unnecessary (8). It is encouraging that the Report on Universal Health Coverage for India, prepared by the High-level Expert Group instituted by the Planning Commission, recommended that no fees should be levied for the use of healthcare services under Universal Health Coverage (9). This document enumerates a number of drawbacks of user charges. Some of these relate to the errors in inclusion and exclusion associated with identifying the economically weaker sections of society; the difficulty of providing equitable services to all economic sections of society through a differential fee arrangement; and limiting corruption and administrative costs associated with receiving payments at the point of care. We should also draw lessons from the experiences of other countries that have attempted to abolish user fees in health services (10).

Apart from user fees, there are indirect costs, such as transportation and opportunity costs, which can be a burden for the ultra-poor. Waivers and exemptions alone may not be sufficient to mitigate the erosion of income that accompanies ill health. More holistic and integrated interventions are needed to improve the healthcare-seeking behaviour of the poor. A study found that a grants-based, integrated intervention that had both health and non-health components improved the use of health services among the most deprived (11). The non-health components included grants for income-generating assets together with training, subsistence allowance in the initial phase, social awareness and pro-poor advocacy. The health component included the provision of essential health services, as well as of counselling and consumer information on health services, free installation of latrines and tube wells, identity cards to facilitate access to health services and financial assistance through community-mobilised funds.

The waiver of user fees is aimed at improving the access of the poor to healthcare services. The identification of the poor, which is the crux of the intervention, is a very complicated matter and poses several ethical issues for public health. These include the potential risks of exclusion, delay in treatment-seeking, leakages, corruption and discrimination. There is a need to come up with a valid and effective system of providing waivers, with regular monitoring and evaluation being an intrinsic part of the system.

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# Corruption in healthcare: a problem in Germany, too


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According to Transparency International, corruption is "the abuse of entrusted power for private gain" (1). In many parts of Latin America, Africa and Asia, corruption is associated with healthcare in the daily life of patients, as well as routines in all types of hospitals. In the developing world, this crude corruption is felt at every moment in life: patients are often (well) treated or even allowed to see a doctor only if they pay a bribe. Money is directly and openly paid to all kinds of players in the health system: to doctors, hospitals, nurses, or administrative staff.

Open forms of corruption are not often seen in developed countries such as Germany. Corruption here is more hidden and subtle. Therefore, there is a misconception that corruption in healthcare is not prevalent in the developed world.

In India, corruption exists both in open and subtle forms. The analysis in this article and its recommendations, therefore, draw a comparison with the Indian situation. As some western countries, such as Canada, the UK, and Australia, have relatively rigid policies on ordering drugs, this article focuses on the German situation. However, as most forms of corruption are prevalent in nearly all the European and western countries, the better part of the analysis and recommendations can be generalised to most western contexts.

The article focuses on both individual and institutional corruption. Corruption in medical practice includes the extent to which individual physicians rely on misleading information and how this influences their prescription behaviour. The influence on prescription behaviour of pharmaceutical marketing practices is also analysed in this article. Institutional corruption focuses on the manipulation of treatment guidelines and educational programmes. In this context, the article also assesses rules of procedure in the allocation of resources and financing by political decision-makers, who abuse their position to retain their power, status, and wealth.

By addressing these issues, this article aims to show how corruption works in the West in comparison to the Indian situation, and discusses how the issues could best be tackled through changes in practice and policy focused on developing possible common strategies against global corruption. Each subsection includes recommendations.

Corruption also plays a role in determining the balance between medical research which is need-driven and that which is market-driven. Other aspects of corruption in medical research are beyond the scope of this article and need to be addressed in detail in a future article.

## Introduction

*The German health system*

Doctors in Germany work either in hospitals or medical practices. Outpatients are commonly treated in a medical practice, which is often the first place where patients seek care. A medical practice usually has a single or a few doctors of the same specialisation, such as primary care physicians, paediatricians, surgeons, or radiologists.

Of all patients in Germany, 87.5% hold policies in one of the 134 public health insurance companies. Only 12.5% are covered by one of the 45 private insurance companies. Since 2007, health insurance has become compulsory. People earning a monthly salary of up to €5800 must enrol themselves in one of the public health insurance companies. Those earning more than €5800 and self-employed people can choose between private and public insurance. On account of this dual system, health insurance coverage of the population is close to 100%. More than 90% of doctors treat patients who are covered by one of the public insurance companies, and most medical practices and hospitals see both private and public patients. Government and private insurance companies pay for most drugs and other medical interventions. Therefore, out-of-pocket payment is rare and limited to certain special conditions (2).

## Legal situation in Germany concerning corruption in the health sector

The legal situation concerning corruption in the health sector is highly problematic. In March 2012 (Az.: GSSt 2/11), the German High Court (*Bundesgerichtshof*) found that the Criminal Code does not allow doctors working in medical practices to be punished for corruption, nor can the companies bribing them be punished. However, the German High Court saw such corruption as a punishable crime. Currently, the Criminal Code applies only to hospital doctors. The High Court, therefore, asked the government to close this gap and bring doctors working in medical practices within the purview of the Code.

However, political parties are debating whether all doctors (in hospitals and medical practices – private and public) should be subject to the same Criminal Code, as suggested by the Left parties. The conservative parties suggest the alternative that doctors working in medical practices covered by public insurance should be subject to the less effective Code of Social Law and private doctors should be totally excluded from the purview of both Codes. The Criminal Code and the Code of Social Law regulate different offences, and the crimes under the purview of the former are considered more serious. The doctors' initiative, *Mein Essen zahl ich selbst* (MEZIS) (www.mezis.de), and other independent health groups feel that all doctors guilty of corrupt behaviour should be subject to the Criminal Code.

## How corruption works in Germany

Doctors in Germany do not openly ask patients for bribes and use other strategies instead. Bussmann concludes that it is common for doctors to receive illegal allocations for referring patients to specific hospitals, other doctors, medical supply stores, and other care providers, such as pharmacists and physiotherapists (3). Transparency International has estimated that corrupt practices in Germany alone account for a loss of €15 billion per year (1).

However, the focus of this article is the often subtle and diverse ways in which industry delivers monetary value to doctors (individual corruption) and medical associations (*Ärztekammern* or institutional corruption). One of the features that all these methods have in common is the misleading health information that characterises them. Such information results in a change in prescribing patterns, creating a tilt towards costlier pseudo-innovative drugs which often do not provide any therapeutic benefit. Health resources are thus wasted and in some cases, the patient's health is even harmed.

## Pharmaceutical representatives and drug advertisement

Pharmaceutical representatives are among the most effective instruments of corruption capable of changing prescribing patterns by promoting drugs that are more expensive but offer no greater therapeutic value than those in use.

The pharmaceutical industry considers this a problem that nearly half of prescribers restrict the access of pharmaceutical

representatives (4). In Germany, as in many western countries, patients can obtain prescription drugs from pharmacies only if they have a doctor's prescription. This means that pharmaceutical representatives play a very important role in drug promotion, as shown by Williams (5). Only the USA and New Zealand allow direct-to-consumer advertisement (DTCA) of prescription drugs. In Germany, most western countries and India, advertisements aimed at professionals are legal and hardly regulated. Chandra M. Gulhati of the Monthly Index of Medical Specialities India (MIMS) is of the view that pharmaceutical representatives create a wide open border to corruption. According to Dr Gulhati, "The commercial needs of innumerable, fiercely competing pharmaceutical companies has led them to depend on the tried and tested 3Cs: convince, if possible, confuse, if necessary, and corrupt, if nothing else works" (6). As the qualitative study of Narendran and Narendranathan shows, pharmaceutical representatives use the same marketing techniques in India as in Germany and other western countries. These include giving samples or gifts and sponsoring travel costs to persuade physicians to prescribe their pharmaceuticals (7). A representative of a leading Indian pharmaceutical company said, "Lay advertising is largely without interest for us. We focus on doctors. As a rule-of-thumb, any doctor has to yield 10 times as much as we invest in them. We often put Rs 5 million per year into a doctor and now you can calculate how much we earn through them" (8).

In Germany, 15,000 pharmaceutical representatives visit doctors in hospitals and medical practices 20 million times a year. They aim to promote their products and suggest the prescription of new, more expensive, and often pseudo-innovative drugs. One example is Inegy®, which is a combination of ezetimib and simvastatin and is promoted to treat familial hypercholesterolaemia. However, the combined therapy results neither in a significant difference, nor in a therapeutic progress compared to simvastatin alone (9). However, the difference in price is immense: while 100 tablets of Inegy® cost € 179.26 in Germany, 100 tablets of the generic version of at least equally effective simvastatin (20 mg) are available for € 16.01. Thus, the pseudo-innovative Inegy® is 12 times costlier. In the German context, in which insurance coverage is close to 100%, such misleading information wastes important health resources. Why do doctors prescribe such expensive "me-too" drugs? This can be a result of the promotional information given by pharmaceutical representatives to doctors in hospitals and medical practices and at industry-sponsored conferences.

The boundaries between information and promotion are blurred since the aim of this biased information is to increase profit and not to independently inform doctors and patients about the best available therapeutic alternatives. Othmann et al showed that the quality of the "information" given by the drug representatives on the products promoted by them is mostly biased and inadequate. Although information on indications and dosages might be present, that on risks and adverse side-effects is often missing (10). Claudill et al showed that the frequent use of information from pharmaceutical representatives is associated with increased prescribing costs (11).

A survey of 300 physicians in Germany found that 77% were visited by drug representatives at least once a week, and 19% were visited every day. Most of the doctors participating in the survey did not believe that pharmaceutical representatives delivered objective information. Only 6% felt that their prescribing patterns had been influenced by these representatives, while 21% believed that their colleagues had been influenced (12). The situation is similar in the USA, where 61% hold that industry promotions do not influence their own prescribing patterns, but only 16% believe their colleagues are similarly unaffected (13).

This shows that the extent of influence is often not recognised even by the recipient himself/herself. There is evidence that any gifts (even of very small value, such as pens), drug samples, invitations to cultural events, or food exert a significant influence on the prescriber's behaviour (14). Another linked advertising strategy of pharmaceutical representatives is to promote off-label use of registered drugs to increase their use and the company's market share (15). One example is Diane 35® (ethinylestradiol and cyproteronacetat), a drug which is registered in Germany only to treat the rare conditions of androgenisation of women and major acne, but which has the profitable "side-effect" of contraception.

Drug samples and consequently, drug advertisements, need to be analysed in the light of this biased information. As Adair and Holmgren showed in a randomised trial, doctors without access to drug samples chose unadvertised drugs significantly fewer times than physicians with access to samples. Therefore, it can be concluded that access to drug samples influences prescribing patterns and needs to be interpreted as an instrument of corruption (15).

In contrast to Germany, DTCA of over-the-counter (OTC) drugs in India is strictly regulated and forbidden, with a few exceptions, under the Drugs and Cosmetics Act of 1940 and the Drugs and Magic Remedies Advertisement Act of 1954 (16,17). The Indian pharmaceutical industry is lobbying for a relaxation in the ban on advertising (18, 19). The industry claims that DTCA of OTC drugs creates greater awareness among patients; however, the boundaries between health information and advertisement are often blurred. It has been proven that DTCA of prescription drugs in the USA and New Zealand (where it is legal) results in a change in prescribing patterns. Therefore, the pharmaceutical industry lobby is seeking a relaxation of the ban on the advertisement of prescription drugs in Europe too. However, the last attempt to legalise DTCA of prescription drugs in the European Union failed. If DTCA of prescription drugs were to become legal in Germany and other European countries, lobbying for such a relaxation in countries such as India could follow. The result would be higher costs for the consumer or tax-payer, as the WHO warns (20).

*Recommendations*

1. Pharmaceutical representatives should be banned in medical practices treating patients covered by the public health insurances in Germany. As 87.5% of all patients in the country are members of one of the 134 public health insurances, this measure would probably have a large impact on independent health information.
2. The ban on DTCA of OTC drugs in India should be maintained and all exceptions should be removed. Such a ban needs to be seen as a model for Germany and other western countries.
3. The ban on DTCA of prescription drugs needs to be maintained.
4. There is a need to regulate the advertisement to professionals as well.

## "*Anwendungsbeobachtungen*" – post-marketing surveys

Post-marketing surveillance consists of prospective observational studies meant to systematically collect knowledge in a standardised way about the safety, effectiveness, benefits, and adverse side-effects of newly registered drugs. However, Edwin Gale shows that in reality, most post-marketing surveys hardly ever generate valid scientific evidence; instead, their main objective is to increase profit. The most common strategy used is to persuade prescribers to switch to a new (more expensive) drug from a less expensive but equally effective treatment (21). Therefore, these post-marketing strategies have an adverse impact on health expenditure, posing a problem both for tax-payers in countries such as Germany and those making out-of-pocket payments in countries such as India.

A common type of post-marketing surveys in Germany are "*Anwendungsbeobachtungen*". They are regulated under Section 67(6) of the German Medicinal Products Act (*Arzneimittelgesetz*). Although in theory, independent "*Anwendungsbeobachtungen*" could be an important surveillance instrument for detecting the rare side-effects of newly registered drugs, in reality, due to a poor study design, company-run post-marketing surveys are mostly a tool to increase the market share of an often expensive new drug. Dietrich found that while the average price of drug therapy in Germany is €40, the average price of drugs in an "*Anwendungsbeobachtung*" is €370 (22). How does it work? Pharmaceutical representatives offer doctors a form with questions about the safety, effectiveness, benefits, and side-effects of the drug. For each form filled, the doctor receives €80–400. In reality, the pharmaceutical representative will hardly ever check whether the drug was actually given to the patient. The idea is to create awareness of new and expensive drugs and therefore, change prescribing patterns.

*Recommendation*

The scientific need for independent post-marketing surveillance can be fulfilled only by better regulations for these types of studies.

## Continuing medical education programmes: he who pays the piper calls the tune

There is an ongoing shift from voluntary to mandatory continuing medical education (CME) in Europe (more than 75% of all European countries had a mandatory CME system by 2013). In October 1999, the European Union of Medical Specialists (UEMS) set up the European Accreditation Council for Continuing Medical Education (EACCME®), which had strong links with the USA and Canada (23). However, the ability of CME to provide valid scientific knowledge is called into question by the fact that CME programmes are often run or sponsored by industry. In the context of Germany, it has been found that CME programmes do not independently inform doctors about the best therapeutic alternatives available. Therefore, CME is often an agent of corruption at the institutional level.

In Germany, doctors treating patients who are covered by public insurance are required to collect "CME points" to prove continuing education. The medical associations ("*Ärztekammern*") decide how many points are accredited for which educational programme. In spite of this, two-thirds of these CME programmes are either run by pharmaceutical companies or at least sponsored by them (24,25). Therefore, in the majority of cases, companies select market-oriented themes centred around profit and speakers with a similar orientation. The speeches are often written by those belonging to the industry and extraordinarily high honorariums are paid to the speakers hand-picked by them. The doctors are invited to four-star hotels for an evening or even several days, and are treated to four-course meals, excellent drinks, and cultural events in a cosy atmosphere. This makes the mandatory CME programmes comfortable. While these practices are ethically illegitimate, according to German law, they are legal.

By sponsoring or supporting CME programmes, pharmaceutical companies aim to increase profit by changing therapies and influencing prescribing patterns. As the boundaries between information and promotion are intentionally blurred, all information disseminated in CME programmes needs to be considered biased. Contrary to this analysis, the general assessment of the doctors is that these medical conferences, where the medical chambers accredit CME points, are of independent scientific value. This goes to show that the attendees of the conferences are unaware of the extent of influence of the pharmaceutical companies. As Wazana has shown in a meta-analysis, attending presentations organised by pharmaceutical representatives and sponsored CME programmes, and accepting funding for travel/lodging are associated with an increase in the rate of prescription of the sponsor's medication. This shifts the pattern of prescribing towards non-rational prescribing (26).

To provide attending doctors with more than travel costs and conference fees is prohibited under Section 32 of the German Medical Association's Professional Code of Conduct (27). However, it is done quite regularly. Only in the medical association in the federal state of Niedersachen is it illegal to provide travel costs and fees. MEZIS, the "no free lunch" initiative

of doctors, has advocated changes in the professional code of conduct everywhere in Germany to match the stricter rules of Niedersachsen.

In response to the demands for change, the pharmaceutical industry in Germany, as well as in India, have imposed upon themselves a voluntary commitment that is not legally binding (28,29). While they promise transparency in the sponsoring of conferences, not holding conferences in very expensive places and making sure that promotional gifts are "modest in value", the reality is often different. While holding a medical conference on the most expensive island, Sylt, is expressly prohibited in the German self-commitment, a palliative care conference sponsored by Grünenthal, Jansen, Mundipharma et al was held from April 13–16, 2013 in the Congress Centrum, Sylt, and doctors who attended the conference were accredited 30 CME points by the Medical Association (30).

*Recommendation*

Instead of voluntary commitments, legally binding rules need to be framed. These should prohibit the practice of accreditation of CME points for continuing education programmes which are either run or sponsored by pharmaceutical companies, since these conferences need to be classified as biased or as an advertisement.

## Advertorials and other hidden advertisements

In Germany, lay advertisement for non-prescription drugs is legal, while for prescription drugs, it is banned. However, there are various ways in which open or hidden advertisements can reach patients. To cite one example, illegal advertisements for prescription drugs were found in several gay magazines. The goal is to manipulate patients so that they ask their doctors to prescribe controversial and pseudo-innovative drugs.

- An advertorial is a mixture of an article and an advertisement in a lay magazine about diseases such as asthma, where "experts" mention only one medicine. In an advertorial in a German lay magazine (*Bunte*), Symbicort® (budesondid + formetorol) is mentioned as the only therapy for asthma and Dr Hartmut Timmermann (who works for Astra Zeneca, the producer of Symbicort ®) is cited as the only expert (31).
- Fear-mongering campaigns about the seriousness of diseases and (non-)diseases, such as Allan-Herndon-Dudley syndrome (AHDS), erectile dysfunction and heavy menstrual bleeding (HMB), are launched with the clear intention of instilling fear among the population and increasing the prescription of certain drugs. In the eyes of the industry, this is a very successful tactic. A good example of this is the video by Jenapharm that aims to create an awareness of the non-disease condition, HMB. At the end of the video, the patients are asked to go and see a doctor to get information about treatment (32).
- Between 2006 and 2011, there was an increase of 42% in the diagnosis of AHDS in Germany. In 2011 alone, 750,000 children, teenagers and adults were newly diagnosed with AHDS. Seven per cent of all 11–year-old boys and 2% of all 11-year-old girls were prescribed the controversial drug, methylphenidate (Ritalin®)(33), 100 tablets (20 mg) of which cost € 89.
- The homepage www.adhs-information.de, which is run by Novartis, the producer of Ritalin®, does not offer information but advertises the drug subtly. The information flyer for parents guides them to the drug. The link to self-help groups guides them only to industry-sponsored support groups.
- The domain www.selbsthilfe.de belongs directly to the German pharmaceutical industry (BDI).
- www.belara.com, which is run by the pharmaceutical company, Gedeon Richter Pharma GmbH, praises the contraceptive pill Belara® (ethinylestradiol and chlormadinonacetate) for its additional qualities of endowing the patient with beautiful hair and skin.
- In Germany, nurses or doctors in medical practices use software to write a prescription, which goes to the pharmacist, who dispenses the medicine. Due to the use of sponsored software in medical practices, the prescription of the companies' brands is preferred over that of the best evidence-based alternative. Software that is not programmatically biased by the pharmaceutical industry is hard to find.

The combination of industry-run or industry-sponsored homepages, self-help groups, biased software, fear-mongering campaigns, or advertorials forms the bedrock of corruption in Germany. Instead of evidence-based medicine, pharmaceutical promotion guides clinical practice.

The situation can be generalised to the whole western and non-western world. Similar instances are seen in India, too, as illustrated by the following two examples.

- The page www.glucobay.com is linked to the Indian Bayer page. It contains scientifically unproven advertising statements for doctors, such as, "Glucobay® delays the progression of diabetes and provides additional cardiovascular benefits." The link to the Indian web page cleverly evades the ban on advertising since one has to state that one is a professional to see the advertisement.
- Bayer subtly engaged in product placement on its website relating to the World Contraception Day held in India in 2010. The brand ambassadors introduced on the start page were called Claire and Diana, after Bayer's contraceptive pills (Diane35®, Qlaira®).

*Recommendation*

Hidden advertisements must be regulated and legally binding rules framed. As advertisements on the Internet, in particular, are difficult to control on a national level, there is a need for global control structures.

## Treatment guidelines

As Smulders and Thiys conclude in the Dutch Health Care Inspectorate report on the influence of pharmaceutical

companies on the development process of clinical treatment guidelines, virtually all opinion leaders are financially supported by pharmaceutical companies (34). This situation of institutional corruption can be generalised to most, if not all, western countries using treatment guidelines.

As the example of dronedarone illustrates, treatment guidelines are subject to the influence of corporate interest. Dronedarone (Multaq®) was approved in 2009. As early as 2010, dronedarone was included as the first-line treatment for atrial fibrillation (AF) in the guidelines of the European Society of Cardiology (ESC). The speed with which dronedarone was recommended may suggest pressure from the pharmaceutical industry. Shortly after the publication of the ESC guidelines in September 2010, several cases of severe liver injury were reported. In addition, an important trial (PALLAS) was terminated prematurely due to an increase in cardiovascular events among patients with permanent AF (35). Therefore, the guidelines were revised in 2011 and the European Medical Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) recommended restrictions on the use of dronedarone. The CHMP recommended that dronedarone should no longer be used for patients who continue to have AF (36). In Germany, too, the indications for the use of the drug were limited. However, despite the severe side-effects and the availability of better alternatives, dronedarone was not withdrawn from the market (37).

*Recommendations*

There needs to be transparency with respect to all conflicts of interest so as to reduce influence on guidelines. This entails the following:

- There should be transparency regarding all funding connections between the members of the guidelines committee and the pharmaceutical companies.
- Pharmaceutical companies should not have the opportunity to comment on draft versions of a guideline.

## Conclusions

This brew of corruption leads to a situation in which the pharmaceutical industry and doctors profit, while the insurance policy holders pay escalating medical bills. In countries such as Germany, this means that everyone pays for the corruption. It is necessary to bring about changes in practice and policy to develop possible common strategies against global corruptive behaviour. The following measures would go a long way towards improving the situation.

*Transparency*

An important requirement for changing behaviours is transparency. A law is needed to force drug companies to openly declare the fees and honorariums paid to doctors for educational events, etc, as is the case in parts of the USA, where this aim is achieved by the Physician Payment Sunshine Act (38). Other countries, including Germany and India, should also enact such a law.

*Need-driven instead of profit-driven R&D*

Why do doctors trust the biased promotional information of drug companies supplied by pharmaceutical representatives or provided at conferences sponsored by the industry? Pharmaceutical companies pretend to be a part of the health system and claim that their aim is to develop new medicines in the interest of patients, as illustrated by Bayer's advertisement, "Science for a better life" (39). However, the fact is that only 10% of the 1556 new chemical entities (2800 new drugs) which entered the global market between 1984 and 2004 could be classified as being of therapeutic value, and only 1% were for neglected diseases, including malaria and tuberculosis (40). The rest were pseudo-innvovations, lifestyle products or marginal innovations. Ninety per cent of the costs for developing and conducting research for the cancer drug, imatinib (Gleevec® or Glivec®), was met by public money, while the share of Novartis was at most $38–96 million (41). In contrast to this minimal share, the global profit of Novartis had reached $4.675 billion by 2012 (42). In April 2013, the Indian Supreme Court denied a patent to this drug under Section 3d of the Indian patent law (43), but a patent has been granted in most countries, including Germany. Due to the monopolistic situation, there has been a dramatic price increase: in Germany, Glivec® is available for €3407.76 per patient per month (ppm), in India, Novartis charges $2200 ppm, while the generic version is available for $170 ppm. Thus, the chief interest of pharmaceutical companies is to develop such expensive, profitable, marginal, and often pseudo-innovative medicines, and need-driven research for diseases such as tuberculosis and dengue fever is highly neglected. The obvious conclusion is that the pharmaceutical industry is not a part of the health system; it is as much a part of the system as the car industry, which produces ambulances, or the building industry, which builds hospitals. The pharmaceutical industry, which produces medicines, is only a support industry, like all these industries. It should simply engage in research and development (R&D) activities and produce only those products needed by the medical sector. The medical sector itself has to determine what is actually required, which is quite different from the profit-driven needs of the pharmaceutical industry. Therefore, it is important to pursue a policy that promotes need-driven instead of profit-driven R&D.

*Independent information*

The provision of independent information will lead to evidence-based and corruption-free medicine. A possible solution is to encourage doctors and patients to read informational material that is not produced by the pharmaceutical industry. In Germany, the independent magazines for doctors include *Arznei-telegramm* (http://www.arznei-telegramm.de), and for patients, *Gute Pillen–Schlechte Pillen* [*Good pills–Bad pills*] (http://gutepillen-schlechtepillen. de/). Independent, neutral information will help healthcare providers to practise evidence-based medicine rather than medicine based on pharmaceutical promotion. A step in this direction is the International Society of Drug Bulletins (www.isdbweb.org) a worldwide network of drug bulletins that are independent (editorially and financially)

of funding from the pharmaceutical industry. It was founded in 1986 and is supported by the WHO Regional Office for Europe. It has 55 full members, among them four from Germany and three from India (44). To promote independence, doctors should also be encouraged to say no to pens, calendars, and free lunch and dinner invitations.

## No free lunch

MEZIS, the German "no free lunch" organisation, currently has 510 doctors under its umbrella. Though this number is small, the members are very active. Patients visiting these doctors can be sure to receive evidence-based therapies instead of pseudo-innovative expensive drugs. There is a need to strengthen the "No free lunch" and "Healthy skepticism" organisations in countries where they exist, and to set them up in countries where they are absent. Other western countries and India can look to MEZIS and learn from the German experience. An ethical healthcare system is possible.

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# Professional misconduct or criminal negligence: when does the balance tilt?

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*On September 13, 2013, the Supreme Court absolved Dr Praful Desai, an oncologist, of conviction on the charge of criminal medical negligence in the treatment of one of his patients. This article examines the judgment of the Supreme Court in the light of medical negligence and criminal jurisprudence.*

This case is about the selfless struggle of Mr Singhi, a man who spent more than 25 years seeking justice for his wife, on whom gross medical negligence was committed. The case concerned the liability of a medical practitioner in the matter of an alleged failure to carry out his duty to care for a woman in an advanced stage of cancer, and his failure to perform a surgery that he had advised, even though he knew of the complications of the case.

The facts are that Ms Leela Singhi had been suffering from cancer for several years and doctors in the USA had declared that she could not benefit from surgical treatment. Yet she was advised an "exploratory laparotomy" by Dr PB Desai, under whose care she was admitted into the Bombay Hospital. The surgery was performed on December 22, 1987, by a junior doctor of Dr Desai, who called upon Dr Desai during the operation and informed him that there was profuse oozing of ascitic fluids and plastering of intestines. Dr Desai did not examine her or even enter the operation theatre and simply asked his junior to close the abdomen as the operation could not be performed. The patient alleged that Dr Desai did not perform it himself, delegating it to his junior, and also failed in his duty to provide her with postoperative care. In his defence, Dr Desai contended that Mrs Singhi was not his patient and that only his opinion had been sought on her medical condition. As a result of the surgery, which was alleged to have been wrongly advised, the patient's health deteriorated and she developed intestinal fistula that never healed. This only added to her pain and suffering till the time she expired, on February 26, 1989.

Three cases were filed against Dr Desai. These were (i) a case before the Medical Council of India, (ii) a suit for breach of contract and damages for tortious medical negligence, and (iii) a case of criminal negligence. It was alleged that the doctor's acts of omission and commission constituted not only professional misconduct, but also criminal negligence, punishable under Section 338 of the Indian Penal Code (IPC). Since the surgery was performed by the junior doctor, charges of abetment were also brought against Dr Desai in the criminal case.

## Professional misconduct – MMC

On January 13, 1991, the Maharashtra Medical Council (MMC) found Dr Desai guilty of professional misconduct and issued him a strict warning. Though it did not pass a detailed order, it found Dr Desai guilty of the allegations made against him. He had been charged not only with professional misconduct, ie neglecting his patient, but also cheating, forgery and criminal negligence (1) During the course of the inquiry, the MMC found that the operation theatre register produced by Dr Desai was not filled properly, was filled by only one person (and did not contain the signature of the sister in charge, whereas the photocopy of the register produced by the complainant had all the required details and signatures. Strangely, Bombay Hospital could not locate the original register, the photocopy of which had been produced by the complainant, and claimed that it was missing. However, all these details did not find a place in the order of the MMC, which merely issued a strict warning to Dr Desai. Dr Desai did not challenge the warning.

## Breach of contract and negligence – Bombay High Court

On September 2, 2011, the Bombay High Court gave a reasoned and detailed order in the civil suit against Dr Desai, awarding