INTERNATIONAL EXPATRIATION AND BUSINESS ETHICS CHALLENGES IN VIETNAM

A cross-case study on French and American clinical trials conducted in a new emerging country

Abstract:

Using a cross-case study approach, we want to understand the cultural adjustment towards business ethics between French and American expatriates top managers in the pharmaceutical sector. Ethical rules to protect participants in drug trials in an emerging country (Vietnam) are one of our concerns. At the same time, we try to analyze everyday practices in clinical trials integrating knowledge about recruitment process and current habits in the business model. We had recently the opportunity to collect and analyze primary data using semi-structured, in-depth and group interviews of top American and French managers in Vietnam. The French demonstrate higher degree of adaptability than the American expatriate top managers in general adjustment but not in work adjustment and fast business model results.

Key words:

International Business Ethics, Drug trials, Ethical dilemmas, cultural adjustment, Emerging country, Vietnam.

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In 2014, it was estimated that of the 120,000 international clinical trials conducted globally, more than 40% took place in poor countries such as Vietnam (Nguyen, 2013). However, only few of these trials have focused on diseases that preferentially affect the poor or the countries where the trials take place even if Vietnam is one of the fastest growing pharmaceutical markets in Asia. In 2012, Vietnam's drug market was worth almost $3 billion – about one-third the size of the Indian market. It is expected to grow at a rate of more than 20 percent through 2017. Vietnam's efforts to attract foreign investment have led the ruling party to seek to improve the business climate for foreign investors. This involves attempts to combat corruption which is rampant throughout the country and permeates the activities of the many state companies that still dominate the economy's strategic sectors. The lack of implementation and weak enforcement mean corruption continues to be cited as one of the most problematic factors for doing business in the country.

For the pharmaceutical labs in Vietnam, the attractions are the lower costs on doing trials and developing activities to enter south East Asian markets. The main incentive for Vietnam is a promise of advanced medical science and an immediate access to the latest medications. However, the process of putting in place a legal and ethical framework to protect participants is not going at the same pace in Vietnam than in other countries (Nguyen, 2013). One of the problem could be how first to implement guidelines between the people and the international pharmaceutical labs. It is also the responsibility of French and American expatriates managers located there with specific attitudes towards local employees and patients to have an effect on a general cultural adjustment and then to improve job satisfaction and work performance. Researchers on expatriate adjustment lead to the conclusion that cultures more different or distant from the expatriate's culture of origin present

bigger challenges and result in greater adjustment difficulties (Black, 1991; Tung, 1998; Stahl & Cerdin, 2004 ; Zhou & Qin, 2009). We try to analyze cultural adjustment and ethics practices from different perspectives dealing with business model orientation and political focus in the pharmaceutical labs. We had recently the opportunity to collect primary data using semi-structured, in-depth and group interviews of American and French managers. In the following sections, we describe our theoretical framework, the research setting and the scope of our qualitative methodology. Then, we discuss previous explanations of ethical dilemmas in the Vietnamese context.

1 - Theoretical framework and research methods

Ethical and cultural considerations are important in our work. It is necessary to consider the consequences of international business ethics within a theoretical framework. The reason on conducting trials in Vietnam could not be only because they have fewer regulations. Anticipatory and in-country variables related to work, interaction, and general repatriation adjustment have to be examined with a focus on different expatriates. Cultural distance can hinder general adjustment. We selected a qualitative methodology that could go beyond the surface of the management rhetoric and we will explore different theories: responsibility, human rights and cultural aspects.

1-1 Ethical business and responsibility

In international business, the cultural context may well affect the shared understanding of what *ethical* actually means. Hellriegel (2012) notes that business ethics involves how a company integrates core values such as honesty, trust, respect and fairness into its policies, practices, and decision making. Business ethics are the standards used to judge the rightness or wrongness of a business' relations to others (Smith, 2007). Rossouw (2004) points out that business ethics is about identifying and implementing standards of conduct that will ensure that, at a minimal level, business

does not detrimentally affect the interests of its stakeholders. Ethical responsibility involves more than leading a decent, honest, truthful life, as important as such lives certainly remain. And it involves *"something much more than making wise choices when such choices suddenly, unexpectedly present themselves. Our moral obligations must ... include a willingness to engage others in the difficult work of defining what the crucial choices are that confront management and society and how intelligently to confront them"* (Sherrer and Palazzo, 2007, 1105). Ethical responsibility means taking account of the organisation's impact socially, environmentally, economically and in terms of human rights. Health and human rights investigations raise complex ethical and theoretical challenges. Key questions have emerged about the roles of human rights in the pharmaceutical labs business in an international basis. Human rights may follow ethical codes and well-being norms. Members of local employees and as well international managers may exert their influence to limit the scope of or impede investigations into human rights abuses.

Any change in a person's life entails a requirement to adjust. Adjustment is the outcome of a learning process that enables the individual to be more effective and content in the new circumstances. We adopt the term adjustment rather than adaptation, assimilation, or acculturation to describe what is happening to top management expatriates (Harrison, Shaffer, & Bhaskar-Shrinivas, 2004).

Black, Mendenhall and Oddou put forth a model of the dimensions and determinants of adjustment to international assignments (Black et al., 1991). According to the model, it is proposed that cultural novelty will be negatively associated with degree of international adjustment, especially with that of interaction and general adjustment. Researchers could show the two dimensions of adjustment: general and work adjustment. Others added the adjustment to interactions with host nationals which separated interactions with host nationals from other aspects of the general environment such as transportation and climate. As early as 1991, Black, Mendenhall and Oddou proposed a comprehensive model of determinants of adjustment to international assignments (Black et al.,

1991). This model was subsequently expanded and tested by Shaffer, Harrison and Gilley who additionally examined two individual factors and three positional factors as moderators of adjustment determinants (Shaffer et al., 1999, pp.291-317). The model of determinants of expatriate adjustment proposed by Mendenhall and Oddou (1991) and expanded by Shaffer, Harrison and Gilley (1999) can be summarized as follows: Individual Factors (achievement and social self-efficacy, relational and perceptual skills, previous assignments and language fluency), Job Factors (role clarity, role discretion, role conflict and role novelty), Organizational Factors (organizational cultural novelty, social support and logistical support), Positional Factors (hierarchical level, functional area and assignment vector), Culture novelty and family Factors (Culture novelty refers to the perceived distance between host and parent country cultures, and has been found to hinder non-work adjustment). Although this model (Black) has advanced our understanding considerably, several authors have pointed out shortcomings (Harrison et al., 2004). One shortcoming is that it measures adjustment on a one-dimensional scale from unadjusted to adjusted. In fact, however, adjustment has multiple dimensions of behaviors, cognitions, and emotions as well as a personal component and one shared with family, work colleagues, and other contacts. Subjectively, expatriates may regard themselves as adjusted if they experienced a satisfactory level of effectiveness in their new environment (behavior) and if they are sufficiently clear about the various aspects of the new culture (cognitions) and neither eel over-stressed nor experience a preponderance of negative emotions especially when they face non ethics practices. The levels of behavioral effectiveness, knowledge of the host culture, and degree of emotional well-being expected naturally vary among observers and among expatriates themselves. The expatriate may have to assimilate the new culture, integrate home and host cultures, or exist in the environmental bubble of an expatriate community (Berry, 1988).

1.2 Research setting and qualitative data

Owing to the exploratory nature of our study on business ethics, we relied on qualitative cases research (Yin, 1994) and planned to be oriented on a quantitative research as far as we get the authorizations from the Vietnamese authorities. We selected a qualitative methodology that could go beyond the surface of the management rhetoric (Alvesson & Sandberg, 2011). We focus on "standard" expatriates and not virtual or off-shore expatriates to prevent the discussion from becoming too diffuse. In order to do that, we first constructed an initial diagnosis of four major pharmaceutical labs in Vietnam (established for more than five years), based on interviews with twenty five actual top expatriate managers, either individually or in small groups during our intercultural management seminar in 2012, 2013 and 2014. This diagnosis generated a broad description of the ethics management and expatriate assignment based on semi-structured interviews and observations in Vietnam. Then, we identified and interviewed twenty top level managers and local middle managers to gain a better understanding of the above-mentioned issues in ethics and cultural adjustment. For our research purposes, the cases study method proved to be appropriate for exploring the characteristics of business ethics and cultural adjustment. We used a field study to understand the multi-dimensionality of business ethics and cultural adjustment, the relationships between top managers and middle managers, and its antecedents and outcomes. We conducted the study in Vietnam in two locations (Hanoi and Ho Chi Minh City) that had formally implemented clinical trials and marketing actions. Verbatim reports, age ranges, management levels, organizational tenure, way of thinking health, ethics approach and cultural adjustment have been essential in defining our sample. We obtained interviews with some difficulty in overbooked agendas and took into account the need to find fully comprehensible English-speakers. We also searched articles, exclusive in-depth interview (International specialists), public databases and company websites for additional information to collaborate, triangulate and validate interviews results. For all interviews, we tried to review our notes for accuracy immediately after the interviews and before transcription. Trustworthiness in interpretative research was ensured by using four criteria:

credibility, transferability, dependability and confirmability. We had the opportunity to collect primary data using semi-structured, in-depth and group interviews of top managers and middle managers. The results of the diagnosis generated a broad description of the ethics management and cultural differences during expatriate assignments. The expatriate assignment is an expatriate's opportunity to build career capital and a company's opportunity to generate social and intellectual capital. The extent of the capital gains will depend considerably on the expatriate's adjustment during the assignment. Based on the analysis of 45 interviewees of top level managers and local middle managers, we defined three main hypotheses on business ethics and cultural adjustment dimensions. *(Hypothesis 1) The American expatriate top managers in Vietnam perceive larger cultural distance between Vietnam and their home country than the French expatriate top managers do, especially in terms of socio-cultural adjustment and business ethics conditions.*

(Hypothesis 2) The French expatriate top managers working in Vietnam demonstrate higher degree of adaptability than the American business expatriates in general adjustment and interaction adjustment, but not in fast business model results.

(Hypothesis 3) French expatriates take a prolonged period of time to adjust, exhibit poor performance on the short run completing their assignment in a low state of effectiveness.

2 – Cross-cases analysis in the specific context of Vietnam

Most clinical trials are initiates with the objective of establishing the effectiveness of new drugs that are being developed. We also consider clinical trials drug combinations or other ways of therapy such as surgery, and some others are designed to test medicines such as vaccines. The clinical trials are extremely carefully regulated and they are also the most effective way to establish the new treatments that can be more beneficial for human health. Though testing drugs in Vietnam is clearly controversial, there are additional ethical dilemmas that arise when conducting research on

treatments to be used locally. One of the main questions is whether studies should use the "best" available drugs or treatments instead of the most practical and available ones. It is important to realize that conducting relevant research in Vietnam might not imply the use of the best and most effective treatments available in Western countries. Realistically, such treatments will not be readily available or will be too expensive for the majority of people in developing countries. *"The testing of less effective treatments for use in poor countries is justly controversial and deeply troublesome. At the same time, the failure to do so would be even more problematic, essentially barring doctors in poor countries from conducting locally relevant research that might save or improve their patients' lives"* (Wagstaff, 2007, 85). Often, their study participants are often poor and may not understand that they are taking part in a study and instead may believe that they are receiving proper or preferential treatment for a condition.

Clinical trials must be conducted under conditions of respect for fundamental human rights and ethical principles affecting biomedical research involving human subjects. Considering these principles we kindly ask American and European top pharmaceutical managers to describe their point of view and their way of conducting clinical trials in Vietnam.

2-1 The American point of view on clinical trials: High level of business model effectiveness in knowing how and knowing-why!

Clinical trials on issues relevant to the U.S. have been conducted in Vietnam in the pharmaceutical firms since 2008. The patient enrollment lasts a maximum of years, usually between 2 and 5. We had the opportunity to get interviewees within two American plants focused on technologies that can identify promising vaccine candidates and refine them before they enter costly and time-consuming clinical trials. They also invest in research to better understand the health factors that affect susceptibility to infectious diseases and vaccine efficacy, such as malnutrition and co-infections. Furthermore, we seek more effective models of collaboration with major vaccine manufacturers to better identify and

pursue mutually beneficial opportunities. These two American subsidiaries in Vietnam work to speed the identification of the best drug candidates, and, as they do with vaccine discovery, they look for opportunities to collaborate with local pharmaceutical companies because of their unique resources and expertise. They also seek to develop new technologies and approaches to slow the evolution and spread of drug resistance, including alternative formulations and drug-delivery technologies. It is convenient to take into account that following the Biomedical Research Association (California, US), *"It takes an average of 12 years for a drug to travel from the research lab to the patient. In addition, only five in 5,000, or 10%, of the drugs that begin preclinical testing ever make it to human testing. Only one of these five is ever approved for human usage"*. The principle of transparency is pointed with an emphasis on Vietnamese people that must be treated with consideration and respect, without significant differences, with special protection for the disadvantaged. It is necessary to contribute to the benefits and risks of research fairly. The principle of efficiency with non-maleficence agrees with not harmful practices, even if the patient requests it. Maleficence is conducting a clinical trial that will not be scientifically valid, either because the working assumption is not plausible or because the design is not methodologically correct. *"With our clinical trial, data helps to improve patient care. It also goes and helps ensure the important contribution made by people who take part in clinical trials is used to maximum effect in the creation of knowledge and understanding. We are committed to public disclosure of all our clinical research, irrespective of whether the results are positive or negative for our medicines. We believe this is fundamental to the advancement of medical science. It is also the best way to tell patients about scientific findings relating to our medicines".* (Nathan, USA, Expatriate in Vietnam in pharmaceutical firm n°1). From an American point of view, in theory, clinical trials are governed by strict regulation. There are always at least three phases to clinical trials. The first time a new treatment or vaccine is tested in humans, it will usually be given to a small group of healthy volunteers. If Phase A is successful, approval will be sought for a trial involving a larger group of people. Phase B trials will usually (but not always) include patients who

have the condition the potential medicine is targeting, and aim to establish: effectiveness in treating the condition, in preventing the condition (if the volunteer does not already have it) and appropriate dosing levels. If the results from Phase B are encouraging, we will seek to start a Phase C trial. This will be a much larger trial, often involving hundreds, possibly thousands of participants coming from a range of different countries. In practices, "*the main reason we do it in Vietnam and not in India or in South Africa is firstly the lower costs and then the availability of "treatment-open minded" patients, who accept authority without so many questions… Regarding local authorities, the main incentive for Vietnam is the promise of advanced medical science and access to the latest medications"* (Brian, American expatriate top manager in a pharmaceutical firm n°1). It is important as well to say that cultural factors in Vietnam seems to create a barrier to complying with the substantive ethical standard of informed consent with how voluntary participation can be ensured in settings in which community leaders may exert pressure on the entire community to enroll in a proposed clinical trial. This verbatim provides a different viewpoint of the close link between economic status and clinical trials from the theoretical point of view and make relevant two more aspects: cost and marketing. *"The cost of development of a new drug has been estimated by the US pharmaceutical firm at 350 million dollars. In addition to this initial cost, once this budget is approved, the marketing and advertising involved in the mentioned development are very costly activities that will rise the overall price of the operations. Therefore, those drugs that have reached the marketing authorization have to raise funds for the development of many other drugs which have not done so. It is estimated within the industry that the true cost of launching a new drug on the market, including failures, exceeds 650 million dollars"* (Sheila, American expatriate top manager in a pharmaceutical firm °2). So it is very important from an American point of view not only to ensure that those placed on the Vietnamese market comply with its sales expectations, but also to ensure that the pharmaceutical company's clinical programs can provide with high quality information to support regulatory arrangements, and also information to support business objectives before and after

launch of the drug on the market. The challenge for clinical and marketing teams is, therefore, to ensure the best interaction as quickly and effectively as possible once the product has entered into clinical development. The objective of almost all clinical studies is to ensure a quick registration through a process of rational development, in order to be able to compensate the big cost of the clinical research. *"The US business strategy in Vietnam can become an operational plan through the profile of a particular product in which the clinical and marketing departments have agreed to collaborate. The marketing department can provide valuable information to determine what information is needed for a particular study and why, and to finance the labeling and advertising. After that, the clinical and regulatory departments may indicate how and when it should be done"* (Brian, American expatriate top manager in a pharmaceutical firm n°1). The clinical team creates the clinical trials and once the outline of the study is decided, they will define the treatment, population and the primary and secondary objectives. The marketing department can advise the most suitable option to compare with the Vietnamese specific basis, advising on competition assays that could hinder the recruitment and provide a global context for research. *"It is the responsibility of a company to provide an extensive training to the Pharmaceutical Representatives about products in promotional phase. The roles and responsibilities of Pharmaceutical Representatives should be clearly defined in order to enable Health Care Professionals to get the best clinical-decision-making. However, it is popularly well known that little is clear about Pharmaceutical Representatives attitudes regarding their roles as educators or marketers from an American point of view"* (Brian, American expatriate top manager in a pharmaceutical firm n°1). *"Vietnamese people at work are disorganized and not disciplined at all. We have to be more focused on controlling the whole process of clinical trials in order to boost the work performance. Otherwise, if we let local people doing the job we will have a low effectiveness. We need to work fast and oriented to be the first ones to enter the market"*(Steve, American expatriate top manager in a pharmaceutical firm n°2). A kind of unadjusted expatriates regarding American point of view may focus more on marketing strategy than

sociocultural aspects with predispositions on a specific business model. Tis specific business model on three phases let American top managers more efficient but with an intentional, interpretive, and memory orientation that can distort their general adjustment related to knowing-how and knowing-why but non so oriented on people at work and delegation.

2-2 The French point of view: knowing whom, regulations and ethical values

The pharmaceutical sector in the European Union is currently governed by several specific directives in the matter of clinical trials and many moral duties rather than marketing ones. They reflect the requirements of monitoring, verification, retention and data files of clinical trials even abroad in Vietnam. In an ethically sound consent process, a French member of the research team provides information to the potential participant, determines that the individual understands the information provided, and ensures that the individual voluntarily agrees to participate. Although consent traditionally has been documented by the signing of a consent form, other methods of documentation often are acceptable or even preferable, such as oral consent with a witness signature. In many settings in Vietnam, it is also required that the person obtaining the consent sign the consent form or other related documents and that a witness (or person designated by the participant) attests to the process. It is always essential to make a distinction between the consent *document* and the consent process and to not allow the document itself to constitute the process. In Vietnamese cultural context, questions also arise regarding the appropriateness of requiring information to be disclosed about the use of a placebo in one arm of a clinical trial, the randomization of participants, and any uncertainty that may exist regarding the efficacy of an experimental intervention. From a French point of view investigators sometimes struggled with these barriers, responding in two ways. For example, in one case, investigators who believed that it would be impossible to obtain valid informed consent for a randomized trial abandoned the use of randomization in their research. However, in another case, investigators used placebos, even though they did not believe that the research participants

understood the implications of doing so. Despite these barriers, cultural differences do not provide adequate justification for foregoing the requirement to disclose key elements of the nature of the clinical trial, such as the use of a placebo or the randomization of participants into different trial arms in Vietnam. The French Clinical Research Unit where we get the interviewees was established in 2006 and is hosted by the National Hospital of Tropical Diseases. This French firm will expand its current 4% market stake in Vietnam. Between now and 2015, the French drug major will invest US$75m in a production plant. The subsidiary, which will be operative by 2015, is designed to meet the raising demand for pharmaceuticals in fast-growing Asian populations such as China, Indonesia and Vietnam. It will have an initial capacity of 90 million units per year, which may be later extended to 150 million units, according to the company. Theoretically from a European point of view, a clinical trial by this institute and the French firm has three characteristics: A pilot study carried out in humans, assigned to one of the intervention groups, a prospective, planned and then carried out, following the evolution of research subjects over time. The experimental nature of the clinical trial requires the researcher to consider three dimensions: methodological or scientific, ethical and regulatory rules because it is necessary to protect the integrity of patients and their rights and the reliability of the data. The principle of beneficence is pointed according to which Vietnamese people should be treated, protecting them from harm and ensuring their welfare, which means no harm maximizing the benefits and minimizing the risks. As well, the principle of autonomy is firstly argued by European top pharmaceutical managers to treat Vietnamese people as autonomous beings and protecting those with diminished autonomy. In application of this principle consent from potential study participants before inclusion must be obtained. The autonomy is decreased in case of ignorance, immaturity or mental disability. *"The participation of a human being in a clinical trial generates a potential situation of vulnerability in which their rights should be clearly protected. When a local doctor participates as an investigator in a clinical trial, he acts simultaneously as a physician and scientist, a situation that can lead to an ethical dilemma. As a physician, you should*

strictly ensure individual welfare of his patient, while as a scientist; you should try to improve the chances of benefit to society thinking of the common good. Therefore it is necessary that any medical research that people behave study meets ethical requirements a series of clearly established in the Declaration of Helsinki (Claire, French expatriate Top manager in a pharmaceutical firm n°3). Whether a clinical trial from a French point of view with healthy volunteers or patients, it is important to consider the ethical aspects of the study, therefore, at present, all clinical trial protocol must be evaluated by an independent body responsible for the review of the ethical and methodological: The Clinical Research Ethics Committee. The clinical trials made by French firms which objective is to evaluate the efficacy and effectiveness of an experimental drug, treatment, device or intervention may be integrated in one of the following four phases (with one more than American) : Phase D studies are carried out after the intervention or the experimental drug has been marketed, or once they have got the marketing authorization. These studies are always designed to monitor effectiveness of the approved drug or intervention while used by general population and to collect information about any associated adverse events that might arise during the course of the treatment. Phase D post-authorization study is a clinical trial, quasi-experimental study, or observational study with the objective of gathering more specific information about a particular drug, biological product, device or procedure that has already got the marketing authorization. Post-approval research in Phase IV post-authorization studies is usually carried out to better understand the used product in real-world situations, with the objective of obtaining evidences for higher reimbursement or submission for expanded labeling, meaning that the product could be used to treat a different or multiple diseases. In the everyday practices, European firms argue that regulations and ethical considerations are more important than marketing. *"Typically, the information provided by the industry has to reference clinical trials and marketing authorization where we can find the presented data. We must make a critical reading and make sure that the presented information comes from independent and objective sources. Furthermore, we must wonder: Is relevant to the*

purpose of the study in Vietnam? Does the local Vietnamese study population reflect the normal clinical practice? Has been compared to the best possible alternative and right dose? Are we doing clinical trial or more and more business? Do we have a non -neocolonialist behavior?" (Patrick, French expatriate Top manager in a pharmaceutical firm n°4). We could point out that following this verbatim, health expenditure and business behaviors are very high in Vietnam. We have seen that the product is sold in Hanoi where they recruit thousands of patients that take a more expensive drug, however other cheaper drugs are sold in the same market and with the same benefits all over the country. Unfortunately, if the drug has got the marketing authorization, there is a reason to keep doing research about the safety of the drug, and the existence of a study is justifiable to improve the product, it seems difficult to me to stop these kinds of studies. From a French point of view there is no Ethics Committee that could reject the start-up of the study. It involves ethical issues of a different magnitude and directly related to the education of the health care professionals. Maybe an Ethics Committee cannot reject this, but a doctor can always reject to participate in a study that will not bring any benefit to his patients or even to the society. Locally, we have seen some studies about expensive drugs that are the best in their category. In those cases, most of the doctors are willing to participate and contribute. But we have also seen studies where the drug is much more expensive than other similar drugs that bring the same benefit to the patients.

In Vietnam, a process of community education acts as a precursor to the process of obtaining individual consent. A physician provided additional information and sought individual informed consent at the monthly vaccination session. A clinical trial for vaccination was preceded by an intensive publicity campaign involving radio, newspapers, and discussions with local leaders. *"When mothers attended the first child health clinic, they received an information sheet about the clinical trial to take home for discussion with their families. When a mother returned for the first vaccination, the trial worker explained the study again, and, if the mother gave oral consent, the trial worker signed the information sheet"* (Lucas, French top manager in a pharmaceutical firm n°4).

Translation and back translation of a written consent form is one way of ensuring that information is correctly disclosed; however, this may not always be effective. Because the consent form had to be reviewed by the Vietnamese authorities and the European firm, a translation in English was also required. The back translation of a consent form *"does not guarantee that volunteers have really understood the objective of the study, the risks and advantages, and their voluntary participation… The problem may not lie in the idea that an offer to possibly receive medical care is an inducement, but rather in the difficulty of determining when such an offer-admittedly an inducement-becomes undue"* (George, French expatriate top manager in a pharmaceutical firm n°3). French top executive argue that participation in research constitutes an undue inducement for poor people in Vietnam would have to maintain that offering high-quality medical care and treatment that participants would not otherwise receive is unwarranted and inappropriate. However, the provision of medical care or treatment that would not otherwise be available to research participants should not, in principle, be construed as an undue influence to participate. *"The clinical trial in lack access to medical care to participate in research, this does not sufficiently diminish the voluntariness of their decision in a way that would make their consent ethically invalid"* (George, French expatriate top manager in a pharmaceutical firm n°3). *"Vietnamese local workforce is bureaucratic and too much focused on details. At the same time to go against corruption practices, it is better to go slow but far rather than to make business on the short run and then to be boycotted by local authorities. We have a huge responsibility of well-being, not just for say but in the everyday practices. To be a leading pharmaceutical lab for one year is not our priority but to go step by step and to get results on the long run is our main concern"* (Claire, French expatriate top manager in a pharmaceutical firm n°3). That is the main reason why French firms say, even if regulations can be improved, it is important to make more efforts in the ethical education of health care providers, which is of a crucial importance to reach the best health care with more efficiency and efficacy. This way, only those products that are more competitive could resist in the Vietnamese market facing aggressive marketing American

campaign. General adjustment to life not at all in expatriate ghettos seems stronger for French expatriate top managers. The level of behavioral, cognitive, and emotional adjustment feeds back on knowing-whom in terms of the motivation to remain and to be oriented on a long term relationships with local authorities and to go against corruption practices with regulations.

Conclusion

Throughout the last decades we have seen an increase of clinical trials and observational studies in Vietnam conducted by American and French firms to develop new treatments and also to improve its efficacy and effectiveness. However, in some of those activities are visible some characteristics that lead us to believe that there is more marketing in the US point of view than science behind them. The attempts of some US pharmaceutical companies to patent new drugs that are basically a copy of an old developed one in order to avoid the expiration of the patent, and the marketing practices of the commercial teams with Doctors have not contributed to improve the image of the overseas pharmaceutical industry in Vietnam. The clinical research from a French point of view is seen as a complex project and also costly and long businesses, where they need to find the customers. The key implication of clinicians is not sufficient to manage the ethical issues that those studies might involve, and we should also take into consideration that marketing and sales activities play a significant role within an industry that invests billions in the development of new products from an American point of view. From a French point of view it has been pointed out that fundamental principle of research ethics is the requirement that participation be voluntary-that is, *"free of coercion and undue influence"*. However, among the most difficult requirements to ensure is the voluntariness with which participants consent to enroll in a study. It I obvious that the pressure from a local community leader in Vietnam, the power and authority of the medical professionals who serve as investigators, and the fear of loss of health benefits that people would normally expect to receive

may compromise individuals' freedom to refuse to participate in research in Vietnam. The provision of medical care and treatment during a study may constitute an incentive for individuals to enroll in a study, but it should not be construed as a coercive offer that would unduly compromise the voluntariness of participation. Based on the detailed results of this observatory research, the major findings can be summarized in the following: Perception of respondents from the two countries differ most greatly in climate and general socio-cultural adjustment, and then business ethics conditions. They consider marketing and human resources orientation differ most from those in Vietnam, and everyday customs and business ethics come next. Therefore, based on the results from the analysis of cultural distance for the respondents from France and the USA, it is tested that hypothesis one is accurate and true. The hypothesis 1 was: the American expatriate top managers in Vietnam perceive larger cultural distance between Vietnam and their home country than the French expatriate top managers do, especially in terms of socio-cultural adjustment and business ethics conditions. To verify the hypothesis 2 *("The French expatriate top managers working in Vietnam demonstrate higher degree of adaptability than the American business expatriates in general adjustment and interaction adjustment, but not in fast business model results"),* we checked five different variables (work adjustment, role clarity, role conflict, relational and perceptual skills, assignment vector). These five different variables are processed in Alceste textual analysis program in order to make connection whether there is any significant relationship between business model orientation and the five facets of general and interaction adjustments. It can be well observed that all interaction and general adjustment variables are significantly connected to a better process of adaptability for French expatriates top managers rather than American ones. Such a result supports hypothesis two only partly because we have to get a better understanding and test of the French and American Business models. *The hypothesis 3 ("French expatriates take a prolonged period of time to adjust, exhibit poor performance on the short run completing their assignment in a low state of effectiveness") will have to be tested with SPSS* correlation analysis and linear regression analysis that will work out the

correlation between cultural distance, cultural adjustment and long term performance. Based on the first results, it seems that this hypothesis could be partly positively true. We will have to consider a longer period of research to prove it. We also find significant implications for policy makers on a national and international level, as health care development benefits all of us in our society from a French point of view. And also for health care institutions where the ethic cannot be committed to the funding of the new projects, the profitability of a particular investment or the general interest, even if we know that we will sacrifice few people for the safety and health of thousands or even millions of humans. One limitation of the study lies in the classifications of similar or dissimilar cultures relative to the US and French expatriates top managers as the parent country. Since the expatriates are working in large multinational pharmaceutical labs, difference in the national culture may be obscured by the corporate culture to some extent. Ethics is a long process and the pharmaceutical sector requires to give a stop to such practices. This practitioner described how key opinion leaders, that is, health care professionals thought to be especially influential on practice or policy, were hired to become marketers presumably without revealing this intention in Vietnam.

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