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# PHARMACEUTICAL LIABILITY FOR INFORMED CONSENT THE LOGIC OF CHRISTIAN MORALS

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(Received 2 June 2011, revised 8 August 2011)

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## **Abstract**

The article elaborates on the duty of information lying on pharmaceutical producers' shoulders regarding the risks, benefits and ingredients of the pharmaceutical product, in the light of the Christian principles applicable by the courts of law in cases of manufacturers' alleged liability for damages caused to consumers. Second, the study is focused on the 'lifestyle medication' – 'serious medication' dichotomy, as producers' liability for informed consent becomes pre-eminent in the field of 'lifestyle medication': while, in the case of 'serious treatment' drugs, it is the physician that is hold responsible for fully and adequately informing the patient on the risks and benefits associated to the consume of the pharmaceutical product, on the contrary, in the case of 'lifestyle drugs', usually the consumers avoid the contact with a physician when deciding to consume the pharmaceutical product (normally accessed without a medical prescription), thus placing on producers the burden of complete information, through the means of advertising announcements, product label or prospect. 'Lifestyle drugs' are thus distinguishable from 'serious medical drugs' on the basis of their focusing on enhancing or easing socially debilitating maladies, rather than addressing life-threatening diseases. Third, the analysis is centred on the duty of information functions, as moralizing factor, contributing to the eradication of inequalities between professionals and consumers, as contractual parties, from the informational, psychological or financial angle.

*Keywords:* pharmaceuticals, Christian morals, consumers' protection, informed consent, producers' liability

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## **1. Introductory comments**

Producers' duty to clearly inform the consumers on risks, benefits and ingredients of the product and to warn the users about any danger associated with the product does not except pharmaceutical manufacturers. On the contrary, on pharmaceutical producers' shoulders lies a very specific burden of adequately informing the consumers, both by the means of some of the advertising content and the prospect or the label of the product, the moral and professional duties

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thus resulting being sometimes in conflict. On the other hand, the traditional, prosaic clinical encounter between the physician and the patient is evolving in an environment increasingly shaped, involving advanced technologies and pharmaceutical discoveries.

Perhaps no part of professionals' duty to inform was more controversial during the last two decades than the duty to warn associated with pharmaceutical products. While consumers' right to be informed has been firmly established in the text of Article 27 of the Romanian Consumption Code, entered into force since 2007, its valences remain highly unknown, both for legal practitioners and final consumers.

On the other hand, the issue is complicated by the fact that medical drugs and health products keep a unique place in modern society, being distinguishable from all the other consumables by their specific nature of addressing consumers' survival, health management, pain relief or disease cure. Thus pharmaceuticals are surrounded by a rather normal aura of altruistic and utilitarian nature that separate these products from other objects of consumption, due to the vital or at least important characteristics of the needs they are generally meant to satisfy.

Fundamental inequalities between commercial contracts parties, such as the professional manufacturers, vendors or services providers, on one hand and the profane, unadvised consumers of goods and services, on the other hand, inequalities that can be observed from an informational, psychological or financial angle, represent one of the major themes, in the contemporary specialized literature, despite the fact that Consumer Law is still to be developed, in the Romanian legal system, the black or grey zones being largely spread.

Many practical and general aspects of the contemporary relationships between contractual parties are worthy of discussion and investigation also on the side of Theology, especially from the angle of several influences exercised over the years by Christian spirituality over European Consumer Law. Between do's and don'ts in the progressive construction of an uniform jurisprudence on producers' liability for informed consent, the theme of legal rights of information over characteristics and dangers of pharmaceutical products welcomes a modern approach, based especially on the way the exercise of duty to warn is conceived by the legislator as moralizing factor for commercial relationships.

While in traditional Contracts law, buyers are requested to play a vigilant role, accumulating by their own efforts all information needed for consent clarification, recent Consumer law changes the perspective, enhancing disequilibria existing between professional parties and profanes, in terms of information on characteristics of goods for example, or on the manufacturing chain. In fact, none of the traditional legal principles of informed consent are applicable to the case of medical drugs purchase, due to the fact that the consumer is rather forced by the power of things to rely on producers' honesty in terms of precise information on risks and benefits associated to the product, in a context in which the consumer does not witness the manufacturing or the

design process, nor has he or she the specialisation requested to comprehend or manipulate data on specific drug production. Thus consumer's dependence on producer's honest informing is total, though completed by the need for professional advice provided by pharmacists or physicians [1].

Contractual culture has significantly changed over the last two decades. As observable for contemporary European Union's Consumer Law, as well as for the Romanian Consumer Law, provisions protecting the consumer, in one's quality of 'vulnerable party', referring to informed consent rights especially in the field of hyper-dangerous contracts as generators of financial debts, are multiplying, being alimented by the amount of inequalities present between professional and profane parties to commercial contracts, in terms of information, finances or psychological balances of power. Commandments such as the solidarity between contractual parties, the moralization of contractual relations, the transparency rule or the behavioural coherence became more and more stringent [2, 3].

As to the concept of Christian contractual morals, despite its apparent simplicity, it is able to hide multiple meanings. First, one of the fundamental approaches of contractual morals is *intuitional*, being constructed on the edges of an immutable paradox: moral rules concerning commercial contractual relationships are articulated around the 'moral' indisposition experienced by contemporary European societies against cultural extravagances, false expectations and social disappointment. 'Intuitive morality' thus marks the profound post-modern hiatus between 'utility' and 'rightfulness', 'functional' and 'ethical', 'utile truth' and 'veritable truth'.

The second approach to morality of commercial relations is a *historical* one: individual's impulse of living in accordance with his or her *perfectibility*, despite societal discrepancies and dysfunctions. Beyond Kant's idealism, each human being formulates the problem of moral conduct in terms of finality: 'respecting morals', of course, but what is the purpose and, more importantly, which are the means? [4]

From the very beginning, contractual morality – both individual and collective – delivers a set of *prêt à porter* norms of conduct, implying a Moses' separation of waters between profit oriented commercial conduct and expected ethical behaviour. The concept of contractual morality has thus generated a fundamental dichotomy between 'judicial rule' and 'moral rule', corresponding to the classical opposition of 'judicial or proven truth' and 'ethical or substantial truth'. Are the two coincident, distanced or superposed, in contemporary Commercial Law? Traditionally, solving the mentioned dilemma preoccupied notorious authors, whose rhetoric discourse on Christian morality of business remains essential for posterior legal thinking [5, 6].

On the Continent, Christian spirituality represented, beyond doubt, the most important factor of influence over the legal thought on licit contractual behaviour [7, 8]. Etymologically, the concept of 'religion' reminds of the Latin root *re-legare*, powerfully suggesting the re-connection between the Creator and the human being. The creation of man and of the world by God, the original sin,

the promise of salvation, of restoration of human body and resurrection, the perfection of the first creation in Jesus Christ, all constitute the basic hermeneutic criteria of Christian teaching on loyal human behaviour, within or without the margins of a contract.

Recent jurisprudence valorised Christian commandments such as the *contractual transparency* (I), *contractual vigilance* or the abnegation principle (II), *contractual coherence* (III), *contractual delicacy* (IV), the prudence principle (V) and that of *contractual fidelity* (VI), as hypostases of good faith in commercial relationships, from which the most salient is thought to be the rule of contractual transparency [9].

Transparency reminds of the brightness of an elegant crystal vase, but also of its fragility, as often underlined. More prosaic, the jurists preoccupied of the theme of lawful conduct during pre-contractual arrangements insisted on both parties' duty to honestly inform the other over essential elements concerning the consent formation, as to permit coagulation of informed, non impulsive consent [10].

The first aim of the article is thus to provide professionals specialised in the field of pharmaceuticals, as well as legal specialists, with information on the judicial standards set for producers' and physicians' liability for violation of the duty to warn consumers on risks and limits of medication, distinguishing 'lifestyle drugs' and 'serious treatment drugs', in terms of informed consent and specific liability.

Another aim of the article is to foster the exchange of ideas between pharmaceutical specialists, and legal practitioners as to the role played by the physicians and pharmacists in the formation of informed consent and to the object of the duty of information, in terms of adverse reactions, serious adverse reactions and unexpected adverse reactions of the pharmaceutical product, also accentuating the idea that a pharmaceutical product may be found to be unsafe due to an information defect, understood as inadequate warning of inherent dangers.

With regard to the theological aspects, the article will deal with the Christian viewpoints on professionals' duty of transparency and its corollary, the duty of information, in their relationship with the profane clients, as reflected in the jurisprudence and in the legal thought of the last decade.

## **2. Christian spirituality, as counterbalance for 'profit oriented' individualism**

Jamin proposes a four-sided classification of Christian solidarity reverberations over contemporary business relations [11]: (a) contractual liability for unethical behaviour, (b) professionals' duty to inform and advise then profane partners, (c) producers' liability for defective products, (d) creditor's duty to actively minimise potential prejudice, aside debtor's efforts. The French specialised literature remains a salient reference point for Romanian Commercial Law, due to the common Romanist roots of both legal systems; thus

the French Commercial Law is seen to be the generating field of a generous, ethically preoccupied matrix of Private Law, the main colonnades of which are the transparency principle and the rational concern for the commercial partner's best interests [12, 13].

The moral lode marking this evolution of European legal cultures is indubitably a Christian one, as liberal individualism visibly present in the texts of Napoleon's Civil Code – adopted in France in 1805, the content of which was massively imported into Romanian Civil Code into force since 1865 (still applicable to contemporary Romanian Civil Law) – is counterbalanced by Christian principles of altruistic behaviour, tolerance and honesty between commercial parties, as reflected in the jurisprudence of the last two decades, both in French and Romanian Law [14, 15]. As opposed to contemporary principles of jurisprudence, contractual individualism represented a pattern of contractual behaviour centred on unemotional, rational distribution of justice between creditor and debtor, in a process in which rigid application of legal norms was vacuumed of spiritual considerations [16]. From the utilitarian point of view, dominant in the late XX<sup>th</sup> century, contracts judicial force was to be found in the idea of mere utility brought by the contractual arrangement on each party's interests: in terms of business relations, 'rightful behaviour' simply meant 'pragmatic behaviour'.

Often accused to be hedonistic in its most intimate nature, the utilitarian analyse of Contracts Law seemed to contradict the very idea of contractual morality, as criterion for courts of law's decisions in matters of contractual unlawful breakage or contractual misconduct [17, 18]. More recently, several jurisprudential trends, both at national level (in legal systems of Romanic tradition, as those of France, Italy, Belgium etc.) and at the European Union's level, may be given as examples of harmonised ethical standards for the contractual behaviour between professionals and consumers. For instance, such trends were materialised in the adoption of Directive 97/7/EC of the European Parliament and of the Council on the protection of consumers in respect of distance contracts and of Directive 84/450/EEC relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning misleading advertising [19-21].

Harmonization of contract law at the EU's level valorised, though indirectly, common Christian principles applicable to commercial relations, such as the transparency principle or the loyal information principle, as shown by the Principles of European Contract elaborated by the Lando group or of the University of Trento's studies on the subject of the Common Fund of European Private Law, as well as the series of casebooks sponsored by Professor Van Gerven or the ample project of The Study Group on an European Civil Code hosted by Professor Von Bar [22, 23]. In addition to academic effort, the European Parliament adopted several resolutions inviting to a codification of the European Private Law, while the European Commission published on July 11, 2001, a communication regarding the *European contract law*, is inviting lawyers, academia, the civil society and all other interested parties to present

their opinions concerning initiatives on harmonisation of European Contracts Law. What it is hoped is the elaboration of a European Civil Code, which is at the moment an extremely delicate mission, in the presence of multiple disparities and divergent traditions in national legal systems. Judicial mechanisms, such as: (i) repression of abusive clauses, (ii) professional's duty to discourage consumers' unsafe conduct, (iii) producers' liability for damages caused by unsafe products and (iv) commercial parties' duty of coherent conduct, concretise moral principles once ignored by profit oriented, economic analyses of Contract Law [24].

Nevertheless, contractual solidarity represents more an egalitarian view over contractual relations than an infinitely tolerant one; in fact, Contracts Law disposes of a small margin of evolution when it comes to responsibility for contractual compliance and sanctioning of negligent debtor, as the judicial assistance of creditor implies an intrinsic right in obtaining contractual performance or, respectively, penalties infringed upon culpable debtor, rather than the application of the Christian principle of turning the other cheek or of endless forgiveness (of the other party's 'seventy times seven' mistakes) [25, 26]. Let us note, however, that though only Christian in part (and secularised in the other), contemporary trends in contractual jurisprudence are nonetheless influenced by traditional biblical spirituality. It is true that creditor's mere appearance in a court of law in pursuit of contractual compliance contradicts the Christian commitment of repeated forgiveness; this aspect represents, however no denial for the presence of other biblical principles in the conflict solving between commercial parties, such as the transparency principle (i), the contractual fidelity principle (ii), the rule of honest counselling of profane partner (iii) or the coherence principle (iv).

Thus the solidarity vision over Contracts Law is rather preoccupied of equity than of infinite indulgence. At least for the consumerist version of contractual solidarity, it may seem difficult to identify a firm moral trend, while the judicial assistance provided by the legislator for the 'vulnerable party' represented by the consumer of goods and services is materialised in technical remedies for the counterbalance of informational, economical or psychological disequilibrium between professional vendors and profanes buyers. If warnings like 'beyond consumerism, there is nothing worse left to experience' are to be trusted, the 'new religion' of the latest century seems to be that of consumption, basically *a-moral*, though preoccupied of equitable justice [7, 27, 28].

Carbonnier observed that the contractual transparency principle enters into a paradoxical conflict with the concept of *simulated contracts*, also licit in contemporary Contracts Law, at least when not braking imperative legal norms, those concerning public interest or collective morals included [29]. The author makes two fascinating, while rigorous observations. The first one is referring to the imminent conflict installed between the licit character of simulated contracts, on one hand and the norm of contractual transparency, on the other hand, in contemporary commercial relations. For instance, in cases in which the parties intend to keep secret the identity of service providers or the judicial nature of

their agreement (thus doubling the official, public contractual text by a secret, confidential agreement), their conduct implies compliance to the duty of information and honest counselling. The other observation refers to the origins of the transparency rule, which was not at the beginning applicable to contract formation, but to matrimonial relationships, being seen as a legal request for the validity of marriage contracts. The latter became a fundamental principle for producers' liability for defective products.

Which are thus the characteristics of merchants' liability for compliance to the duty of information? Though legislator's efforts are not negligible in this field, the rules of contractual transparency are in their essential part of jurisprudential origin and define an original judicial regime attempting to realise a desired equilibrium between, on one hand, the interests of commerce and concurrence and, on the other, the necessity of protecting profane consumers by assuring equitable compensation for victims of defective products or for those of professionals' unlawful conduct [30, 31]. Thus the duty of information concerns the delivery of all relevant data on essential elements of the prepared contract, coagulated around the contractual object, as to ensure the formation of an informed, sufficiently conscientious consent.

However, the mutual character of the duty of information – both parties of the commercial contract being subject to the rule of informing the other of all essential elements influencing the consent formation – may induce the wrong idea of reciprocal annulment of the two identical duties! Therefore the contemporary problem raised by the question of reciprocal commercial information is no longer one of acceptability (the duty of information receiving jurisprudential and legal consecration, by the text of Article 27 of the Romanian Consumption Code), but one of quantification: who is the final debtor of the duty of information – the producer, the distributor or the consumer, on one's specific needs and, most importantly, what are the legal consequences and intricacies over judicial liability brought by the non-compliance to the mentioned duty?

### **3. 'Lifestyle drugs' versus 'treatment drugs', in terms of informed consent**

Producers' liability for informed consent becomes pre-eminent in the field of 'lifestyle' medication: while, in the case of 'serious treatment' drugs, it is the physician that is hold responsible for fully and adequately informing the patient on the risks and benefits associated to the consume of the pharmaceutical product, on the contrary, in the case of 'lifestyle drugs', usually the consumers avoid the contact with a physician when deciding to consume the pharmaceutical product (normally accessed without a medical prescription), thus placing on producers' shoulders the burden of complete information, through the means of advertising announcements, product label or prospect. 'Lifestyle drugs' are distinguishable from 'serious drugs' on the basis of their focusing on enhancing or easing socially debilitating maladies, rather than addressing life-threatening diseases [32] and have been defined as those developed to treat certain

discomforts associated to social living standards enhancement or to keep chronic problems in check, not necessarily curing them. For instance, usual cold or pain relief medication, Viagra, stomach problems reducers, cholesterol reducers, Fen Phen (obesity reducer pulled from the USA's pharmaceutical market in September 1997, after found to have serious side effects, including heart and lung failure) or other obesity reducers, alimentary supplements, such as those containing vitamins and minerals are seen to be 'lifestyle drugs', as opposed to 'serious' medication intended to cure life-threatening diseases.

However, the boundaries between the two species of medication are not easy to establish, in practice, as, for instance, obesity may become life-threatening and thus the medical drugs taken may be argued to be oriented towards serious health problem solving. The comparison criteria are thus far from being perfect, as the opposition 'complete' – 'partial' cure of disease, as well as the dichotomy 'life-threatening disease' or 'merely socially debilitating' discomfort do not always offer the best solution when deciding whose responsibility is to be held for pertinent information delivered to consumers, physician's or manufacturer's.

Arguing that lifestyle drugs should be the field of application for the physicians' duty of information towards consumers means, in our opinion, taking into account the fact that such pharmaceutical products are destined to enhance the quality of life and to make chronic problems socially bearable rather than to deal with serious health issues, thus being distinguishable from other pharmaceuticals consumables. In their case, as long as the consumer is not held to consult a physician in order to access the medication, it is manufacturers' duty to properly inform the consumers on all relevant aspects related to ingredients, active substances, side effects, risks and benefits, especially by the means of product's label and prospect, as the consumer usually solicit no professional advice when deciding to consume the pharmaceutical product.

From the angle of Christian morals applied to the legal doctrine of professionals' liability for informed consent, it is important to observe that the dichotomy 'lifestyle drugs' – 'serious medication' may help distinguish in a court of law between mere marketing strategy, including advertising and promotion of lifestyle drugs and the purpose of the pharmaceutical product's existence, in terms of solid scientific reasons for the manufacture of a certain medication and in terms of transparent attempts by the manufacturing company to create a rather cash-rich product than one oriented towards medical treatment.

#### **4. Role played by the physicians in the formation of informed consent**

In the field of pharmaceutical products, usually it is the physician who ultimately decides what medications the patient will take, while making the diagnosis normally implies the prescribing of proper medication. As well known, medication is classified into two distinctive groups: medical drugs freely and directly accessed by consumers without a medical prescription (a) and medication accessed by prescription (b). While, in the first case, it is obviously



the producer who remains the only person responsible for damages caused to consumer by the use of medication and improper information, it is in the second case, of medication accessed on prescription, that discussions have been centred on the role played by the professional intermediary or the physician in the formation of consumer's informed consent. Producer's failure to warn consumers on risks and precautions thus may be corrected through physician's direct efforts of advising the consumer while prescribing a certain medical drug.

It is also worth reminding that producers' responsibility for physical injury and economic harms caused to consumers by defective products has been regulated at the European Union's level by Directive 85/374 /EEC of the European Parliament and of the Council of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, modified and completed by Directive 1999/34/EC of the European Parliament and of the Council. The mentioned Directive had been transposed in the Romanian legal system by Law 240/2004 on producers' responsibility for damages generated by defective products, modified by Law 363/2007 on repressing illegal commercial practices in contracts concluded by consumers and the harmonization of national law and the European Communities Law in the field of consumers' protection. In addition, it is the Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use that becomes incident in terms of uniform rules applicable to pharmaceutical products, in terms of safety standards, duty of information and manufacturers' liability.

## **5. Object of the duty of information**

Violation of professional's duty of information represents an hypothesis of delusive (illicit) conduct, professionals being presumed to know the technical limits and precautions associated to the use of the respective pharmaceutical product, being compelled to self-informing in order to be able to adequately inform the profanes. Thus, in contemporary Private Law, professional's duty of information is materialized in the chronic need for transparency that the profane is resenting in the field of medical services.

### ***5.1. Information on 'adverse reactions', 'serious adverse reactions' and 'unexpected adverse reactions' of the pharmaceutical product***

The 'adverse reaction' is defined in terms of a response to a medicinal product which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function, while a 'serious adverse reaction' is that resulting in death or is life-threatening, requiring inpatient hospitalization or prolongation of existing hospitalization, resulting in persistent or significant disability or incapacity or is a congenital anomaly/birth

defect (Article 1 of Directive 2001/83/EC on the Community code relating to medicinal products for human use). An ‘unexpected adverse reaction’ of the pharmaceutical product is seen to be an adverse reaction, the nature, severity or outcome of which is not consistent with the summary of product characteristics, as defined by the producer. Let us note, from the very beginning, that the judicial stake is a decisive one: if the patient is found not to have applied producer’s or physician’s warnings, the profane is the one supporting the prejudice resulted; on the contrary, any lack of proper information on the ‘adverse reactions’, ‘serious adverse reactions’ and ‘unexpected adverse reactions’ of the pharmaceutical product is seen as imputable to the professional, thus transferring the financial burden of the consumer’s prejudice on professional’s shoulders.

### ***5.2. The ‘excessive risks’ argument***

Legal theory and practice on manufactures’ responsibility retained that a product is ‘defective’ when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including: (a) the presentation of the product; (b) the use to which it could reasonably be expected that the product would be put; (c) the time when the product was put into circulation. However, a product is not considered defective for the sole reason that a better product is subsequently put into circulation (as stated by Article 6 of Directive 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, modified). Directive provisions were conceived to protect the physical well-being and property of the consumer, stating that the defectiveness of the product should be determined by reference not to its fitness for use, but to the lack of the safety which the public at large is entitled to expect, whereas the safety is assessed by excluding any misuse of the product not reasonable under the circumstances.

Whereas products age in the course of time, higher safety standards being developed and the state of science and technology progressing (moral and/or material aging of product), it has been held unreasonable to make the producer liable for an unlimited period for the defectiveness of his product; therefore, the liability in discussion expires after a reasonable length of time, that is a period of 10 years since the commercial launch of each lot of products on the market. As underlined by specialized doctrine, consumers dispose of a 3 years period from the manifestation of the defect for the preparation of trial and the introduction of a judicial action against the producer; however, the 3 years term is to be calculated between the borders of the 10 years period of safety warranty. According to Articles 10 and 11 of Directive 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, modified, Member States were called to provide in their national legislation that a limitation period of three years applies to proceedings for the recovery of damages and that the limitation period begins to run from the day on which the plaintiff became aware or should

reasonably have become aware of the damage, the defect and the identity of the producer. On the other hand, Member States were called to provide in their legislation that the rights conferred upon the injured person pursuant to the mentioned Directive are extinguished upon the expiry of a period of 10 years from the date on which the producer put into circulation the actual product which caused the damage, unless the injured person has in the meantime instituted proceedings against the producer, therefore suspending the rolling of the 10 years term.

A closer look at the development of producer's liability criteria reveals the existence of a fundamental distinction of three types of defect, delimiting those imputable to a manufacturing flaw from those due to a defective design or to insufficient/inadequate warning. Manufacturing defects describe an accidental flaw in the manufacturing process, usually non perceivable by producer's representatives (*e.g.* engine defects, engine imperfections, accidental misconstruction of one component). Manufacturing flaws are therefore easily measured against like products (safe products, manufactured as intended); in other words, in these cases, aberrations of manufacturing may be tested against the norm to determine whether a product is defective.

As to design defects, courts and authors have struggled with the concept of what constitutes defective design of a product, as in opposition to manufacturing products, where a safety standard already exists (represented by non defective products, manufactured as intended on a regular basis), design defects do not benefit from an objective/alternative standard. Originality or unique character of design usually complicates analyzes, as the courts weigh non homogenous factors, such as product functions, aesthetical aspects or presence of alternative design on the market. In addition, it is in the field of defective design that producers may be exonerated on the basis of the 'risk of development' concept, as the producer may free himself from liability if he proves that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of a defect to be discovered (Article 7 (e) of Directive 85/374 /EEC, modified).

In the field of the producers' responsibility for the prejudice caused by the consume of a pharmaceutical product presenting a manufacturing defect, the product concerned may be declared 'unsafe for human consume' simply if the risks resulting from its utilization are excessive, even if mentioned on the medicinal drug prospect, only medical drugs representing the sole cure for a serious disease being excepted from the application of the mentioned rule. Additionally, it should be underlined that, in the field of pharmaceutical products safety, the 'unsafe for consume' character may result both from the lack of information offered to consumers by the producer or the distributor, on the potential risks associated to consume and from the disproportionate character of the implied risks, in comparison with the benefits attributed to the consume of medical drug, as regulated by Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

Producer's failure to warn consumers on risks and precautions is usually seen as a third type of defect, in addition to manufacturing defects and defects due to design. Therefore, a pharmaceutical product may be found to be unsafe due to an information defect, understood as inadequate warning of inherent dangers. For instance, as mentioned above, in the perimeter of pharmaceutical products, warning considerations are generally inextricable, from the angle of producer's liability for damages caused, as whether the product instructions contained adequate warning or not, as well as nature, explicit character and sufficiency of the warning are relevant to the issue of establishing producer's responsibility and delimiting unreasonably dangerous products from safe for consume ones.

### ***5.3. Potential exceptions from physician's direct liability for uninformed consent***

As argued in the above lines, it is in principle pharmaceutical producer's responsibility to adequately inform the consumers on risks and benefits of the manufactured medication. On the contrary, if in case it is a medical drug accessed on a medical prescription, the courts of law have found the physician to be directly responsible for completely informing and advising the patient, thus supporting the damages eventually caused to the profane consumer [30, 31]. In the case of mass vaccination, however, the liability switch operates on manufacturer's behalf, replacing the liability on producer's shoulders. In fact, in the field of compulsory vaccination, the duty to warn is shifted back to the manufacturer, but only in the context in which no doctor was expected to directly communicate to the patient. Unfortunately, there is no Romanian jurisprudence to be cited in the matter of potential exceptions from physician's direct liability for uninformed consent, thus complicating the practical solution applicable in future potential cases of liability split between the physician and the pharmaceutical producer.

Medical services is one field in which a dialogue between Science and religion helps discussing each unique case, taking into account the religious and social values that each human being possesses. Producers' duty of information is contemporarily seen to be a common judicial principle, but its origins are to be found at least partially in the Christian commandments that influenced the European judicial orders over the decades.

## **6. Conclusive remarks**

Many general aspects of relationships between professional vendors or service providers and profane consumers are worthy of discussion and investigation also on the side of Theology. The perspective opened by Georges Ripert in 1949 in respect to Christian theology and ethics applied to legal obligations in his book entitled *La règle morale dans les obligations civiles* (in

an approximate translation, 'Moral Roots of the Civil Legal Duties') was continued over the last decades both by jurisprudence and legislator's efforts.

Christian commandments, such as the solidarity between contractual parties, the transparency rule or the behavioural coherence became more and more stringent. Problems related to business ethics are now among the main topics in the discussion between Science and Theology. Researchers' theological task was devoted to find new ways to reconcile the traditional Christian spirituality with the modern business techniques, profit oriented while potentially dangerous for profane consumers. It is a fact that the hyper-industrialization experience and expanded consumerism had a great importance in generating the general disequilibrium in economic relationship visible between the two sides: professional vendors and service providers and profane consumers.

The article focuses on Christian influences over the crystallization of concepts as *contractual equity and social justice* in the field of producers' and physicians' liability for unfair information or defective pharmaceutical products. Each component in the commercial relationship between the pharmaceuticals manufacturer or the physician and the consumer has the same rights and dignity as any other; the equal contractual capacity is recognized, so that the final contractual effects need to be 'equitable', 'fair' and 'transparent', determined by the interaction between producers or importers and consumers, really looking at the needs of both the parties.

Contractual culture has significantly changed over the last two decades. As observed above, in the contemporary Romanian Consumer Law, provisions referring to professionals' liability for prejudice caused to consumers are alimeted by the amount of inequalities present between professional and profane parties to commercial contracts, in terms of information, finances or psychological balances of power. Commandments such as the solidarity between contractual parties, the moralization of contractual relations, the transparency rule or the behavioural coherence became more and more stringent. Simply stated, the test is whether the judicial instruments used by the legislator to temporize the formation of commercial contracts on pharmaceutical products considered to present a exceptional amount of risk for the consumer will help avoiding the excessive indebt of consumers or, on the contrary, the lack of judicial education and of information would retain consumers from exercising their discretionary legal rights. A corollary to the matter mentioned above is that, since the professionals are compelled to respect the duty of information, the legislator should be more preoccupied to elaborate future concrete norms describing the sanctions enforceable in case of rights violations, as contemporary legal texts do not always sufficiently stretch the legal powers allocated to the National Authority for the Protection of Consumers representatives and does not offer details on the concrete role allocated to the consumers' organizations, regarding the defence of individual or collective interests of their members.

As argued in the lines above, it is pharmaceutical producer's responsibility to adequately inform the consumers on risks and benefits of the manufactured medication. On the other hand, in the case of medical drugs accessed on a medical prescription, the physician may be held directly responsible for completely informing and advising the patient, thus supporting the damages eventually caused to the profane consumer. To apply this argument in a litigation context, the plaintiff must be able to illustrate the existence of a direct relationship with a physician associated to a defective or dangerous pharmaceutical product, thus placing the burden of liability on physician's shoulders. In other cases, however, pharmaceutical manufacturers' illicit attempts to manipulate the consumer through the means of delusive or incomplete information may interfere with the eventual physician-patient relationship, permitting judges to establish the existence of producers' liability for the violation of the duty to inform. The dichotomy 'lifestyle drugs' – 'serious medication' may help distinguish in a court of law between mere marketing strategy, including advertising and promotion of lifestyle drugs and the purpose of the pharmaceutical product's existence, in terms of solid scientific reasons for the manufacture of a certain medication and in terms of transparent attempts by the manufacturing company to create a rather cash-rich product than one oriented towards medical treatment.

### Acknowledgement

This paper is the outcome of research activities undertaken under the project code PN II-RU 396/2010, contract number 86/2010, supported by the Romanian National Council for Research in Higher Education, CNCSIS-UEFISCSU.

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