

**THE FOX AND THE GRAPES: AN ANGLO-IRISH PERSPECTIVE ON
CONSCIENTIOUS OBJECTION TO THE SUPPLY OF EMERGENCY HORMONAL
CONTRACEPTION WITHOUT PRESCRIPTION**

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ABSTRACT

Emergency hormonal contraception (EHC) has been available from pharmacies in the UK without prescription for eleven years. In the Republic of Ireland, this service was made available in 2011. In both jurisdictions, the respective regulators have included “conscience clauses”, which allow pharmacists to opt out of providing EHC on religious or moral grounds, providing certain criteria are met. In effect, conscientious objectors must refer patients to other providers who are willing to supply these medicines. Inclusion of such clauses leads to a cycle of cognitive dissonance on behalf of both parties. Objectors convince themselves of the existence of a moral difference between supply of EHC and referral to another supplier, while the regulators must feign satisfaction that a form of regulation lacking universality will not lead to adverse consequences in the long term.

We contend that whichever of these two parties truly believes in that which they purport to, must act to end this unsatisfactory status quo. Either the regulators must compel all pharmacists to dispense emergency contraception to all suitable patients who request it, or a pharmacist must refuse to either supply EHC or to refer the patient to an alternate supplier, and challenge any subsequent sanctions imposed by their regulator.

A BRIEF HISTORY OF EHC IN GREAT BRITAIN AND IRELAND

Emergency hormonal contraception (EHC), an intervention within 72 hours of unprotected intercourse, dates back almost 40 years to the Yuzpe regimen.¹ This regimen allows a woman who has had unprotected sex to avoid pregnancy by taking two combined doses of estrogen and progestogen separated by twelve hours. A licensed Yuzpe product, Schering PC4™ (50 mcg ethinyloestradiol; 250 mcg levonorgestrel), was available on prescription in the UK from 1984 until 2002, at which time it was discontinued following the introduction of progestogen-only EHC, in the form of the Levonelle® (1.5 mg levonorgestrel) tablet. Although Schering PC4™ was never licensed in the Republic of Ireland, many common combined oral contraceptives (COCs) could be used for the Yuzpe regimen, and Ovrán® 50 tablets (50 mcg ethinyloestradiol; 250 mcg levonorgestrel) were commonly prescribed off-label for this purpose. Levonelle® has been available on prescription in Ireland since 2003. In 2011, the Irish Medicines Board issued a marketing authorisation (MA) for Norlevo® (1.5 mg levonorgestrel) tablets, allowing EHC to be supplied to patients without a prescription for the first time.² In the UK, Levonelle® was removed from prescription-only control in 2001.³ It can currently be supplied against a prescription or patient group direction (PGD) under the brand name Levonelle®, or over the counter as Levonelle® One-Step: both products contain a single 1.5mg tablet.

THE LEGAL STATUS OF EHC

Between 1922, when the Republic of Ireland gained independence from the UK, and the enactment of the Abortion Act in 1967, “procuring a miscarriage” was illegal in both jurisdictions under s.58 of the Offences against the Person Act 1861. Since 1967, the 1861 Act continues to be the basis of a ban on abortion in Northern Ireland and the Republic only.

In response to the legalisation of therapeutic abortion in England, Scotland and Wales by the 1967 Act, numbers of Irish women travelling to these parts of the UK each year to obtain an abortion increased markedly. In response to this, pro-life groups began to lobby for an explicit amendment to the Irish constitution banning abortion. In 1983, the Constitution was amended to assert that the unborn had an explicit right to life from the time of conception, with the Irish State guaranteeing to vindicate that right. In 1992, in a case involving a suicidal minor who was a statutory

rape victim, and who became pregnant, the Supreme Court of Ireland interpreted the amendment as giving a right to abortion in certain limited circumstances.⁴ Following its ruling in this case, women could more readily leave Ireland for an abortion that was lawful in another country. A further referendum in 1992, led to two amendments, which established the “right to travel” and the “right to information”.

The “morning-after” pill is not classified as an abortifacient under UK or Irish law. In the case of *Smeaton*, the High Court of England & Wales ruled that the morning after pill is a form of contraception.⁵ The claimant attempted to assert that EHC is a method of early abortion and, as such, should be subject to the legislation governing abortion. It was argued that the supply and use of EHC involved the commission of criminal offences under the Offences Against the Person Act 1861, which prohibits the supply “of any poison or noxious thing” with intent to cause miscarriage.⁶ The judgment handed down ruled that emergency contraception is indeed lawful with specific reference to the fact that until an embryo has been implanted, it is not actually attached to the woman in any way.⁷

A similar legal challenge was threatened by pro-life group “Ireland for Life” against the IMB’s decision to reverse its consideration that Levonelle® was an abortifacient.⁸ The IMB had refused to grant an MA for Levonelle® on those grounds in 2000,⁹ but subsequently licensed the product on a prescription-only basis in 2003. This threatened legal challenge remained just that: to date, no judicial review of the IMB’s classification of Levonelle® as a contraceptive has been heard by either of Ireland’s Superior Courts.

RELIGIOUS BELIEFS & CONSCIENTIOUS OBJECTION

“The religion ... of every man must be left to the conviction and conscience of every man; and it is the right of every man to exercise it as these may dictate.”

James Madison (1809-1817)

In 1792, Madison described religion as an “*unalienable right*”; he believed religious freedom was an entitlement that no earthly power could rightfully deny.¹⁰ In contemporary healthcare, religious affiliation has been shown to be a predictor of pharmacists’ willingness to dispense EHC.¹¹

Leaders of numerous faith groups have expressed opinions on the topics of contraception and abortion. Pope Benedict XVI affirmed previous stance of the Catholic Church against the use of EHC when he exhorted pharmacists to act only such that “all human beings are protected from conception to natural death, and so that medicines truly play a therapeutic role”.¹² Similar opinions have been expressed by various Jewish and Islamic faith groups.¹³

In the context of EHC, we will use the term “conscientious objection” to refer to the refusal by a healthcare professional to comply with the request of a patient on the basis of their own moral or religious code. The supply of EHC has been cited as the unprompted ethical issue most frequently mentioned in interviews with UK-based community pharmacists.^{14 15} In the US, a 2010 study indicated that 6% of pharmacists would refuse to dispense prescriptions for EHC on moral grounds.¹¹ Many of the pharmacists in this study considered EHC to be a form of abortion, and claimed this outlook was due to their fundamental religious views.

SOME ARGUMENTS FOR, AND AGAINST, CONSCIENTIOUS OBJECTION

Although this article does not claim to constitute a review of the arguments surrounding pharmacists’ right of refusal in dispensing morally-objectionable medications, it would be useful at this point to briefly identify some of the claims made on each side.

Beauchamp and Childress argue that it is possible to identify four key ethical principles in the healthcare tradition, namely: autonomy; beneficence; non-maleficence; and justice.¹⁶ Those pharmacists not wishing to supply EHC often state say that refusal is supported by two of these principles: autonomy and non-maleficence.^{17 18} They argue that their professional autonomy is compromised when they are not allowed to act in line with their own conscience, in particular when doing so causes harm.

In the context of the four principles, it is generally accepted that autonomy refers to that of the patient, rather than that of the healthcare provider, and it has been strongly argued that it, as a necessary component of the other three, must be given primacy.¹⁹ Respect for patient autonomy is a core tenet of contemporary healthcare. The traditional, paternalistic approach to medicine has made way for a relationship

based on a more fiduciary partnership between patient and professional.²⁰ The obligation for healthcare professionals is to ensure that patients' autonomous decisions should not be constrained by others. This can be viewed as both a negative and a positive obligation. While the negative obligation requires that a patient's path to obtaining that which is in the best interests of their health is not unnecessarily impeded, the positive obligation calls for "respectful treatment in disclosing information and fostering autonomous decision-making".¹⁶ Beauchamp and Childress mean for healthcare providers to respect patients' decisions, even when these are made on the basis of inclinations, rather than a rational decision-making process, or when they do not agree with their own.²¹

The principle of non-maleficence is often quoted by those who refuse to supply EHC, which they contend causes harm to another person in the form of the embryo or foetus. As was the case with autonomy, the person to whom this principle is intended to apply is wilfully ignored by conscientious objectors, who choose to relate it to eight human cells with no ability to survive outside the body of a non-consenting adult female, rather than to the woman herself.

Arguing against the right of conscientious objection, one might start by asserting that, if people have strong and sincere objections to performing a basic, routine aspect of their profession, then they shouldn't take up that profession, and they certainly shouldn't demand that the world revolve around them by adjusting the parameters of the work to suit themselves. What pharmacists in such cases are demanding is the power of veto over the liberty of others, and over the implementation of public policy. They are acting directly to prevent women from obtaining a legal and clinically-appropriate medicine because they would be unable achieve this goal through the normal democratic process.

Pulitzer Prize-winning American journalist, Ellen Goodman, argues that "[w]hat the pharmacists and others are asking for is conscience without consequence. The plea to protect their conscience is a thinly veiled ploy for conquest".²² Refusing to do something because your conscience won't allow it may be laudable in some cases, but it stops being laudable when you refuse to accept the consequences of your refusal. Society cannot function if people are able to ignore whatever rules, regulations, standards, or laws they want on the basis of "conscience" or religious

desire.

For many patients, seeking emergency contraception it is a distressing experience: refusal may be interpreted as moral intimidation, discouraging them from seeking further help. Refusals also inevitably curtail a patient's right to have appropriate & legal medications to treat their physical symptoms on the basis of another's moral wants.²³

These arguments, however strong, have failed to remove the right of conscientious objection from those wishing to exercise it; nor have their counter-arguments allowed pharmacists to refuse to supply EHC without ensuring that set criteria are met. The pharmacy regulators and those dissenters from within the group whom they regulate have reached a point where, rather than follow their lines of reasoning through to a conclusion, they both espouse the existing, unsatisfactory stalemate.

WHAT THE REGULATORS SAY

Although the legal status of EHC is not in question, the law in this case serves only to remove prohibitions on supply; it does not compel any pharmacist to supply EHC against their own religious or moral beliefs. Statute could force pharmacists to provide every service legally requested, if access to treatment was more highly regarded than religious freedom.²⁴ As a lesser measure, legislators could choose to allow individuals of conscience to exempt themselves up to a point that it creates hardship for the patient.²⁵ When the law fails to provide even this level of ethical guidance, regulatory bodies and professional organisations must step in to remind pharmacists of the standard to which they, as professionals, must be held.

Standard 3.4 of the General Pharmaceutical Council's (GPhC) *Standards of conduct, ethics and performance* states that, as a pharmacist, one must:

“[m]ake sure that if your religious or moral beliefs prevent you from providing a service, you tell the relevant people or authorities and refer patients and the public to other providers”.²⁶

Further guidance is provided in the form of the GPhC's *Guidance on the provision of pharmacy services affected by religious and moral beliefs*.²⁷ Pharmacists are reminded here that “if [they] do not supply EHC ... women should be referred to an

alternative appropriate source of supply available within the time limits for EHC to be effective.” However, the guidance falls short of instructing pharmacists that, should they be unable to relay the patient to an alternate supplier within that timescale, that they must supply the EHC themselves.

This approach is mirrored by the Pharmaceutical Society of Ireland’s (PSI) *Code of Conduct for Pharmacists*, and associated guidance, which state that;

“[i]f supply to a patient is likely to be affected by the personal moral standards of a pharmacist, he or she must inform their superintendent and supervising pharmacist, who must ensure that suitable policies and procedures are in place to ensure patient care is not jeopardised and the patient is facilitated in accessing the information or service required to meet their needs.”

Here, again, the pharmacy regulator stops short of providing guidance to the pharmacist who is at the end of this line of referral from one pharmacist-unwilling-to-dispense-a-legal-medicine to another.

The primacy of the pharmacist’s duty of care to their patient is acknowledged by both the British and Irish regulators, both of whom make this the first principle of their respective codes of ethics.^{26 28} The PSI even go so far as to state that “[t]his is the primary principle and the following principles must be read in light of this principle.” Indeed, a recent study of pharmacy codes of conduct from English-speaking jurisdiction the primacy of patient care was paramount in 28 out of the 34 codes examined.²⁹ Although the important distinction between objection and obstruction seems to be recognised by the regulatory bodies,²³ they lack the impetus to follow their assertions through to their logical conclusion.

The UK and Ireland are not alone in this lack of leadership: the American Pharmacists Association (APhA) also compromises on the issue. APhA’s policy supports the ability of a pharmacist to opt out of providing a service for personal reasons, as long as the patient’s access to appropriate health care is not disrupted. That is to say, its policy supports a pharmacist “stepping away” from participating but not “stepping in the way” of the patient accessing the treatment.³⁰

DISCUSSION

Unlike more classical cases of conscientious objection, such as refusal to carry out abortions, restricting access to EHC often involves denying the patient access to effective treatment, due the relatively narrow windows in which it is effective. Despite the fact that, “objecting pharmacists themselves embrace the moral difference between [supplying EHC] and allowing [it to be supplied]”,³¹ replacing a duty to dispense EHC with a duty to refer to a pharmacist who is willing so do to “does not remove the pharmacist from the causal chain of events that leads to the use of [EHC]”.³² Even if the use of EHC does constitute abortion to these pharmacists, signposting a patient (or ‘offender’) to another pharmacist who is willing to make the supply does not prevent its use in the vast majority of cases. Wicclair suggests the following conditions must be met in order to ascribe moral complicity to one healthcare practitioner referring a patient to another for treatment that the first practitioner considers unethical:

1. Disclosure of the option and provision of a referral;
2. Acceptance of the treatment by the patient following referral is a reasonably foreseeable outcome;
3. The referral contributed to the unethical behaviour of the second practitioner.³³

In the context of EHC, all three of these conditions are met: the objecting pharmacist is required to make the referral; the patient is seeking the treatment, so acceptance is probable; and without a patient the second pharmacist is unable to engage in practices deemed unethical by the first. A true defender of a pharmacists’ right to conscientious objection should see no ethical difference between dispensing the medication and enabling another willing pharmacist to do so. In either case, the result is the same. The situation is morally no different than refusing to supply 200 paracetamol tablets to a depressed customer for the purpose of committing suicide, but explaining to him that he can purchase 16 tablets in each of the dozen newsagents in the surrounding area. If they do not believe that paracetamol should be put to this purpose, then they must remove themselves entirely from the chain of supply. When it comes to EHC, however, their objections are not absolute.

Kelleher argues that such pharmacists would be morally required to dispense [EHC]

if this would lead to the frustration of two additional requests by two other customers at two other pharmacies". This may seem to many like a purely hypothetical situation, but if all stock in a given geographical area is drawn from the same wholesaler, whom has limited stock, the dispensing of a double dose to a single patient could deplete the available supply, thus ensuring two other requests go unmet. The Faculty of Family Planning and Reproductive Health Care of the Royal College of Obstetricians and Gynaecologists (RCOG) has produced guidance on the issue of use of levonorgestrel for emergency contraception in women who are concurrently using liver enzyme inducing drugs, which advises that an increased single dose of 2.25 mg (equivalent to one-and-a-half tablets) should be taken.³⁴ Why, then, are these pharmacists so conscientious in their objection? Why is their rejection not absolute? It would appear that religious belief is paramount as long as it does not incur any serious financial penalty, such as may result from a fitness to practice investigation, or having to defend oneself against an aggrieved patient in the courts.

On the other side of this unfortunate stalemate are the regulators. The GPhC and PSI have created a "pass the buck" system that does not preclude conscientious objection; rather this makes it extremely unlikely that a patient will not have access to EHC, albeit following the indignity of being morally judged by those whose duty it is to see to their healthcare needs. However, as making something extremely unlikely is not the same as precluding it, this system lacks universality.

From the perspectives of both moral defensibility and legal practicality, any rules or regulations governing the supply of EHC must be universally applicable. Kant's first formulation of the categorical imperative requires that one "[a]ct only according to that maxim whereby [one] can at the same time will that it should become a universal law without contradiction".³⁵ This has practical, as well as philosophical, advantages: those charged with the regulation of a profession such as pharmacy could not be expected to draft bespoke codes of conduct for each of their members; rather they are required to compose a single set of standards to which all members must be held.

It would be wholly unacceptable to allow pharmacist to refuse patients in a city, where pharmacies abound, but to forbid them to do so in the countryside, where

large distances may separate them. What is required, then, are standards that ensure every woman who fulfils the criteria for EHC should be able to obtain it within the effective timescale without exception. The current standards in both the UK and Ireland would allow most, but not all, women to obtain EHC from a pharmacy following, at worst, being subject to the moral judgment to which we earlier alluded. However, although both parties are desperately trying to avoid a situation that would expose the flaws in their respective arguments, regulators and objectors alike must be acknowledged the existence of such a scenario: a woman walks into a rural pharmacy almost 72 hours after unprotected intercourse and asks for EHC from a pharmacist who does not wish to supply it on religious grounds. With the option of referral removed, the pharmacist must make a decision between his belief and his professional duty. If he decides to supply, he reveals to himself that his religious principles are secondary to the practice of his profession; if he refuses, he faces possible disciplinary action, and the regulator may have failed in their duty of care to a member of the public, as this situation might have been avoided through stronger regulation.

CONCLUSIONS

Pharmacy may be regarded as a profession as its members are bound by regulated standards of education and a code of conduct. A central tenet of professionalism is the relationship of trust between the practitioner and their patient. The fiduciary nature of this relationship requires the pharmacist to put the interests of the patient ahead of their own. If a pharmacist denies a service to a patient, the relationship of trust and respect may be put in jeopardy.

The current status quo is not satisfactory to either conscientious objectors, or to those who must regulate them. The former have allowed themselves to be convinced that referral to another willing supplier is ethically any different from supply, while the latter merely postpone the inevitable incidence of a pharmacist refusing to supply EHC to a patient for whom referral is not an option. Both groups fall back on strong arguments in support of the position that they believe they hold: however, until each accepts the fact that that the current situation supports neither stance, patient care is philosophically compromised.

Either the GPhC and PSI must compel all pharmacists to dispense emergency

contraception to all patients meeting the clinical criteria whom request it, regardless of their own moral or religious objections; or a pharmacist must refuse both to supply EHC and to refer the patient to an alternate supplier, and confront the possible consequence of a complaint against them for poor professional performance or professional misconduct. The alternative is to remain locked in the current cycles of mutual cognitive dissonance, wherein the objectors convince themselves that referral does not constitute supply, and the regulators do not place themselves in the position of having to deal with a vocal religious minority of whom they are terrified. As it stands, neither side wants the high-hanging grapes, as they will be sour anyway.

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