

# Sāls LETTER

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*Information and tips for pharmaceutical executives*

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*"The number of times I succeed is in direct proportion to the number of times I can fail and keep on trying." Tom Hopkins*

## MEDICAL MALPRACTICE

Janssen Pharmaceuticals Inc. (JPI) to plead guilty and pay heavily to resolve allegations of misbranding and filing false claims for Risperdal.

### **J & J to Pay \$2.2 Billion To Settle Marketing Allegations**

(Courtesy: Associated Press, Mon 4:41 PM, Nov 04, 2013)  
On behalf of the U.S. Food and Drug Administration, the U.S. Department of Justice on November 4th, 2013 announced a guilty plea agreement with Janssen Pharmaceuticals, Inc., (JPI). Its parent company Johnson & Johnson has agreed to pay over \$2.2 billion to resolve criminal and civil allegations that the company promoted powerful psychiatric drugs for unapproved uses in children, seniors and disabled patients, the Department of Justice announced on Monday. **The agreement is the third-largest settlement with a drug maker in U.S. history, and the latest in a string of actions against drug companies allegedly putting profits ahead of patients.**

Justice Department officials alleged that J&J used illegal marketing tactics and kickbacks to persuade physicians and pharmacists to prescribe Risperdal and Invega, both antipsychotic drugs, and Natrecor, which is used to treat heart failure. "J&J's promotion of Risperdal for unapproved uses threatened the most vulnerable populations of our society - children, the elderly and those with developmental disabilities," said Zane Memeger, U.S. Attorney for the Eastern District of Pennsylvania. The settlement amount includes \$1.72 billion in civil payments to federal and state governments as well as \$485 million in criminal fines and forfeited profits.

In its plea agreement, J&J subsidiary Janssen Pharmaceuticals admitted to promoting Risperdal as a way to control erratic behavior in seniors with dementia. Today that use is explicitly barred in the drug's warning label because it can increase the risk of stroke and death in elderly patients. Janssen agreed to plead guilty to violating drug marketing laws and will pay \$400 million in fines and forfeited sales. In a separate civil complaint, the government alleged that J&J and Janssen promoted Risperdal and a similar drug, Invega, to control numerous behavioral problems in seniors, children and the mentally disabled between 1999 and 2005.

Despite such warnings, the company's marketing plan targeted nursing homes and doctors who treated the elderly. Marketing materials distributed by an "ElderCare sales force" emphasized Risperdal as a treatment for seniors suffering from everything from agitation to depression to hostility. The company also downplayed the drug's risks, including diabetes and weight gain. At the same time the drug maker was allegedly paying kickbacks to the nation's largest nursing home pharmacy, Omnicare. J&J paid millions in bogus grants and education payments to persuade the company's hundreds of pharmacists to recommend Risperdal to nursing homes. The government said the payments amounted to kickbacks. The company also set business goals to increase drug sales to children and adolescents.

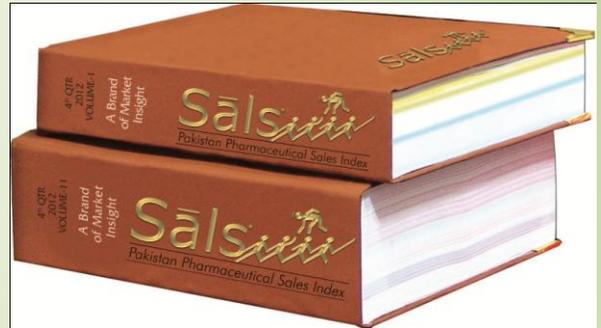
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## FDA Approves Opsumit To Treat Pulmonary Arterial Hypertension

The U.S. Food and Drug Administration approved Opsumit (macitentan), a new drug to treat adults with pulmonary arterial hypertension (PAH). PAH is high blood pressure that occurs in the arteries that connect the heart to the lungs. It causes the right side of the heart to work harder than normal, which can lead to limitations on exercise ability and shortness of breath. Opsumit belongs to a class of drugs called endothelin receptor blockers, which act to relax the pulmonary arteries, decreasing blood pressure in the lungs. Opsumit's safety and effectiveness were established in a long-term clinical trial where 742 participants were randomly assigned to take Opsumit or placebo. The average treatment duration was about two years. In the study, Opsumit was effective in delaying disease progression, a finding that included a decline in exercise ability, worsening symptoms of PAH or need for additional PAH medication. Opsumit is marketed by San Francisco-based Actelion Pharmaceuticals US, Inc.

## FDA Approves New Leukaemia Drug From Roche

The Food and Drug Administration approved a new drug from Roche to help treat patients with a type of cancer of the blood and bone marrow. The agency cleared Gazyva to fight chronic lymphocytic leukemia in combination with chemotherapy in patients who haven't previously been treated for the disease. Gazyva works by killing cancer cells and encouraging the immune system to fight against them. Chronic lymphocytic leukaemia develops slowly over time and is usually diagnosed in the elderly. More than 15,600 Americans will be diagnosed and 4,580 of them will die from the disease this year (2013), according to estimates from the National Cancer Institute.



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## High-dose Statins Could Have Added Benefit Of Reducing Gum Inflammation

The use of high-dose statins to lower cholesterol in heart disease patients appears to have the added benefit of reducing gum inflammation, according to research published in the Journal of the American College of Cardiology. The findings suggest that measures taken to reduce arterial inflammation also reduce nonarterial inflammation in tissues such as the periodontium, and vice versa.

## Top Medical Innovations For 2014

**Retinal Prosthesis :** More than 100,000 people in the United States have retinitis pigmentosa, a disease that leads to blindness. Until recently, there has been no effective treatment. The Argus Retinal Prosthesis, approved in the United States in 2013, combines a surgically implanted 60-electrode retinal prosthesis that receives signals from a pair of external video processing unit that is worn at the waist or carried. The retinal system works when the video unit transforms images from the miniature camera into electronic data that is wirelessly transmitted to the device in the eye, which contains an antenna and electrodes that replace the degenerated cells in the retina. At that point, the data are transformed into small electrical impulses that stimulate the retina's remaining inner neurons. Also known as the "bionic eye," some blind patients have been able to read the blind chart using the prosthesis.

**Fecal Microbiota Transplantation :** Half a million cases of C.diff are reported in the United States annually, along with 15,000 deaths. The human gut contains more bacterial DNA than human DNA, and the stool is biologically active. In fecal microbiota transplantation, C.diff patients that don't respond to antibiotic therapy, a colonoscopy or enema is used to transfer a liquid suspension made from a healthy person's fecal matter into a sick person's colon, in order to restore bacterial balance and cure C.diff. Result of the procedure have been extraordinary, with some patients being

cured of their symptoms within 24 hours, with no recurrences. The procedure may also be effective in treating inflammatory bowel disease and other nongastrointestinal conditions, like Parkinson's.

**Relaxin For Acute Heart Failure :** Heart failure is the number one cause of hospital admission. One in five patients with heart failure are readmitted to the hospital within 30 days, and 10 percent die during the same period. In women, relaxin-2, a naturally-occurring hormone, helps loosen tissues in the reproductive organs and pelvic ligaments to help prepare for child-birth. In heart failure, Novartis's serelaxin, a synthetic version of relaxin-2, function as a vasodilator with anti-inflammatory properties capable of increasing blood flow in the body, which helps a poorly functioning heart work more effectively. It also prevents organ damage related to reduced blood flow in the kidney and liver, and helps resolve fluid building in the lungs. Phase III data from the serelaxin trial reported a reduction in death rates by 37 percent, six months after therapy. If approved, serelaxin will become the first meaningful treatment for heart failure in two decades.

## New Hope For Adults With Amblyopia (Lazy Eye)

Amblyopia is a visual developmental disorder in which the vision through one eye fails to develop properly in early childhood. The deficit is not in the eye itself but in the visual areas of the brain.

The disruption to early visual development can be due to a misaligned eye or an eye out of focus. Later, when the alignment is corrected by surgery or the focus corrected with lenses, the visual loss remains. The treatment for the last 200 hundred years has involved patching of the fellow sighted eye, under the rationale of forcing the "lazy" eye to work. Not too long ago, the patching was all day, but more recently, it has been restricted to 3-6 hrs a day. In the majority of cases this does produce visual improvements, though there is a great deal of variability. The cost in terms of inconvenience and psychological stress for the patient, usually a child at school age, is tremendous and the

compliance is often low. The end result after 6 months to 2 years of patching is certainly improved function in the majority of cases, but once the patch is removed the two eyes often don't work together as they should, 3D vision is often not obtained and the fellow eye suppresses the amblyopic eye, which eventually leads to some reduction in acuity.

The more time the eyes worked together combining information (for the first time), the stronger their binocular capacity became and over time, the viewing conditions could be slowly moved in the direction of more normal viewing where both eyes sees the same images. The acuity of the amblyopic eye also improved as a result of eliminating the suppression from the fellow sighted eye. Even more remarkable all these results were obtained in adults, some of whom were middle aged, for whom there is no current treatment.

### What Makes Strategic Decisions Different

The past decade has seen a wealth of research on decision making, yet business executives seem impervious to its lessons. The problem is not that they lack the desire to make better decisions. It's that the bulk of the research does not apply to the kind of decision that's most challenging for them.

Decisions vary along two dimensions. The first considers whether the decision maker can influence the terms and the outcome. The second addresses whether the aim is to do well or to do better than others.

But strategic decisions, such as entering a new market or acquiring another company, are completely different. Executives can actively influence outcomes. Furthermore, success means doing better than rivals. For these decisions, executives need more than an ability to avoid common biases. They require a talent for clear-eyed analysis and the ability to take bold action.

*Good design can't fix broken business models - Jeffrey Veen*

### Strategic Leadership: The Essential Skills

The more uncertain your environment, the greater the opportunity – if you have the leadership skills to capitalize on it. Research at the Wharton School and at a consulting firm, involving more than 20,000 executives to date, has identified six skills that, when mastered and used in concert, allow leaders to think strategically and navigate the unknown effectively. They are the abilities to anticipate, challenge, interpret, decide, align, and learn. It has been found that strength in one skill cannot easily compensate for a deficit in another. An adaptive strategic leader has learned to apply all six at once.

### HBR: Why Sales And Marketing Don't Get Along

by Andris A. Zoltners, PK Sinha, and Sally E. Lorimer

Sales teams and marketing teams pursue a common objective: create customer value and drive company results. But sales and marketing don't always get along. Certainly, all-out war between the two teams drains productivity. Yet having the two teams work in perfect harmony and reach an easy consensus on every decision is a pipedream, and in fact, is not the best answer either.

Some tension between sales and marketing is healthy and productive. Four strategies help companies accomplish all of this work with a healthy balance of sales-marketing harmony and tension.

**1. Make sure all sales tasks to get done well.** Design a high-impact sales organization, hire sellers with characteristics such as interpersonal ability and results-drive, and develop the competencies sellers need to succeed. Support the sales force with structures, processes, systems, and programs that enable sales success. **2. Make sure all marketing tasks get done well.** Design a high-impact marketing organization, hire

marketers with characteristics such as analytical savvy and strategic thinking ability, and develop the competencies marketers need to succeed. Support the marketing team with structures, processes, systems, and programs that enable marketing success. **3. Implement processes and systems that encourage communication and collaboration.** Ensure that Sales and Marketing communicate about tasks that the two teams perform independently, and collaborate around tasks that require joint effort. **4. Create a culture that facilitates teamwork.** Start with strong sales and marketing leaders who, through their words and actions, consistently reinforce a cooperative, customer-focused culture.

### HBR: The Trend That Is Changing Sales

by Steve W. Martin

Over the past several decades the structure of sales organizations has remained largely the same. They have been primarily based on outside field salespeople who make face-to-face sales calls with prospective customers and current clients. In turn, the field salespeople have been supported by inside sales representatives who helped them complete their daily tasks. Today, the traditional sales organization structure is undergoing a significant change. Many sales organizations are transitioning from a field sales model to an inside sales model, where the inside salespeople work independently and are directly responsible for closing business, working primarily by phone and email. In order to understand the magnitude of this trend, in-depth interviews and extensive surveys were conducted with over 100 vice presidents of sales at leading high technology companies and business services providers. The resulting research provided detailed insights about the evolution of sales organizations. The key finding: Over the past two years, 46% percent of study participants reported a shift from a field sales model to an inside sales model, while 21% reported a shift from inside sales to a field sales model. More than twice as many study participants reported moving to an inside sales model. There are three key factors that determine

whether a sales organization will utilize a field or inside sales model. They are the sales organization's stage of development, the complexity of the products that are sold, and to a lesser extent, the sales leader's perception of inside and outside sales model effectiveness.

### HBR: Sales Organization Development Stage

Every sales organization can be classified into a "Build," "Compete," "Maintain," "Extend," or "Cull" stage based upon its development. The Build stage is when the sales organization is first establishing itself. If successful, it will proceed to a high-growth Compete stage and then to Maintain stage that is contingent upon predictable success. As the sales organization ages, it will enter either the Extend stage and enjoy longevity or the Cull stage, where it declines and is forced to reduce its size. The ratio of outside or inside salespeople changes as the organization moves from the Build to Compete to Maintain development stages. The challenges sales organizations face is dependent upon the stage of their development. The top sales challenge in the Build stage is creating sufficient sales coverage to push the product into the market. The Compete stage challenge revolves around quickly scaling the sales organization so it can compete effectively against larger established competitors. The focus shifts to maximizing sales productivity by lowering the cost of sale and increasing the average sales price in the Maintain stage. The Extend stage challenge is to attain widespread customer adoption so their solution becomes the de facto standard. The Cull stage challenge is to revitalize a demoralized and marginalized sales force. These challenges directly influence the sales organization's structure and whether a field or inside sales model will be deployed.

There are three things to aim at in public speaking: first to get into the subject, then to get your subject into yourself, and lastly, to get your subject into your hearers. — Gregg.

## HBR: Primal Leadership: The Hidden Driver Of Great Performance

by Daniel Goleman, Richard Boyatzis, and Annie McKee

When the theory of emotional intelligence at work began to receive widespread attention, we frequently heard executives say—in the same breath, mind you—“That’s incredible,” and, “Well, I’ve known that all along.” They were responding to our research that showed an incontrovertible link between an executive’s emotional maturity, exemplified by such capabilities as self-awareness and empathy, and his or her financial performance. Simply put, the research showed that “good guys”—that is, emotionally intelligent men and women—finish first. We’ve recently compiled two years of new research that, we suspect, will elicit the same kind of reaction. Our observation about the overwhelming impact of the leader’s “emotional style,” as we call it, is not a wholesale departure from our research into emotional intelligence. It does, however, represent a deeper analysis of our earlier assertion that a leader’s emotional intelligence creates a certain culture or work environment. High levels of emotional intelligence, our research showed, create climates in which information sharing, trust, healthy risk-taking, and learning flourish. Low levels of emotional intelligence create climates rife with fear and anxiety. Because tense or terrified employees can be very productive in the short term, their organizations may post good results, but they never last.

## HBR: The Five Messages Leaders Must Manage

by John Hamm

If you want to know why so many organizations sink into chaos, look no further than their leaders’ mouths. Leadership, at any level, certainly isn’t easy—but unclear, vague, roller-coaster pronouncements make many top managers’ jobs

infinitely more difficult than they need to be. Leaders frequently espouse dozens of cliché-infused declarations such as “Let’s focus on the key priorities this quarter,” “Customers come first,” or “We need a full-court press in engineering this month.” Over and over again, they present grand, overarching—yet fuzzy— notions of where they think the company is going. Too often, they assume everyone shares the same definitions of broad terms like vision, loyalty, accountability, customer relationships, teamwork, focus, priority, culture, frugality, decision making, results, and so on, virtually ad infinitum. Think of the way a high-reliability team—say, an emergency room staff or a SWAT team—works. Every member has a precise understanding of what things mean. Surgeons and nurses speak the same medical language. SWAT teams know exactly what weapons to use, and when and how and under what conditions to use them. In these professions, there is absolutely no room for sloppy communication. If team members don’t speak to each other with precision, people die. People don’t die in corporations, but without clear definitions and directions from the top, they work ineffectively and at cross-purposes. For the past five years, I’ve worked with hundreds of CEOs as a leadership coach, a board member, a venture capital investor, and a strategy consultant. I’ve also been a president and CEO myself (my company, Whistle Communications, was acquired by IBM in 1999). The companies whose CEOs I’ve worked with—typically technology firms—range in size from about 100 to several thousand people. In observing CEOs, I’ve come to the conclusion that the real job of leadership is to inspire the organization to take responsibility for creating a better future. I believe effective communication is a leader’s single most critical management tool for making this happen. When leaders take the time to explain what they mean, both explicitly (by carefully defining their visions, intentions, and directions) and implicitly (through their behavior), they assert much-needed influence over the vague but powerful notions that otherwise run away with employees’ imaginations. By clarifying amorphous terms and commanding and managing the corporate vocabulary, leaders effectively align

precious employee energy and commitment within their organizations. I like to think of good leaders as comparable to skilled locomotive drivers. The train is controlled by a set of switches and levers. When the driver pulls one lever, the train goes forward; when he pulls another, it stops, and so on. When an organization is well aligned, all the managerial levers are easily and neatly moved. They function smoothly so that driver, passengers, and train gracefully move forward as one. In my experience, five such topics control the train: organizational structure and hierarchy, financial results, the leader's sense of his or her job, time management, and corporate culture. Messages on these subjects wield extraordinary influence within the firm. When leaders take it for granted that everyone in the organization shares their assumptions or knows their mental models regarding the five subject areas, they lose their grip on the managerial levers and soon have the proverbial runaway train on their hands. But properly defined, disseminated, and controlled, the five topics afford the leader opportunities for organizational alignment, increased accountability, and substantially better performance.

### Chinese Medicine in an Emerging Market

It was estimated in 2002 that the size of the traditional Chinese medicine (TCM) market in China would be around \$5 billion. A decade of Chinese regulatory reforms, Chinese pharmaceutical industry liberalization, changing Chinese lifestyle & demographics, and the Chinese pharmaceutical research and development facilities were factors explaining the huge TCM market potential in China. Multinationals wanting to enter this market might have to deal with inadequate intellectual property protection, corruption in health insurance reimbursement, complex regulatory procedures, & underdeveloped pricing, bidding, and distribution practices.

### Winners And Losers

Good for presentation to your sales force.

1. A winner paces himself; A loser has only two speeds hysterical and lethargic. 2. A winner has healthy appreciation of his abilities, and a keen awareness of his limitations; A loser is oblivious both of his true abilities and his true limitations. 3. A winner takes a big problem and separates it into smaller parts so that it can be easily manipulated; A loser takes a lot of little problems and rolls them together until they are unsolvable. 4. A winner knows that people will be kind if you give them the chance; A loser feels that people will be unkind if you give them the chance. 5. A winner tries never to hurt people. And does so only rarely, when it serves a higher purpose; A loser never wants to hurt people intentionally, but does so all the time without even knowing it.

### The Rubaiyat Omar Khayyam

Whether at Naishapur or Babylon,  
Whether the Cup with sweet or bitter  
run ,  
The Wine of life keeps oozing drop by  
drop,  
The Leaves of life keep falling one by  
one.

Each Morn a thousand Roses brings,  
you say ;  
Yes, but where leaves the rose of  
Yesterday ?  
And this first Summer month that  
brings the Rose  
Shall take Jamshyd and kaikobad away.

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## ON MANAGEMENT

### Nobody trust the boss completely - Now what

Catching problems early is a big advantage to any manager, and the best way to find out about developing headaches is to have your subordinates tell you. But how you get them to be candid? How do you get them to talk freely about their own mistakes and harder yet, about yours? Candor depends on trust. But have strict natural limits. People keep their mouth shut in order to protect themselves or their subordinates, to avoid the limelight or because they are afraid of seeming timid or ineffectual, and so they try to fix their own problems without help. Company politics can also stand in the way of plain talk. Since employees always see the boss as judge, managers need to be aware of how they can increase trust or destroy it. There are six critical areas. **1.** Communication must always be a two way street. **2.** Support means being approachable, helpful and concerned, especially when the chips are down. **3.** Respect is a question of delegating authority and listening to what subordinates have to say. **4.** Fairness means giving credit and assessing blame where they are due. **5.** Predictability is being dependable and keeping promises. **6.** Competence means knowing your own job and doing it well.

## WISE MEN'S WISDOM

**1.** Too many people are thinking of security instead of opportunity. They seem more afraid of life than death. --- *James F. Byrnes*. **2.** Keep true, never ashamed of doing right; decide on what you think is right, and stick to it. --- *George Eliot*. **3.** It is less important to redistribute wealth than it is to redistribute opportunity. --- *Arthur H. Vandenberg*.

**4.** Keeping a little ahead of conditions is one of the secrets of business; the trailer seldom goes far. --- *Charles M. Schwab*. **5.** The important thing is to know how to take all things quietly. --- *Michael Faraday*. **6.** Salesmanship consists of transferring a conviction by a seller to a buyer. --- *Paul G. Hoffman*. **7.** He who rules must humor full as much as he commands. --- *George Eliot*. **8.** The spirit of man is more important than mere physical strength, and the spiritual fiber of a nation than its wealth. --- *Dwight D. Eisenhower*. **9.** Words without actions are the assassins of idealism. --- *Herbert Hoover*. **10.** Prosperity is only an instrument to be used, not a deity to be worshipped. --- *Calvin Coolidge*.

## Don'ts At Table

**1.** Don't mop your face or beard with your napkin. Draw it across your lips neatly. **2.** Don't turn your back to one person for the purpose of talking to another; don't talk across the one seated next to you. **3.** Don't forget that the lady sitting at your side has the first claim upon your attention. A lady at your side should not be neglected, whether you have been introduced to her or not. **4.** Don't talk when your mouth is full-never, in fact, have your mouth full. It is more health-ful and in better taste to eat by small morsels. **5.** Don't be embarrassed. Endeavor to be self-possessed and at ease; to accomplish which try and not to be self-conscious. Remember that self-respect is as much a virtue as respect for others. **6.** Don't drop your knife or fork; but, if you do, don't be disconcerted. Quietly ask the servant for another, and give the incident no further heed. **7.** Don't be disquieted at accidents or blunders of any kind, but let all mishaps pass off without comment and with philosophical indifference.

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Contents of **Sāls 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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