

Sāls LETTER

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Information and tips for pharmaceutical executives

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"Obstacles are necessary for success because in selling, as in all careers of importance, victory comes only after many struggles and countless defeats."

Og Mandino

Test Of Pfspz Malaria Vaccine Encouraging

A trial of an experimental malaria vaccine called PfSPZ gave protection to 12 of the 15 people who received it. But researchers caution that more work is needed. An experimental malaria vaccine is safe and effective, researchers said, performing better in early trials than any vaccine tested so far in the fight against the disease. In a small clinical trial involving 40 U.S. adults, 12 of the 15 people who received doses of the PfSPZ vaccine were protected from malaria, according to a study published Thursday in the journal Science. Though preliminary, the results represent hope in the battle against an illness contracted by hundreds of millions of people every year. In 2010, about 219 million cases of malaria and 660,000 deaths from it were reported. Most of those who died were African children, according to the World Health Organization.

The team working on PfSPZ for the biotech company Sanaria figured out a way to home in on the shape-shifting parasite by developing a vaccine containing whole sporozoites that had been zapped with X-rays. The radiation prevented the sporozoites from generating disease-triggering merozoites in study participants' bodies. The irradiated sporozoites stayed dormant in their livers, stimulating the production of sporozoite antibodies that protected against future infection. Researchers tested the vaccine in 2010 with disappointing results. Back then, they injected it in subjects' skin or muscle. This time, they administered it in a vein instead.

In the business world, the rearview mirror is always clearer than the windshield

– Warren Buffett

Federal Officials Issue Strong New Warning About Anti-Malaria Drug

Mefloquine hydrochloride was once routinely given to U.S. troops, some of whom say it damaged them permanently.

Federal drug officials have issued a strong new warning about a controversial anti-malaria medication once routinely given to U.S. troops, some of whom say it damaged them permanently.

The Food and Drug Administration ordered manufacturers of mefloquine hydrochloride to give the medicine a black box label, the agency's strongest warning, reserved for drugs with significant risks of serious side effects. The FDA said that some neurological and psychiatric side effects can last for months or years after a patient stops taking the drug.

The medication was approved by the FDA in 1989 under the brand name Lariam and quickly became a leading drug for preventing and treating malaria — among travelers and the military.

While other drugs must be taken daily, one tablet a week of mefloquine offers protection against the sometimes-deadly mosquito-borne parasite, including against strains that are resistant to other medications.

FDA Approves New Drug For Advanced Prostate Cancer Xofigo Approved

The U.S. Food and Drug Administration approved Xofigo (radium Ra 223 dichloride) to treat men with symptomatic late-stage (metastatic) castration-resistant prostate cancer that has spread to bones but not to other organs. It is intended for men whose cancer has spread after receiving medical or surgical therapy to lower testosterone.

According to the National Cancer Institute, an estimated 238,590 men will be diagnosed with prostate cancer and 29,720 will die from the disease in 2014. Xofigo is being approved more than three months ahead of the product's prescription drug user fee goal. "Xofigo binds with minerals in the bone to deliver radiation directly to bone tumors, limiting the damage to the surrounding normal tissues," said Richard Pazdur, M.D., director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research. "Xofigo is the second prostate cancer drug approved by the FDA in the past year that demonstrates an ability to extend the survival of men with metastatic prostate cancer."

FDA Approves Simponi To Treat Ulcerative Colitis

The U.S. Food and Drug Administration approved a new use for Simponi (golimumab) injection to treat adults with moderate to severe ulcerative colitis. Simponi works by blocking tumor necrosis factor (TNF), which plays an important role in causing abnormal inflammatory and immune responses. Previously approved to treat rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis (arthritis affecting the joints in the spine and the pelvis), Simponi is now approved to treat adults with moderate to severe ulcerative colitis that is resistant (refractory) to prior treatment or requires continuous steroid therapy. Ulcerative colitis is a chronic disease that affects about 620,000 Americans. It causes inflammation and ulcers in the inner lining of the large intestine and is one of two main forms of chronic inflammatory bowel disease. The inflammation can lead to abdominal discomfort, gastrointestinal bleeding, production of pus and diarrhea.

"Simponi is an important new treatment option for patients with moderate to severe ulcerative colitis," said Andrew E. Mulberg, M.D., deputy director of the Division of Gastroenterology and Inborn Errors Products in the FDA's Center for Drug Evaluation and Research.

The safety and effectiveness of Simponi for ulcerative colitis were established in two clinical studies. Evaluations of patients included measures of stool frequency, rectal bleeding, endoscopic findings and a physician's overall assessment.

***Prosperity is only an instrument to be used,
not a deity to be worshipped***

– Calvin Coolidge

FDA Approves Nymalize—First Nimodipine Oral Solution For Use In Certain Brain Hemorrhage Patients

The U.S. Food and Drug Administration approved Nymalize, a new nimodipine oral solution, to treat patients experiencing symptoms resulting from ruptured blood vessels in the brain (subarachnoid hemorrhage). Nimodipine previously was available only as a liquid-filled gel capsule. Subarachnoid hemorrhage is serious, life threatening bleeding that occurs in the subarachnoid space – the area between the brain and the thin tissues that cover the brain. Nimodipine is a medication given in a critical care setting to treat neurologic complications from subarachnoid hemorrhage.

Over the years, the FDA has received reports of serious and sometimes fatal consequences from intravenous (IV) injection of the liquid contents of oral nimodipine capsules. IV administration of nimodipine meant for oral use can result in death, cardiac arrest, severe decreases in blood pressure and other heart-related complications. The agency reminded health care professionals about the risks of IV administration of nimodipine from oral capsules and in 2006 a Boxed Warning was added to the drug to warn against such use.

Having an oral version of this product may help reduce the medication errors. Based on the potential of the oral formulation, Nymalize, to decrease or eliminate medication errors, the application received fast track designation and priority review. Nymalize is made by Atlanta-based Arbor Pharmaceuticals Inc.

Novartis's COPD Therapy Receives EU Recommendation

The EU's CHMP have recommended the approval of Novartis's indacaterol maleate inhaler (formerly known

QAB149) for maintenance bronchodilator treatment of airflow obstruction in adults with COPD. The company plans to launch the drug in the EU, its first market, under the trade name Onberz Breezhaler, following an expected approval by the European Commission.

The long-acting beta2-adrenergic agonist (LABA) was filed in the US in late 2008, but the FDA has yet to make a decision on the drug. A Novartis spokesman said that the company hopes to get an update for the agency soon.

Once approved for COPD, indacaterol maleate will be competing against corticosteroid/LABA combination products such as AstraZeneca's Symbicort (budesonide plus formoterol) and GlaxoSmithKline's Advair (fluticasone plus salmeterol), and against Boehringer Ingelheim/Pfizer's muscarinic receptor antagonist Spiriva (tiotropium).

FDA Approves A Drug To Reverse Anticoagulation

Ever since the drug warfarin was discovered to be a highly effective anti-clotting agent as well as a good rat poison in the early 1950s, it has been the frontline weapon in preventing stroke among those with atrial fibrillation. But its growing use has always raised the specter of dangerously hard-to-stanch bleeding if someone taking it is wounded or bleeds internally from a fall or a car accident.

Roughly six decades after its introduction, Kcentra has been approved by the Food and Drug Administration. It's a new product designed to quickly reverse the effects of warfarin. The prothrombin complex concentrate is made from the pooled plasma of healthy donors, and it joins a cluster of other "reversal agents" capable of restoring coagulation, including vitamin K and fresh-frozen plasma, in people who take warfarin.

But vitamin K takes time to work, and so does frozen plasma, which must be thawed and typed to the recipient's blood group. Kcentra does not need to be typed to the recipient's blood and so can be used more quickly to reverse the effects of warfarin.

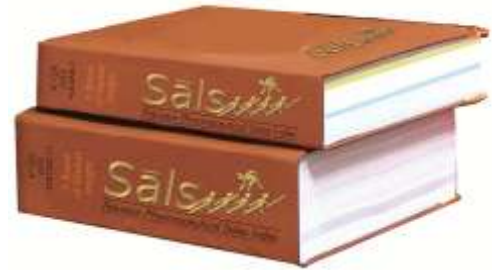
The new agent does not, however, work to reverse the effects of two anticoagulants that are new to the market -- dabigatran (marketed as Pradaxa) or rivaroxaban (marketed as Xarelto). Last year, a case study in the Journal of Neurosurgery underscored that physicians still lack reversal agents that can restore coagulation in patients taking these new medications, with sometimes deadly results.

The Rubaiyat

Omar Khayyem

Now the New Year reviving old Desires,
The thoughtful Soul to Solitude retires,
Where the white hand of Moses on the Bough,
Puts out, and Jesus from the ground surprises.
Iram indeed is gone with all its Rose
And Jamshyd's Seven-ring'd Cup where no one knows;
But still a Ruby kindles in the Vine,
And many a Garden by the Water blows.

Sāls



➤ There are 83 reasons to subscribe Sāls.

➤ There are 51 reasons to prefer Sāls over its multinational competitor.

➤ Sāls is clearly superior to the multinational brand and the fact is well accepted by all pharma executives.

➤ We are gaining the confidence of pharma companies who are switching over to Sāls from the multinational brand.

➤ There are valid reasons for their switch over.

➤ These are quality and cost. Unmatched! Unparalleled!

Six Ways to Sink A Growth Initiative

The conventional wisdom about how best to pursue growth—launch a slew of initiatives in high-potential areas; appoint some promising young managers to lead them; locate them safely away from the established businesses—is a recipe for failure. Meanwhile, CEOs spend too much time on managing today's earnings and too little time on building the kind of learning organization and culture that growth requires. This article explores six common mistakes that executives make in this arena:

- 1. Failing to provide the right kind of oversight.** The CEO should spend meaningful time with the team and with potential customers.
- 2. Not putting the best, most experienced talent in charge.** Seasoned executives in the core businesses, rather than ambitious young MBAs, should be assigned to growth initiatives.
- 3. Assembling the wrong team and staffing up prematurely.** CEOs should focus on capabilities, not who's available, and staff up only when the strategy, business model, and value proposition are clear.
- 4. Taking the wrong approach to performance assessment.** Milestones relevant to each stage of an initiative's development should be established, and key assumptions in the business plan should be linked to the financial forecast.
- 5. Not knowing how to fund and govern a start-up.** The funding of early-stage ventures should be separated from the corporation's annual budget cycle.
- 6. Failing to leverage the organization's core capabilities.** CEOs must play a central role in helping growth initiatives tap the resources of the core business.

Brush Up on Your Grammar

People see your language as a reflection of your competence. Make lots of writing mistakes, and you'll come across as uneducated and uninformed. But it's probably been a long time since you learned about dangling participles and parts of speech in school. So take it upon yourself to brush up on the rules. Consult guides on grammar and usage, such as Strunk and White's *Elements of Style*. Ask knowledgeable colleagues to proofread your material and to explain their corrections. Pay attention to what talented writers inside and outside the organization do. Read first-rate nonfiction, which will help you cultivate an appreciation of the skills you're trying to acquire.

Create a Happier Team

Happy, engaged employees are good for an organization. Research shows they are more creative, produce better results, and are willing to go the extra mile. What's more, happiness is contagious; it creates a virtuous cycle that leads to further engagement. To bring more of that into your team, focus on what psychologists have identified as the three pathways to happiness: pleasure, engagement, and meaning. Consider whether you are actively encouraging these things in your people. Do they enjoy their relationships and their environment at work? Do they laugh? Do they fill roles that fit their skill sets and offer appropriate challenges? Do they feel they're a part of something that matters? If the answer is no to any of these questions, brainstorm how you can adjust the team environment to bring more happiness in.

Lead Ideas Through To Action

Take these actions to ensure that your brainstorming sessions aren't a waste of time:

- **Set the parameters.** Posing the challenge the right way can avoid ending a session with a list of ideas that have no hope of moving forward. Encourage team members to voice any idea that can lead to the ultimate goal, but then refine ideas based on the limits you face. Example: "How could we do that without adding staff?"
- **Involve others.** Including employees from throughout your organization adds greater perspective to your brainstorming session, but it also does something else that is very important: It gives people in other departments a stake in seeing those ideas succeed.
- **Establish deadlines.** Once you have vetted the ideas and decided which to pursue, make specific assignments. Remember that you can pursue ideas in multiple timelines. Example: John can implement a simple idea by week's end while Addison checks with multiple vendors about a more complex idea and reports back to the team on her progress next month.
- **Follow up with participants.** Keep the people who contributed to the brainstorming session in the loop. If you tell them about a roadblock, they might have another idea to work around it. If you have put an idea on hold until next quarter, when more funding will be available, tell them that too. Otherwise they will lose enthusiasm for the effort.

- **Try small-scale tests.** Pilot projects allow you to try ideas without a major investment in resources and to fine-tune them before a full rollout.

Ways To Boost Sales

1. Become highly aggressive. Change your marketing strategy to fit the psychology of the times. Emphasize how your products or services save time, cut costs and increase productivity. Take this route, and you'll stand out in the marketplace because most of your competitors will be depending only on the momentum of the economy to carry them forward. **2. Work at retaining customers.** When things start looking up, it's easy to forget about existing customers. Don't tempt your customers to take their business elsewhere. Studies show it costs five times as much to gain a new customer as it does to keep an existing one. Work harder than ever to demonstrate that you care about your present customers. **3. Increase sales to current customers.** Only a fool assumes that all customers know everything you do. Whether you've been doing business with a customer for a month or a decade, plan a marketing program that aims at educating your customers about all your products and services. **4. Build your prospect list.** Call it a "drutchers" list, one that reverts attention and action on specific prospects that you would have as customers if you had "drutchers". Depending on the size of your company, make the list as inclusive as possible, but define your prospect profile carefully. Then, develop a plan for making regular contact with these prospects. Explain why you have a special interest in them and that you want their business. Show them how dealing with you has special benefits for them. Ask what you will have to do to get their business. **5. Use "Value-Added" techniques to get an edge on competitors.** Distinguishing your organization from others on the same field is more important now than ever before. To discover what you can do to dramatize your techniques, think like a customer. It's never the value you want to add makes the difference. It's the value the customer wants to receive that's important.

Three Ways to Get a Promotion

If you've been at your company for a few years and hope to move up to the next level, here are three things you can do to increase your chances:

1. Take initiative. Producing results in your job is just table stakes. Go beyond the confines of your current role and find ways to improve your group's performance. Take on problems that no one else is

solving. **2. Choose your battles wisely.** Display a sense of professional maturity by choosing battles that can be won. Not every inefficiency is worth tackling. Only take on problems that increase customer satisfaction, revenue, or productivity. **3. Show you can manage people.** This can be hard if it's not one of your official responsibilities. If so, try to show your interpersonal and people management skills when working with groups.

Winners & losers

Good for presentation to your sales force.

1. When a **winner** makes a mistake, he says, "I was wrong"; when a **loser** makes a mistake, he says, "It wasn't my fault." **2. A winner** knows what to fight for, and what to compromise on; **A loser** compromises on what he shouldn't, and fights for what isn't

worthwhile fighting about. **3. A winner** would rather be admired than liked, although he would prefer both; **A loser** would rather be liked than admired, and is even willing to pay the price of mild contempt for it. **4. A winner** listens; **A loser** just waits until it's his turn to talk. **5. A winner** feels strong enough to be gentle; **A loser** is never gentle – he is either weak or pettily tyrannous by turns.

Don'ts At Table

Don't fill your mouth with too much food, and don't masticate audibly. Eat gently and quietly and easily. Don't put your knife into the butter, into the salt-cellar, or into any dish. Don't spread out your elbows when you are cutting your meat. Keep your elbows close to your side. Don't, when you drink, elevate your glass as if you were going to stand it inverted on your nose, as some do. Bring the glass perpendicularly to the lips, and then lift it to a slight angle. Do this easily. Don't eat vegetables with a spoon. Eat them with a fork. The rule is not to eat anything with a spoon that can be eaten with a fork. Even ices are now often eaten with a fork.

Wise Men's Wisdom

"Perseverance is not a long race; it is many short races one after the other." — **Walter Elliot**. "Friendship is unnecessary, like philosophy, like art... It has no survival value; rather it is one of those things that give value to survival." — **C. S. Lewis**. "When everything seems to be going against you, remember that the airplane takes off against the wind, not with it." — **Henry Ford**. "There is no love without

forgiveness, and there is no forgiveness without love.” — **Bryant H. McGill**. “Thinking: the talking of the soul with itself.” — **Plato**. “Always bear in mind that your own resolution to succeed is more important than any other.” — **Abraham Lincoln**. “A dream doesn't become reality through magic; it takes sweat, determination and hard work.” — **Colin Powell**.

Management Humor

The American and the Japanese corporate offices for a large multi-national corporation decided to engage in a competitive boat race. Both teams practiced hard and long to reach their peak performance. On the big day they felt ready. The Japanese team won by a mile. Afterward, the American team was discouraged by the loss. Morale sagged. Corporate management decided that the reason for the crushing defeat had to be found, so a consulting firm was hired to investigate the problem and recommended corrective action.

The consultant's finding: The Japanese team had eight people rowing and one person steering; the American team had one person rowing and eight people steering. After a year of study and millions spent analyzing the problem, the firm concluded that too many people were steering and not enough were rowing on the American team. So, as race day neared

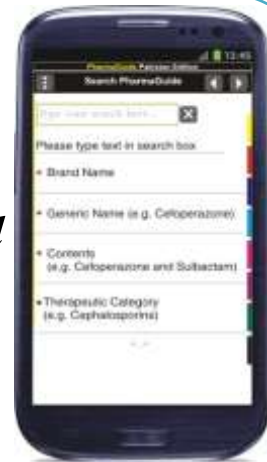
again the following year, the American team's management structure was completely reorganized. The new structure: four steering managers, three area steering managers and a new performance review system for the person rowing the boat to provide work incentive. The next year, the Japanese won by two miles. Humiliated, the American office laid-off the rower for poor performance and gave the managers a bonus for discovering the problem.

Joke

A lorry driver said to his mate, ‘Do you remember, about six months ago, when we broke down in Scotland?’ His mate nodded. ‘And do you remember,’ said the driver. ‘that we walked for miles until we came across a cottage?’ His mate nodded. ‘And do you remember that the only occupant of this cottage was a young widow who gave us a room for night?’ His mate nodded. ‘And,’ went on the driver. ‘Didn’t you leave your room and visit the widow’s room for a kiss and a cuddle?’ His mate acknowledged the fact with a smile. The driver raised his voice: ‘And before we left the next day, you gave her my name and address?’... His mate laughed and admitted it. ‘Well,’ said the lorry driver, looking at a letter, ‘She died last week and left me £ 50,000!’

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- *Also good for the sales force*



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