

# Sāls LETTER

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Information and tips for pharmaceutical executives

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***"Cherish your visions and your dreams as they are the children of your soul, the blueprints of your ultimate achievements."*** Napoleon Hill

## **FDA Drug Safety Communication: Azithromycin And The Risk Of Potentially Fatal Heart Rhythms**

The U.S. Food and Drug Administration (FDA) is warning the public that azithromycin can cause abnormal changes in the electrical activity of the heart that may lead to a potentially fatal irregular heart rhythm. Patients at particular risk for developing this condition include those with known risk factors such as existing QT interval prolongation, low blood levels of potassium or magnesium, a slower than normal heart rate, or use of certain drugs used to treat abnormal heart rhythms, or arrhythmias. Health care professionals should consider the risk of fatal heart rhythms with azithromycin when considering treatment options for patients who are already at risk for cardiovascular events. FDA notes that the potential risk of QT prolongation with azithromycin should be placed in appropriate context when choosing an antibacterial drug: Alternative drugs in the macrolide class, or non-macrolides such as the fluoroquinolones, also have the potential for QT prolongation or other significant side effects that should be considered when choosing an antibacterial drug.

FDA released a statement about a New England Journal of Medicine (NEJM) study that compared the risks of cardiovascular death in patients treated with the antibacterial drugs azithromycin, amoxicillin, ciprofloxacin, and levofloxacin, or no antibacterial drug. The study reported an increase in cardiovascular deaths, and in the risk of death from any cause, in persons treated with a 5-day course of azithromycin (Zithromax) compared to persons treated with amoxicillin, ciprofloxacin, or no drug. The risks of cardiovascular death associated with levofloxacin

treatment were similar to those associated with azithromycin treatment.

## **FDA Approves Weight-Management Drug Qsymia**

The U.S. Food and Drug Administration approved Qsymia (phentermine and topiramate extended-release) as an addition to a reduced-calorie diet and exercise for chronic weight management. The drug is approved for use in adults with a body mass index (BMI) of 30 or greater (obese) or adults with a BMI of 27 or greater (overweight) who have at least one weight-related condition such as high blood pressure (hypertension), type 2 diabetes, or high cholesterol (dyslipidemia).

"Obesity threatens the overall well being of patients and is a major public health concern," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research. "Qsymia, used responsibly in combination with a healthy lifestyle that includes a reduced-calorie diet and exercise, provides another treatment option for chronic weight management in Americans who are obese or are overweight and have at least one weight-related comorbid condition. Qsymia is a combination of two FDA-approved drugs, phentermine and topiramate, in an extended-release formulation. Phentermine is indicated for short-term weight loss in overweight or obese adults who are exercising and eating a reduced calorie diet. Topiramate is indicated to treat certain types of seizures in people who have epilepsy and to prevent migraine headaches.

Results from the two trials show that after one year of treatment with the recommended and highest daily dose of Qsymia, patients had an average weight loss

of 6.7 percent and 8.9 percent, respectively, over treatment with placebo. Approximately 62 percent and 69 percent of patients lost at least five percent of their body weight with the recommended dose and highest dose of Qsymia, respectively, compared with about 20 percent of patients treated with placebo.

Qsymia must not be used in patients with glaucoma or hyperthyroidism. Qsymia can increase heart rate; this drug's effect on heart rate in patients at high risk for heart attack or stroke is not known. Therefore, the use of Qsymia in patients with recent (within the last six months) or unstable heart disease or stroke is not recommended. Regular monitoring of heart rate is recommended for all patients taking Qsymia, especially when starting Qsymia or increasing the dose. The most common side effects of Qsymia are tingling of hands and feet (paresthesia), dizziness, altered taste sensation, insomnia, constipation, and dry mouth.

### **Nicotine Replacement Therapy Labels May Change**

When nicotine replacement therapy (NRT) products were first marketed almost 30 years ago to help people stop smoking, there wasn't a lot of data available on how long consumers could safely use them, and whether they could be used in combination with other NRTs or continued smoking. That has changed in the intervening years as researchers conducted studies and clinical trials.

Now, the Food and Drug Administration—after reviewing scientific research on the safety of NRT products sold over the counter (OTC)—has decided that some warnings and limitations specified in the directions for use on the labels of these products are no longer necessary to make sure they are used safely and effectively to quit smoking.

The changes that FDA is allowing to these labels reflect the fact that although any nicotine-containing product is potentially addictive, decades of research and use have shown that NRT products sold OTC do not appear to have significant potential for abuse or dependence. The changes being recommended by FDA include a removal of the warning that consumers should not use an NRT product if they are

still smoking, chewing tobacco, using snuff or any other product that contains nicotine—including another NRT. NRTs are FDA-approved for adults ages 18 and over who want to quit smoking. Smokers' dependence on nicotine prevents many who try to quit from being successful, and these products supply controlled amounts of nicotine to ease withdrawal symptoms.

"The agency heard from several public health groups that the labeling for OTC NRT products may stop consumers who are trying to quit smoking from using them," says FDA Commissioner Margaret A. Hamburg, M.D. "FDA hopes the recommended changes will allow more people to use these products effectively for smoking cessation and that tobacco dependence will decline in this country."

### **UAE Approves Local Oseltamivir Production**

The United Arab Emirates' ministry of health has given approval to the local firm, Neopharma, to produce the antiviral oseltamivir, a generic version of Roche's Tamiflu, which is being used to prevent and treat pandemic A influenza H1N1 in the region. Neopharma's oseltamivir is the outcome of a joint venture with Hetero Drugs and is the first in a series of drugs the company plans to produce over the next few years.

Currently, Neopharma has production units for the manufacture of betalactam products. Neopharma, which is based in Abu Dhabi and was set up in 2003, manufactures a range of products including antibiotics, analgesics, antihistamines, and treatments for cardiovascular conditions and diabetes.

### **GSK Links With Japanese Institute**

GlaxoSmithKline has entered into a formal agreement with Japan's Chemo-Sero. Therapeutic Research Institute (Kaketsuken) for the joint development of cell cultured flu vaccines, including against H1N1 pandemic strains.

The partners said the alliance would enable them to contribute technology and expertise and speed up the development of flu vaccines in Japan. GSK said the tie-up would cover its adjuvants used to improve potency and extend vaccine supplies, as well as technology licensed from third parties. For the UK

firm, this includes the EB66 duck embryonic stem cell-derived cell line licensed from Vivalis.

Several Japanese manufacturers are already working on vaccines for H1N1 swine flu, although domestic capacity will fall far short of the supplies needed for the government's planned inoculation programme, necessitating imports. The hope is to secure vaccines sufficient for well over half of the country's population of around 128 million by next spring. A deal to import vaccines for around 50 million manufacturers set to cover some 27 million people.

GSK noted that the government was encouraging links between domestic and foreign vaccine manufacturers, and that the ministry of health, labour and welfare's latest budget included an allocation for research into cell cultured flu vaccines.

Separately, the company said that it was planning to supply enough Relenza (zanamivir) to treat 13.5 million people in Japan over the coming winter seasons from September to March. Stocks of the inhaled neuraminidase inhibitor would be further increased depending on need, it said, adding that no cases of A type seasonal or H1N1 flu resistant to the product had emerged so far. Chugai (Roche) said recently it would triple the planned supply of its oral flue antiviral Tamiflu (oseltamivir) in Japan, to 12 million treatment courses.

## Organisations And Innovation

The business organisation itself has to provide an environment in which creativity and innovation can flourish and the five hallmarks of those organisations that actually are good at innovation (and not just paying lip service to it) are:

1. top level commitment
2. flexible in organizational structure
3. tolerant of failure (and not risk averse)
4. encouraging of team work and innovation
5. good at open and constructive communication.

## Creativity

There are a number of obstacles which inhibit creativity. The seven main ones are:

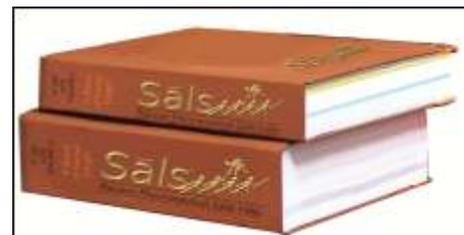
1. Negativity
2. Fear of failure.
3. Lack of quality thinking time.
4. Over-conformance with rules and regulations
5. Making assumptions
6. Applying too much logic
7. Thinking you are not creative.



- **The First Pakistani Multinational in its own segment**
- **The distinctive company offers a distinctive product**

## Sāls

(Pakistan Pharmaceutical Sales Index)



- **Sāls is authentic from the stringent quality control point of view**
- **Sāls offers share of the product in the content sale which the multinational competitor does not provide**
- **Sāls Dynamics offers more than 300 options to view your data**
- **Sāls offers after sales service in terms of providing you the user's special requirements for data presentation and analysis**
- **Free analysis, free consultancy for Sāls subscribers**
- **Sāls is clearly a superior product as compared to its multinational competitor and it is a PROVEN FACT**
- **Superior people prefer superior products!**

Creativity can be improved by remembering that the creative process has four main stages and each needs to be properly 'worked':

**1. Preparation** (information gathering, analysis and solution exploration) **2. Incubation** (letting the mind work to continue the process) **3. Illumination** (inspiration – which can come when the individual is not necessarily thinking about the problem but is in a relaxed frame of mind) **4. Verification** (testing ideas, solution, hunches, insights for applicability).

## How To Give A Killer Presentation

For more than 30 years, the TED conference series has presented enlightening talks that people enjoy watching. In this article, Anderson, TED's curator, shares five keys to great presentations:

**1.** Frame your story (figure out where to start and where to end). **2.** Plan your delivery (decide whether to memorize your speech word for word or develop bullet points and then rehearse it—over and over). **3.** Work on stage presence (but remember that your story matters more than how you stand or whether you're visibly nervous). **4.** Plan the multimedia (whatever you do, don't read from PowerPoint slides). **5.** Put it together (play to your strengths and be authentic).

According to Anderson, presentations rise or fall on the quality of the idea, the narrative, and the passion of the speaker. It's about substance—not style. In fact, it's fairly easy to "coach out" the problems in a talk, but there's no way to "coach in" the basic story—the presenter has to have the raw material. So if your thinking is not there yet, he advises, decline that invitation to speak. Instead, keep working until you have an idea that's worth sharing.

## The Difference Between Management And Leadership

Management is about coping with complexity. Its practices and procedures are largely a response to one of the most significant developments of the twentieth century: the emergence of large organizations. Without good management, complex enterprises tend to become chaotic in ways that threaten their very

existence. Good management brings a degree of order and consistency to key dimensions like the quality and profitability of products.

Leadership, by contrast, is about coping with change. Part of the reason it has become so important in recent years is that the business world has become more competitive and more volatile. Faster technological change, greater international competition, the deregulation of markets, overcapacity in capital-intensive industries, an unstable oil cartel, raiders with junk bonds, and the changing demographics of the work-force are among the many factors that have contributed to this shift. The net result is that doing what was done yesterday, or doing it 5% better, is no longer a formula for success. Major changes are more and more necessary to survive and compete effectively in this new environment. More change always demands more leadership.

## Brand Positioning

The pharmaceutical landscape is filled with products that, despite offering a distinctive customer benefit, never achieve their revenue potential. In many cases, this is because their marketers failed to create a compelling brand proposition—without which the most effective product can never hope to captivate customers.

In our experience, many pharmaceutical campaigns miss the mark when they fail to clearly articulate a drug's essential brand advantage. While this may occasionally reflect a superficial understanding of the market, accompanied by under-investment in foundational market research, more often it is a failure to apply that understanding effectively to the task of identifying their brand's core selling benefit.

Research, of course, is crucial in crafting a marketing campaign. When you use it right, foundational research grounds brand strategy in the business opportunity—and specifically, a deep understanding of how the brand's benefits satisfy important customer needs as well as what beliefs or barriers must be overcome in order to change customer behavior. A brand's position should emerge from its core benefits and a deep understanding of the customer. Concept-testing can be used to refine a

campaign around that position, but it can never adequately substitute for effective strategy development. The key to brand positioning is to identify and occupy a unique space in customers' hearts and minds. Every drug can be differentiated in the marketplace.

The marketer's role: cut straight to that knowledge and form it into a clear, compelling customer message. Asking your customers or convening a committee only confuses the matter. You know what differentiates your product; that is the brand proposition to be championed.

### Winners and Losers

Good for presentation to your sales force.

1. **A winner** works harder than a loser, and has more time; **A loser** is always "too busy" to do what is necessary.
2. **A winner** makes commitments; **A loser** makes promises.
3. **A winner** goes through a problem; **A loser** goes around it, and never gets past it.
4. **A winner** Isn't nearly as afraid of losing **A loser** is secretly afraid of winning.
5. **A winner** Says "Lets find out"; **A loser** says "Noboby khows".

### Don'ts At Table

Don't as an invited guest, be late to dinner. This is a wrong to your host, to other guests, and to the dinner.

2. Don't be late at the domestic table, as this is a wrong to your family, and is not calculated to promote harmony and good feelings.
3. Don't seat yourself until the ladies are seated, or, at a dinner-party, until your host or hostess gives the signal.
4. Don't introduce, it you introduce at all, after the company is seated.
5. Don't sit a foot off from the table, or sit jammed up against it.
6. Don't tuck your napkin under your chin, or spread it upon your chest. Bibs and tuckers are for the nursery. Don't spread your napkin over your lap; let it fall over your knee.
7. Don't serve gentlemen guests at your table before all the ladies are served, including those who are members of your own house-hold.
8. Don't eat soup from the end of the spoon, but from the side. Don't gurgle, or draw in

your breath, or make other noises when eating soup. Don't ask for a second service of soup.

9. Don't bend over your plate, or drop your hand to get each mouthful. Keep an upright attitude as nearly as you can without being stiff.
10. Don't bite your bread. Break it off. Don't break your bread into your soup.

### Don't Ignore Gender's Impact On Communication

*Amy Beth Miller*

Men and women might as well be speaking different languages, not in words but in their communication styles. Those differences can lead to misunderstanding and conflict.

Not everyone exhibits the communication habits associated with their gender, of course, but those habits are prevalent enough that you should be aware of the tendencies of both your gender and the other. Here are some examples of the misinterpretations that can happen between men and women:

- A woman telling a story may not be beating around the bush or wasting time. Instead, she may be laying the groundwork for her point, thinking aloud or attempting to build rapport.
- A man who is silent may not be disengaged from the conversation. Instead, he may be thinking things through before speaking.
- A man who makes a decision without consulting you may not be shutting you out. He simply may not have the collaborative style that women tend to exhibit.
- A man who leans back while you are speaking may not be tuning out. On the contrary, he may be listening intently.
- A woman who nods her head while you speak may not agree. She may just be showing that she is listening.
- A woman who offers help or advice may not think that you're incapable of handling the situation yourself. A man who doesn't ask for help or advice may be afraid that it would show weakness to do so.

### Managing Your Boss

Successfully managing your relationship with your boss requires that you have a good understanding of

your supervisor and of yourself, particularly strengths, weaknesses, work styles, and needs. Once you are aware of what impedes or facilitates communication with your boss, you can take actions to improve your relationship. You can usually establish a way of working together that fits both of you, that is characterized by unambiguous mutual expectations, and that makes both of you more productive and effective. No doubt, some managers will resent that on top of all their other duties, they must also take responsibility for their relationships with their bosses. But these managers fail to realize that by doing so, they can actually simplify their jobs, eliminating potentially severe problems and improving productivity.

### Wise Men's Wisdom

"Nobody can bring you peace but yourself." — **Ralph Waldo Emerson**. "Old friends pass away, new friends appear. It is just like the days. An old day passes, a new day arrives. The important thing is to make it meaningful: a meaningful friend - or a meaningful day." — **Dalai Lama**. "Effort only fully releases its reward after a person refuses to quit." — **Albert Camus**. "We must use time wisely and forever realize that the time is always ripe to do right." — **Nelson Mandela**. "Communication is a skill that you can learn. It's like riding a bicycle or typing. If you're willing to work at it, you can rapidly improve the quality of every part of your life." — **Brian Tracy**. "Insanity: doing the same thing over and over again and expecting different results." — **Albert Einstein** "The friend is the man who knows all about you, and still likes you." — **Elbert Hubbard**. "Always bear in mind that your own resolution to succeed is more important than any other." — **Abraham Lincoln**

**To succeed as a team is to hold all of the members accountable for their expertise**

— Mitchell Caplan

### Career Tips

1. The fastest way to advance your career is to drive innovation, rather than fall victim to it.
2. Dramatically reduce complexity.
3. Teach your company to talk How can I help?
4. Be utterly transparent – be more open and honest than any of your competitor: Honesty is a competitive advantage.
5. Make loyalty dramatically easier than disloyalty.

### Management Humor

A man in a hot air balloon realized he was lost. He reduced altitude and spotted a woman below. He descended a bit more and shouted, "Excuse me, can you help me? I promised a friend I would meet him an hour ago, but I don't know where I am."

The woman below replied, "You're in a hot air balloon hovering approximately 30 feet above the ground. You're between 40 and 41 degrees north latitude and between 59 and 60 degrees west longitude." "You must be an engineer," said the balloonist. "I am," replied the woman, "How did you know?" "Well," answered the balloonist, "everything you told me is, technically correct, but I've no idea what to make of your information, and the fact is I'm still lost. Frankly, you've not been much help at all. If anything, you've delayed my trip."

The woman below responded, "You must be in Management." "I am," replied the balloonist, "but how did you know?" "Well," said the woman, "you don't know where you are or where you're going. You have risen to where you are due to a large quantity of hot air. You made a promise which you've no idea how to keep, and you expect people beneath you to solve your problems. The fact is you are in exactly the same position you were in before we met, but now, somehow, it's my fault."

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 Contents of Sals LETTER are taken from world's best and authentic periodicals e. g. Harvard Business Review (HBR), FDA Consumer. All information are authentic and reliable. We strongly recommend that information and tips mentioned in these pages be adopted and exercised for maximizing management and marketing effectiveness.

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