices. Biosimilars are always different in composition, which differentiates them from generic drugs, which are exact replicas of other drugs.

An interchangeable biological product is biosimilar to an FDA-approved reference product and meets additional standards for interchangeability. An interchangeable biological product may be substituted for

the reference product by a pharmacist without the intervention of the health care provider who prescribed the reference product.

FDA requires licensed biosimilar and interchangeable biological products to meet the Agency's rigorous standards of safety and efficacy. That means patients and health care professionals will be able to rely upon the safety and effectiveness of the biosimilar or interchangeable product, just as they would the reference product. For more information about biosimilars, visit the links below and FDA's, consumer, health care professional and industry pages on biosimilars.

In Europe[3], on October 30, 2005 the "Guideline on similar biological medicinal products," came into effect. This paved the way for the launch of 19 biosimilars[4], so far:

1. Abasaglar (previously Abasria)
2. Abseamed
3. Accofil
4. Bemfola
5. Binocrit
6. Biograstim
7. Epoetin Alfa Hexal
8. Filgrastim Hexal
9. Grastofil
10. Inflectra
11. Nivestim
12. Omnitrope
13. Ovaleap
14. Ratiograstim
15. Remsima
16. Retacrit
17. Silapo
18. Tevagrastim
19. Zarzio

An authorized biosimilar is generally used at the same dose to treat the same conditions. If there are specific precautions to be considered when taking the reference medicine, the same will generally apply to the biosimilar.

So far, guidance for the development of biosimilar products has been developed for seven different product classes, with two more currently being drafted.

Guidance published, or being developed, by the Agency includes overarching biosimilar guidance, non-clinical and clinical aspects for the development of biosimilars, and product-class specific guidelines in the areas of:
• epoetins;
• filgrastims;
• insulins;
• growth hormones;
• alfa interferons;
• monoclonal antibodies;
• beta interferons;
• follitropins;
• low-molecular-weight heparins (LMWH).

However, the principles of biosimilar drug development apply in general to all biological medicinal products.

Top 10 for Women

The National Association for Female Executives (NAFE), a division of Working Mother magazine publisher Working Mother Media, released its annual list of the top 50 companies for executive women. Women still have a long way to go until they are well-represented in corporate leadership. Only 4.6% of the 1,000 largest U.S. companies have female CEOs. That's the same number as last year. Even among the top 50 companies on NAFE's list, only five have women in the top job. From that list, NAFE highlights 10 companies it says are the "best" for women. They aren't ranked from one to ten. They're all considered to be great places for women to work and advance.

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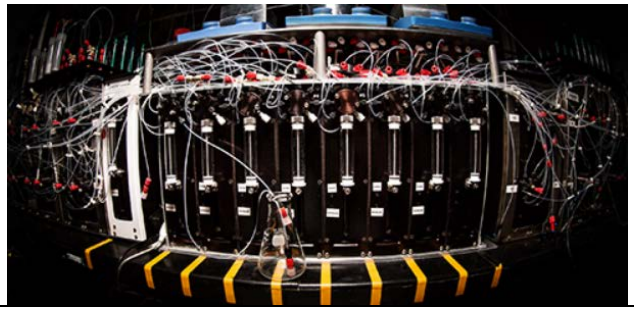
1. IBM stands out because it's the only one of the top 10 with a female CEO. In 2011 the century-old tech giant tapped Virginia Rometty for the top job. IBM also has an impressive share of female senior managers, 29%, and 26% of its executives are women, according to NAFE.
2. Johnson & Johnson is another standout. For 20 years the pharma, medical device and consumer products multinational has had something called the Women's Leadership Initiative, which has grown to 50 chapters nationwide and works to advance women inside J&J. Of the company's 38,000 U.S. employees, nearly half, 45%, are women, and of those, 40% are senior managers. Three women sit on the company's 13-member board.
3. Ernst & Young is another standout with 46% of its 31,000 employees being women and 46% of senior managers female.
4. Abbott: Percentage of employees who are women: 47%; Percentage of senior managers who are women: 42%
5. General Mills: Percentage of employees who are women: 40%; Percentage of senior managers who are women: 40%
6. KPMG: Percentage of employees who are women: 46%; Percentage of senior managers who are women: 36%
7. Marriott: Percentage of employees who are women: 54%; Percentage of senior managers who are women: 40%
8. MassMutual Finance Group: Percentage of employees who are women: 56%; Percentage of senior managers who are women: 32%
9. Procter & Gamble: Percentage of employees who are women: 39%; Percentage of senior managers who are women: 35%
10. State Farm: Percentage of employees who are women: 59%; Percentage of senior managers who are women: 39%

Print Your Body Parts and Medicines

3D printing is increasingly becoming popular nowadays, permitting the direct digital manufacture (DDM) of a wide variety of materials, including body parts. The 3D printers that print the body parts are called bioprinters and they use bioink. These printers artificially construct living tissue by outputting layer-upon-layer of living cells[5].

Similarly, a new molecule-making 3-D printing machine could make medicines fast, flexible and accessible to anyone. A new process for synthesizing organic compounds from 14 different classes of

small molecules. In a university statement, "built the machine to assemble complex small molecules at the click of a mouse, like a 3-D printer at the molecular level, reported in journal Science[6]. The pharmaceutical industry has a long history of using natural products with complex structures as the basis for new drugs, especially in fields like antibiotics, antifungals, and cancer chemotherapies. One of the more common generic cancer chemotherapies, paclitaxel, was famously discovered in the bark of the Pacific yew tree, and it took years for scientists to learn how to quit extracting it from the tree, and synthesize it in labs.



Om! Asatoma Sadgamaya, Tamasoma Jyotirgamaya, Mrityorma Amritamgamaya, Om Shantih, Shantih, Shantih!
(Aum! Lead the world from wrong path to the right path, from ignorance to knowledge, from mortality to immortality, and peace!)

[1] http://www.janssenpharmaceuticalsinc.com/assets/risperdal.pdf: accessed on March 30, 2015.
5.6 Hyperprolactinemia: As with other drugs that antagonize dopamine D2 receptors, RISPERDAL elevates prolactin levels and the elevation persists during chronic administration. RISPERDAL ® is associated with higher levels of prolactin elevation than other antipsychotic agents. Hyperprolactinemia may suppress hypothalamic GnRH, resulting in reducedpituitary gonadotropin secretion. This, in turn, may inhibit reproductive function by impairing gonadal steroidogenesis in both female and male patients. Galactorrhea, amenorrhea, gynecomastia and impotence have been reported in patients receiving prolactin-elevating compounds. Long-standing hyperprolactinemia when associated with hypogonadism may lead to decreased bone density in both female and male subjects.
[2] http://www.forbes.com/sites/greatspeculations/2015/03/10/here-is-how-much-lawsuits-cost-jj-every-year/; accessed on March 30, 2015.
[3] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000408.jsp&mid=WC0b01ac058002958c; accessed on March 30, 2015.

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[4] http://www.ema.europa.eu/ema/index.jsp?curl=pages%2Fmedicines%2Flanding%2Fepar_search.jsp&mid=WC0b01ac058001d124&searchTab=searchByAuthType&alreadyLoaded=true&isNewQuery=true&status=Authorised&keyword=Enter+keywords&searchType=name&taxonomyPath=&treeNumber=&searchGenericType=biosimilars&genericsKeywordSearch=Submit; accessed on March 30, 2015.

[5] US 8,931,880 B2 (Murphy et al.) 13 January 2015 (13.01.2015)

[6] http://www.forbes.com/sites/luketimmerman/2015/03/12/scientists-hone-synthetic-drugs-based-on-mother-natures-handiwork/?ss=pharma-healthcare; accessed on March 30, 2015.

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