AT ISSUE
THE RIGHT TO SAY YES: THE ETHICS OF CONSENT TO MEDICAL TREATMENT

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The question of "consent" in feminist debate usually centres in the right to say no. Whether a woman is importuned sexually by a stranger, an acquaintance, boyfriend, or husband, women advocate strongly for the right to articulate our denial of a desire to participate, and for this denial to be heard. Not only does the argument centre on women's right to say no, but it emphasises our right to have that "no" taken for an answer – a negative answer.

Traditionally the law has favoured not women's right to say no to sexual importuning, but men's unprincipled privilege to ignore any woman's reaction or response to sexual imposition. Rape and indecent assault laws have been framed from a macho-male perspective: "I want, I will, I do," for the man; imposed silence for the woman (whatever her words or acts). This silencing means that the law generally interprets the woman as consenting or, at minimum "leading the man on." Courts are disposed to *assume* or *presume* acquiescence of a woman to the importuning of *any* man, whatever the woman's acts and words, and whatever the reality. Judges have even interpreted the actions of a 3-year-old or a 6-year-old girl as "provocative," and thus supportive of the man's plea that the girl was "consenting," or at least he honestly believed she was.

Is there any parallel between the interpretation of "consent" to sexual imposition and "consent" to medical treatment, whether "accepted" or "therapeutic," or experimental? Just as the right to say no to sexual imposition is worthless if "no" means "yes," the right to say yes to medical treatment is of little value if "yes" is premised on inadequate advice, misinformation, misrepresentation – or no advice or information. The right to say yes to medical treatment is meaningless unless there is a realistic corollary, the right to reject treatment. Just as with sexual activity women should have a right to say no and a right to say yes in circumstances of *women's* fully informed understanding, active agreement, and self-determination, so the notion of consent to medical treatment must carry with it this dual aspect of agreement to participate in the treatment, and its corollary, a rejection of the treatment.

"CONSENT," LAW, AND MEDICINE

"Informed consent" is a term bruited about in the medical field. Carolyn Faulder (1985, p. 11) points out that there is a broad range of opinion in the medical community as to its meaning:

> **ask** . . . of any doctor, nurse, medical researcher or other health profession [the meaning of the expression "informed consent"] and you will be met by a variety of confusing and confused reactions: dismay, concern, defensiveness and, occasionally, a barely concealed anger that you, a lay person, are intruding into an area of professional behaviour which is really none of your business. Persist, and you will be surprised by the diversity of

interpretations which is offered to you.

She goes on to say that these can range from "the nervously uttered statement that 'informed consent means telling patients everything about their condition and leaving the choice of treatment to them'" to the "dismissive assertion that 'informed consent is a nonsense because patients can't understand all that they are told and shouldn't be allowed to make decisions for themselves.'" Between these two extremes are

> vast numbers of conscientious doctors . . . who agonise daily about how much information they should be giving to their patients, in what way they should be communicating, and whether, if they involve their patients in the onerous decision-making process, they may not be making things worse rather than better for them. (Faulder, 1985, pp. 11–12)

As Carolyn Faulder acknowledges (1985, p. 12), the medical profession is "divided within itself as to the meaning and purpose of informed consent":

> The doctor's first duty is . . . to act always in the best interests of the patient. It is how those best interests are interpreted and whose opinion prevails which is the crux of the problem.

As long ago as 1767, an English court held that an action in trespass against the person was available if a medical procedure was carried out without a patient's consent. That is, the patient could sue the doctor (and the hospital) in a court of law for the nonconsensual imposition of treatment. It was said that consent as a requirement for medical treatment arises out of the general practice of the medical profession, and that it "is reasonable that a patient should be told what is about to be done to him [sic], that he may take courage and put himself in such a situation as to enable him to undergo the pain." Indeed, if a person does not consent, but surgery is carried out on that person, the doctor would be guilty of a criminal act of unlawful wounding, assault, or grievous bodily harm, depending upon the degree of harm caused to the "patient" (*R. v. Donovan*, 1934; *Reibl v. Hughes*, 1980).

Yet what is the quality of "consent" required? The notion of "choice" is often put forward as a measure of valid consent. But "choice" is too often isolated from any acknowledgement of political and social context. A choice between yes and no when there is no full information, or when information is false or distorted, is hardly "choice." And if considerable risk is involved in a particular treatment that is offered, or because of inadequate, self-interested research the depth of risk is unknown or unacknowledged, should the "choice" be available anyway?

Legal cases illustrate the way in which the law fails to acknowledge power relationships and their relevance to acquiescence to medical treatment. The question of *what* information should be given to found a full and free consent, and the *quality* of that information, is also unsatisfactorily determined by the courts.

In the early 1980s, Ms. Amy Sidaway had an operation to her spinal column to relieve a persistent pain in her neck (*Sidaway v. Bethlem Royal Hospital and Maudsley Hospital Health Authority and Ors*, 1985). The surgeon did not tell her that there was about a 1-2% risk that her spinal cord would be damaged and she could become a paraplegic (1985, p. 485). This is what happened. The complaint brought by Ms. Sidaway against her surgeon, a Mr. Falconer (who died before the case came to trial), was that he was "in breach of his duty as her medical adviser in failing to warn her of the risk of damage to the spinal cord." The surgeons who gave evidence were agreed that "the extent of the warning is a

matter for medical judgment with especial importance attached to the doctor's assessment of his patient." The question for the English House of Lords to consider was "whether the omission by Mr Falconer to warn his patient of the risk inherent in the operation of damage to the spinal cord with the possible result of a partial paralysis was a breach of duty owed by him to his patient." Her case for damages on the basis of negligence was rejected by the High Court, then the Court of Appeal, and finally the House of Lords.

One of the English House of Lords judges observed that the questions in the case had never before been raised directly in a court in England. He outlined the problem, saying (1985, p. 483):

> Has the patient a legal right to know, and is the doctor under a legal duty to disclose, the risks inherent in the treatment which the doctor recommends? If the law recognises the right and the obligation, is it a right to full disclosure or has the doctor a discretion as to the nature and extent of his [sic] disclosure? And, if the right be qualified, where does the law look for the criterion by which the court is to judge the extent of the disclosure required to satisfy the right? Does the law seek guidance in medical opinion or does it lay down a rule which doctors must follow, whatever may be the view of the profession?

Earlier decisions of English courts were referred to for assistance in answering these questions. These decisions are relevant not only to United Kingdom residents but also to people living in countries which adopted English law, such as Australia and New Zealand. In the United States and Canada, the decisions may be relevant, but the courts have developed the position further.

In *Bolan v. Friern Hospital Management Committee* (1957) the rule was laid down that a doctor is not negligent if she or he acts in accordance with a practice accepted at the time as proper by a responsible body of medical opinion, even though other doctors adopt a different practice. In short, the law imposes the duty of care; but the standard of care is a matter of medical judgment: What does the particular doctor treating the patient think, in conjunction with the standard of what do reasonable doctors in the same circumstances think about the treatment and its possibilities?

One of the judges in *Sidaway's* case said that the implications of this test are disturbing if this is the criterion used to determine "whether a doctor is under a duty to warn his or her patient of the risk, or risks inherent in the treatment which she or he recommends." He said it would be

> a strange conclusion if the courts should be led to conclude that our law, which undoubtedly recognises a right in the patient to decide whether he will accept or reject the treatment proposed, should permit the doctors to determine whether and in what circumstances a duty arises requiring a doctor to warn his patient of the risks inherent in the treatment which she or he proposes. (*Sidaway v. Bethlem Royal Hospital and Maudsley Hospital Health Authority and Ors*, 1985, p. 488)

He went on to suggest, along the lines of United States and Canadian decisions (*Canterbury v. Spence*, 1972; *Cobbs v. Grant*, 1972; *Reibl v. Hughes*, 1980), that doctors have a legal duty of care to respect the patient's right to make her or his own decision, and common law principles should allow a patient to seek a legal remedy, through negligence law, if that duty is not fulfilled. A duty to warn a patient of risks involved in treatment is part of the legal duty of care, and the principle in *Bolan's* case is inadequate to cover this:

> The doctor's duty can be seen to be one which requires him not only to advise as to

> medical treatment but also to provide his patient with the information needed to enable the patient to consider the balance of the medical advantages and risks alongside other relevant matters . . . of which the doctor may be only partially, if at all, informed.

By "other relevant matters," he alluded to the living circumstances of the patient, and social and other human aspects associated with the patient's existence in the world as a person. Yet other of the judges in *Sidaway's* case made clear their paternalistic, class-based, and sex-biased view of the world – at least that inhabited by persons who are patients, or prospective patients. Thus a second judge observed that Ms. Sidaway had raised with the surgeon no concerns about the treatment she was to receive (1985, p. 192):

> We are dealing in the present appeal with a patient who has expressed to the neuro-surgeon no anxiety about any risks of the proposed operation going wrong.

He considered that had the patient asked Mr Falconer, the surgeon, what the risks were, the situation would be different, but as this case was concerned with "volunteering unsought information," the test of the responsible or reasonable doctor was to be applied (1985. p. 500):

> To decide what risks of the existence of which a patient should be voluntarily warned and the terms in which such warning, if any, should be given, having regard to the effect that the warning may have, is as much an exercise of professional skill and judgement as any other part of the doctor's comprehensive duty of care to the individual patient and expert medical evidence on this matter should be treated in just the same way.

This judge astonishingly (although on reflection as to the origins and predictable mindset of English House of Lords members, perhaps not so astonishingly) granted a higher right of information to persons in a category similar to himself, saying (1985, p. 500):

> when it comes to warning about risks, the kind of training and experience that a judge will have undergone at the Bar makes it natural for him [sici to say (correctly) it is my right to decide whether any particular thing is done to my body and I want to be fully informed of any risks there may be involved of which I am not already aware from my general knowledge as a highly educated man of experience, so that I may inform my own judgment as to whether to refuse the advised treatment or not.
>
> No doubt if the patient in fact manifested this attitude by means of questioning, the doctor would tell him whatever it was the patient wanted to know; but we are concerned here with volunteering unsought information about risks of the proposed treatment failing to achieve the result sought or making the patient's physical or mental condition worse, rather than better. The only effect that mention of risks can have on the patient's mind, if it has any at all, can be in the direction of deterring the patient from undergoing treatment which in the expert opinion of the doctor it is in the patient's interest to undergo . . .

Another of the judges thought that Ms. Sidaway's common sense should have alerted her to the dangers of the surgery. He assumed that, had Mr Falconer explained what he was going to do (which begs the question anyway), "the possibility of damage to a nerve root or to the spinal cord was obvious." He too considered that the patient should ask questions if she is to receive any information. He said (1985, p. 508):

I do not subscribe to the theory that the

patient is entitled to know everything nor to the theory that the doctor is entitled to decide everything.

The problem is, however, that "if you don't ask, then you won't find out" – and the good judge sees nothing wrong with this!

On the "special relationship" between doctor and patient, this judge concluded (1985, p. 509):

> At the end of the day, the doctor, bearing in mind the best interests of the patient and bearing in mind the patient's right to information which will enable the patient to make a balanced judgment, must decide what information should be given to the patient and in what terms that information should be couched. The court will award damages against the doctor if the court is satisfied that the doctor blundered and that the patient was deprived of information which was necessary [sic] . . . In the present case . . . I am satisfied that adequate information was made available to Ms. Sidaway.

This, although she was not informed that she could end up paralysed as a consequence of the operation.

Ironically, the judgments in *Sidaway's* case seem to mean that the "better educated" one is; the more powerful vis-a-vis the doctor; and the more social, economic, and cultural resources one has, the greater the duty of the doctor to inform: the more like "us" (judges), the greater the doctor's responsibility in ensuring the patient "knows" all. This also implies that persons (men) in the most powerful positions in the dominant culture are "more intelligent," more capable of making determinations is in their own interests, more able to give proper and appropriate consideration to factors relevant to their bodies, their health, and their treatment: As they are more likely to ask questions, because of the lesser differential in power between themselves and the doctor, they are thus granted greater "right" by the courts as to the degree of information the medical practitioner should impart to them. If the measure of the degree of information the patient should receive is whether or not she asks questions, women will be particularly disadvantaged. Women are more likely to be intimidated into not asking questions, if women ask questions, the doctor may well not "hear." Women in particular are likely to miss out on information and a relevant opportunity to make determinations about health treatment, going ahead with (or declining) an operation, and the like: Few women are judges; few women would fit into any category on a par with judges – according to dominant cultural standards.

In the United States and Canada, theoretically the law is better positioned to enable women to have a "real say" in the medical treatment to which they are subjected. The courts have generally not allowed medical opinion of what is 'best' for the patient to override the patient's right to decide for her or himself. The landmark decision is that of the United States Court of Appeals in *Canterbury v. Spence* (1972). The court enunciated four principles:

1. The root premise is the concept that every humanbeing of adult years and of sound mind has a right to determine what shall be done with his or her own body.
2. Consent is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risk attendant upon each.
3. The doctor must, therefore, disclose all "material risks": What risks are "material" is determined by the "prudent patient" test.
4. The doctor, however, has what the court called a "therapeutic privilege"–this exception enables a doctor to withhold from his patient information as to risk if it can be shown that a reasonable medical assessment of the patient would have indicated to the doctor that disclosure would have posed a

> serious threat of psychological detriment to the patient.
> The "prudent patient" test provides
>
> a risk is material when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forgo the proposed therapy. (*Canterbury v. Spence*, 1972)

Yet does the "prudent patient" include women? In law, the "reasonable man" is the test commonly applied in a number of situations, involving legal interpretation and trials both criminal and civil. In negligence, a question is "what the 'reasonable man' could foresee" (or not foresee) (Boyle, 1985; West, 1988). How many women can fit into the "reasonable man" test? Although non-gender-specific and inclusionary language strictures now have a grasp on at least some judges and legal scholars, there is no assurance that in talking of the "reasonable person," women are any more likely to be included.

Even under the United States and Canadian principles, if a woman could come within the "prudent patient" or "reasonable person" test, are women likely to be in a position to make a full, free, informed consent to medical treatment? There are too many instances of information directly relevant to treatment that is withheld from women patients or prospective patients. The corollary is *false* or "constructed" information being made available – or at least information the source of which, or the source of funding of which, should give reason for pause.

HOW SO "CONSENT"? MANUFACTURING MEDICINE

As early as the mid-1970s, salesmen and officials of Dow Corning Corporation knew that the firm's breast implants broke and leaked in women's bodies. On Monday 10 February 1992 the company released a statement that, while it had known for some 20 years that some silicone would seep out of its envelope, it did not believe this would create health problems. The statement went on (Aubin, 1992; Frank,1992):

> "Bleed" has long been considered by surgeons as a characteristic of silicone gel-filled breast implants, whether made by Dow Corning or other manufacturers.
>
> Tests do not indicate an association between these silicone materials and cancer, or diseases of the immune system.

Surely "bleeding" is bad enough – and ought to have been fully explained to women prior to any move toward implantation. But additionally, the advice that doctors did give, far from alerting women to the risks of breast implants, may well have created more problems for them. Frank (1992) reports:

> Today, Dow Corning released a three kilogram package of scientific studies, complaint letters and internal memos dating from the mid-1960s to the present. The documents were released in response to a flood of government and consumer concerns that the silicone gel-filled sacs might cause serious health problems.
>
> Internal memorandums among the documents raised concerns that exercises recommended to keep the implants supple might contribute to their rupture.
>
> Patients who received breast implants were *instructed by their plastic surgeons to massage their breasts regularly* to prevent a hardening of the breast that results after scar tissue is formed around the implant. *But that massage, some of the memos suggested, could cause some implants to break, leaking silicone gel into surrounding tissues*, (emphasis added)

The surgeons were well-aware of the problems

of breast implants, as in "numerous memos from the mid-1970s, Dow Corning staff said the gel bleed and the implant ruptures were the top complaint of surgeons who inserted the devices" (Frank, 1992).

Similarly in Australia: In February 1992 the managing director of Dow Corning Australia confirmed that his company knew of the risks (Aubin, 1992). A spokesman for the Australian Society of Plastic Surgeons, Dr. Cholm Williams, was reported as saying: "Of course we knew there were risks of hardening, rupture and leaking, but there is no surgery that is without risk" (Aubin, 1992). Ms. Phillipa Lowrey of the Consumers' Health Forum found many women had "complained to the forum that they were not adequately informed about the risks associated with the implants" (Aubin, 1992). Where women complained to medical practitioners, attributing health problems to breast implants, their assessments of their own health and bodily integrity were denied. A United States Federal Drug Administration (FDA) panel reviewing data on implant safety was told by Barbara Herzog, a Pennsylvania farmer, that despite her attribution of health problems to implants she had received in 1977, after an MRI scan at Johns Hopkins University Hospital in 1989 she was "told the implants were fine." Merle Hoffman (1992, p. 7) reports that 8 weeks later "doctors discovered that both silicone implants had ruptured and spilled out over her chest." In 1990 Barbara Herzog gave birth to a child and now is forced to confront having "breast fed silicone to [her] infant daughter."

So much for English judges asserting that women should "ask questions" before medical practitioners are obliged to give information as to risks of treatment or surgery. The Dow Corning experience shows the tendency toward ignoring concerns, questions, or considerations raised by women as to implants and their associated risks. The managing director of Dow Corning Australia, Mr. Bernard McMahon, was reported (Heath, 1992) as saying he was "appalled that the issue [of the risks of breast implants] had degenerated into emotional rather than scientific debate." He said no one had produced "scientific" evidence against the implants. No prizes for guessing whose statements of concern brought about the "degeneration" of the debate.

There is a problem, too, of the source of any "scientific evidence." In Australia in the 1980s, Michael Briggs, then of Deakin University, was exposed as having distorted "results" from various tests he had allegedly carried out in relation to the effect of the contraceptive pill on women's health. His funding came from manufacturers of the pill he reported as having no negative effects. He left the university "under a cloud" after his exposure, and subsequently was reported as having died in Spain.

It is all too common to discover that "research" put forward and published in so-called "respectable," "scientific" journals results directly from grants made to the researchers by companies that manufacture the very drugs or devices that are the subject of the studies. Sometimes the involvement of corporations is even more blatant. Renate Klein, Janice G. Raymond, and Lynette J. Dumble in RU 486 – *Misconceptions, Myths and Morals* observe (1991, pp. 10-II):

> Despite scant research on animals and the dubious results from Geneva [on the "abortion pill" RU 486], clinical trials on women began in France, Sweden, Australia, Holland, USA, England, Finland and China. Roussel Uclaf [the manufacturer of the drug] supplied the drug and its staff and consultants are listed among the authors of the resulting publications from any of these trials. Andre Ulmann of Roussel Uclaf is even credited with designing a Chinese study of RU 486 . . .

And later (Klein et al., p. 12):

> Until the publications of the results of Chinese Trials with RU 486/PG [prostaglandins] in 1989, which reported that 2321 women had participated in four multi-center clinical trials, the numbers of women in the clinical trials were small. From the initial 11 women in the Geneva study, the numbers ranged from 35 . . . to 100 . . . and 271 women. . . . Even a 1989 WHO publication of a multi-center trial with eight medical centers participating included only 261 women. Two publications in 1990 reported larger numbers: Louise Silvestre of Roussel Uclaf and colleagues Dubois, Baulieu and Ulmann listed 2040 French women as participants in their study, and a UK multi-centre trial had 588 participants, a number still significantly lower than the 50,000 or 60,000 women who are said to have undergone chemical abortion by the beginning of 1991. *Importantly, the three largest studies conducted to this point were either undertaken by Roussel Uclaf or were affiliated with the French company. As the authors of the UK multi-trial paper acknowledged, they 'prepared their report from data provided by Roussel Uclaf*' . . . (emphasis added)

Can a study funded by a manufacturer of a product, or run by persons employed by that manufacturer, be placed in the category of "disinterested research"? A fundamental legal principle is *nemo debet essejudex inpro-pria sua causa* (no one man [sic] can be a judge in his own cause). This embodies the notion that a tribunal making a decision must be free from bias when doing so. Legal cases hold that a reasonable suspicion of bias may exist:

- where a person acts as prosecutor as well as adjudicator (*Freedman v. Petty*, 1981);
- where the adjudicator expresses opinions, prior to hearing the evidence, that show the vital issues have been prejudged (*R. v. Watson; Ex parte Armstrong:* 1976);
- where the circumstances as a whole show that the adjudicator has made up her or his mind that, come what may, she or he will reach a particular decision (*McDade v. State Rail Authority*, 1985);
- where the adjudicator is related to one of the parties (*Metropolitan Properties Co. (FGC)Ltd. v. Lannon*, 1969);
- where the adjudicator is employed by one of the parties, even if he or she is on leave without pay (*R. v. Cavit; Ex parte Rosenfield*, 1985);
- where, in the course of proceedings, the adjudicator communicates with the legal advisers or witnesses of one party in relation to the proceedings without the knowledge of the other party or his legal advisers (*Tahmindjuis v. Brown, 1985; Re Baird; Ex parte Aitco Pty Ltd*, 1985).

The bias rule "requires that a member of a tribunal who is making a decision should not have a direct or indirect pecuniary interest in the subject matter of the decision" (*Dimes v. Grand Junction Canal Company*, 1852), although the bias rule "is not confined to cases of pecuniary interest" (Kyrou, 1991, p. 878; *R. v. Watson; Ex parte Armstrong*: 1976, pp. 258-259, 262–264). Should these principles – particularly regarding pecuniary interest and the contract of employment – not be applicable to work carried out under the banner of "scientific research"?

Not only are there problems with quality and/or source of information, of informing women of risks or potential dangers of treatment *at the time treatment is proposed*, and of listening to women's complaints and anxieties following the treatment. There is what some might consider a failure to recognise fully and appropriately that, after treatment has been found to place women at risk, women should be informed adequately and immediately of that risk.

Late in 1991, the human hormone-based fertility drug hPG (human pituitary

gonadotropin) was reported as having been linked to the deaths of two women in Australia from a rare degenerative disease. The infected hPG was reported as coming from the Commonwealth Serum Laboratories, and was given to 1,500 women in Australia between 1964 and 1985 (Hammond, 1991). The drug was used on women in other countries, including the United States. When the link between hPG and Creutzfeld-Jacob disease was reported in the United States in 1985, "use of the hormone was quickly stopped in the US, Australia and elsewhere" (Hammond, 1991). However, women were not informed on any systematic basis of the dangers of the treatment to which they had been subjected.

When the issue was raised in the Australian Parliament in November 1991, a Member of the House of Representatives said:

> I don't want to panic anybody, but I am worried there are some people who are at risk but may not know it.
> And there are some people who are not at risk but have not been reassured. (Hammond, 1991)

Disputing a "cover up," Professor Colin Masters, a Melbourne University medical researcher specialising in Alzheimer's disease and related brain diseases, said that Australian authorities had, upon learning of the dangers of hPG, "immediately withdrawn all products derived from human pituitary tissue" (O'Neill, 1992). O'Neill goes on to report:

> On the Australian decision to withdraw hPG, Professor Masters said: "Everything went quiet for a while, people were fearing an epidemic but it didn't occur."
>
> Professor Masters denied there was any cover up, saying: "It looked like very low-level contamination. As soon as the first case was identified, there was an immediate recognition of the problem here.
>
> "I believe *it was decided that it was not in the recipients' interest to tell them unnecessarily – there was nothing to be gained from worrying people*. That picture changed a little bit when the second case [culminating in death] occurred, and if we get another case, we will be even more concerned." (emphasis added)
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> The first death occurred 15 years after the use of the drug on the women who died. According to O'Neill (1992): Dr Dumble said she was concerned that most of the women treated with hPG in Australia had never been informed that they might be at risk of contracting Creutzfeld-Jacob disease.
>
> "It is negligent not to inform these women, to the extent that now affects the wider community," Dr Dumble said.
>
> Professor Masters stressed . . . that the risk of infection from transplanted peripheral organs like the heart, lung or kidneys was extremely low. But Dr Dumble said the episode raised ethical and social issues. "The issue has grave implications for society in general. By not telling the women, it denies that they can behave responsibly in the management of their own lives. They are entitled to know."

The press coverage indicated it was apparently only *after* these concerns were raised as to the informing (or lack of informing) of women who had been treated by hPG that a campaign was instituted by the federal Health Department to contact the 1,600 Australian women who were treated with a course of human pituitary-derived hormone in injections for infertility between 1964 and 1985. Heath points out (1992) that it was only in 1991 that information from the head of the Pituitary Advisory Committee was sent to all doctors involved in the treatment programs "to help them counsel women about their chances of contracting or transmitting the disease." Yet as the treatment ceased in 1985 *as a direct consequence of concerns* about its safety, it is

difficult to see that the doctors so informed would be in any position to contact many – or any – of their patients with much certainty. Anyway, why didn't they do so – why weren't they required to do so – when treatment was cancelled in 1985? Undoubtedly the Health Department recognised the problem of delay, in that a spokesperson said that women "who thought they might have been involved in the program, but who had not been contacted or counselled by their doctor, could ring the department's inquiry line" (Heath, 1992). What reason for the delay of some 6 or 7 years? A pattern may be discerned as identifying itself with monotonous regularity where women's health, medical treatment and "informed consent" are concerned. The Dalkon Shield (Corea, 1977; Mintz, 1985), diethylstylbestoral (DES) (McKenna, 1992), hPG, and silicon implants are only examples of a much wider malaise. Doctors and manufacturers are alerted to the risk. Women complain of discomfort, but the complaints are ignored or dismissed as hypochondria, or simply what women "have to put up with" if they are to receive the treatment. Women are not told of the risk, or of manifold dangers. The product is withdrawn from the market. Women are still not told of the dangers to them (and, sometimes, to their offspring, as in the case of DES), or there is no systematic program planned or implemented to ensure an urgent alert to the women. Activist women take responsible stands, publicising the dangers and deceit of manufacturers and medical practitioners (Coney, 1988). These women are dismissed as "scaremongers," who exaggerate or tell untruths, and who drag the debate into the realm of the "emotional." (As if there is some fault in becoming "emotional" about women's lives being placed at risk, and women not being alerted to the realities of their position.)

Finally, members of the "establishment" – the male – dominated power groups – see that they had better take matters in hand (reassert control) by "informing" women (somewhat late in the day) of the truth (within limits determined by the power group) about the treatment to which they have been subjected.

As Drs. Renate Klein and Lynette Dumble point out in a letter to the editor of *The Age* (Melbourne) consequent upon the public revelations of the dangers of hPG, even when an alert goes out for women the tenor is one of reassurance rather than respect for women as adults who have a right to receive information that they ought to have received years before (Dumble & Klein, 1992). Further, where groups other than women may have been harmed or at risk, their care is focused on specifically. Thus considerable concern was expressed in medical journals as to the dangers of treatment derived from the human pituitary gland, used on children. There is no matching concern for women (Dumble & Klein, 1992):

> The tone of the articles [published in *The Age* about hPG] is one of reassurance: Jacobs disease has a frequency of less than one per million in the general population and out of supposedly 2000-odd women who received hPG for fertility treatment the two deaths [in Australia] demonstrate that we need not fear an epidemic from this disease for which there is no cure.
>
> This reassurance amounts to a dangerous denial of the risks associated with developing Jacobs disease. The medical literature reports a dramatic increase of this disorder in the UK, the US, Japan, Finland, Brazil and New Zealand after administration of human pituitary growth hormone (hGH) prescribed to children for growth problems. Like hPG for infertility treatment, the growth hormone is prepared from pituitary glands from cadavers. In fact, it was the occurrence of deaths associated with this growth hormone treatment which led to abandoning the fertility hPG regimen in Australia in 1985.

Dumble and Klein confirm that while there is "considerable anxiety" in the medical literature over the increasing incidence of Jacobs disease among individuals (mainly children) treated with human growth hormone, resulting in intensive follow-up, *women* who underwent hPG fertility treatment have not received the same attention. Applying common sense, they assert that every woman involved in the hPG program should have been told in 1985 of the risk. The chief medical adviser of the Commonwealth Department of Health responded with a denial that "important information was withheld from women treated with pituitary hormones for infertility" (Adams, 1992):

> I am writing to correct some factual errors in a letter from Drs Dumble and Klein . . . about the possible association between a rare fatal brain disease, Creutzf eld-Jacob disease and a treatment involving hormones derived from the human pituitary gland.
>
> It implied, totally incorrectly, that there has been a dramatic increase in the incidence of the disease in a number of countries, that it is contagious in the same manner as hepatitis, and that important information was withheld from women treated with pituitary hormones for infertility.
>
> An increased incidence of the disease has been reported in people who received a treatment which involved hormones derived from the human pituitary gland. (Out of 30,000 people worldwide who received this treatment, 17 since have died of the disease, which generally still affects only one in a million people.)
>
> The hormones were used in Australia between 1964 and 1985 in a program for women with infertility problem, men with hormonal deficiencies and children with growth problems. This program was stopped in 1985 after international reports of a possible link between these hormones and the disease.
>
> Doctors have been asked by this department on three occasions to notify people involved in the program of these concerns and the remote possibility of their developing the disease.
>
> Doctors were also asked to advise patients not to donate tissues, such as corneas, or blood. Clinics, professional medical colleges, the Red Cross and transplant organisations were also notified.
>
> The department is now helping doctors to track down patients involved who may not yet have been counselled. Anyone who is concerned that they may have been involved in the program and have not yet been contacted by their doctor, can call the department's telephone inquiry line on (008) 020103, or write to me at GPO Box 9848, Canberra, ACT, 2601.
>
> I stress that the chance of anyone who was on the program contracting the disease remains small. I also stress the safety of current hormone therapy programs which involve the use of hormones not derived from human pituitary glands.

It is admirable indeed that the Health Department is now taking the stand it is, amongst other matters providing a direct line for women who are concerned about the possible consequences of hPG treatment, and on this point Dr. Adams and the department are to be commended. Whether or not the "chance of anyone . . . on the program contracting the disease remains small," one could hardly blame women, who *have the chance*, for being disconcerted that, despite doctors having been "asked . . . on three occasions to notify people involved in the program of these concerns and the remote possibility of . . . developing the disease," it is only now that the "department is . . . helping doctors to track down patients involved who may not yet have been counselled."

Dumble and Klein's follow-up letter stated:

Dr Tony Adams in his letter to "The Age" . . . disputes information we provided four days earlier. For the benefit of readers, we re-emphasise that Creutzfeld-Jacob disease (CJD) is transmitted via the bloodstream, in the same manner as hepatitis B, and for that matter AIDS. We made no claim that CJD was as contagious as the air-borne viruses which, for example, cause influenza, measles, and poliomyelitis. However the threat from human pituitary hormone (hPH) treatments, administered between 1964 and 1985, is real indeed, to the extent that body fluids and tissue from individuals who developed CJD following hPH treatment have reproduced a similar fatal disease when injected into animals.

A 1991 World Health Organization Drug Information report cites that seven cases of CJD are confirmed amongst the first 700 individuals treated with hPH in the USA and that more cases "may well yet occur." Similar figures have emerged from hPH programs in other countries, including the UK and France. Is this not sufficient to confirm that 21 years of hPH therapy has increased the frequency of CJD, for those so treated, by ten thousandfold? Is this not also sufficient to justify our concern for the 2000-odd Australian women who received this treatment for their infertility, most of whom remain unaware of the treatment hazards?

We acknowledge that the Department of Health has, on several occasions, encouraged the medical practitioners responsible for hPH infertility treatment to warn women of its potential dangers. This approach has failed as many women continue to be denied this information due to a complicated bureaucracy which limits its communication to medical consultants. It is time for the Department of Health to commence a new initiative; one that communicates directly with women exposed to hPH and ceases to be reliant on medical practitioners, who for reasons known only to them are reluctant to pass on the details. This may result in litigation against the offending institutions and the pharmaceutical laboratory and a wave of disrepute for present reproductive technologies. However, in the interests of the physical and mental health of the women concerned, direct truth is the only conscionable pathway.

This letter was not printed by *The Age*, despite personal communication with the editor of the Letters to the Editor page.

CONCLUSION

Risks attendant on women who "choose" to undergo various medical treatments, drug regimens, or surgery are viewed differently, as a consequence of the perspective of the viewer. It is clearly not enough for women to call for "more information." Choices that are determined within a political framework of power differentials; sex discrimination; economic disparity; and sociocultural mores dictated by sex, race, and ethnic difference are limited (or no) choices. Consent to be "done to" is similarly hindered by the parameters of this same framework.

The responsibility lies on drug and treatment manufacturers, the medical profession, and the government to acknowledge and abide by ethical standards of research and treatment. At the same time, we as women must question our own "participation" in the field, where too often we are relegated to the category of guinea pig – when guinea pigs themselves ought not to be so treated and in fact are not. (Why else are the women being used?)

As Mary E. Ames says, reporting upon a public forum held by the National Academy of Science in May 1973 in the United States (1978, p. 129):

> Safety . . . is not a scientific question. It may be asked in scientific terms, but it cannot be answered by science. It is a policy question to be answered by the public.

Where the treatment centres upon women and women's concerns, then the policy question is one for specific and direct women's input and assessment. But so long as scientists, manufacturers, researchers, and medical practitioners do not give prompt and accurate answers to the scientific questions, the policy formulation is fraught.

The emptiness of any standard of "informed consent" to medical treatment for women is clear. The right to say yes to medical treatment is deprived of meaning when women are not supplied with all relevant information, and while "gatekeepers" determine what is and is not relevant. Furthermore, even gaining information may be of little value to women if the information is limited, masked, or conveyed directly from studies based on research undertaken with funds from manufacturers of treatments applied by medical practitioners. Sometimes, information is not enough to turn "yes" into an informed affirmation.

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