Restoring the pharmaceutical industry's reputation

Mark Kessel

Big pharma's storehouse of trouble has fostered consumer mistrust and a negative view of the industry. How does the industry go about restoring its flagging reputation?

It wasn't that long ago that the pharmaceutical industry was considered among the most respected industries and Merck (Whitehouse Station, NJ, USA) the most admired corporation in the United States. This is in sharp contrast to consumer attitudes today, when the industry's reputation is not much better than that of the financial sector or tobacco companies[1]. Why has an industry in the business of developing lifesaving drugs garnered such a negative reputation, and how should it go about fixing it?

Deconstructing a reputation

According to Alexander Brigham and Stefan Linssen of the consulting firm Ethisphere Institute[2] (New York), over the past three decades, the percentage of a company's value attributable to tangible assets has dropped from 90% to just 25%. Other estimates[2,3] also suggest that it is the intangible assets of a company (including reputation) that currently represent as much as 40–60% of a corporation's market capitalization. Thus, a company's reputation is among its most valuable assets.

Corporate reputation depends on both the past experience that people have had with a company and the extent or nature of their communication with it through the media and word of mouth. It is thus a mixture of perception by its different stakeholders as well as the reality of its policies, practices, systems and performance. According to public relations consultant Karen Harrison[4], a person's past experience with a company can account for about two-thirds of their view of that company.

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The GlaxoSmithKline office in Beijing, China, was the center of a 2013 scandal in which local managers were accused of paying millions of dollars in bribes to Chinese doctors to prescribe the company's drugs. Numerous other scandals and ethical lapses across the industry have contributed to a decline in reputation.

For companies in the pharmaceutical sector, how stakeholders view companies is influenced primarily by the lay professional media (through print, TV, radio and online) and the internet (blogs and social media). In addition to companies themselves, key contributors to the conversation include the following: trade bodies, such as the Pharmaceutical Research and Manufacturers of America, the European Federation of Pharmaceutical Industries and Associations and the Biotechnology Industry Organization; regulatory and government agencies, such as the US Food and Drug Administration (FDA) and the US Department of Justice; professional bodies, such as the American Medical Association; patient groups; and lawyers representing patients. Indeed, a key differentiator of the pharmaceutical sector from other industry sectors is that its consumers are also patients.

A recent PatientView survey[5] that asked patient groups (~80% from Europe, with the rest from North America) their opinions on the reputation of the pharmaceutical industry as a whole and of its leading companies found that only 34% believed that multinational drug companies have an excellent or even good reputation (a 19% decline from the prior year).

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Box 1 Changing attitudes of stakeholders

The pharmaceutical industry is different from other industries. Its business is focused on improving the lives of patients while at the same time generating profits to satisfy the needs of shareholders and funding further research. George Merck believed these objectives were not inconsistent with each other—if Merck served patients, the profits would naturally follow. Over time, however, there has been a shift in ideology of corporations that the only social responsibility is to increase profits and enhance investor returns, and pharma has followed this mantra. As Jurgen Drews, the former head of Roche research, candidly stated in 2003, in the pharmaceutical business today "the ethics of successful business have replaced those of medicine. The supreme loyalty of today's companies is not primarily directed at patients and their physicians but at shareholders. Consequently, the most influential figures in today's pharmaceutical companies are no longer the heads of R&D but the heads of marketing and finance"[13]. Tellingly, when pharma executives were polled about the reputation of the industry, 85% agreed that patient-centricity is the best route to future profitability[14]. And yet, it is hard to reconcile the views of these executives with their record in balancing patient needs with those of shareholders.

Patients as consumers. The shifting emphasis on shareholder value of pharmaceutical company management must also be considered in the context of shifting attitudes of patients. As the past century has progressed, consumer expectations have shifted. In the early twentieth century, access to drugs was viewed as a luxury available to those who could afford it. Today, in the West, the provision of medicine is viewed as an entitlement and even a human right. This has led to disillusionment with an industry perceived as placing profits above the rights of patients to access medicine. Headlines attacking pharmaceutical pricing practices for putting needed medicines out of reach of patients foster the view that the pharma industry has pivoted away from patients to financial goals. Patients and the public do not relate to the measure of financial success that these corporations trumpet in relation to their performance. In the public eye, pharmaceutical organizations are also perceived differently from companies in other sectors, because in the provision of medicine, traditional market forces do not apply; the market for drugs is not like buying a new garment or an iPhone. Sick patients must have access to a pharmaceutical product if they are sick—the consequence of not having access to a drug is very often a matter of life or death. In this way, the pharmaceutical industry is perceived differently from other industrial sectors like technology or household products, both in terms of economics and in terms of consumer choice.

At the same time, deciding which vacuum cleaner to buy is a very different prospect from the types of complex healthcare decisions that patients face and have traditionally worked through with their personal physicians. And yet in the United States, for example, drugs are now promoted to patients using DTC advertising, along the lines of other consumer products. Industry defends such advertising under the guise of 'informing consumers'. But DTC ads have resulted in the emergence of consumer self-prescription and shifted the balance and trust in the relationships between patients and prescribing physicians.

Physicians as consumers. Physicians have long been targeted by big pharma's marketing activities, which has affected them indirectly and directly. Indirect effects have resulted from DTC "ask your doctor" ads, which have eroded physician relationships with patients; for example, patients may come to the doctor's office demanding a new drug seen on a DTC ad with the implicit threat that they will seek out another doctor who will prescribe them the DTC medication if the physician refuses to prescribe for valid medical reasons. So a physician's role as gatekeeper of information has been eroded through big pharma's consumer marketing campaigns.

Direct effects of big pharma marketing on physicians relate to paid consultancy work and promotional activities, such as cruises, free drugs and other gifts. It also relates to continuing medical education of doctors, which in the United States is driven by key opinion leaders, who are often on the payroll of industry. All of these factors have in their turn had a negative knock-on effect for the reputation of doctors themselves and eroded the doctor-patient relationship.

Those surveyed pointed to several industry shortcomings: a failure to assist patients in securing medications in a difficult economic environment; offering drugs with only short-term health benefits; not serving the needs of neglected patient groups; inappropriate marketing of drugs; a lack of fair pricing policies; making drugs unaffordable to many patients; a lack of transparency in corporate activities, adverse news about products; not having a patient-centered strategy; and not acting with integrity. This is a fairly strong indictment of an industry that promotes itself as a lifesaver.

The impact of this reputational decline needs to be viewed in the context that approximately two-thirds of people's willingness to say positive things about a company is influenced by their perception of the company and only one-third by what they think of its products. Such results have been shown to be similar across multiple stakeholder groups—policymakers, regulators, media, investors, employees and government bodies[6]. Therefore, the tarnished reputation of the pharmaceutical industry, mainly through self-inflicted wounds, has had a major impact on its business and value in the marketplace.

Root causes of reputational decline

The relationships between the pharmaceutical industry and its various stakeholders have changed over the past few decades (**Box 1**). These changes have contributed to the loss of reputation, which has been due to numerous factors. Each factor taken in isolation would not have been sufficient to have brought about the decline all in itself; it is the combination of these factors that has brought about the loss of prestige.

Big pharma and big business. To some extent, reputational decline can be attributed simply to the fact that many pharma companies are large multinational corporations that are now facing strategic issues that require an adjustment to the traditional business model. The increasing price and cost pressure, patent expirations on blockbuster drugs leading to aggressive generic competition, public policy and changes in how consumers access medicine are leading to erosion of profit margins. Big pharma, like other industries, is not immune from the pressure of having to meet Wall Street quarterly earnings expectations; indeed, today's companies are measured on how well their stock performs and boards of directors incentivize management accordingly to meet Wall Street's demands. The needs of patients are secondary. This has resulted in a greater emphasis on a return on investment from R&D and reducing the amount of capital it is allocated. In turn, this has increased off-shoring, the elimination of in-house teams and the flight of scientific expertise into the biotech/biopharmaceutical sector.

Box 1 Changing attitudes of stakeholders (continued)

Industry has also played a hidden role in biasing the clinical literature that physicians rely on to practice evidence-based medicine. It is increasingly clear that cherry picking of results and selective publishing practices directed by pharmaceutical company marketing teams to highlight favorable trial results and drive product sales have corrupted the literature; in some cases, the obfuscation of damaging side effect risks associated with the use of certain products (e.g., Vioxx in pain and Paxil in adolescents) has misled physicians, encouraging them to prescribe drugs in inappropriate clinical situations. These revelations have driven a wedge between professional physician societies and associations such that industry researchers are often unable to present their work at conferences or contribute reviews to the literature.

An increasingly disenfranchised workforce. After decades of layoffs and offshoring of R&D as well as the scaling down of sales reps, there are now many disgruntled pharmaceutical employees and ex-pharmaceutical company employees around the world. Disenfranchised employees can fuel negative information in the media and on the internet, and are often critical of decision making by pharma management.

Many of these R&D employees question the corporate line that industry remains focused on R&D and true innovation when it seems more effort is placed on share buybacks or extending existing franchises through incremental innovation, with accounts of promising discovery programs shelved, not because of scientific challenges, but rather because of the reassignment of corporate priorities. In addition, some disgruntled sales employees have become whistleblowers, speaking out against questionable practices in the marketing and detailing of pharmaceutical products.

Journalists and the new media. As information travels more quickly around the world, coupled with the 24/7 news cycle and trial by Twitter, industry lapses in business ethics, regulatory violations, manufacturing failures and other wrongdoing have been magnified and propelled around the globe at the speed of the internet. Not only is the web providing a wealth of health information at newsbyte speed, but also that information frequently may be false or of poor quality, gratuitously demonizing the pharmaceutical industry and blaming it for all manner of healthcare ills when culprits may lie elsewhere.

A further issue for an industry involved in the complex process of the creation, development and provision of medicine is the dwindling expertise of journalists with relevant expertise about health and the industry in the mainstream media. This means that media coverage of pharmaceutical industry issues is increasingly less likely to present a balanced discussion or nuanced view, particularly in relation to drug pricing, marketing and conflicts of interest.

The above changes to the media have exacerbated the problems encountered by big pharma corporate communications departments, particularly when dealing with internal wrongdoing. Often, pharmaceutical companies and their public relations teams cannot be assured that they will have the luxury of time to try to mitigate reputational damage in the media. In addition, the legally neutered communications that originate from large companies often come across as corporate, anodyne and dehumanized to members of the general public.

Lawyers and class-action lawsuits. Lawyers who have targeted asbestos and tobacco manufacturers in the past are increasingly turning their attention to drug companies, alleging that they have hidden the harm caused by medicines from consumers. With their ability to advertise, class-action tort lawyers have created a cottage industry over the safety issues that have arisen with respect to drugs. These follow a familiar formula: "Have you or a loved one endured a negative reaction" to a drug? If so, "legal action is an option for you and your family," often with a listing of the millions of dollars won in previous lawsuits. These lawyers are not solo practitioners with limited resources but a well-financed trial bar that can afford to advertise and attract thousands of claimants. Some of the more prominent litigation brought by these firms involved Pfizer's (New York) Rezulin, GSK's Paxil, Wyeth's (now Pfizer) diet drugs Fen-phen, Merck's (Whitehouse Station, NJ, USA) Vioxx and the list goes on. These suits reinforce the view that pharma cares less about their patients than profits.

At the same time, consolidation in the industry continues unabated with the aim of furthering revenue growth and circumventing corporate taxes. Recently, mega mergers (by means of a so-called inversion into a company located in a jurisdiction with lower taxes than the jurisdiction in which the acquirer is located) overtly take place without reference to benefits to patients; indeed, such deals often emphasize that such mergers are valuable because they reduce US tax burden for a company—all against a background where the public outcry about tax dodges by big business and "the 1%" is becoming ever more strident. Although pharmaceutical executives have trumpeted that these consolidations result in more efficient R&D organizations, the true import has been the further curtailment of R&D spending devoted to high-risk, high-reward R&D—all to the detriment of patients. The fact that such consolidations have been discredited has not tempered the appetite in boardrooms to pursue this growth strategy. None of this goes down well with consumers.

R&D restructuring has had other reputational consequences. These decisions, involving local companies that employ hundreds or even thousands of people, may threaten large swathes of a nation's economy, employment and business (e.g., Pfizer and AstraZeneca's aborted merger in the spring, which prompted a UK parliamentary enquiry). Also several multinational pharmaceutical companies already present in a particular country have reorganized or relocated their R&D centers to other countries on the basis of short-term decisions to meet Wall Street expectations or short-term financial performance, which again can decimate local economies, leading to hardship and disenchantment with large pharmaceutical companies.

In the United States, big business has an increasingly long reach into policymaking in Washington, DC. As large corporations, US drug companies spend more than any other sector on lobbying each year: $234 million in 2012, according to the Center for Responsive Politics (CRP), a nonprofit research group in Washington, DC. Prominent companies have sought to influence the outcome of elections through campaign donations and the activities of elected legislators. It is doubtful that the public perceives this lobbying power as fostering patient interests over industry profits.

Lastly, as companies bridge many different markets in a globally interconnected world, differences between ethical standards in different national jurisdictions can translate into scandals for pharma on an international scale. The Chinese government's recent clampdown on the Shanghai office of GlaxoSmithKline (GSK, London) for its practices in marketing medicines is a case in point. Many of the practices (e.g., paying hospital doctors to prescribe)

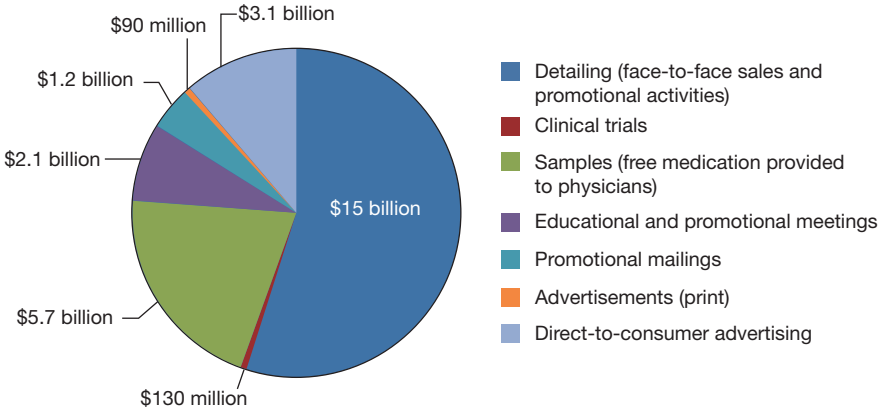

Figure 1 Main areas in which pharmaceutical marketing departments spent funds in 2012. Source: Pewtrusts.org

were detailed by a shocked media and are indeed unacceptable and criminalized in the West; however, Western media coverage often failed to highlight that such practices are not unusual in the Chinese drug marketplace. Even so, the negative publicity in the West has a detrimental effect on the company's (and therefore the industry's) reputation, even though it may have been acting in line with common business practice in China at the time. The question for multinational companies is, which national ethical standards should they follow?

Dubious marketing practices. It needs to be recognized that many of the industry's marketing practices have alienated patients and influenced the medical profession. During 2012, the pharmaceutical industry spent over $27 billion on promoting drugs, of which $24 billion was on marketing to physicians with the balance spent on consumers (**Fig. 1**). The majority or about $15 billion was spent on detailing—face-to-face promotional activities aimed at doctors and pharmacy directors, including wining and dining doctors, and promotional gifts. As of 2012, ~72,000 pharmaceutical sales representatives were employed in the United States alone. The next largest expenditure, $5.7 billion, was in samples—the free medication given to physicians—which has been shown to result in substantial increases in new prescriptions for the promoted drug. Big pharma companies assert that samples are intended to benefit indigent patients. Yet, research has shown that free medications are dispensed mostly to insured patients whose medications are covered[7]. These patients ultimately incur higher prescription costs than those who are not provided with samples because they are then prescribed the sampled drug rather than a less-expensive generic alternative.

The list of activities that are designed to influence physician prescription practices goes on: educational and promotional meetings at restaurants; promotional mailings highlighting a drug's benefits in trials sponsored by the company, which have been shown to be highly biased in favor of the company's drug; journal and web advertisements criticized by the FDA for highlighting a drug's effectiveness without pointing out its risks; and direct-to-consumer (DTC) ads encouraging consumers to ask doctors for the more expensive branded drug. Indirect marketing has also been effective in promoting drug sales. For example, continuing medical education, which used to function as veiled marketing, is now regulated but is still perceived as a marketing initiative; grants to health advocacy organizations intended to galvanize patients around a disease have the effect of promoting the drugs manufactured by the sponsoring company for these diseases.

All such marketing practices have inured to the detriment of patients. The historical focus on blockbuster drugs has been regarded by critics of big pharma as emphasizing sales volume over whether patients receiving a drug actually derive any benefit from it. The ubiquitous DTC ads in the United States not only promote a drug but increasingly reframe and medicalize human traits to create a need for the drug—Paxil (paroxetine) for social anxiety disorder or general anxiety disorder (shyness), Rogaine (minoxidil)/Propecia (finasteride) for baldness (male-pattern), Viagra (sildenafil) for erectile dysfunction (andropause, aging) or recently marketed low testosterone and 'low T' (andropause, aging). Big pharma is no longer just marketing drugs; it now markets diseases to consumers. Again, to many in the public, these DTC ads give the perception that industry's focus is more on peddling elixirs for trivial human conditions rather than focusing on finding drugs that ameliorate or cure debilitating diseases. Also, big pharma's use of 'pay-for-delay' deals and patent evergreening—in which intellectual property is used to enable line extensions of 'me-too' drugs and prevent generic competition—not only does nothing to reburnish its image as an innovative industry searching for cures but also has gotten pharma in the crosshairs of regulators. Last month, in a widely publicized lawsuit, the US Federal Trade Commission (FTC) alleged that the AbbVie (Deerfield, IL, USA) and TEVA Pharmaceuticals (Petach Tikva, Israel) pay-for-delay deal for AndroGel forced consumers to overpay hundreds of millions for that drug. The FTC said that it is hoping to get a billion dollar settlement in this and similar cases.

Big pharma's marketing practices have also alienated the medical profession. Allegations of companies withholding or failing to report negative data about marketed products—even making payments to certain physicians to overstate the benefits of drugs—have dogged the sector. Legislators have moved to pass legislation to counter corruption and conflicts of interest that have been attributed to companies in the pharmaceutical sector. Last month, the Open Payments Program of the Physician Payment Sunshine Act, a part of the 2010 Affordable Care Act came online, creating a database of drug company financial interactions with physicians and hospitals. Counterintuitively, it is possible that more transparency in these interactions will in the short term create more reputational damage for the pharmaceutical industry (and for doctors), particularly if distorted media coverage of the extent of industry-physician collaborations shocks a public who is unaware of the interaction between the two worlds and who wrongly assumes physicians and academics work in isolation from industry.

Finally, the preeminence of the marketing imperative in big pharma has meant industry has played a prominent role in the suppression of negative data in academic publications and in restricting the freedom of academics to disclose such data. These allegations have caused a backlash in several quarters. First, it has damaged the credibility of industry-sponsored publications so that prescribers have become increasingly skeptical about the data presented and increasingly concerned about the data supporting the safety and efficacy of the drugs they are prescribing. Second, it has angered many of the thought leaders and prominent medical journal editors like Catherine DeAngelis (*Journal of the American Medical Association*), who have become outspoken critics of the pharma industry in general. Books written by these leaders (e.g., *The Truth about Drug Companies, Overdosed America* and *Bad Pharma*) are read widely by the public and reviewed and discussed in the popular media.

Critical editorials and articles have been circulating for several decades in the

scientific literature, but they have been more prominent of late. Journals like the *British Medical Journal* have considered banning all submissions from industry authors; the *Lancet* and the *New England Journal of Medicine* decline to publish any review articles by industry authors; and several clinical conferences no longer allow big pharma speakers to present their results. The fact that infractions by industry are not exceptional is what has prompted these blanket measures to be taken by clinical journals and learned societies.

Pricing and access to drugs. The high price of drugs is a problem increasingly blamed on the pharmaceutical industry (despite the fact that drug prices are not the biggest contributor to healthcare costs as a whole). In the US reimbursement system, the burden of high drug costs falls upon individuals, and state and local governments and insurers, which will need to balance access and affordability to an increasing extent. Such costs are unsustainable for healthcare systems that are facing infinite demand and finite resources, but in particular for the way in which these costs are being passed on to patients, in some cases leading them to bankruptcy.

Although industry cites the high costs of bringing a proprietary drug to market and the relatively short time of market and data exclusivity available to recoup these costs before generic competition, an increasingly strident group of physicians, legislatures and pharmacy benefit managers have weighed in, questioning whether the cost of these drugs are reasonable. For example, Zaltrap (ziv-aflibercept), a newly approved drug marketed by Sanofi at $11,000 per month, garnered national headlines when physicians at Memorial Sloan-Kettering Cancer Center in New York declared they would not include it in the formulary because of its high price in relation to benefit, causing Sanofi to effectively drop its price in half[8]. Interestingly, although big pharma has had its fair share of criticism over the pricing of its products, more often than not the most exorbitant prices are being charged by smaller biotech or biopharma companies (which spend substantial resources on differentiating their image and reputations from big pharma).

One recent case concerns the hepatitis C drug Sovaldi (sofosbuvir) from Gilead Sciences (Foster City, CA, USA), which has been subject to mounting criticism from the World Health Organization (Geneva), healthcare companies and patients over the drug's $1,000-a-day price. The debate has moved the US Senate Finance Committee to request information about the cost, and pharmacy benefit manager CVS Caremark has joined Express Scripts in urging Gilead to price its drug more reasonably. Other stakeholders like the National Coalition on Health Care and America's Health Insurance Plans also have criticized the cost of treatment, which could total $84,000 to $200,000 per patient, depending on the length of treatment. This represents about 10 to 20 times the cost of the current treatment regimen. It should not be lost on industry leaders that this furor has the echoes of past criticism of the pharmaceutical industry when it was accused of putting lifesaving HIV drugs out of reach of poorer populations.

Table 1 Endemic problems of criminal behavior and civil infringements across the sector

Date	Company	Fine ($ millions)	Infringement
February 2014	Endo Health Solutions and its subsidiary Endo Pharmaceuticals (Dublin)	192.7	Criminal and civil liabilities arising from Endo's marketing of the prescription drug Lidoderm (lidocaine). As part of the agreement, Endo admitted that it intended that Lidoderm be used for unapproved indications and that it promoted Lidoderm to healthcare providers this way.
November 2013	Johnson & Johnson	2,200	Criminal and civil allegations relating to illegal promotion of the prescription drugs Risperdal (risperidone), Invega (paliperidone) and Natrecor (Nesiritide) for uses not approved as safe and effective by the FDA, the targeting of elderly dementia patients in nursing homes, and the payout of kickbacks to physicians and to the nation's largest long-term care pharmacy provider, Omnicare.
December 2012	Amgen (Thousand Oaks, CA, USA)	762	Criminal and civil charges that the company illegally introduced and promoted several drugs, including Aranesp (darbepoetin alfa), a drug to treat anemia. Amgen pleaded guilty to illegally selling Aranesp to be used at doses that the FDA had explicitly rejected, and for an off-label treatment that FDA had never approved.
	Sanofi-Aventis (Paris)	109	Allegations that company gave doctors free units of Hyalgan (hyaluronate injection to relieve knee pain) to encourage sales, lowered the effective price by promising doctors free samples, while at the same time obtaining inflated prices for the drug from government programs by submitting false price reports.
October 2012	Boehringer Ingelheim	95	Allegations that company promoted several drugs including Aggrenox (aspirin/dipyridamole), Atrovent (ipratropium), Combivent (Ipratropium/albuterol) and Micardis (telmisartan) for nonmedically accepted uses.
July 2012	GSK	3,000	Civil and criminal liabilities regarding misbranding of Paxil for treating depression in patients under 18, even though the drug had never been approved for that age group as well as failure to disclose safety information about Avandia to the FDA.
May 2012	Abbott	1,500	Illegal promotion of Depakote (divalproex) in indications for which it had never been approved: schizophrenia and control of aggression and agitation in elderly dementia patients.
November 2011	Merck	950	Illegal promotion of Vioxx as a treatment for rheumatoid arthritis before it had been approved for that use and misrepresentation of the drug's heart safety to increase sales.
April 2010	AstraZeneca (London)	520	Allegations of illegal promotion of Seroquel (quetiapine) for a variety of unapproved uses, such as aggression, sleeplessness, anxiety and depression. The company paid the fine but denied the allegations.
September 2009	Pfizer	2,300	Misbranding Bextra with "the intent to defraud or mislead," promoting the drug to treat acute pain at dosages the FDA had previously deemed dangerously high. Bextra was pulled from the market in 2005 due to safety concerns. The government alleged that Pfizer also promoted three other drugs illegally: Geodon (ziprasidone), Zyvox (linezolid) and Lyrica (pregabalin).
January 2009	Eli Lilly	1,420	Off-label promotion of Zyprexa (olanzapine) to elderly populations to treat dementia. The US government also alleged that Lilly targeted primary care physicians to promote Zyprexa for unapproved uses and "trained its sales force to disregard the law."

Source: Department of Justice

In response to the uproar, Gilead announced in September that it will allow seven Indian generic companies to make and market Sovaldi in >90 countries in the developing world to provide more affordable access. Even so, some organizations still criticized Gilead for excluding from this arrangement other highly burdened countries, such as China and Brazil, that represent potential lucrative markets.

A second issue is the inflexible drug pricing schemes that these companies are bringing to emerging economies, in many cases leading governments to issue compulsory licenses as a last ditch means of bringing affordable drugs to their countries. Given the fact that many large pharmaceutical companies are still highly profitable and frequently engage in share buybacks or dividends for the benefit of shareholders, industry should not be surprised that its lack of impetus to find solutions to providing its products to developing countries has a negative effect on its reputation.

Prominent public censure of industry malpractice. Industry has now been subjected to numerous regulatory and congressional investigations, billion-dollar fines for illegal marketing (gabapentin (Neurontin)), misleading DTC ads, off-label promotion of drugs, enquiries about pricing (Solvadi), lawsuits for the sale of drugs with known safety risks (e.g., Merck's Vioxx (rofecoxib)), and allegations of price fixing and kickbacks (including arrangements to delay access to generics). The list of companies fined in the billions of dollars by the US Department of Justice for violating the False Claims Act and the Federal Food, Drug & Cosmetic Act has not dampened such activities over time (**Table 1**).

Pharmaceutical companies are seemingly oblivious to the consequences of these fines to their reputations, even if they shrug them from their balance sheets as the cost of doing business. These activities, at times in violation of criminal statutes, are publicized in many different media outlets across the world for all to see. This has led consumers to espouse that there is too little regulation of the industry. How can industry continue to engage in these activities and not expect its reputation to be damaged?

Restoring a reputation

Once a company's reputation declines, some sources[3] estimate that it takes about 3.5 years to rebuild it, even in the best of circumstances. Given the many missteps of the pharmaceutical industry over the years, there is no single panacea to fix the current reputation problem. And the process of restoring reputation will be complex, requiring the rebuilding of trust among multiple stakeholders. Therefore, improving the pharmaceutical industry's standing is going to require both industry as a whole (through its trade bodies and other organizations) and individual pharmaceutical companies to come to grips with the factors precipitating reputational decline and seek to address them. The following are some of the steps that can start the industry on the road to recovery.

Refocus on patient's needs. Among the main components that are used in reputational measurement are ethics (the company behaves ethically and is trustworthy) and customer focus (the company cares about and is strongly committed to its customers). As can be gleaned from patient surveys, the pharmaceutical industry has fallen short in these key ingredients in recent years. Therefore, a good place to start rebuilding the reputation of the pharmaceutical industry is to focus on its key stakeholder—its consumers. This is a large task, and it will require establishing a sense of caring about patients on an industry-wide basis.

The public needs to be convinced that pharmaceutical companies are concerned about them and about curing their maladies. Thus, George W. Merck's admonition "We try to remember that medicine is for the patient. We try never to forget that medicine is for the people. It is not for the profits. The profits follow, and if we have remembered that, they have never failed to appear. The better we have remembered it, the larger they have been" needs to be inculcated in the center of big pharma's core values and its behavior. This requires programs that reach out and forge bonds with patients and their physicians. A good place to start is to collaborate with patient organizations to understand patient needs and how to fulfill them, by developing creative support programs, providing educational as opposed to marketing materials to patients, and where needed, cost-effective patient access to drugs. For example, lack of adherence to drug regimens is a serious health issue, especially among the elderly. Companies could develop adherence programs for their drugs. Through the use of social media, drug companies can implement this and other programs and engage in an effective dialog with patients. Recently, Pfizer (New York) has taken this tack by launching a social media campaign using the hashtag, #FOGO (fear of getting old), which attempts to stimulate a dialog related to the aging process and its import. This is intended to burnish the Pfizer brand rather than promote particular products.

Cease DTC advertising. The industry needs to take a critical look at DTC advertising and determine whether it strengthens the perception of patients that drugs companies care more about selling more drugs to enhance earnings than they do about patients. These ads are ubiquitous on television, tend to demean the image of the companies, generally talk down to patients and detract from the benefits that the drugs are intended to provide to the appropriate patient population. The ads may also promote inappropriate use of the drugs by patients deriving their information from the advertisement rather than from their personal physicians.

Price for prestige as well as profit. Among the many perceptions that patients have of pharmaceutical companies is that their current focus is on improving their earnings rather than the lives of patients. Clearly, the cost of developing a truly innovative drug is expensive and can exceed $1 billion when failures are factored into the equation. But is the pricing justified?

There is a need to educate stakeholders about the costs associated with drug development and to justify the pricing of a new drug by describing the benefit to affected patients and the cost savings to the healthcare system. Even then a drug company should consider whether its pricing policy should still be tempered to avoid the potential outcry from its stakeholders and the longer term impact on its reputation.

Restore an ethical culture. The ethics of a company are at the top of many reputational measurement systems. Thus, it should not come as a surprise that ethical lapses attributed to pharmaceutical employees garner much of the attention of the pharmaceutical stakeholders, including regulators. A corporation's culture is a system of shared values that guides the behavior of the company's members. To foster an ethical culture, the boards of directors of companies need to question whether the company is run with ethical leadership, which is inculcated throughout the organization. If companies tolerate unethical behavior from senior management and give them a free pass, then it sends a message within the organization that it is fine to weigh ethical conduct on a cost-benefit basis or to seek ways to circumvent potential liability. As pharmaceutical companies conduct operations globally, the industry needs to take steps to instill its ethical framework into diverse cultures where the respect for such conduct is often wanting. Executives should always consider whether they would be comfortable if their company decisions involving ethics were ever made public.

If the fundamental culture of the pharmaceutical industry is principally focused on promoting corporate profit, ethical conduct will suffer. Therefore, boards of directors should

consider whether the percentage of executive compensation based on equity is fostering the wrong behavior. Twenty years ago, about 20% of an executive's compensation was in the form of stock; today, in large companies, it accounts for about 60% (ref. 9). With such a large amount of value tied to a stock's performance, are boards fostering the wrong behavior in company leadership? Absent the right culture, ethical lapses will just continue to be the cost of doing business. Big pharma needs to take steps, such as Johnson & Johnson (New Brunswick, NJ, USA) management did in the 1980s when it pulled Tylenol capsules from the market nationwide because of tampering in Chicago, or as Merck executives did when they developed a drug for river blindness at a cost of hundreds of million of dollars, and provided it free to victims living in abject poverty.

To be sure, restoring ethical behavior in today's profit-driven environment is not without its challenges. It has been reported that GSK, in an attempt to be the poster child for ethical behavior, has taken steps to reform its marketing practices by altering its pay structure and incentives to drug detailing representatives, severing the connection between sales and their compensation and eliminating compensation to doctors for promoting its products. Some analysts are concerned, however, that these reforms may be responsible for the deteriorating sales of some of GSK's products. It is notable that other big pharma companies have not followed the GSK lead[10].

Stop flaunting regulations and law. From January 2009 through February 2014, 11 pharmaceutical companies (including Merck and Johnson & Johnson) agreed to pay over $13 billion in fines stemming from allegations running the gamut of fraudulent marketing practices to failure to report safety-related data. Despite the adverse media publicity stemming from these billions of dollars in fines, the public does not believe that senior management ever was held accountable. To avert such failings in the future, the industry needs to restore ethical behavior, put in place better controls and punish misconduct of executives responsible for the infractions. Interestingly, there has not been the same clamor for the government to hold pharma's management to account for such wrongdoing as there has been in relation to the financial sector's malfeasance.

Implement data transparency. Drug companies have been accused of a reckless disregard for patient safety. In April of this year, a jury in the United States ordered Takeda (Tokyo) and Eli Lilly (Indianapolis) to pay $9 billion in damages for hiding evidence possibly linking their drug Actos (pioglitazone) to a form of cancer. Although the size of this award is not likely to stand, it reflects the public's disdain for the lack of transparency of drug industry data affecting patients. Allegations also abound that pharmaceutical companies publish successful trial data and withhold from publication negative data, and rig study designs to foster favorable outcomes. Such a controversy surrounds Tamiflu, where Roche (Basel) spent years resisting efforts by the Cochrane Collaboration to obtain missing efficacy data from clinical trials. Although some attempts have been made for greater sharing of data—GSK, Roche and Johnson & Johnson have taken steps to make data available to those who request it—the industry as a whole has not embraced data sharing with open arms. Indeed, in 2013, AbbVie even filed a lawsuit (which has subsequently been dropped) to stop the European Medicines Agency from releasing clinical trial data for its blockbuster drug Humira (adalimumab) to the public. Although industry argues that confidential business information needs to be protected, there is no excuse for withholding safety data that could affect clinical decision making—whether before or after the drug has been approved by the regulators. The continued lack of data transparency further gives credence to industry critics and the public that drug companies have lost their ethical compass.

Change industry messaging. Although it is the actions of big pharma that have really hammered its reputation, industry's messaging has also played a role. The sector has not had an effective program to educate consumers and other stakeholders on how it has improved lives and the difficulty and costs associated with bringing new therapies to patients. In this respect, it should think about two key aspects.

First, industry needs to focus on its messengers. Surveys have shown that more than half of a company's reputation can be attributed to the CEO. In the past, pharmaceutical companies were run by CEOs who had both scientific training and credibility in the marketplace and were perceived as individuals concerned about patient well-being and devoted to their health. In recent times, large drug companies have often been run by lawyers or individuals coming out of sales and marketing, who are not likely to garner the same respect among stakeholders. Thus, companies need to overcome this perception. For example, it would behoove pharmaceutical companies to encourage executives grounded in science to interact more frequently with the relevant stakeholders in connection with the launch of an expensive drug. Such discussion could explain a new drug's benefits and why it is worth the high cost, its development expenses, the company's program to provide it to patients not fully covered by insurance and other relevant information. Having the CEO or CFO crow about a new drug's impact on the bottom line to securities analysts and the financial and trade press is not effective messaging to the greater public and stakeholders.

Second, beyond the usual trite epithets about caring for patients, industry needs to educate the public about what it really does, the value it brings to the discovery of medicines, and the complexity and time involved in bringing a new drug to market. Because the lay media is constantly bombarding readers with reports of breakthroughs in genomics and new technologies that promise to revolutionize drug discovery, the average consumer is unaware that it can take as many as 15 years to bring a drug to patients, or that the odds of a chemical going from discovery to launch are 5,000 to 1, and the cost of developing a new drug is in the hundreds of millions of dollars. For the foreseeable future, drug discovery and development will continue to be a long and costly process. What's more, industry needs to counter the misinformation from certain academics, politicians and pharmascolds who claim that it is academia and the US National Institutes of Health that bring drugs to market, not industry. Therefore, instead of squandering funds on DTC, pharmaceutical companies and the industry's trade associations should consider investing in a communications strategy designed to deliver this information.

Reduce government lobbying. For years, the pharmaceutical industry has been spending well over $200 million per year on lobbying activities in the United States. At the same time, these expenditures have not totally diminished congressional criticism of the industry. The industry has been criticized by both the US Congress and the FDA for several activities, ranging from violations for misleading advertising to targeting children with candy-flavored nicotine replacement products. A Congressional report even concluded that GSK tried to intimidate independent scientists and deliberately misrepresent medical data to rebut safety concerns over its Avandia (rosiglitazone) drug to treat diabetes. And when the US Congress goes after the FDA for its handling of Vioxx or Avandia, it is likely to have a ripple effect on the pharmaceutical industry's relationship with its principal regulator.

This type of conduct makes governmental bodies and regulators look askance at drug companies. Companies thus need to present the facts with complete candor to restore

confidence in both their testimony and their data.

Do good and do it loudly. History is replete with examples where companies addressed social issues, which at the same time fostered the interest of the company. A recent *New York Times* article[11] entitled "Motivating corporations to do good" points out that corporations in the past not only were motivated by self-interest but also addressed some social and economic issues and listed a few of the more prominent examples: Henry Ford doubling his worker's pay; Eastman Kodak Company providing profit sharing, retirement and sickness benefits; and Coca-Cola pronouncing that corporate executives served workers, customers and the community and not just stockholders.

Today, like other large companies in other sectors, big pharma corporate ethos is to 'make the shareholder king'. Restoring reputation will mean placing more emphasis on patients and convincing shareholders this is worth the effort. For example, there is a dearth of innovation to develop new antibiotics to combat antibiotic-resistant infections. Big pharma has shunned development of these drugs and has proclaimed publicly that there are insufficient economic incentives for development programs to go forward. Shouldn't pharma, with its vast amount of resources—and a track record of producing antibiotic innovations in the past—reenter this area rather than bowing out? If no pharma company is willing to go it alone, perhaps a consortium could take on the development program.

To this end, the pharmaceutical industry needs to effectively communicate how it has reformed unethical practices (tiptoeing around the specter of class-action lawsuits), so that past dubious practices will not be repeated. It can also counter negative publicity by being more vocal about altruistic activities, such as philanthropic drug access programs, or other forms of assistance to community and humanitarian causes, including to the developing world. Pharma can also garner goodwill by embracing environmentally friendly technology and emphasize sustainability and moving toward the use of green chemistry and away from environmentally harmful processes. Finally, it should communicate how it is promoting research through investment, establishing private research institutes and foundations, and providing grants and scholarships to support young scientists.

But perhaps the most fruitful avenue in terms of restoring reputation is for big pharma to be seen as engaged in activities that promote and aid patients and patient groups. As much as possible, the pharmaceutical industry needs to find better routes to reach foundations, which are skeptical of industry's motives, in promoting research, and it should expand its consultations with patients to garner and incorporate their feedback. Ultimately, if the pharmaceutical industry can gain the support of patient groups who communicate with the media and public on its behalf, such communication will have substantially more weight with the public than any communications coming from a pharmaceutical company internal public relations department.

Conclusions

A strong reputation can benefit a pharmaceutical company in manifold ways—increasing sales from its various customer groups; enhancing relationships with collaborating companies; attracting and retaining a strong employee talent pool; improving relationships with regulators and governmental bodies; enhancing loyalty from its various stakeholders in the event of negative publicity or crisis; ensuring an ability to obtain premium prices for its products; and enabling better patient enrollment in its clinical trials. And yet the industry has neglected to address many of the factors that are damaging its name, resulting in a reputation that is worse than at any other time in its recent history.

The public's trust in big pharma is likely to worsen unless both individual companies and the industry sector as a whole make a concerted effort to address the fundamental problems that are eroding reputation. Rebuilding this lost reputation will be difficult and will take years. In addition, as the reputation of a single company is affected by the actions of others in the same industry, rebuilding reputations in an industry that is itself declining will be even more arduous.

To restore its good name, the pharmaceutical industry has to radically alter the way it is perceived by the public. The good news is that as the damage was self-inflicted, it should be possible to address it. However, this will require a change from an industry mindset that has been focused on profits and meeting the goals of securities analysts to a mindset that reemphasizes patients. This can only happen if the industry's corporate leadership and Wall Street believe that profits will naturally follow. Perhaps pharmaceutical executives can take their cue from recently arisen benefit-type corporations that have as their mission social as well as business goals, proving that investors do not view these goals as incompatible[12]. This may mean that rather than denying AIDS drugs to the poor populations of Africa and being vilified for it, drug companies take the high road. Merck did this when freely providing its drug for river blindness, which garnered enormous goodwill.

Brand reputation has come to represent a most valuable asset. Shouldn't the pharmaceutical industry treat its brand reputation with the same care it does its other assets and manage it and invest in it accordingly?

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The author declares no competing financial interests.

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