

Presidenza del Consiglio dei Ministri



**NOTE ON THE PHARMACIST'S CONSCIENTIOUS
OBJECTION TO THE SALE OF EMERGENCY
CONTRACEPTIVE PRODUCTS**

25th of February 2011

INDEX

| | |
|--|----|
| Presentation..... | 3 |
| 1. Premise..... | 5 |
| 2. The various arguments concerning conscientious objection..... | 6 |
| 3. The right to obtain the drug..... | 10 |
| Personal Remarks..... | 12 |
| Appendix:..... | 15 |
| Request made by the Hon. Luisa Capitanio Santolini | |

PRESENTATION

The NBC, with the document entitled *Note on the pharmacist's conscientious objection to the sale of emergency contraceptive products*, responds to a question raised by the Hon. Luisa Capitanio Santolini¹ on the conscience clause² invoked by those pharmacists not to sell pharmaceuticals of emergency contraception, also referred to as "morning-after pill," for which the leaflet does not exclude the possibility of a mechanism of action that leads to the removal of a human embryo.

The Committee pointed out in general terms that conscientious objection, which has a foundation in the constitutional right to religious freedom and freedom of conscience, must still be made in respect of other fundamental rights provided for by our Constitution, which include the inalienable right of the citizen to protect health and receive health care recognized by law.

Different bioethical standpoints emerged within the National Bioethics Committee.

Some members, highlighting numerous reasons, believed it possible to recognize the role of the pharmacist as being akin to those of "health care workers" and therefore, analogous to what happens with other healthcare professionals (Law No. 194/1978 and Law No. 40/2004), the right to conscientious objection must necessarily be recognized also to this category. The fact that the pharmacist has a "less direct" role compared with whosoever clinically practices an abortion was not considered sufficient grounds to invalidate the argument in favour of the moral clause, since the distribution of the product contributes to the possible outcome of abortion in a chain of cause and effect without interruption.

Other members believed, for other reasons, that the figure of the pharmacist and physician cannot be assimilated, since the pharmacist is not responsible for the prescription of the drug, or the personal circumstances and the health of whoever requests it. The relationship with the user is generic and impersonal: it is the prescription that legitimizes the distribution of the drug and not the identity of the person collecting it. It is entirely the physician's responsibility, while there is no legal involvement on the part of the pharmacist who has no authority to go into the merits of the choices made. It was pointed out that in the event of the pharmacist being granted, in legislative terms, the right to conscientious objection (through the refusal to fill prescriptions for the so-called morning-after pill) he would be conferred a dual faculty. On the one hand, to censure the work of the physician, with consequent risks for the patient's mental and physical health; and on the other, to intervene in the most private and intimate sphere of a woman, preventing de facto self-determination.

Assuming that the legislature acknowledges the right to conscientious objection on the part of pharmacists and pharmacy personnel, the components of the NBC agreed that, in accordance with constitutional principles, the interests of all the parties involved must be considered and guaranteed. An essential and

¹ In the Appendix.

² The document will address the issue of conscientious objection without a specific distinction as regards the conscience clause. This reflection will be discussed in detail in another NBC document on conscientious objection in general.

indispensable premise for the possible legal extension of conscientious objection to pharmacists is, therefore, that the woman in question must in any case be able to access the requested drug elsewhere or through different means and that it is for the institutions and competent authorities, in consultation with the professional bodies involved, to provide the most appropriate systems to make explicit the necessary tools and figures responsible for the implementation of this right.

The document was drawn up on the basis of a text prepared by Prof. Lorenzo d'Avack who made use of extensive debate within the NBC, with the written contributions of Profs. Salvatore Amato, Luisella Battaglia, Stefano Canestrari, Cinzia Caporale, Roberto Colombo, Francesco D'Agostino, Antonio Da Re, Maria Luisa Di Pietro, Riccardo Di Segni, Silvio Garattini, Laura Guidoni, Assunta Morresi, Andrea Nicolussi, Laura Palazzani, Monica Toraldo di Francia.

In the plenary session of the 27th of January 2011 Dr. Andrea Mandelli, President of the Italian Federation of Associations of Pharmacists, and Dr. Anthony Mastroianni, Director General of the Federation were audited.

In the plenary session of the 25th February 2011 the document received the consent of Profs. Luisella Battaglia, Stefano Canestrari, Roberto Colombo, Francesco D'Agostino, Antonio Da Re, Lorenzo d'Avack, Riccardo Di Segni, Silvio Garattini, Marianna Gensabella, Laura Guidoni, Claudia Mancina, Assunta Morresi, Andrea Nicolussi, Laura Palazzani, Monica Toraldo di Francia.

Prof. Demetrio Neri voted against.

Profs. Salvatore Amato and Emma Fattorini abstained.

Profs. Adriano Bompiani, Cinzia Caporale, Bruno Dallapiccola, Maria Luisa Di Pietro, Aldo Isidori, Alberto Piazza, Vittorio Possenti, Rodolfo Proietti, Lucetta Scaraffia and Giancarlo Umani Ronchi absent at the voting of the document, have subsequently given their support.

Published along with the document are the personal remarks of Prof. Salvatore Amato, who states the reasons for his abstention, those of Profs. Antonio Da Re, Emma Fattorini and Andrea Nicolussi who propose additional reflection, that of Dr. Riccardo Di Segni, who explains his standpoint in relation to the text and that of Prof. Demetrio Neri who sets out the reasons for his dissent. Prof. Grazia Zuffa, absent at the meeting, subsequently submitted her endorsement to the personal remark made by Prof. Neri.

The President
Prof. Francesco Paolo Casavola

1. Given that:

- under Article 38 of the Regulations for pharmaceutical services (Royal Decree 30th of September 1938, No.1706) every chemist, pharmacist or auxiliary pharmacy, operating as part of a public service, has the obligation to deliver medicinal products to those requesting them and showing the relative medical prescription, and – if the product is not in stock- to obtain it as soon as possible³;

- the obligations provided for by the aforementioned Regulations carry criminal penalties for violation and are valid for pharmacists and auxiliary staff working in community pharmacies, hospital pharmacies, and private and health district pharmacies;

- at the time of the Royal decree of 1938, on the one hand, abortion was prosecuted as a crime and abortive medications were not available, and on the other, conscientious objection was not part of the prevailing sensibility of the legal culture of the time;

- in our pluralistic society, even from the standpoint of understanding the values and fundamental rights accepted by the Constitution, a new sensitivity has developed that allows the possibility, in particularly problematic situations, to raise objection of conscience (understood as an 'option of conscience', leaving it up to the individual to choose between alternative legitimate behaviour in legal terms), so that in the most common case of conscientious objection to military service, conscientious objection is legislatively granted in areas that primarily regard the medical and health context;

- currently in the spheres of medicine, health and experimentation our legal system allows conscientious objection in the following regulations:

- Law No. 194/1978, Art. 9 (Regulations for the social protection of motherhood and on the voluntary interruption of pregnancy);

- Law No. 413/1993, Art. 1 (Regulations for conscientious objection to animal testing);

- Law No. 40/2004, Art. 16 (Rules of medically assisted procreation);

- various bills have been presented to both Houses from different political factions aimed at regulating the introduction of "conscientious objection" to pharmacists, in consideration of the new feature represented in particular by the introduction and marketing of drugs commonly referred to as emergency contraceptives;

- the current Pharmacist's Code of Ethics (2007) Art. 3, paragraph 1, letter c) provides that the professional must act "independently and conscientiously in accordance with ethical principles, and always keeping in mind the patient's rights and the respect for life";

³ Art. 38 `Pharmacists can not refuse to sell available medicines or refuse to fill prescriptions signed by a physician for medicines present in the pharmacy. A pharmacist with a request for a national medicinal product, which is not in stock, is obliged to obtain it as soon as possible, provided that the requester advances the amount for postage. Pharmacists are required to send the prescription in the shortest possible time in order to masterfully carry out product preparation. All prescription must be signed by a doctor or a veterinary surgeon. Pharmacists must keep copies of all filled prescriptions for a period of five years.

- the NBC has directly and indirectly on several occasions dealt with the issue of conscientious objection in health care, recognizing that right whenever the moral decisions of physicians are involved (*Purpose, risks and limits of medicine* (2001); *Advance treatment statements* (2003); *Note on emergency contraception* (2004), *Alternative medicines and the problem of informed consent* (2005), *Bioethics in dentistry* (2005); *Refusal and Conscious renunciation of health treatments in the patient – doctor relationship* (2008); *Alternative methodologies, Ethics Committees and Conscientious objection to animal testing* (2009);

- the question submitted to the Committee identifies as the subject of conscientious objection “pharmaceuticals for which the mechanism of action does not exclude the possibility of eliminating a human embryo, whatever its stage of development”⁴;

- the Committee states from this moment that conscientious objection, which has a constitutional basis in the general right to religious freedom and freedom of conscience, must still be made in respect of other fundamental rights, among them the inalienable right of citizens to protect health and to receive the health care recognized by law;

In consideration of this, the National Bioethics Committee puts forward the following arguments.

2. The various arguments concerning conscientious objection

Different bioethical standpoints emerged within the National Bioethics Committee, which are set out below.

2.1 Some members⁵ acknowledge the extension of conscientious objection to pharmacists as regards the sale of so-called emergency contraceptives for the following reasons.

a) With regard to the characteristics of the drug, it is still considered that the experimental and clinical data do not consent the reaching of definite and shared conclusions to exclude a shared mechanism of action, which, at least in a number of cases, prevents the early development or implantation of the embryo in the endometrium, this effect is considered as abortion by those who believe that pregnancy begins from the time of fertilization.

The fact is, however, that the pharmacist dispensing the drug has no discretion to judge the scientific content and must abide by the leaflet, which now accompanies and describes it by law. This, even under the provisions of the

⁴ Currently, the drug on sale is NorLevo (levonogestrel) whose leaflet refers to the possible elimination of the embryo http://www.angelini.it/public/schede/norlevo_gen06.pdf.

The NBC acknowledges that there is wide scientific debate on the subject. The possibility for the interceptive mechanism of action of levonorgestrel was challenged by C. Flamigni, A. Pompili, *Contraception*, Rome 2011, p. 154 that link up with the study of P.G. Laliktumar, *Mifepristone but not levonorgestrel, inhibits human blastocyst attachment to an in vitro endometrial three-dimensional cell culture mode*, in "Human Reproduction", 2007, 22, pp. 3031-3037.

⁵ Bompiani, Caporale, Colombo, D'Agostino, Dallapiccola, Da Re, d'Avack, Di Pietro, Gensabella, Isidori, Morresi, Nicolussi, Palazzani, Possenti, Proietti.

Regional Administrative Court of Lazio⁶, contains the aforementioned features; one of the effects also indicated is the prevention of implantation of an embryo which may already be present in the womb. It is evident that if the leaflet of the drug subsequently contained different scientific indications, which exclude such an effect of the product, the objective reasons that support the moral illegitimacy of its sale by the pharmacist would cease.

Should a pharmacist sensitive to the rights of embryonic life, consider the data contained on the current leaflet non compliant with the latest scientific evidence, so as to exclude the "interceptive" mechanism of action of levonorgestrel, he may therefore draw valid personal reasons not to object.

b) Notwithstanding the nature and effects of the active ingredient, among the principle reasons that lead some to question the legal legitimacy of the conscientious objection of pharmacists is the role they play, regarded as not akin to those of "health care workers" as pharmacists are to be considered merely dispensers of drugs to the public. This justification was not shared by the NBC.

The President of the Federation of the Association of Pharmacists, Dr. Andrea Mandelli, at a hearing held at the NBC, purposely made clear that in accordance with current legislation the pharmacist is a healthcare worker⁷ "and that, if there is no obvious intervention in the diagnostic process and indication of therapy, he nevertheless, has his own specific expertise with regard to the drug as regards the citizen, the proof being that he is required to check the prescription"⁸. It is his duty and responsibility not only to sell the requested drug, but also to inform the patient on the correct use of the drug, to point out possible interaction with other medicine taken by the patient, to dissipate any doubts on the active ingredient and excipients, also referring, where appropriate, the client to the physician. As regards a possible "therapeutic alliance", he stated that: "the pharmacist interacts with the client-patient; in fact he is the health care worker that is closest to the patient and at the service of the people"⁹.

It is clear that the discussion about whether or not the pharmacist can be ascribed the category of "health care worker" has decided implications for the legal possibility that, analogous to what occurs with other health professionals (Law No. 194/1978 and Law No. 40/2004), the right to conscientious objection must necessarily be recognized also to this category.

Nevertheless, the abovementioned question is not conclusive in moral terms. In this sense, even those not belonging to the category of health personnel are entitled to invoke conscientious objection. This is a principle, for example, that the law recognizes those who work in the field of animal experimentation (Cf. Law No.

⁶ Regional Administrative Court of Lazio, sentence n. 08465 of 12.10.2001.

⁷ Cf. R.d. 27 July 1934, n.1265, which at Art. 1999 onwards includes pharmacists and pharmaceutical services in the health professions and arts: Title II is dedicated to the "Pursuit of the health professions and arts and activities subject to health surveillance" and inside Chapter II deals with "pharmaceutical services." Confirmation of this interpretation is also apparent from l. No 833 of 23 December 1978 on the establishment of the National Health Service in relation to Articles.1, 2, paragraph. 1 No 7; 14, paragraph 3 letter n); 28, paragraph. 1.

⁸ In ASCA, 28.01.11 and in the plenary hearing of January 27th 2011.

⁹ Ibid.

413/1993). The pharmacist as a citizen in a democratic society characterized by ethical pluralism, has the right not to perform an action, indicated under certain physiological conditions as scientifically capable of preventing the development of a human embryo, when it conflicts with their moral beliefs regarding the respect and protection due to a human being from the beginning of its development. Even more so if one considers that the unborn have constitutional protection (see Constitutional Court No. 27/1975, 35/1997, 151/2009, cf. also Law No.194/1978, Art.1), and that therefore conscientious objection is invoked here in an appeal not only to freedom of conscience but also to the importance of the principle of respect for human life, which in the same way ascends to a good of constitutional significance.

c) The fact that the pharmacist has a “less direct” role compared with whosoever clinically practices an abortion was not considered sufficient grounds to invalidate the argument in favour of the conscientious objection. The distinction between direct or indirect participation has no moral relevance, as both actions contribute to a possible outcome of abortion in a chain of cause and effect without interruption: even the less direct role (the distribution of the drug, after examining and checking the prescription) is still a crucial link in the chain of professionally qualified and informed choices that lead to, as a result of taking the product, the possible chemical elimination of the embryo. Abstention from encouraging (or simply making possible), such practices can therefore represent not only the physician but also for the pharmacist, a moral and ethical¹⁰ duty towards the protection and promotion of human life.

d) Moreover, since in the majority of cases the doctor, consulted shortly after intercourse, is unable to diagnose a real danger to the woman's health in the case of a hypothetical pregnancy, but can only determine if considered the apparent health conditions of the woman that there are no objective contraindications to taking the drug, the prescription is not a proper indication of treatment. Consequently, as in the case of other products, the role of the pharmacist in the dispensing of the preparation seems no less decisive than that of the doctor.

e) Lastly, the possibility that the woman may not immediately and personally use the purchased drug is not a relevant argument against conscientious objection. Otherwise this kind of argument should also apply to the physician prescribing the product, without the certainty of it being purchased and/ or administered exclusively to the person to whom it was prescribed. In order to invoke conscientious objection, it is essential that a law exists which imposes an action that is seriously in contrast with the conscience of those who should respect it: referring to possible circumstances which `de facto` void of sense, is irrelevant in terms of `principle`.

Members who put forward these bioethical observations believe, therefore, that the delivery of drugs, which, as mentioned in the leaflet, through their prescribed use bring about even the possibility of preventing the development of an embryo, preventing its implantation in the uterine endometrium, is configured as

¹⁰ Pharmacist's Code of Ethics, 2007, Art. 3, paragraph 1, letter c).

an activity that can justify the pharmacist and pharmacy employees to avail themselves of conscientious objection.

2.2 Other members¹¹ believe we must recognize the absolute correctness of professional conduct and the ethics of the pharmacist who invokes the conscience clause in order to refuse to sell "pharmaceutical products for which the possibility of a mechanism of action that leads to the removal of a human embryo is not excluded".

In the opinion of those members, the possible *legislative* recognition of the right to object to the pharmacist is nevertheless a much more complex issue, therefore the refusal to fill prescriptions of the so called morning-after pill (NorLevo). In relation to this issue, the role of the pharmacist can not be assimilated to that of the physician. The difficult composition of the contrast between the freedom of conscience of the pharmacist (and / or of the pharmacy auxiliary) - indisputable however in a pluralistic State - and a woman's fundamental right to physical and mental health, do not consent reference to the achievements of the debate regarding conscientious objection of the physician.

The proposal for legislative recognition to the pharmacist of the right to conscientious objection as regards the so-called morning after pill does not appear to be shared, for a multitude of reasons.

a) The importance of the scientific nature of the premise must be reiterated. The possibility of the interceptive mechanism of action of levonorgestrel - namely the effectiveness as an abortifacient of the drug NorLevo - has been authoritatively challenged¹².

b) It is highlighted that the role of the pharmacist is very different from that of the physician. In fact the pharmacist is not responsible for the prescription of the drug or the personal circumstances and the health of whoever requests it. It is entirely the responsibility of the physician – who in fact is not obliged to prescribe a particular drug – while there is no legal involvement on the part of the pharmacist, who is limited to ensuring the efficiency of the structure in which he operates, without going into the merits of the choices made and sometimes without even personally knowing the person who will take the drug.

The pharmacist's intervention is limited to cases in which he has doubts, on the basis of his scientific background, regarding the appropriateness of a prescription (and in such cases there is the obligation to immediately contact the physician that wrote the prescription to verify its correctness or authenticity).

c) In the event of the pharmacist being granted, in legislative terms, the right to conscientious objection - through the refusal to fill prescriptions for the so-called morning-after pill - he would be conferred a dual faculty: on the one hand, to censure the work of the physician prescribing the drug, presumably "to the best knowledge and belief"; and on the other, to intervene in the most private and intimate sphere of a woman, actually preventing self-determination. In both cases, it is to be noted that the rights of others are damaged, - with possible serious risks-

¹¹ Battaglia, Canestrari, Garattini, Guidoni, Mancina, Piazza, Scaraffia, Toraldo di Francia, Umani Ronchi.

¹² See Note 4.

to the woman's mental and physical health. The pharmacist, far from occupying a secondary and indirect role, would ultimately take on a decision making role, overseeing the assessment of the physician and the choices made by the woman, without a thorough knowledge of the complexities of the reasons and conditions - both medical and existential - which motivated each one.

d) An indispensable prerequisite for the possible legal extension of conscientious objection to pharmacists should however be the identification, as a priority, of the appropriate measures to ensure with absolute certainty the delivery of the drug prescribed by the physician. The plenary hearing of the President of the Federation of the Association of Pharmacists, Dr. Andrea Mandelli, confirmed fears that the legal recognition of conscientious objection to pharmacists may undermine in certain situations the fundamental right of the patient to have the drug prescribed by the physician dispensed. The prospect that each pharmacy may be expected to include in its available staff at least one pharmacist that is not a conscientious objector in practice seems very difficult to implement. Legislative recognition of conscientious objection to pharmacists would therefore endorse a kind of conscientious objection to the pharmacy. As such, this is absolutely unacceptable, because the different types of pharmacies perform, in any case, a public service. Lastly, it is noted that possible legislative recognition of conscientious objection to pharmacists may lead to objection on the part of other workers in the cycle of synthesis of drug preparation and distribution, determining at least unavailability.

e) Ultimately, the legal recognition of conscientious objection to pharmacists could lead to an unacceptable impeditive outcome, interrupting the process that leads to the free resolution of the patient, to the next option (still revocable) to take the so-called morning-after pill, under the sole legal responsibility of the physician. This would deny the centrality of the alliance created between physician and patient, the importance of which has been emphasized strongly and clearly in many NBC documents. The pharmacist does not dispose of all the necessary knowledge regarding individual cases to be able to exercise to the best of knowledge and belief and in accordance with the law the right to conscientious objection, to the point of refusing to deal with the physician's request of the drug, sacrificing as a consequence the basic right of the patient to have the so-called morning-after pill dispensed. It is not a question of denying rights to the pharmacist, but to take note of the inability to guarantee with absolute certainty the priority right to physical and mental health of the patient.

3. The right to obtain the drug

Assuming that the legislature acknowledges the right to conscientious objection on the part of pharmacists and pharmacy personnel, the components of the NBC agreed that, in accordance with constitutional principles, already referred to in the premise, the interests of all the parties involved must be considered and guaranteed.

Conscientious objection should be exercised in a responsible manner so as not to interrupt the process that leads to the free resolution of the patient, to the

successive options to take a drug, under the moral and legal responsibility of the physician.

A necessary and indispensable prerequisite for the eventual legal recognition of conscientious objection is, therefore, the assertion of everyone's right to get the benefits due by law: only if this condition is established as a priority and with the indication of appropriate measures that ensure that it is not in fact undermined, are the conditions created to avoid a conflict of conscience that could be harmful to the orderly conduct of social life.

The NBC therefore believes that the woman should in any case have the possibility to obtain the prescribed drug and that it is for the legislature to provide the most appropriate systems to make explicit the necessary tools and figures responsible for the implementation of this right.

The NBC recommends that the Institutions and competent Authorities, in consultation with the professional bodies involved, in accordance with Art. 117, letter m of our Constitution, faced with specific regulatory intervention that may provide for the right to conscientious objection to pharmacists and their auxiliaries, will take the necessary steps to provide correct and complete user information and guarantee, for the protection of citizens, to dispense prescribed drugs on medical prescription in a timely manner in relation to their effectiveness.

Personal remarks

A Personal Remark signed by Prof. Salvatore Amato

The legislature does not give us a definition of conscientious objection, but merely identifies some typical situations. It tells us "who" can exercise this right however not "what" it is. The document notes this and builds its own structure by analogy: the analogy with the professional figure of the physician, the analogy with chemical abortion. I myself was strongly convinced of the basis of both similarities, so I had no doubt about constructing the Opinion "tracing" the *Note on emergency contraception* (2004).

The development of our discussions and the surprising intensity of the ensuing debates showed that this was not the case. The similarities were very subtle and not clear enough to allow us to set aside the right of women to obtain a drug on regular NHS prescription.

At this point, it would have been appropriate to begin clear and direct questioning on the meaning and extension of conscientious objection. Does it have a symbolic value as an expression of freedom of thought? Does it have a political value as an aspect of civil disobedience? Does it have a militant value as an "answer to evil?" Does it have a general and undifferentiated nature, because it addresses the conscience of humanity, or has it a relational and personal value, because it addresses the consciousness of the other party? Does the pharmacist want to induce humanity or the woman to change her mind? And, in the latter case, can we neglect the impersonality of the relationship between the pharmacist and service user? Can we overlook the fact that the conscience of the pharmacist think to abortion, but that woman to contraception? Can we ignore that the pharmacist decides on one way of life, while the woman decides on her life?

All these questions are surreptitiously, or in a Freudian manner, present in the opinion: when we put alongside conscientious objection the “moral clause” or “option of conscience”; when we question the “less direct” or “indirect” role of the pharmacist in the causation of the event (is there a considerable difference in the moral evaluation of the causal link between the physical handing over of the drug and the indicating of the nearest pharmacy where it is obtainable?); when we discuss about the pharmacist (here the figure of the professional comes into play), the owner of the pharmacy (here the organization of the structure comes into play) and the auxiliary staff (here, above all, the sensitivity of the individual comes into play).

It seemed absurd to expect to answer a specific question, if we did not have the total picture completely clear, and without outlining an attempt to provide an answer that covered all these different aspects. Unfortunately, in the Opinion, it is not clear what we think of the nature and limits of conscientious objection, nor does the identity of the pharmacist emerge from the fog of vague ambiguity. This is why I decided to abstain from voting.

A Personal Remark signed by Profs. Antonio Da Re, Emma Fattorini e Andrea Nicolussi

A further question - not dealt with in the Response because not object of the specific query addressed to the NBC - deserves to be highlighted regarding the issue of conscientious objection (in the broad sense, i.e. including the so-called conscience clause) of pharmacists to the sale of so-called emergency contraception. We believe that there should be more in depth consideration of the issue as regards vulnerable individuals, in this case minors, who, as all the data seem to confirm, are the largest consumers of emergency contraception (cf. C. Pasolini, *La corsa delle minorenni alla pillola del giorno dopo*, “La Repubblica” dated 10.1.2011). It is a worrying phenomenon, especially in view of the marketing of new drugs with possible abortive effects or preventative effects of embryo development, these vulnerable individuals would then be deprived of even minimal assistance and those procedural rules which are also provided for by Law 194 of 1978.

It is hoped that there will be unprejudiced reflection on drug privatization; an eventual *laissez faire* policy in this area could result in conflict with the underlying choices set out as principles in the first articles of that very Law No.194 of 1978. There is special emphasis on the urgency of appropriate instruments for assistance, prevention and education aimed at under age persons; more generally there is reference to the importance of fostering a better and more effective relationship between professionals (physicians and pharmacists) and women who “urgently” request such drugs, in order to ensure a more conscious response to the needs of women – and above all minors – so that they are not left alone to hastily take the drug.

We would like to emphasize the scope of the social and cultural phenomenon which has much wider ranging implications that risk being detracted from faced with the problem of mere conscientious objection of pharmacists, which, in actual

fact, is a final moment in the moral questions and social issues that - especially related to minors – have their origin well before. It is there that they should be addressed.

A Personal Remark signed by Dr. Riccardo Di Segni

I approved the document agreeing with its conclusions, which in any case, call for the availability of the drug throughout the country. I have reservations as regards the discussion on the right to conscientious objection that precedes the conclusions, which proposes two different positions: one in favor of conscientious objection, assigning to the State the responsibility to make the drug otherwise available, the other against conscientious objection. I do not recognize myself in either position. On the one hand, I believe that there is a right to conscientious objection; on the other, I carefully evaluate the observations of those who deny this right, but I do not use them, as do their supporters, to deny the right to legislative recognition for conscientious objection, in as much as it is a “weak” right, not absolute, which must yield before a right that I consider stronger, that is the right of the service user to obtain the drug prescribed by the physician. As explained by the representatives of pharmacists, in this country theory collides with organizational reality, in that in point of fact, in certain areas, the refusal of one or more pharmacists may signify the real unavailability of the drug. I believe at this point that, while recognizing the right to conscientious objection in general, wherever, for reasonable organizational reasons it may be impossible to locate the drug in emergency situations in a specific area, the right of the patient is prevalent and therefore the right to exercise conscientious objection may not be permitted to the only pharmacist in the area.

A personal remark signed by Prof. Demetrio Neri

1. In a letter sent to NBC on November 23, 2010 Hon. Luisa Capitanio Santolini calls upon the NBC “to make a statement regarding the deontological correctness and/or the ethics of the pharmacist who invokes the conscience clause that is however provided for in their Code of Ethics in art. 3, comma 1 letter c), refusing to sell pharmaceutical products for which the possibility of a mechanism of action that leads to the removal of a human embryo can not be excluded”.

2. As for the ethical correctness, regarding the question - as evidenced by the documents attached to the letter of Hon. Santolini - the Order of Pharmacists of Perugia has already answered in a positive sense, on a request from Dr. Maria Lena: and there is nothing to add, except to note that Article 3, paragraph 1, letter c of the Code of Ethics of Pharmacists is formulated less clearly and incisively, concerning the basis of ethics of conscientious objection, compared to the formulation present in the Italian Medical Code of Ethics (Art.22 version 2006).

3. As to correctness, “however, ethical”, it must be noted that the *moral* right to conscientious objection stems from the value of freedom and integrity of

conscience of each individual: anyone who is obliged to perform a service (to which refusal by other means is impossible) has the *moral* right to appeal to his own conscience when the performing of the service is deemed contrary to it. The call for freedom of conscience is, *morally*, entirely unobjectionable, whatever the underlying motivations, it being clear that no one can replace the conscience of another to determine ethical propriety. However, when the objector comes out from the sphere of individual conscience in order to publicly testify his obedience to a duty which he considers greater than that imposed by law, one enters on a different plane from ethics and deontology. Indeed, on this level, it is certainly not permission to disobey that is being requested – although this conduct is still possible, at whatever the cost - but rather authorization to do so without incurring any possible penalties provided by law. It can be said that, by so doing, the objector weakens the symbolic value of “resistance to power” linked to all acts of objection to request, instead, that the regulations leave to the individual the choice between equally legitimate alternative behaviors, within the limits and the most appropriate methods in order to ensure that this area of individual choice is compatible with the orderly conduct of social life.

4. Indeed, in liberal democratic societies respectful of ethical pluralism - which constitute the most favorable terrain not so much to cultivate integrity and inviolability of conscience, but also to see it respected - individuals (and consciences) with different moral orientations must be able to coexist and it is for this reason that the appeal to the conscience of some must never result in the claim to construct coexistence according to ones’ own beliefs, preventing the satisfaction of the legitimate expectations of others: it would be as if they imposed de facto their own moral beliefs on others, in clear contradiction with the very nature of the democratic principle to which they make appeal. If everyone were allowed to break the laws for reasons pertaining to conscience - and as the dictates of conscience are potentially endless – the protection of the law would be undermined and the very fabric of society would become impossible.

5. It is in the light of the aforementioned that the issue must be addressed – it is only hinted at the beginning of the letter of Hon. Santolini, but not the actual subject of the specific question - of a possible law that allows the pharmacist to evade, without incurring the consequences, the legal obligation to fill the prescription: and, by logical consequence and under the principle of equality, anyone else, directly or indirectly, working in the causal chain that leads to the action objected to. The NBC has set up a working group that is examining the general issue of conscientious objection, in view of the increasing number of instances of appeal to conscience in various other areas of social life. Pending the completion of the work, it is to note here that the necessary and indispensable condition for the eventual legal recognition of conscientious objection is the assertion of the right of every citizen to obtain the services due by law: if and only if that condition is established as a priority, and on indication of suitable measures to ensure this, will the conditions be created to avoid a conflict of conscience that could be detrimental to the orderly conduct of social life. In other words, any prospective law should, as a priority, establish everyone’s right, on explication of the necessary instruments for implementation and, in particular, of the figures responsible for their accomplishment, and then recognize the right of some (or

even of one person) to exemption according to the dictates of personal conscience. A reversal of this order, or the mere reference to general measures, which then - as experience shows - are easily disregarded without any consequences to be paid by those who contravene, is unacceptable. Whoever appeals to the law in order to leave to the individual the choice between equally legitimate alternative behaviour, apparently accepts democratic logic and should not therefore be contrary to the fact that the law establishes procedures for the exercising of conscientious objection to make it compatible with the orderly conduct of social life.

With this purpose in mind, the idea here is to suggest that instead of keeping, as has been done, to the limits of sectoral regulations, uniform regulations on the subject of the rights and duties regarding health should be reached, even considering the variety of professional figures and roles involved in this sector of social life.

Prof.ssa Grazia Zuffa endorses this *personal remark*.

Appendix

Request made by the Hon. Luisa Capitanio Santolini

Chamber of Deputies

Hon. Luisa Capitanio Santolini

NATIONAL BIOETHICS COMMITTEE
Via della Mercede 96,
00187 Roma

Roma, 23.11.2010

The undersigned Hon Santolini Luisa Capitanio, MP

GIVEN THAT

- It is the task of the NBC, as is clear from its decree of establishment, to provide Opinions in view of the preparation of legislative acts;
- Following formal complaints on national territory against pharmacists that appeal to the so-called "conscience clause" to avoid to sell products whose mechanism of action does not exclude the elimination of human embryos prior to implantation in the uterus;
- The Council of Europe in its Resolution No. 1763, "The right to conscientious objection in Lawful medical care", adopted on 07.X0.2010, affirmed that among other things: "No person, hospital or institution shall be coerced, held liable or discriminated against in any manner because of a refusal to perform, accommodate, assist or submit to an abortion, the performance of a human miscarriage, or euthanasia or any act which could cause the death of a human foetus or embryo, for any reason" (see attachment1);
- The Council of the Order of Pharmacists of Perugia in the meeting of 27.05.2010 adopted the concern of a member who had requested a deontological opinion regarding the matter. (see attachment. 2) approving " unanimously the view that gives pharmacists the right to conscientious objection" (see attachment. 3);

CONSIDERED THAT

The National Bioethics Committee, already called upon in relation to the possibility for doctors to exercise conscientious objection faced with the request for prescription of so-called emergency contraceptive products, had replied affirmatively to the question with a note approved on 28.05.2004, referring to the right for doctors to appeal to the "conscience clause."

Given and considered the above, the undersigned

REQUESTS

That the National Bioethics Committee should rule on the deontological correctness and / or ethics of the pharmacist who, by invoking the conscience clause provided for in Article 3 paragraph 1 letter c) of their own Code of Ethics refuses to sell pharmaceutical products for which the possibility of a mechanism of action that leads to the removal of a human embryo can not be excluded.

Thank you for your attention.

Yours sincerely,

Luisa Capitanio Santolini