MIC, University of Limerick

# A philosophical investigation into coercive psychiatric practices

2 Volumes

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## Volume 2 of 2

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## Appendix A: Some relevant sections of the Irish Mental Health Acts

Provisions of the *Mental Treatment Act* (1945) which have been referred to in the main body of the dissertation are given in full in <u>Section I</u>; those of the *Mental Health Act* (2001) are given in <u>Section II</u>.

#### Section I: The Mental Treatment Act (1945)

#### Commencement of proceedings by patients or ex-patients

#### Time limit on certain proceedings.

259.—Proceedings by a person who has been detained in a mental institution and has ceased to be so detained and which are in respect of an act purporting to have been done in pursuance of this Act shall not be instituted after the expiration of six months after the cesser of the detention.

#### Leave of the High Court for certain proceedings.

260.—(1) No civil proceedings shall be instituted in respect of an act purporting to have been done in pursuance of this Act save by leave of the High Court and such leave shall not be granted unless the High Court is satisfied that there are substantial grounds for contending that the person against whom the proceedings are to be brought acted in bad faith or without reasonable care.

(2) Notice of an application for leave of the High Court under sub-section (1) of this section shall be given to the person against whom it is proposed to institute the proceedings and such person shall be entitled to be heard against the application.

(3) Where proceedings are, by leave granted in pursuance of sub-section (1) of this section, instituted in respect of an act purporting to have been done in pursuance of this Act, the Court shall not determine the proceedings in favour of the plaintiff unless it is satisfied that the defendant acted in bad faith or without reasonable care.

(4) Where, on an application under sub-section (1) of this section, leave is given to bring any proceedings and the proceedings are commenced within four weeks after the date on which leave was so given, the proceedings shall, for the purposes of section 259 of this Act and of the Public Authorities Protection Act, 1893, be deemed to have been commenced on the date on which notice of the application was given to the person against whom the proceedings are to be brought.

#### Section II: The Mental Health Act (2001)

#### 'Mental disorder'

3.—(1) In this Act "mental disorder" means mental illness, severe dementia or significant intellectual disability where —

(a) because of the illness, disability or dementia, there is a serious likelihood of the person concerned causing immediate and serious harm to himself or herself or to other persons, or

(b) (i) because of the severity of the illness, disability or dementia, the judgment of the person concerned is so impaired that failure to admit the person to an approved centre would be likely to lead to a serious deterioration in his or her

condition or would prevent the administration of appropriate treatment that could be given only by such admission, and

(ii) the reception, detention and treatment of the person concerned in an approved centre would be likely to benefit or alleviate the condition of that person to a material extent.

(2) In subsection (1) —

"mental illness" means a state of mind of a person which affects the person's thinking, perceiving, emotion or judgment and which seriously impairs the mental function of the person to the extent that he or she requires care or medical treatment in his or her own interest or in the interest of other persons; ...

#### Criteria for involuntary admission to approved centres.

8.—(1) A person may be involuntarily admitted to an approved centre pursuant to an application under *section 9 or 12* and detained there on the grounds that he or she is suffering from a mental disorder.

(2) Nothing in *subsection (1)* shall be construed as authorising the involuntary admission of a person to an approved centre by reason only of the fact that the person —

(a) is suffering from a personality disorder,

(b) is socially deviant, or

(c) is addicted to drugs or intoxicants.

#### Best interests of person

4.—(1) In making a decision under this Act concerning the care or treatment of a person (including a decision to make an admission order in relation to a person), the best interests of the person shall be the principal consideration with due regard being given to the interests of other persons who may be at risk of serious harm if the decision is not made.

(2) Where it is proposed to make a recommendation or an admission order in respect of a person, or to administer treatment to a person, under this Act, the person shall, so far as is reasonably practicable, be notified of the proposal and be entitled to make representations in relation to it and before deciding the matter due consideration shall be given to any representations duly made under this subsection.

(3) In making a decision under this Act concerning the care or treatment of a person (including a decision to make an admission order in relation to a person) due regard shall be given to the need to respect the right of the person to dignity, bodily integrity, privacy and autonomy.

#### *Power to prevent voluntary patient from leaving approved centre.*

23.—(1) Where a person (other than a child) who is being treated in an approved centre as a voluntary patient indicates at any time that he or she wishes to leave the approved centre, then, if a consultant psychiatrist, registered medical practitioner or registered nurse on the staff of the approved centre is of opinion that the person is suffering from a mental disorder, he or she may detain the person for a period not exceeding 24 hours or such shorter period as may be prescribed, beginning at the time aforesaid. ...

#### Treatment not requiring consent

57.—(1) The consent of a patient shall be required for treatment except where, in the opinion of the consultant psychiatrist responsible for the care and treatment of the patient, the treatment is necessary to safeguard the life of the patient, to restore his or her health, to alleviate his or her condition, or to relieve his or her suffering, and by reason of his or her mental disorder the patient concerned is incapable of giving such consent.

(2) This section shall not apply to the treatment specified in section 58, 59 or  $60.^{1}$ 

#### Referral of admission order and renewal order to a tribunal

17.—(1) Following the receipt by the Commission<sup>2</sup> of a copy of an admission order or a renewal order, the Commission shall, as soon as possible —

(a) refer the matter to a tribunal<sup>3</sup>,

(b) assign a legal representative to represent the patient concerned unless he or she proposes to engage one,

(c) direct in writing (referred to in this section as "a direction") a member of the panel of consultant psychiatrists established under section 33 (3)(b) to — (i) examine the patient concerned,

(ii) interview the consultant psychiatrist responsible for the care and treatment of the patient, and

(iii) review the records relating to the patient,

in order to determine in the interest of the patient whether the patient is suffering from a mental disorder and to report in writing within 14 days on the results of the examination, interview and review to the tribunal to which the matter has been referred and to provide a copy of the report to the legal representative of the patient. ...

#### Review by a tribunal of admission orders and renewal orders.

18.—(1) Where an admission order or a renewal order has been referred to a tribunal under section 17, the tribunal shall review the detention of the patient concerned and shall either —

(a) if satisfied that the patient is suffering from a mental disorder, and

(i) that the provisions of sections 9, 10, 12, 14, 15 and 16, where applicable, have been complied with, or

(ii) if there has been a failure to comply with any such provision, that the failure does not affect the substance of the order and does not cause an injustice, affirm the order, or

(b) if not so satisfied, revoke the order and direct that the patient be discharged from the approved centre concerned.

(2) A decision under subsection (1) shall be made as soon as may be but not later than 21 days after the making of the admission order concerned or, as the case may be, the renewal order concerned. ...

<sup>&</sup>lt;sup>1</sup> S. 58. concerns psycho-surgery; S. 59, electro-convulsive therapy [ECT] and S.60, the administration of medicine.

<sup>&</sup>lt;sup>2</sup> The Mental Heath Commission is established under S. 32 of the Act.

<sup>&</sup>lt;sup>3</sup> Under S. 48 of the Act, the Mental Health Commission is given power to establish Mental Health Tribunals.

#### Leave of High Court for certain proceedings.

73.—(1) No civil proceedings shall be instituted in respect of an act purporting to have been done in pursuance of this Act save by leave of the High Court and such leave shall not be refused unless the High Court is satisfied:

(a) that the proceedings are frivolous or vexatious, or

(b) that there are no reasonable grounds for contending that the person against whom the proceedings are brought acted in bad faith or without reasonable care.(2) Notice of an application for leave of the High Court under subsection (1) shall be given to the person against whom it is proposed to institute the proceedings and such person shall be entitled to be heard against the application.

(3) Where proceedings are, by leave granted in pursuance of subsection (1) of this section, instituted in respect of an act purporting to have been done in pursuance of this Act, the Court shall not determine the proceedings in favour of the plaintiff unless it is satisfied that the defendant acted in bad faith or without reasonable care.

# Appendix B: Coercive, non-psychiatric, medical interventions

A number of coercive, non-psychiatric, medical interventions are discussed in this appendix: the coercive use of caesarean sections is discussed in <u>Subsection B-1</u>; the forcible detention and treatment of tuberculosis sufferers is discussed in <u>Subsection B-2</u> and the use of compulsory preventive medication is discussed in <u>Subsection B-3</u>.

#### **B-1:** Forced Caesarean Sections

Since the 1980s, some US State courts have, on occasion, granted orders compelling a woman to submit to a caesarean section; these orders were, in the main, sought by obstetricians as a preemptive defence against possible liability in the event of injury to the foetus.<sup>1</sup>

The first application<sup>2</sup> to an English court for such an order was made in 1992; it concerned a mother who refused, on religious grounds, to submit to a caesarean section. The court declared that the operation, being vital to the protection of the interests of the patient and her unborn child, was lawful.<sup>3</sup> This decision was criticised by the Royal College Of Obstetricians and Gynaecologists firstly, because the judgement "… *[elevated] the status of the fetus in law to such an extent that its supposed rights become more important than its mother's.*"<sup>4</sup> but, more importantly, because similar decisions might immeasurably damage the doctor-patient relationship and drive away those in greatest need of help.<sup>5</sup> This argument is of particular interest in that it is similar to that put forward by some psychiatrists and civil libertarians in arguing against the practice of

coercive psychiatry.

Though the decision in Re S was also widely criticised by legal experts, similar decisions followed at an ever increasing rate.<sup>6</sup> These cases were reviewed by the Court of Appeal in 1996<sup>7</sup> and it laid down the general principle that a competent woman has an absolute right to refuse medical intervention even where that decision might lead to her death or the death of the foetus.

<sup>&</sup>lt;sup>1</sup> Royal College of Obstetricians and Gynaecologists (1996), S 2.1.

<sup>&</sup>lt;sup>2</sup> Re S (Adult: refusal of medical treatment) [1992].

<sup>&</sup>lt;sup>3</sup> Wilson & Smith (1995) have argued that:

<sup>[</sup>it is unclear] whether the declaration was ordered upon the basis of protecting the incipient interests of the unborn child alone or in tandem with those of the mother. If the former, it might be difficult to insulate such decisions from authorising other coerced medical interventions, for example, a kidney 'donation' on an unwilling relative, or even mother! (p.395)

<sup>&</sup>lt;sup>4</sup> Royal College of Obstetricians and Gynaecologists (1996), S. 3.8.9.

<sup>&</sup>lt;sup>5</sup> *Ibid.* S. 3.9.2.

<sup>&</sup>lt;sup>6</sup> At the rate of over one a month during 1996; see Goldbeck-Wood (1997).

<sup>&</sup>lt;sup>7</sup> Re MB (Caesarean Section) (1997).

Some subsequent court applications have sought to use the protection afforded by the UK Mental Health Acts to circumvent the Court of Appeal ruling. In one such case a pregnant woman, X, on visiting her GP was told that she had pre-eclampsia<sup>8</sup>. He advised immediate hospitalisation which she refused. He then contacted a social worker who arranged that X, who had had no previous history of mental disorder, be committed to hospital under the Mental Health Acts and an application was made to the High Court to proceed with a caesarean section without the knowledge of X or her legal advisers.<sup>9</sup> In subsequent proceedings taken by X the Court of Appeal ruled that her admission to a mental hospital was unlawful and entitled her to substantial damages for false imprisonment and for being forced to undergo treatment against her will.<sup>10</sup>

Because of the constitutional protection afforded to the unborn under the Irish Constitution, the Irish courts are unlikely to follow the English precedents limiting coercive caesarean section in that these were based on the view that, before birth, the foetus has no defensible right as against its mother.<sup>11</sup> In view of newspaper reports<sup>12</sup> of threats, by a Dublin hospital, of legal proceedings against a woman who refused to have a caesarean section, the question is likely to come before the Irish courts in the foreseeable future.

Before leaving this topic, there is a final point which is of importance in assessing the question of *'for whose sake'* the intervention is being made. This concerns the additional risk placed on the woman by being subjected to a caesarean section, and the point was made by the chairman of the American Medical Association's Council on Ethical and Judicial Affairs in speaking against the practice of forced caesarean sections:

It is a fundamental ethical and legal principle that patients cannot be forced to accept a risk to health to benefit another, whether the other is a person or a foetus. ... The risk of death for the pregnant woman from a caesarean section is two to four times higher than that from a vaginal delivery.<sup>13</sup>

This issue finds a parallel in the assessment of, and the weight that should be accorded to, any additional health risks attendant on forced psychiatric treatment undertaken on the grounds of perceived dangerousness to others.

<sup>&</sup>lt;sup>8</sup> Pre-eclampsia is a hypertensive disease which is a major cause of maternal and foetal morbidity and mortality.

<sup>&</sup>lt;sup>9</sup> Dyer (1998a).

<sup>&</sup>lt;sup>10</sup> Dyer (1998b).

<sup>&</sup>lt;sup>11</sup> Royal College Of Obstetricians and Gynaecologists (1996), S. 5.3: "Although obligations to the fetus in utero increase as it develops, UK law does not grant it personal legal status. This comes from the moment of birth."

<sup>&</sup>lt;sup>12</sup> The Sunday Times (2005). 'Mother threatened with forced caesarean'. *The Sunday Times*. 24 April. <sup>13</sup> Dyer (1994).

#### **B-2:** Forcible Intervention Against Tuberculosis Sufferers

Tuberculosis (TB) is a contagious disease which presents a serious threat to world health; it currently infects one third of the world's population and kills approximately 2 million individuals annually.<sup>14</sup> Due to some patients not fully completing their course of treatment, new drug resistant strains of the disease have emerged which are difficult and expensive to treat.<sup>15</sup>

The legal situation in the UK in relation to detention and compulsory treatment of persons suffering from TB is set out in the *Code of Practice of the British Thoracic Society*:

Compulsory treatment is not allowed but in exceptional circumstances it may be necessary to consider compulsory admission of a patient who is causing serious risk of infection to others. ... Clearly this is not the kind of action to be undertaken lightly as it involves depriving someone of his or her liberty. ... If the person has to be detained it will be necessary to obtain a magistrate's order for admission ... and another order for detention.<sup>16</sup>

During 2005, a number of news stories appeared in the British media highlighting the danger of drug resistant TB and the inability of the health authorities to ensure that patients completed their treatment programmes. The manner of reporting amounted to a campaign in favour of introducing compulsory treatment for TB. One newspaper, for example, under the heading *'TB human timebomb infects 12'*<sup>17</sup> reported that a convicted criminal with a highly contagious form of tuberculosis had infected at least 12 people because the authorities were powerless to make him accept medical treatment. It claimed that doctors were *"furious"* that legislation had not been enacted to enable compulsory treatment and it reported a consultant with the Government's Health Protection Agency as stating that *"the biggest problem with TB is that we cannot compulsorily treat people*". The article quoted a Government spokesperson as stating that a review of Britain's public health laws was being considered but that human rights legislation might prevent imposing compulsory treatment orders.

*The Guardian*, under the heading '*Law lets TB patient infect 12 others – No one can be forced to take treatment*',<sup>18</sup> carried essentially the same story but added:

But the idea that an individual can knowingly be infectious and retain his anonymity due to rules on patient confidentiality is potentially politically

<sup>&</sup>lt;sup>14</sup> DeAngelis & Flanagin (2005).

<sup>&</sup>lt;sup>15</sup> It has been reported that medication normally costs \$11 per patient whereas treatment of the drug resistant strain can cost up to \$250,000 per patient; see The Irish Times. (1996). 'WHO Warns of Global TB Disaster'. *The Irish Times*. 22 March.

<sup>&</sup>lt;sup>16</sup> Joint Tuberculosis Committee of the British Thoracic Society (2000), p.888.

<sup>&</sup>lt;sup>17</sup> The Mail on Sunday. (2005). 'TB human timebomb infects 12'. The Mail on Sunday. 8 May.

<sup>&</sup>lt;sup>18</sup> The Guardian. (2005). 'Law lets TB patient infect 12 others - No one can be forced to take treatment', The Guardian. 9 May.

explosive. Seven in 10 people with the disease come from an ethnic minority and two-thirds were born abroad.

The same story was again carried by the BBC online news story but with a gloss: a Professor Peter Davies, secretary of the charity TB Alert, was quoted as stating: "To insist on compulsory treatment would be a step too far. Forced treatment would be just *horrendous*.<sup>19</sup> In that Professor Davies is one of the leading experts on the treatment of TB<sup>20</sup>, it seems that coercive treatment might not be the 'obvious solution' that many considered it to be.

A parallel may be drawn between the depictions of TB and mental illness in the popular media where mental illness is often viewed through the narrow and distorting prism of dangerousness; as a consequence, ideas of mental illness and dangerousness are often conflated in the public mind.<sup>21</sup> The link between dangerousness and mental illness is the subject of Chapter 6 of the dissertation but it may be of assistance in the disentangling of these ideas to, at this stage, briefly examine the academic response to media demands for coercive treatment of individuals with TB.

An editorial in the *British Medical Journal*<sup>22</sup> described how, in response to an epidemic of TB in the early 1990s, New York City instituted a successful programme of eradication by adopting a twin track approach: investing in model treatment programmes but also by relying on a coercive strategy. Prior to this, coercion had been invoked only if the individual posed a serious risk to the health of others (a riskassessment strategy); the New York programme, however, permitted coercion in respect of non-infectious individuals who were adjudged unlikely to fully complete a treatment programme (a non-compliance strategy). More than 200 non-infectious patients were detained under this provision, some for over two years. The editorial argues against the employment of such coercive strategies:

Before detention is resorted to, practical (and cheaper) alternatives should be available. If an order for detention is sought then details of attempts at less

<sup>&</sup>lt;sup>19</sup> BBC (2005). 'Care refusal spread TB to others' *BBC News* [online], available:

http://news.bbc.co.uk/2/hi/health/4528543.stm [accessed: 21 August 2006].

According to the British Medical Journal, Professor Davies:

<sup>...</sup> set up, and is now Director of the Tuberculosis Research and Resources Unit. In 2004 he was appointed Honorary Professor to Liverpool University. Professor Davies has written extensively. He edited Clinical Tuberculosis, the only definitive reference work on tuberculosis published outside the USA.

<sup>[</sup>Online], available: http://www.bmjmasterclasses.com/respiratory/speakers [accessed: 20 April 2006.]. <sup>21</sup> Such public perceptions, even if erroneous, create a momentum and actuality of their own and lead to the development of government policies designed to assuage, rather than correct, these perceptions; this, in the view of many commentators was what motivated the (English) Mental Health Bill 2004 which has now been withdrawn following strong criticism by a coalition of civil libertarians and the psychiatric profession. The Royal College of Psychiatrists (2004), for example, argued that: "the proposed legislation is extremely unlikely to have any impact on suicide or homicide rates." <sup>22</sup> Coker (1999b).

restrictive alternatives should be presented to the magistrate. Moreover, an explicit objective examination of the potential threat posed by each non-compliant individual should be made and legal representation made available for those at whom the order is directed.<sup>23</sup>

The editorial – which anticipates that, as happened in New York, media campaigns in the UK will call for the detention of non-compliant individuals – urges that "*Both civil rights and public health can be protected, but the emphasis should be on resource and organisational requirements, rather than coercion.*"<sup>24</sup>

Writing in response to this editorial, a correspondent described how in Australia, even though legislation had provided for the coercive treatment of TB:

... in over eight years, not a single order has led to a patient with tuberculosis being imprisoned. ... over 4000 cases have been effectively managed in the community. ... Rather than investing in a good public health system and well resourced community based services, the United States seems to be using 'deprivation of liberty' to solve not only its social problems but also its tuberculosis epidemic. This is an abuse of human rights and makes no sense in terms of public health.<sup>25</sup>

An editorial<sup>26</sup> in the journal *Thorax*, in discussing the New York campaign, emphasised

the importance of distinguishing between the perception of risk and the actual risk

posed by an individual with TB. Whereas the perception of risk, fuelled by media, was

that all New Yorkers were at risk, the reality was quite different.

... those using homeless shelters in which beds were spaced 18 inches apart and HIV prevalence was high were obviously at greater risk of exposure than those in the leafy suburbs. But the perception was high in New York that all were at risk, and undoubtedly encouraged the response seen.<sup>27</sup>

This emphasis on assuaging the perception of risk rather than estimating the actual risk

led even civil libertarian critics to ignore:

... the actual magnitude of the threat posed by non-infectious poorly compliant individuals, particularly by those opposing the regulatory changes. The Health Department officials simply suggested that "over time, it is likely that they (poorly compliant, non-infectious individuals) will pose a very serious threat to large segments of the public."<sup>28</sup>

The editorial concluded that:

An approach to our understanding of risk with regard to tuberculosis must therefore attempt to define the risk of an event occurring (for example, the transmission of tuberculosis from a smear negative poorly compliant individual), determine the gravity of that event, weight different available measures to be taken, and alter the perception of risk with time both as our understanding

<sup>&</sup>lt;sup>23</sup> *Ibid.* p.1435.

<sup>&</sup>lt;sup>24</sup> Ibid.

<sup>&</sup>lt;sup>25</sup> Levy & Alperstein (1999).

<sup>&</sup>lt;sup>26</sup> Coker (1999a).

<sup>&</sup>lt;sup>27</sup> *Ibid*. p.96.

<sup>&</sup>lt;sup>28</sup> *Ibid.* p.95.

improves and as circumstances change. ... The global control of tuberculosis may be harmed more than it is assisted by inappropriate, ill judged, culturally insensitive coercive public health measures.<sup>29</sup>

Aside from the US, the international consensus<sup>30</sup> on TB control appears not to favour coercive public health measures – a position reemphasised in a recent *British Medical Journal* editorial.<sup>31</sup>

The parallel between coercive intervention in relation to TB and coercive psychiatric interventions was noted in a submission made by The Royal College of Psychiatrists to the (UK) Joint Committee on the Draft Mental Health Bill:

Nonetheless there are a small number of mentally disordered people who present serious risks to others. ... the central issue is what degree of certainty should be required before determining that such a person is dangerous. For example if a person suffering from tuberculosis, or other notifiable infectious disease, refuses treatment they will only be detained if the form of TB makes it almost inevitable that other people will become infected. Any lesser standard in relation to the mentally disordered would be inappropriate. Clinically this is particularly difficult to determine, hence, for example, the estimation that, with current knowledge and skills, between 2000 and 5000 people would need to be detained to prevent one homicide  $\dots^{32}$ 

Adding further emphasis to its views on coercive psychiatry, the College prefaced its

submission with a quotation:

The whole picture (on the provision of care and treatment) is distorted by the use or prospect of compulsion, which deters people from seeking treatment, denies them the right to choose the treatment they want, and prioritises certain kinds of patient in the offer of services.<sup>33</sup>

A case concerning the compulsory detention in relation to TB came before the Irish courts in 2008.<sup>34</sup> The applicant who had, some years earlier, been treated for TB in South African, was suspected of suffering from TB when she became ill in Ireland. She refused treatment and was detained under the S.38 of the *Health Act* (1947) but had been assessed by psychiatrists as competent. She had been detained for over a year and began *habeas corpus* proceedings seeking her release. It transpired that though the *Health Act* (1947) provides for detention and segregation it does not provide for compulsory treatment.

<sup>&</sup>lt;sup>29</sup> *Ibid*. p.96.

<sup>&</sup>lt;sup>30</sup> Coker (1999a), p.96; Ribeiro (2003).

<sup>&</sup>lt;sup>31</sup> Maher (2003).

<sup>&</sup>lt;sup>32</sup> Royal College Of Psychiatrists (2004), p.17-8.

<sup>&</sup>lt;sup>33</sup> *Ibid.* p.1, quoting Baroness Hale of Richmond, Sieghart lecture, British Institute of Human Rights 2004.

<sup>&</sup>lt;sup>34</sup> See O'Connell, B. (2008). 'Court action over TB woman's year-long forced hospitalisation.' *The Irish Times.* 6 November.

#### **B-3:** Compulsory Preventive Medication

Even the most cursory outline of this topic is far beyond the scope of this appendix; my purpose in adverting to it is to draw attention to the existence of occasions when, in a non-psychiatric setting, preventive medication is made compulsory. By 'preventative medication' in this context, I mean medication given to an individual for a condition from which he presently does not suffer, but for which he is considered to be at risk. The discussion is restricted to developments in the UK and Ireland as these are the areas of most relevance to the argument being developed in this dissertation.

Compulsory vaccination was first attempted in the UK in 1853 when smallpox vaccination was made mandatory for infants. In reaction, an anti-vaccination movement was quickly established whose political influence grew to such an extent that by 1889 a Royal Commission was appointed to find more acceptable methods of resolving the problem. Their report in 1898 was something of a compromise in that it recommended that, whilst compulsion should remain, any parent who could satisfy magistrates that they conscientiously believed that vaccination would be harmful to their child, was excused. Even this was not acceptable to the anti-vaccinationists (who included such eminences as George Bernard Shaw) and in 1907 a new Act was passed which allowed parents to obtain exemption by simply attesting to their honestly held belief that vaccination was not in the best interests of their child; within a few years this resulted in 25 per cent of newborns avoiding vaccination. The resistance to vaccination arose not only because it was believed to carry risk (some believed it to cause leprosy) but also because it contravened deeply held beliefs about the integrity of the body. The attempt at compulsion can be viewed as a struggle between, on the one hand, the protection of the common good and, on the other, the safeguarding of the rights of the individual, and - in that smallpox is a highly infectious disease – the interest of the body politic was no mere theoretical one, yet individualism triumphed over the common social interests.<sup>35</sup> Although the political struggle over compulsory smallpox vaccination occurred over a hundred years ago it seems that public attitudes in the UK have changed but little in the intervening period as is evidenced by the depth of emotion engendered by the introduction of the (non-mandatory) MMR vaccine.

The issue of compulsory mass medication became a topic of controversy in Ireland in 1960 with the introduction of legislation permitting the fluoridation of the public water

<sup>&</sup>lt;sup>35</sup> In writing this section, I have relied heavily on Pedersen (2005) and Dalrymple (2006).

supply. The constitutionality of this legislation was challenged in *Ryan v AG* (1965) which is one of the most important cases in Irish Constitutional Law in that it established that the personal rights of citizens were not limited to those enumerated in the constitution but included unspecified rights such as the right to bodily integrity. The plaintiff argued that the process of fluoridating water not only amounted to 'mass medication' (and that the state had no power to administer drugs in such a fashion)<sup>36</sup> but was also a source of danger to the public. The court held that even if it was agreed that fluoridation was dangerous (a position that it did not accept) the plaintiff's case failed because:

The plaintiff has no legal right to a supply of piped water and the Act of 1960 does not impose any obligation on her ... to drink or use the water coming through the piped water supply. ... Moreover, ... [the plaintiff] can, by the expenditure of a few pounds, remove all or almost all the fluoride ions coming through the piped water supply.<sup>37</sup>

There has been continuing controversy in Ireland over the use of fluoridation with some arguing that it increased the risk of childhood bone cancer.<sup>38</sup> In response to such concerns, the Irish government established a 'Forum on Fluoridation' whose report<sup>39</sup> in 2002 recommended that fluoridation should continue but with a decrease in the permissible level of fluoride. In an appendix to the report, Professor Binchy examined the developments in Irish Constitutional Law since the Ryan case with a view to determining whether a new constitutional challenge to mass fluoridation might be decided differently. He argued that if mass fluoridation were to be regarded by the courts as a form of mass medication then, in so far as there is a right to refuse medical treatment,: " ... *it is hard to see how there is nonetheless an obligation to submit to legislatively authorised State action that constitutes medical treatment.*"<sup>40</sup> He considered such an interpretation unlikely.

The question of compulsory vaccination came before the Irish courts in *North Western Health Board v HW and CW* (2000) where the Health Board sought an injunction to compel the parents to consent to a PKU test<sup>41</sup> on their child. The parents had refused consent on the grounds that the test was invasive. The court refused to grant the injunction holding that (other than in exceptional circumstances) parents were entitled to make these decisions even if, as it believed in the instant case, they made the

<sup>&</sup>lt;sup>36</sup> *Ibid.* at p.345.

<sup>&</sup>lt;sup>37</sup> *Ibid*. at p.314.

<sup>&</sup>lt;sup>38</sup> The Irish Independent. (2006). 'Dentists warn of flouride water dangers'. The Irish Independent. 8 April.

<sup>&</sup>lt;sup>39</sup> Department of Health and Children (2002).

<sup>&</sup>lt;sup>40</sup> *Ibid*. p.222.

<sup>&</sup>lt;sup>41</sup> This is a test for disability which requires the taking of a blood sample.

wrong decision. The judgement noted that the State did not seek to use compulsion in relation to the innoculation and vaccination of children where the case for compulsion was far stronger than in respect of the PKU test.

The riposte made in the Ryan case (that there is no obligation on anyone to use the medicated supply and that non-medicated alternatives can easily be obtained) is likely to be used as a defence against any possible criticism of recent proposals<sup>42</sup> to add folic acid to bread in an attempt to reduce the number of cases of infants born with spina bifida. The agency anticipated " ... general ethical population concerns about prospect of 'compulsory' or 'mass medication' issues."<sup>43</sup>

A practice of administering preventive psychiatric medication has been recently adopted in the US in relation to young people who have not, as yet, developed schizophrenia but who are believed to be susceptible to developing it later in life. Although the results of a recent study using antipsychotics were less than impressive – they were summarised by one of the lead authors in the words: *"The positive result was only marginally significant, and the negative result was clear."*<sup>44</sup> – they have not lessened the enthusiasm for future trials. Though such medication is not mandatory at present, it may become so in view of proposals by the US administration for the mass screening of schoolchildren for susceptibility to mental illness.<sup>45</sup>

<sup>&</sup>lt;sup>42</sup> As advocated by The Food Standards Agency in the UK. Similar proposal have recently been made in Ireland; Donnellan E. (2006). 'Body calls for use of folic acid in bread'. *The Irish Times*. 18 July.
<sup>43</sup> The Times. (2006). 'Folic acid in bread to cut birth defects'. The Times. 5 April; The Independent.

<sup>(2006). &#</sup>x27;Add folic acid to bread' to tackle birth defects'. The Independent. 5 April.

<sup>&</sup>lt;sup>44</sup> The New York Times. (2006). '*Mixed Result in Treating Schizophrenia Pre-Diagnosis*'. The New York Times. 1 May.

<sup>&</sup>lt;sup>45</sup> Lenzer (2004).

The American Psychiatric Association, in their July 2004, Advocacy News took some credit for keeping this story out of the American news: "*The BMJ story has gained some traction in derivative reports on the Internet, though mainstream media have not touched the story, in part thanks to APA's work, for which the administration is appreciative.*" [Online], available:

http://www.psych.org/join\_apa/mb/newsletters/advocacy/AdvNewsJuly2004.htm#21 [accessed: 3 May 2006.].

## Appendix C: The Amy case: conflicting perspectives

The details of this case are set out in Chapter 2.<sup>1</sup> The focus of this appendix is on the conflicting testimony of Dr. Cameron who was Amy's hospital physician [*Subsection* <u>*C*-1</u>], Dr. Watler [*Subsection C-2*] and Dr. Gervais [*Subsection C-3*] who were her psychiatrists and Dr. Cameron's response to the psychiatric testimony [*Subsection C-4*]. *Subsection C-5* contains some observations on the case and <u>Subsection C-6</u> draws some conclusions.

## *C-1: Cameron (hospital physician)*<sup>2</sup>

The person I encountered was a petite, bright and charming woman who came across as younger than her 77 years. She exuded a vivacity, a determination to make the most of every moment, but hinted that she was aware of the bad news the biopsy might bring. During her history and physical she regaled me with a long, rambling monologue. Her garrulousness didn't strike me as at all unusual. Many people deal with anxiety by talking, and Amy was evidently concerned about the biopsy.

- on her haematologist:

... found her to be "an alert and intelligent lady" ... "She has an excellent understanding of this disease and has decided not to have any treatment."

- on her psychiatrist:

For him, her habit of speaking tangentially was evidence of mental illness. He recorded inconsistencies in her behaviour, such as reporting "*intense pain*" while refusing to take analgesics. ... the psychiatrist raised the issue of paranoid ideation and said that psychosis could not be ruled out. He ... suggested that Amy be certified ...

- on her attending physician:

... was convinced that Amy was competent. ... He conferred with Amy's family physician; both agreed that, as difficult as the situation was, Amy had the right to take her own life. ... [he] felt that her actions were rational: she had a value system and had made a decision consistent with her beliefs. He also noted wryly that the current test of rationality was often concurrence with the opinions of one's physician.

- on her social worker:

... expressed concern that Amy appeared mentally ill. She felt that she was "... unstable, paranoid and grandiose ... not rational."

- on legal considerations:

Curiously, there was little consideration of the legal implications. No one suggested that a lawyer's opinion be sought. ... Any concerns we might have had about legal liability were pushed aside by the debate about the patient's interests.

<sup>&</sup>lt;sup>1</sup> See Subsection A.

<sup>&</sup>lt;sup>2</sup> All text in the body of Subsections C-1 to C-4 are direct quotations from Cameron (1997a), Watler (1997), Gervais(1997) and Cameron (1997b) respectively.

#### - <u>on autonomy</u>:

The decision to let Amy leave hospital was not a black-and-white issue. ... Amy didn't have to die; her death lacked the inevitability that accompanies terminal illness. I didn't feel that she was mentally ill in the clinical sense. Her decision to die was, to me, not the defeated wish of a depressed person, but an affirmative act to conclude her life on her own terms. ... As I grappled with this ambivalence, I kept returning to one theme, one certainty. I was confident that we had respected Amy's rights. She died the way she wanted to, with her dignity intact. ... I think Amy taught me that it is imperative to respect the autonomy of the people we care for even if we disagree with their reasoning.

### C-2: Watler (psychiatrist)

#### - <u>on mental disorder (generally)</u>:

There is no evidence that patients with serious medical illnesses '*rationally*' choose to die. ...

There is common belief that the forensic term *'mental disorder'* is synonymous with psychiatric classification or *'clinical'* conventions. ... Mental disorder is, in fact, very poorly defined in the various mental health acts, and this omission is quite deliberate. The physician need not establish an *'identifiable psychiatric illness'* as a requirement for involuntary committal. Rather, persons should be detained for evaluation when there is high-risk behaviour and evidence to suggest any form of mental disorder. The brevity of this detention — a maximum of 7 days in Nova Scotia — does not represent a significant deprivation of freedom.

#### - <u>on mental disorder (Amy)</u>:

What evidence was there to suggest that Amy was suffering from a mental disorder?

- Months before, she had refused a life-saving intervention with a high therapeutic index.

- Her speech and writing demonstrated significant thought-form disorder.
- There was psychomotor agitation, irritability and lability<sup>3</sup> of mood.
- There was social withdrawal and suspiciousness.

It seems speculative to conclude that Amy was not mentally ill in the '*clinical*' sense or, more important, in the forensic sense.

With recent suicidal behaviour and evidence to suggest a mental disorder, the law requires that an unwilling patient be involuntarily committed. That Amy's clinicians could not agree on the presence of a mental disorder is precisely the reason for detaining high-risk patients for further evaluation.

## C-3: Gervais (psychiatrist)

#### - <u>on Amy's refusal of treatment</u>:

There is no doubt that the patient's rights, such as refusing treatment, must be respected. Nevertheless, one should look into this refusal and its meaning, ... She was an intelligent, articulate person who talked in an apparently logical way and was listened to in a similar logical way, but she was certainly not listened to with the '*third ear*.'

<sup>&</sup>lt;sup>3</sup> "Emotionally or behaviourally unstable." Shorter Oxford Dictionary (1997).

#### - on Amy's psychiatric symptoms:

In psychiatric terms, this woman was showing signs of grandiosity: she was called *"The Queen"* in her neighbourhood and she would not let nature or fate or destiny or God take her life. Instead, she would be the one who decided when to live and when to die, and in a way she would act like God. This, to me, is manic denial.

#### C-4: Cameron's response

I find it illuminating that most people who knew this woman superficially, whether from reading about her or after a single consultation, felt that she was mentally ill. By contrast, those who came to know her well over time, who had established a relationship with her, were convinced she was eccentric but competent.

I reject Watler's assertion that anyone refusing treatment with a '*high therapeutic index*' must be mentally ill. ... People who refuse blood transfusions for religious reasons are not mentally ill, even when their decision does not seem rational when measured against our values.

#### C-5: Some observations on the Amy case

I wish to make a number of observations on the Amy Case under some specific headings:

#### (i) Consent

Dr. Gervais argues to the effect that even though Amy stated that she did not want any psychiatric intervention, she 'really' did and this would have been obvious had she been listened to with the "*third ear*". To imagine this argument being made by one charged with rape, is sufficient to demonstrate its folly; furthermore to argue that, against clear evidence to the contrary, one's belief can be justified by listening with one's 'third ear' is – if not itself delusional in the clinical sense<sup>4</sup> – sufficient to immunise any delusion against rational argument.

#### (*ii*) <u>'Facts'</u>

Dr. Watler proceeds to draw conclusions from what he believes to be established facts amongst which are: "*Her speech and writing demonstrated significant thought-form disorder*"; "*There was psychomotor agitation, irritability and lability of mood*", yet which seem curiously at odds with Cameron's description: "*Her garrulousness didn't strike me as at all unusual. Many people deal with anxiety by talking*".

#### (iii) <u>Mental Illness</u>

Watler draws a distinction between suffering from mental disorder and being diagnosed with a specific psychiatric illness.

<sup>&</sup>lt;sup>4</sup> *Vide* Chapter 3 and the clinical definition of delusion.

This distinction is capable of two interpretations, a narrow and a broad: the narrow interpretation would be that the individual who has a mental disorder, has – because of difficulty in carrying out a differential diagnosis – not yet been diagnosed as suffering from a *specific* psychiatric illness. A similar such situation might occur in a non-psychiatric medical setting, when a patient is suffering from a fever but it is not clear yet whether he is suffering from a malarial or some other fever. The broad interpretation is when it is possible that an individual might suffer from a 'mental disorder' and not suffer from *any* identifiable psychiatric illness. It is clearly this broad sense that Watler has in mind when he says:

Mental disorder is, in fact, very poorly defined in the various mental health acts, and this omission is quite deliberate. The physician need not establish an *'identifiable psychiatric illness'* as a requirement for involuntary committal. Rather, persons should be detained for evaluation where there is high-risk behaviour and evidence to suggest any form of mental disorder.

This poses grave difficulties for any analysis of misdiagnosis in psychiatry for not only does the term 'misdiagnosis' cover a diagnosis which was not made in accordance with the specific diagnostic criteria for the various psychiatric disease categories as specified in the standard diagnostic manuals – such as the ICD-10 and the DSM-IV – but it also covers those who were never believed to suffer from an identifiable psychiatric illness but who have been wrongly diagnosed as having 'mental disorder'.

This distinction is discussed further in Chapter 4.

#### (iv) *Default presumptions relating to coercive psychiatric interventions*

When presented with a recalcitrant individual for psychiatric evaluation, Watler's 'default position' is to urge involuntary committal for evaluative purposes; he states: "*It seems speculative to conclude that Amy was not mentally ill*". Transposed to the criminal law, this principle would read: '*It seems speculative to conclude that the accused is not guilty*' whereas the relevant legal principle actually is '*If a reasonable doubt exists as to the guilt of the accused, he should go free*'.

Such a stark contrast between psychiatric and legal principles seems difficult to justify unless one believes that coercive psychiatric intervention is essentially benign and this appears to be Watler's position: *"The brevity of this detention – a maximum of 7 days in Nova Scotia – does not represent a* significant *deprivation of freedom."* It was argued earlier that, in some circumstances, a coercive psychiatric intervention might be compared to a rape because of the intimacy of its intrusiveness. If this comparison is well-founded, then arguments as to the brevity of the detention are comparable to a rapist seeking to mitigate his crime by arguing that the rape lasted but a short time.

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#### (v) Irrationality

The term 'irrationality' is not mentioned explicitly in the discussion, whereas the terms 'not rational' and 'rational' do occur: Cameron describes one such use by Amy's attending physician who "... *felt that her actions were rational: she had a value system and had made a decision consistent with her beliefs;*" Watler considers the refusal of treatment with a high therapeutic index to be "*not rational*". The contrast between these two positions highlights the difficulty in determining the meaning to be accorded to these terms when used in a psychiatric setting.

#### (vi) *Psychiatric Labels*

The usage of psychiatric labels<sup>5</sup> -

"manic denial" ... ... "signs of grandiosity" ... ... "significant thought-form disorder" ... ... "psychomotor agitation, irritability and lability of mood" ... ... "social withdrawal and suspiciousness" ... ... "unstable, paranoid and grandiose ... not rational" ... ... "paranoid ideation" ... ... "psychosis could not be ruled out",

– is so pervasive as to be promiscuous and as if the terms were benign; it shows little awareness of the potency of these terms and of the serious consequences that may flow from their inappropriate use.

#### C-6: Conclusions

Although the Amy case is but a single case of psychiatric intervention on the grounds of irrationality, it is a particularly powerful example in that the psychiatrists involved must be assumed (in responding to an article in a medical journal which was critical of their professional expertise and judgement) to have carefully considered their reply and drafted it in a manner which would meet with the approval of their professional colleagues. Unless the Amy case is truly exceptional, the (tentative) conclusion may be drawn that the psychiatric usage of terms such as 'irrational' is so lacking in precision and awareness of the detrimental consequences of their ascription, as to merit the description 'cavalier'.

<sup>&</sup>lt;sup>5</sup> The labels which follow, were applied to Amy by various professionals and are direct quotations from either Cameron (1997a), Watler (1997), Gervais(1997) or Cameron (1997b).

### Appendix D: Estimates of the rate of marital infidelity

The goal of this appendix is to see whether it is possible to estimate the probability that the wives of individuals in circumstances such as Blehein's<sup>1</sup> or Fulford's Mr. O.S.<sup>2</sup> – *i.e.* jealous husbands in unhappy marriages who believe their wives to have been unfaithful – actually have been unfaithful.

Some general statistics are given in <u>Subsection D-1</u>; some more particular estimates are given in <u>Subsection D-2</u> and some conclusions are drawn in <u>Subsection D-3</u>.

#### D-1: Some general statistics on rates of infidelity

Hargrave (2000) whilst noting the difficulties involved in estimating rates of marital infidelity, summarises some studies:

Kinsey (1953) ... estimated that 50% of husbands and 26% of wives engage in at least one extramarital affair<sup>3</sup> ... Glass and Wright (1992) put the estimates at 44% for men and 25% for women. ... So it is probably realistic to assume that the rate of infidelity is somewhere between 30% and 55% for men and between 25% and 40% for women.<sup>4</sup>

UK studies give comparable estimates:

- A 1949 survey (the results of which were withheld at the time)<sup>5</sup> found that 20% of women admitted to having had an extra-marital affair.
- A 2005 study by the counselling service *Relate* found that 24% of wives admit to having had affairs.<sup>6</sup>

#### D-2: Some more particular statistics on rates of infidelity

More nuanced estimates are available where, for example, the sample population is restricted to couples who describe themselves as 'unhappy' or where a husband exhibits jealousy or where a husband believes that his wife has had an affair.

#### Unhappy marriages

The Kinsey Institute quotes<sup>7</sup> a study in relation to 'unhappy' couples:

Respondents who reported that their relationships were "*pretty happy*" and "*not too happy*" were two and four times more likely, respectively, to have reported

<sup>&</sup>lt;sup>1</sup> See Chapter 3.

 $<sup>^{2}</sup>$  Ibid.

<sup>&</sup>lt;sup>3</sup> A 1991 update to the Kinsey study found a rate of 31% [see University of Berkley, Department of Statistics, (2006)].

<sup>&</sup>lt;sup>4</sup> Hargrave (2000), p.165.

<sup>&</sup>lt;sup>5</sup> Sussex University, Press release, 'Sussex archive reveals secret sex lives of 1940s Britain'. [online], available:http://www.sussex.ac.uk/press\_office/media/media505.shtml [accessed 5 July 2006].

<sup>&</sup>lt;sup>6</sup> The Sunday Times (2005) 'Secret Passions of the Grey 1940's'. 4 September.

<sup>&</sup>lt;sup>7</sup> The Kinsey Institute. '*Frequently asked sexuality questions to The Kinsey Institute*' [online], available: http://www.kinseyinstitute.org/resources/FAQ.html#Laumann [accessed: 10 August 2006].

extramarital sex than respondents who reported that they were "very happy" with their relationships [Atkins (2001)].

#### Jealous husbands

A US study examined the effect of a husband's jealousy on the wife's propensity to have an extramarital affair:

Women who complained that their husbands are jealous and possessive reported a higher probability that they will have brief affairs with other men. ... Although causality cannot be inferred from these correlational data, the pattern does suggest that the husbands' displays of jealousy and possessiveness may veridically reflect a higher likelihood of their partners' infidelity, especially in the form of a brief affair.<sup>8</sup>

#### Suspicious husbands

Andrews (2008) sought to determine the reliability of a partner's belief in the unfaithfulness of their spouse. Men who reckoned that the probability that their wives had had an affair exceeded 50%, were classified as 'suspicious'; the study concluded that the likelihood that the beliefs of such suspicious husbands, was correct, was 69.2%.<sup>9</sup> Hence, given that a husband is 'suspicious', it is 2.3 times more probable that his wife was unfaithful, than that she was not.

#### **D-3:** Conclusions

Taking 25% as a tentative estimate of the extent of female marital infidelity and restricting the discussion to marriages where the husband was jealous and the couple were "*not too happy*", a tentative estimate<sup>10</sup> of the probability that the wife was unfaithful exceeds 50%, *i.e.* it is more likely than not that the wife of a jealous husband in an unhappy marriage has had, or will have, an extramarital affair. The presence of jealousy on the husband's part would, according to Buss (1997) increase the probability of wife being unfaithful. The suspicion that she was having an affair would, according to Andrews (2008), increase the probability to 70%.

<sup>&</sup>lt;sup>8</sup> Buss & Shackelford (1997), p.213.

<sup>&</sup>lt;sup>9</sup> Data abstracted from Andrews (2008), Table 3, p.353.

<sup>&</sup>lt;sup>10</sup> Talking a sample of 84 couples [84 is chosen to avoid the occurrence of fractions] and assuming that an equal number of couples were "*very happy*", "*pretty happy*" and "*not too happy*", then assuming that 25% of wives (*i.e.* 21) were unfaithful [Atkins (2001) *supra*]:

<sup>- 3</sup> would be in marriages described as "very happy"

<sup>- 6</sup> would be in marriages described as "pretty happy"

<sup>- 12</sup> would be in marriages described as "not too happy"

Thus the probability that the wife was unfaithful in a marriage described as "*not too happy*" would be 12/21 = 57%.

More formally, the following conclusion can be drawn:

In marriages which were described as 'unhappy' and where the husband exhibited jealousy, a tentative estimate of the probability that the wife was unfaithful, exceeds 50%. A tentative estimate of the likelihood of the correctness of a 'suspicious' husband's belief that his wife is unfaithful, is 70%.

In attempting to apply such results to cases such as Blehein's, the objection might well be made that the spouses studied by, for example, Andrews (2008) were not reported as exhibiting any evidence of mental illness. To this, it can be countered that in cases such as Blehein's, the *only*<sup>11</sup> evidence of mental illness in cases of delusions of infidelity, is often just the supposed 'delusion'.

A further point of interest arising from Andrews (2008) is that those 'suspicious' husbands who believed their wives to be having an affair were unable to justify this belief (in the sense discussed in Chapter 3) but based their belief on hunches or 'guesses'; their doing so did not appear to raise the spectre of mental illness (*pace* the psychiatric analysis of such cases as discussed in Chapter 3).

<sup>&</sup>lt;sup>11</sup> See Enoch (1967) (*supra*):

I have now in an asylum two quite rational-looking men, whose chief delusion is that their wives, both women of undoubted good character, had been unfaithful to them. Keep them off that subject and they are rational. But on that subject they are utterly delusional and insane. (p. 47)

## Appendix E: Prevalence of unjustifiable beliefs amongst 'normal' subjects

As discussed in Chapter 3, one who cleaves, unshakably, to a belief (other than a religious belief) without being able to justify it, can be clinically diagnosed as 'delusional'; implicit is the presumption that such beliefs do not occur amongst the 'normal'<sup>1</sup> population. The goal of this appendix is to examine the prevalence of such tenaciously held, unjustifiable, beliefs amongst the general population [*Subsection E-1*], amongst some academic or professional subgroups [*Subsection E-3*].

### E-1: Unjustifiable beliefs in the general population

Some US studies are first examined and then some UK studies.

#### United States

A Harris (2003) survey into the beliefs of Americans, found that:

Many people believe in miracles (84%), the devil (68%), hell (69%), ghosts (51%), astrology (31%) and reincarnation (27%). ... The 84% of the public who believe in miracles falls to 72% among those with postgraduate degrees, and rises to 90% among women and 90% among African-Americans.

A Gallup (2005) poll found that three in four Americans held paranormal beliefs in at

least one of the following:

... extra sensory perception (ESP), haunted houses, ghosts, mental telepathy, clairvoyance, astrology, communicating with the dead, witches, reincarnation, and channeling. There are no significant differences in belief by age, gender, education, or region of the country.

#### United Kingdom

A 1998 survey<sup>2</sup> to determine the prevalence of paranormal beliefs found that 47% believed in thought reading (14 % having had direct experience) and 34% believed that objects can be moved by the power of the mind (4% having had direct experience).

A Mori (2003) survey found that:

... 40% now said they believed in ghosts, and 15% that they had "personal experience" of ghosts; 6% of the public, indeed, said they had based a decision on their belief in ghosts. ... 18% of the public said they believed in fortune telling or tarot, and 38% in astrology.

<sup>&</sup>lt;sup>1</sup> The ambiguities inherent in the term 'normal' are discussed in Chapter 3.

<sup>&</sup>lt;sup>2</sup> *Daily Mail* (1998) 'Survey of Britons' 2 Feb. Copy available online: http://www.uri-geller.com/survey1.htm [accessed 31 July 2006].

### E-2: Examples of unjustifiable beliefs amongst the professions

Lest it be thought that the professions and academia might be inured from such unjustifiable beliefs, I wish to mention a 2007 survey of the beliefs of university students and then two particular examples: the first concerns the beliefs of a Harvard professor, in alien abduction; the second concerns the beliefs of UK social workers, in the prevalence of the 'satanic abuse'.

#### Student survey

This study examined the beliefs of 800 German university students of psychology,

philosophy and science and was published in Philosophy, Psychiatry & Psychology; it

#### found, *inter alia*:

That extrasensory perception and telepathy may occur is assumed by 64% of the students, incidences of miraculous mental healing by 45%, the validity of horoscopes by 17%, and the use of exorcism under extreme circumstances by  $14\% \dots^3$ 

#### Alien Abduction

Mack was professor of psychiatry and wrote extensively on alien abduction<sup>4</sup>. He

believed that:

... "aliens" from higher space-time dimensions are visiting Earth, and that this "Phenomenon is occurring in the context of the threat to the earth as a living system, a response to the ecological devastation that our particular species has undertaken." The aliens are engaged in what he called a "cosmic correction"; they appear to function "as a kind of intermediary between the Source of creation and us, emissaries perhaps of that correction."<sup>5</sup>

#### Satanic Abuse

This example is of interest in relation to the evidential base that supposedly normal

professionals use to ground their beliefs.

Satanic abuse, as described in the *British Medical Journal*:

 $\dots$  seemed to have reached epidemic proportions in a small part of the north east of England. The paediatricians and social workers seemed to be zealots – children who turned up at hospital with minor unrelated symptoms were diagnosed as having been sexually abused, with reflex anal dilatation as the sole criterion, and were taken into care.<sup>6</sup>

One of the most controversial interventions occurred in Rochdale where, without

warning, police and social workers took 16 children into care for what was to be a total

of 34 years and four months.<sup>7</sup> It was alleged they had been forced into devil worship

<sup>&</sup>lt;sup>3</sup> Fahrenberg & Cheetham (2007), p 190.

<sup>&</sup>lt;sup>4</sup> Mack (1994) is a sympathetic study of such cases.

<sup>&</sup>lt;sup>5</sup> The (London) Independent, (2004) 'Obituaries John E. Mack', 8 Oct.

<sup>&</sup>lt;sup>6</sup> Essex (1997).

<sup>&</sup>lt;sup>7</sup> BBC News (2006). 'Lost years of 'satanic panic' children'. *BBC*. 11 January. [online], available: http://news.bbc.co.uk/2/hi/programmes/real\_story/4602302.stm [accessed 1 Aug 2006].

and had been sexually abused. The event that precipitated the intervention was the experience of one boy who appeared to be unduly fearful and who often spoke about ghosts, which (to the social workers involved) was his way of referring to sexual abusers. Yet there was never any proof – forensic, medical or otherwise – to support claims of ritual abuse against any of the families. When police raided the house they took as 'evidence' a cross made by one child from two lollipop sticks and a religious wall plaque that she had given her mother, portraying Jesus on the Cross, which bore the words "*God bless our home*" and featured a small well for holy water. It was later alleged that this had been used to hold blood.<sup>8</sup>

None of these allegations were upheld by the courts.

Subsequently the British Government appointed Jean La Fontaine (an anthropologist) to head an investigation, she found that:

... to those for whom the status of the accuser allowed of no doubt, evidence was irrelevant, although there was faith that it would be forthcoming. To show scepticism was to be accused of supporting paedophiles; to try and explain was seen as an attempt to excuse. The claim that satanic abuse was the cause of serious psychic damage to children and adults was a moral judgement, not a rational argument from the facts.

It is this belief in unverified and unverifiable mystical evil that, *par excellence*, classes belief in satanic abuse with belief in witchcraft whether in the European distant past or in the recent past  $\dots$ <sup>9</sup>

One point of especial interest, in the context of coercive psychiatric interventions, is that the judge in the Rochdale case, did accept that the social workers were motivated by zeal rather than by malice: "*I do not question the good faith or good intentions of the social workers, who I acknowledge were working under considerable pressure.*"<sup>10</sup> Such a defence would<sup>11</sup> exonerate psychiatrists (unlike social workers) from civil liability for a coercive intervention based on similarly unjustifiable grounds.

#### E-3: Conclusions

I wish to avoid, what biologist Richard Dawkins calls, the "*Argument from Personal Incredulity*"<sup>12</sup> and simply conclude, not that all the above beliefs are untrue, but that the psychiatric perception of the beliefs of normal subjects – especially the perception that normal people are able to justify their beliefs – is not possible to sustain in the face of such evidence.

<sup>&</sup>lt;sup>8</sup> The Times (2006). 'Our stolen childhood' *The Times*. 10 January.

<sup>&</sup>lt;sup>9</sup> La Fontaine (1998), p.185.

<sup>&</sup>lt;sup>10</sup> The Times (2006). 'Our stolen childhood' supra.

<sup>&</sup>lt;sup>11</sup> See the *Mental Health Act* (2001), S. 73.

<sup>&</sup>lt;sup>12</sup> *I.e.* that if it seems impossible to me, it must not be true; see Dawkins (1995), p 29.

# Appendix F: Problematic aspects of psychiatric probability assessments

The importance of the role played by probability assessments in medical decision making<sup>1</sup> is most clearly manifest when the consequences of an erroneous probability assessment become apparent; the criminal conviction in the Sally Clark case [*Subsection F-1*] provides a striking example. The Clark conviction was overthrown because the medical expert based his testimony on explicit data and a probability calculation both of which were provably incorrect.

Much more insidious are 'intuitive' probability assessments made in response to an inadequately formulated problem and which are made in the absence of explicit data (*e.g.* psychiatric assessments as to what is 'normal'); it is extremely difficult to mount a direct challenge to any such assessments in the absence of explicit data especially since 'intuitive' judgements have a natural affinity with 'common-sense' perceptions; accordingly it is important to emphasise the often radical difference between a probability assessment which has been rigorously calculated, and one based on intuition – a phenomenon encapsulated in the description of probability assessments as often being '*counter–intuitive*'; examples are given in <u>Subsection F-2</u>. Intuitive probability assessments underlie many psychiatric diagnoses either explicitly (as in the definition of delusion<sup>2</sup>) or implicitly (as in the assessment that a particular behaviour or belief is not 'normal'); many such intuitive psychiatric assessments will be shown<sup>3</sup> to be erroneous; in consequence many psychiatric assessments of what is pathological (assuming the pathological and the normal to be mutually exclusive categories) are also necessarily erroneous.

Theoretically more complex errors – the so-called '*Base Rate*'<sup>4</sup> errors – feature prominently in the mis-interpretation of test results whether in general medical practice (*e.g.* mammography) [*Subsection F-3*] or in clinical psychiatry (*e.g.* assessments of dangerousness) [*Subsection F-4*]. The presence of such errors is pervasive in the psychiatric literature on dangerousness,<sup>5</sup> moreover the errors are of such a magnitude [*c*.

<sup>&</sup>lt;sup>1</sup> Sutherland (1992), for example, states: "Whether doctors acknowledge it or not, most medical diagnosis relies on probabilities, …" (p. 176).

<sup>&</sup>lt;sup>2</sup> Sedler (1995), p.256: "Bizarre delusions are generally impossible, whereas nonbizarre delusions are generally improbable."

<sup>&</sup>lt;sup>3</sup> *Infra* and Chapters 3 and 6.

<sup>&</sup>lt;sup>4</sup> Also known as 'Conditional Probability' or 'Bayesian Analysis'.

<sup>&</sup>lt;sup>5</sup> See Chapter 6 for an extended discussion.

ten–fold]<sup>6</sup> as to render such assessments not only deeply flawed but, in themselves, parlous – an ironic conclusion in that some psychiatrists believe that the cause of some psychiatric illnesses lies in an inability to make correct probability assessments.<sup>7</sup> Conclusions are listed at the end of subsections <u>*F*-2</u> and <u>*F*-4</u>.

#### F-1: The Sally Clark case

In 1999 a solicitor, Sally Clark, was convicted of smothering one baby son and of shaking her other son to death. Her conviction hinged on expert evidence given by an eminent paediatrician Professor Sir Roy Meadow who estimated the likelihood of two infants from the same family dying of SIDS<sup>8</sup>, as one in 73 million. The Royal Statistical Society took the unprecedented step of writing to the Lord

Chancellor to register its objection to the way the statistic had been calculated,<sup>9</sup> and stated that:

... a medical expert witness drew on published studies to obtain a figure for the frequency of sudden infant death syndrome ... He went on to square this figure to obtain a value of 1 in 73 million for the frequency of two cases of SIDS in such a family. This approach is, in general, statistically invalid ...

Aside from its invalidity, figures such as the 1 in 73 million are very easily misinterpreted. Some press reports at the time stated that this was the chance that the deaths of Sally Clark's two children were accidental. This (mis-)interpretation is a serious error of logic known as the '*Prosecutor's Fallacy*'.<sup>10</sup>.

Clark's conviction was subsequently quashed.<sup>11</sup>

A number of points arising from this case are of interest in the present context:

- Meadow's probabilistic estimates were not based on intuition but on published

data, furthermore he used (albeit inappropriately) accepted mathematical

techniques. Thus both the data and the calculation were open to external scrutiny and rebuttal.

The statement of the Royal Statistical Society<sup>12</sup> emphasised the severe consequences that could flow from erroneous probability assessments. The

<sup>&</sup>lt;sup>6</sup> See, for example, Szmukler (2001a) *infra*.

<sup>&</sup>lt;sup>7</sup> See *infra* and Blankenburg (2001), p.308.

<sup>&</sup>lt;sup>8</sup> Sudden Infant Death Syndrome.

<sup>&</sup>lt;sup>9</sup> BBC News, (2003). 'On This Day:2003: Solicitor cleared of killing sons' *BBC News* [online], available: http://news.bbc.co.uk/onthisday/hi/dates/stories/january/29/newsid\_3412000/3412647.stm [accessed: 7 August 2006].

<sup>&</sup>lt;sup>10</sup> The Royal Statistical Society (2001); the 'Prosecutor's Fallacy' is discussed in F-III (infra).

<sup>&</sup>lt;sup>11</sup> BBC News, (2003) (*supra*).

<sup>&</sup>lt;sup>12</sup> The Royal Statistical Society (2001):

Society does not tolerate doctors making serious clinical errors because it is widely understood that such errors could mean the difference between life and death. The case of R v Sally Clark is one example of a medical expert witness making a serious statistical error, one which may have had a profound effect on the outcome of the case.

consequence that might follow from an erroneous psychiatric probability assessment based on clinical intuition are no less severe in that they may equally result in wrongful incarceration but, lacking an explicit evidence base (as was used by Meadow) they would not be open to the independent scrutiny of bodies such as the Royal Statistical Society; in the absence of explicit statistical evidence to the contrary, such probability assessments would be effectively immune from review.<sup>13</sup>

- The true probability of a double cot death (in excess of 1 in 214)<sup>14</sup> would, when viewed from the perspective of intuitive probability, be regarded as highly improbable and as providing no reason to set the verdict aside; it exemplifies the falsity of the intuitive nostrum (*infra*): "*that the extremely low probability of an event happening is evidence that it has not happened*."

Because of the absence of 'raw data', many probability judgements that arise in the course of psychiatric clinical practice are not amenable to a mathematical analysis<sup>15</sup> and are thus wholly reliant on intuition ('clinical judgement'). It is relatively easy to correct intuitive probability assessments when they can be compared with mathematical probability assessments based on the agreed data; however, in the absence of such data, the evidence would suggest that intuitive probability assessments should be treated with extreme caution. In such circumstances Montaigne's advice is apposite: "... there is a silly arrogance in continuing to disdain something and to condemn it as false just because it seems unlikely to us."<sup>16</sup>

As will be shown in the following section, Montaigne's advice is well founded.

## *F-2: The Counterintuitive Nature Of Some Probability assessments*

The counterintuitive nature of probability assessments will be shown by:

- taking some common intuitive probability assessments which can be shown to be erroneous, [*F*-2(*i*)]
- outlining some research on the unreliability of intuitive probabilistic reasoning, [*F*-2(*ii*)]

<sup>&</sup>lt;sup>13</sup> See the discussion in Chapter 6 on psychiatric assessments of dangerousness.

<sup>&</sup>lt;sup>14</sup> The author of the original study stated that:

<sup>...</sup> although his study contained the one in 73 million figure, it was "somewhat unreliable" because of the "extreme rarity" of double cot deaths. "It was never intended as a real statistical estimate," he told the hearing. The true rate could range between 1 in 214 and 1 in 8,500.

Laurance, J. (2006) 'Child abuse expert 'used statistics out of context' at cot death trial'. *The Independent*. 24 June.

<sup>&</sup>lt;sup>15</sup> See, for example, the discussion in Chapter 3 on the phenomenon of 'hearing voices'.

<sup>&</sup>lt;sup>16</sup> de Montaigne (1991), p.200.

considering some seemingly commonsensical – but nonetheless unsustainable – statements concerning probability which are implicit in many 'common sense' type arguments and which are also to be found in some academic writings on psychiatry.<sup>17</sup> [F-2(*iii*)]

#### F-2(i): Examples of counterintuitive probability assessments

I will give three examples.

(a) The longest record for a run on black in a game of roulette occurred in a Monte Carlo casino in 1913 when the ball landed on black a record twenty-six times in succession. Amongst watching gamblers this precipitated:

... a near-panicky rush to bet on red, beginning about the time black had come up a phenomenal fifteen times ... players doubled and tripled their stakes (believing) that there was not a chance in a million of another repeat. In the end the unusual run enriched the Casino by some millions of francs.<sup>18</sup>

The error (known as '*The Gambler's Fallacy*') is based on a failure to understand statistical independence. Two events are statistically independent when the occurrence of one has no statistical effect upon the occurrence of the other; in playing roulette the occurrence of black has no effect on the colour to occur on the next throw of the ball. A similar error is involved when a coin thrower believes that after he has tossed three Heads in succession, Tails is more likely.

(b) The second example concerns the (unjustified) belief that in a family of six children the outcome BBBGGG<sup>19</sup> is more likely because it appears to better represent the 'typical' member of the distribution than GGGGGG which seems 'unusual' and hence less probable. This exemplifies the so-called '*Representative Bias*' which occurs when thinking is overly influenced by what is stereotypically true; in the psychology of decision making it is known as the '*representativeness heuristic*<sup>20</sup> and is responsible for many cases of misdiagnosis.<sup>21</sup>

This "representativeness" heuristic frequently yields accurate results because representativeness often correlates with likelihood. Unfortunately, it also leads people to overweight highly representative individuating evidence and to undervalue relevant prior probabilities. Positive test

<sup>&</sup>lt;sup>17</sup> E.g. Blankenburg (2001) *infra*.

<sup>&</sup>lt;sup>18</sup> Huff & Geis (1959), p.28.

 $<sup>^{19}</sup>$  B= Boy; G= Girl.

<sup>&</sup>lt;sup>20</sup> Klein (2005):

Kahneman and Tversky showed this heuristic in a classic experiment in which they presented participants with descriptions of people who came from a fictitious group of 30 engineers and 70 lawyers (or *vice versa*). The participants then rated the probability that the person described was an engineer. Their judgments were much more affected by the extent to which the description corresponded to the stereotype of an engineer (for example, "*Jack is conservative and careful*") than by base rate information (only 30% were engineers), showing that representativeness had a greater effect on the judgments than did knowledge of the probabilities.

<sup>&</sup>lt;sup>21</sup> Bornstein & Emler (2001):

(c) In an attempt to emphasize "how simple intuition can be misleading", Holt &

Anderson (1996) cite:

... the (true) story about a man who received a positive outcome on a firststage test for the virus that causes AIDS. The test that was used had a 4% rate of false positives and, for simplicity, it is assumed that there were virtually no false negatives. The person committed suicide before follow-up examinations, presumably not realising that the low incidence of the virus in the male population (about 1 in 250 at that time) resulted in *a posterior* probability of having the virus of only 10%.<sup>22</sup>

This provides an example of a typical 'base-rate' error [see F-III infra].

#### F-2(ii): Some research on the unreliability of intuitive reasoning

Tversky & Kahneman (1983) examined the lack of congruence between intuitive and formal (*i.e.* mathematical) probability assessments. Their research had lead them to hypothesize that intuitive probability assessments are often made on what is intuitively perceived as being a representative instance rather than on truly probabilistic considerations; they sought to test this hypothesis by asking subjects which of two propositions '*A*' and '*A* and *B*' are more probable.<sup>23</sup> They asked practising physicians to make intuitive predictions on the basis of clinical evidence and found that:

The incidence of violations of the conjunction rule in direct tests ranged from 73% to 100%, with an average of 91%. Evidently substantive expertise does not displace representativeness and does not prevent conjunction errors. ... Most participants appeared surprised and dismayed to have made an elementary error of reasoning.<sup>24</sup>

#### F-2(iii): Intuitively correct, but erroneous, probability statements

I have chosen three statements which are, I suggest, intuitively plausible yet are in fact, erroneous:

- (a) that the extremely low probability of an event happening is evidence that it has not happened;
- (b) that estimates of probability point to what is true and that it is irrational to believe in other than the most probable outcome;

results are especially salient in this respect and difficult to ignore, leading doctors in many cases to overestimate the probability of disease. For example, a positive mammogram is perceived as so indicative of breast cancer that it may lead doctors to ignore the relevant base rate — such as that women in a certain age group, without other symptoms, have a very low prior probability of breast cancer — and hence to overweight the import of the positive test result. (p. 99.)

Tversky & Kahneman (1983) proposed that the use of the representativeness heuristic is one of the main causes of base rate errors.

<sup>&</sup>lt;sup>22</sup> Holt & Anderson (1996), at p.179.

<sup>&</sup>lt;sup>23</sup> Irrespective of content, 'A' must always be more probable than 'A and B' since every occurrence of 'A and B' is necessarily an occurrence of 'A'.

<sup>&</sup>lt;sup>24</sup> Tversky & Kahneman (1983), p.301-2.

(c) that probabilistic estimates are objective and thus if estimates conflict, one must be erroneous.

## F-2(iii)(a): The extremely low probability of an event happening is evidence that it has not happened

A simple thought experiment is sufficient to dispel this belief: imagine one tosses a box of matchsticks into the air and that one carefully notes the precise position and orientation of each of the fallen matches and the relationship it bears towards its adjoining matches. Had one calculated – before tossing the matches in the air – the chance that this particular 'aggregate orientation' (out of all possible aggregate orientations) would happen, then its probability would have been miniscule. A similar error is pointed out by Blackburn when he notes the fallacy inherent in arguing that because "… much statistical research argues that since X has a low probability of being caused by chance therefore X is caused by ---."<sup>25</sup>

## F-2(iii)(b): Estimates of probability point to what is true and to how the future will unfold

The use of probability measures in relation to the unfolding of events is an indication of the existence of a state of ignorance in relation to the true mechanism, or cause, of the unfolding. Probability, unlike entropy, does not function as 'time's arrow'; determinations of the most probable outcome do not point unequivocally to the true or to how the future will unfold.<sup>26</sup>

The error being discussed appears to be not uncommon even within the philosophy of psychiatry: Blankenburg (2001), for example, seeks to interpret psychiatric illness – and, in particular, schizophrenia – as a deficiency in common sense and, in furthering his arguments, argues for the proposition that the probable provides the basis for what is true:

<sup>&</sup>lt;sup>25</sup> Blackburn (1999), p.224.

<sup>&</sup>lt;sup>26</sup> A thought experiment which took an existing complex situation and which asked whether it had evolved along the path of the most probable outcome, should be sufficient to dispel overestimations of the role of probability assessments.

The noted biologist Stephen Jay Gould died in 2002; twenty years earlier he had been diagnosed with mesothelioma and had been told that "*mesothelioma is incurable, with a median mortality of only eight months.*" He posed the question [Gould (1985)]:

What does 'median mortality of eight months' signify in our vernacular? I suspect that most people, without training in statistics, would read such a statement as "*I will probably be dead in eight months*".

He described his intellectual reaction:

<sup>...</sup> fine, half the people will live longer; now what are my chances of being in that half. ... I immediately recognized that the distribution of variation about the eight-month median would almost surely be what statisticians call "right skewed."

In the event, Gould lived for another 17 years -a telling reminder of the limitations of probability assessments especially those based on intuition.

As far as judgement is concerned, it is less a matter of differentiating true from false than of distinguishing the probable from the improbable. Vico had emphasized that just as science is concerned with the truth, so common sense is concerned with the probable (verisimile). It is precisely those errors and derailments at the beginning of the hebephrenic psychoses that make evident for us the fact that the significance of the probable is in no way a deficient mode of cognition of what is true. <u>Rather, the probable is encompassing and provides the basis for what is true</u>, which is here meant in the sense of what is correct and demonstrable.<sup>27</sup> [Emphasis added]

When Blankenburg uses the term 'common sense' he is using it as meaning that sense

which is common or shared within a society as is evident when he states that:

... it is not uncommon for the relatives of the patient to report that the illness began with the patient raising questions about "*the most ordinary things*". These are things, which, to the common sense of the healthy person, are the most obvious, naturally understood things in life. In contrast, the patients still manage to solve difficult, intellectually more demanding tasks without considerable effort.<sup>28</sup> [Emphasis added]

Blankenburg is not alone amongst philosophers in seeking to elevate the status of

'common sense' to that of incontrovertible truth; a tendency of which Papineau is

highly critical:

Any amount of nonsense was once part of common sense, and much nonsense no doubt still is. It was once absolutely obvious that the heavens revolve around the earth each day, that the heart is the seat of the soul, that without religion there can be no morality,  $\dots^{29}$ 

When common sense can, on principle, be elevated by philosophy and be buttressed by coercive psychiatry, then the danger of a militant orthodoxy being able to exert an intellectual hegemony, becomes real; the cases of Soviet dissidents<sup>30</sup> provide a stark warning of the possible dangers.

## F-2(iii)(c): Probabilistic estimates are objective and thus if estimates conflict, one must be erroneous.

Building on the analysis of the previous section it is clear that probabilistic estimates are objective – and thus command acceptance – if, and only if, the data on which they are based is explicit and is accepted, by all parties, as being the appropriate basis of calculation.<sup>31</sup> In particular, intuitive probability assessments are not objective and

<sup>&</sup>lt;sup>27</sup> Blankenburg (2001), p.308.

<sup>&</sup>lt;sup>28</sup> *Ibid*. p.306.

<sup>&</sup>lt;sup>29</sup> Papineau (2006) see also Chapter 2.

<sup>&</sup>lt;sup>30</sup> See Chapters 2, 3 and 4.

<sup>&</sup>lt;sup>31</sup> Jaynes (1994) emphasises this point:

Perhaps this makes clearer the reason for our seemingly fanatical insistence on indicating the prior information 'I' explicitly in every formal probability symbol P(A | BI). Those who fail to do this may be able to get along without disaster for a while, ... But eventually they are sure to find themselves writing nonsense, ...

cannot command assent. Such probability assessments are estimates – more correctly, 'hunches' – based on 'information' which may be long forgotten and inaccessible to conscious scrutiny; accordingly they may conflict without either party being necessarily 'wrong'. The psychiatric testimony given during the trial of Zacarias Moussaoui,<sup>32</sup> provides an example of the subjectivity of some psychiatric probabilistic assessments. During Moussaoui's trial, his defence team sought to establish that he was mentally ill and they introduced a number of psychiatrists to so testify; the prosecution introduced psychiatric evidence in rebuttal.<sup>33</sup>

Dr. First, a psychiatrist and editor of the DSM-IV, was one of the defence witnesses. First told the court that Moussaoui suffered from paranoid and grandiose delusions one of which was that he would be freed by President Bush; he testified that:

Moussaoui's most persistent grandiose belief, First said, is that President Bush will free him from jail, perhaps as part of a prisoner exchange with al Qaeda. Moussaoui also believes he could be of value to the United States, First said, because his testimony could "*clear up September 11 in 15 minutes.*"<sup>34</sup>

In order to argue that this belief is delusional it is first necessary to establish its falsity;<sup>35</sup> the nature of Moussaoui's belief rendered this impossible and First argued that the belief was so highly improbable as to be false.<sup>36</sup> But such probabilistic estimates are a highly subjective exercise and manifest little other than the particular and limited background of the one who makes these estimates: the estimate made by a WASP academic as whether the President of the USA might pardon a Muslim terrorist is likely to be radically different to that made by a disaffected young Muslim.<sup>37</sup> The point was well made by the psychiatrist for the prosecution:

<sup>&</sup>lt;sup>32</sup> USA v Zacarias Moussaoui (2002); Moussaoui was charged with withholding information in relation to the September 11<sup>th</sup> 2001 attacks on the US.

<sup>&</sup>lt;sup>33</sup> The clash of psychiatric testimony is relevant to the validity and consistency of psychiatric diagnosis; see Chapter 4.

<sup>&</sup>lt;sup>34</sup> Hirschkorn, P. (2006) 'Defense experts call Moussaoui schizophrenic.' *CNN News* [online], available: http://www.cnn.com/2006/LAW/04/19/moussaoui.trial/index.html [accessed: 17 August 2006].

<sup>&</sup>lt;sup>35</sup> See the discussion of delusion in Chapter 3 where it is noted that clinical psychiatrists often replace the 'falsity criterion' by a 'justifiability criterion'.

<sup>&</sup>lt;sup>36</sup> Arthur & Elsibai (2006):

Dr. Michael First, a psychiatrist at Columbia University, told a federal jury that Moussaoui is preoccupied with delusions such as his belief that President Bush will free him. *"It is so completely implausible on the face of it that it qualifies as a false belief,"* First said yesterday.

Arthur, B & Elsibai, N. (2006) 'New defense testimony given on Moussaoui mental state.' *The Boston Globe*, 20 April [online], available:

http://www.boston.com/news/nation/articles/2006/04/20/new\_defense\_testimony\_given\_on\_moussaoui\_mental\_state/ [accessed: 17 August 2006]

<sup>&</sup>lt;sup>37</sup> It might be argued that the *DSM-IV* requirement that, to be delusional, a belief "... *is not one ordinarily accepted by other members of the person's culture or subculture*", would make this distinction unnecessary. It would have fallen to the prosecution to make the argument that Moussaoui's belief was accepted in his subculture; and whilst it seems this argument was made, it was not substantiated: "*Dr*.

On cross-examination, Patterson refused to concede that Moussaoui's belief he will be freed is irrational, saying it is plausible that Moussaoui could be freed as part of a hostage exchange. "*I know we traded arms for hostages*," Patterson said, referring to the Reagan-era Iran-Contra scandal.<sup>38</sup>

The disparity between the beliefs of Muslims in the UK and the wider UK population was highlighted by some research<sup>39</sup> which suggest that intuitive assessments made by an American psychiatrist, of the prevalence of beliefs such as held by Moussaoui – being, as he is, a French Muslim of Algerian extraction and thus closer to fellow Europeans than to Americans – are singularly unlikely to accord with the actual prevalence of such beliefs.

The conclusion that I wish to draw from the above discussion is that psychiatric assessments of the improbability, or of the pervasiveness, of beliefs should be treated with considerable scepticism unless they can be shown to be grounded in reliable statistical data.

#### F-3: Base Rate errors in general medical diagnosis

Before discussing base rate errors it is crucially important that the following two statements be distinguished:

- the probability that A is true, given that B is the case;<sup>40</sup> and
- the probability that B is true, given that A is the case.<sup>41</sup>

For example, the probability that a man, who was born in Ireland (B), speaks English (A) is radically different from the probability that a man who speaks English (A), was born in Ireland (B).<sup>42</sup>

The main source of errors occurring in medical and psychiatric probability assessments<sup>43</sup> is occasioned by the ignoring of relevant base rates.<sup>44</sup> In the present

Patterson does not elucidate in his report how he determined other persons of Mr. Moussaoui's subculture would act or believe as Mr. Moussaoui does in Mr. Moussaoui's situation."

<sup>[</sup>See USA v Zacarias Moussaoui, Reply To Government's Position On Competency].

 <sup>&</sup>lt;sup>38</sup> Barakat, M. (2006). 'Testimony Concludes in Moussaoui Trial'. *The Washington Post.* 21 April.
 <sup>39</sup> A survey of the attitudes of Muslims living in Britain found, for example, that:

<sup>-</sup> half of Muslims aged 18-24 (51%) feel that 9/11 was a conspiracy, this proportion drops to 43% amongst those aged 25-44 and 45+

<sup>-</sup> to the question "*Do you believe that Diana was killed to stop her marrying a Muslim?*" More responded 'Yes' (36%) than responded 'No' (31%).

Channel 4 (2006).

 $<sup>^{40}</sup>$  P(A | B).

<sup>&</sup>lt;sup>41</sup> P(B | A).

<sup>&</sup>lt;sup>42</sup> The error committed by Fulford (2006) *supra* and others lies in not distinguishing between the probability that a jealous man is dangerous (*e.g.* might commit murder) and the radically different problem of calculating the probability that a murderer exhibits jealousy. See *infra* and Chapters 3 and 6. <sup>43</sup> With the possible exception of those based on intuition.

context the error is best described by means of an example drawn from clinical medicine: Eddy's (1982) classic study of the misinterpretation of probability assessments in relation to mammography.<sup>45</sup>

The problem posed by Eddy (1982) was:

The prevalence of breast cancer in a specified population is 1%. The probability that the result of mammography is positive if a woman has breast cancer is 79% and 9.6% if she does not. What is the probability that a woman with a positive result actually has breast cancer?

Eddy reports that, of 100 clinicians, 95 estimated the probability to be c.75%. The correct probability is  $c.\ 8\%$  – a tenfold error.<sup>46</sup>

The solution is most easily understood by translating the probabilities into a 'frequency analysis' based on a hypothetical population of 1,000.

- *"the prevalence of breast cancer in a specified population is 1%"* implies that 10 have cancer and 990 do not.
- "probability that the result of mammography is positive if a woman has breast cancer is 79%" implies that of the 10 that have cancer, 8 (0.79 x 10 rounded to the nearest unit) will test positive and, hence, 2 negative.
- *"probability that the result of mammography is positive if a woman does not have breast cancer is 9.6%"* implies that of the 990 that do not have cancer, 95 (0.96 x 990 rounded to the nearest unit) will test positive and, hence, 895 negative.

The above data can be portrayed in tabular form:

	(A): Women with cancer	(B): Women with no cancer	Total
I): Women with positive test	8	95	103
II): Women with negative test	2	895	897
<i>Total</i>	10	990	1000
	10 neer compared to mammoar	,,,,	

Table F-1: Presence of cancer compared to mammography results.

Based on an examination of the tabular data, a positive test [Row (I)] implies that the subject has an 8 in 103 chance of actually having cancer; in contrast, if the woman actually has cancer [Column (A)], then she has an 8 out of 10 chance of testing positive. Eddy cites many medical textbooks and journals which confuse these probabilities; Sutherland cites<sup>47</sup> a US study which found that 95% of doctors also confuse these figures. Ayton (1995) reports that most of the staff at Harvard Medical School give incorrect answers when presented with the problem; a study by Hoffrage & Gigerenzer (1998) found that only 10% of a group of German physicians were able to determine the

<sup>&</sup>lt;sup>44</sup> The 'base rate' being the rate of occurrence in the main population, of the phenomenon under examination.

<sup>&</sup>lt;sup>45</sup> The use of X-rays to detect breast cancer.

<sup>&</sup>lt;sup>46</sup> Ayton (1995) reports preventive mastectomies being performed on the basis of such errors.

<sup>&</sup>lt;sup>47</sup> Sutherland (1992), p.173.

positive predictive value of four diagnostic tests when given the appropriate probabilistic information.

The '*Prosecutor's Fallacy*' (mentioned by the Royal Statistical Society statement on the Clark case) is also attributable to a base-rate error.<sup>48</sup>

## *F-4: Base Rate errors in psychiatry*

Some theoretical aspects of these errors are first discussed [F-4(i)]; the magnitude of some of the errors involved are then examined [F-4(ii)] and, lastly, the contention that the inability to apply base rate analysis can be diagnostic of psychiatric illness, is discussed. [F-4(iii)]

#### F-4(i): Theoretical aspects

Base rate errors are both prevalent and generally unacknowledged in academic discussions of psychiatric risk assessment (*i.e.* assessments of dangerousness, or propensity to commit acts of violence); such assessments will be discussed in Chapter 6 and (from a more theoretical perspective) in this section.

In assessing the ability of tests to predict future violence, one is faced with the problem *'given a positive test, what is the probability that the subject will behave violently?'* Quite a different problem is involved when one gives the test to

those who have behaved violently, and determines the proportion who have a positive test (*given that a subject behaved violently, what is the probability that he has a positive test*). Ignoring the distinction between these two problems constitutes the base rate error.<sup>49</sup>

As an example from academic psychiatry, consider a research paper<sup>50</sup> entitled '*Forensic importance of jealousy*' where the authors examined 200 cases of individuals who had been convicted of murder in which jealousy played a role and attempted to draw conclusions "which will help in everyday work in forensic psychiatry in the field of

<sup>&</sup>lt;sup>48</sup> Assume that a sample of DNA found at the scene of the crime matches that of the accused; assume also that (given the accused is innocent) there is a 1-in-a-million chance of a match. The fallacy arises when a prosecutor argues that this means that there is only a 1-in-a-million chance the accused is innocent. In fact if the total population consists of 10 million then there are 10 possible matches in the whole country and thus - in the absence of other evidence – there is a 90% chance the accused is innocent. This error is essentially the same as that made by the physicians in relation to their misinterpretation of mammography results:

The physicians confused 'the probability of cancer (given a positive test)' with 'the probability of a positive test (given cancer)';

The prosecutor confuses 'the probability of guilt (given a positive test)' with 'the probability of a positive test (given guilt)'.

<sup>&</sup>lt;sup>49</sup> More accurately, the error is due to a confusion of two conditional probabilities P(A | B) and P(B | A). <sup>50</sup> Muzinić (2003).

*expertise and in the field of forensic psychiatric treatment*".<sup>51</sup> The authors do not advert to base rates nor to Bayesian analysis and fail to differentiate between '*the probability that an individual who is jealous will commit murder*' (the question which is of crucial significance to the clinician who wishes to assess dangerousness) and '*the probability that an individual who has committed murder, was jealous*'.

Ignoring such distinctions could have extremely serious consequences for the liberty of many individuals especially in that some eminent academic psychiatrists [*e.g.* Maden *infra*] display an almost contemptuous disdain for the subtlety of reasoning required when these issues are being discussed [*e.g.* Szmukler *infra*].

Maden, who is Professor of Forensic Psychiatry at Imperial College, London, has noted that "*Doctors have little experience of working explicitly with probability and they are not very good at it.*" <sup>52</sup> McManus, who is Professor of Psychology and Medical Education at University College, London, expresses feelings similar to Maden's:

It's not easy. I'm a doctor, I teach multivariate statistics, I set questions such as this for postgraduate exams; but even though I can work it out, I still have no intuitive sense of what the correct answer is. I'm not the only one. Gigerenzer gave questions such as this to experienced clinicians who deal with these matters all the time and they had no idea either. He could see the sweat on their brows as they tried to beat these few simple numbers into shape and knew that they were failing. Eventually, most of the doctors told him that there was about a 90 per cent probability that a woman with a positive mammogram had breast cancer. That answer is very wrong. The correct answer is actually about 10 per cent.<sup>53</sup>

There, however, the similarity ends. Whilst McManus (and Gigerenzer) are deeply conscious of the importance of a correct understanding of probability to medical decision making, they make serious and sustained efforts to correct the misunderstanding of fellow medical practitioners; in contrast, the response by some eminent psychiatrists to closely argued, understated criticism of psychiatric misunderstanding of probability, is to attack the messenger rather than heed the message; Maden (2001), for example, chides Szmukler for pointing out the misunderstanding of probability inherent in Dolan & Doyle's (2000) analysis. Maden (2001) begins:

I was disappointed by Szmukler's (2001) negative response to Dolan & Doyle's (2000) excellent review of attempts to measure the risk of violence in psychiatric patients. His pessimism about the practical application of structured risk assessment results from a misunderstanding of the way in which these instruments may be used. First, he emphasises the low baseline. Of course, we do not know

<sup>&</sup>lt;sup>51</sup> Ibid.

<sup>&</sup>lt;sup>52</sup> Maden (2003a).

<sup>&</sup>lt;sup>53</sup> McManus (2002).

the baseline, as the information has never been collected accurately in this country.

And concludes:

Psychiatry must not persist in assuming that violence, an uncommon complication of mental disorder, is unimportant because of its rarity. *Reforming the Mental Health Act* (Department of Health, 2001) illustrates that concern about violence dominates the thinking of politicians in this area. It is unlikely that they are going to lose votes by overstating the level of risk associated with psychiatric patients, so the profession is going to have to come up with something better than bland reassurance.

Maden's response, in that it appears to be more mindful of the concerns of politicians than of fellow academics and, coming as it does from one who occupies a prestigious teaching post and is thus in a position to influence the education of psychiatrists, bodes ill for the practice of psychiatry as an intellectually rigorous – let alone 'scientific' – discipline.

Seeking to determine whether Maden's eschewal of rigor in relation to the use of probability is unusual, I consulted two textbooks on the philosophy of psychiatry;<sup>54</sup> the indices of neither made reference to any probabilistic considerations. Whilst it is understandable that such texts would not include a thorough discussion of probability (this being, rightly, the province of texts on Statistics), it might have been expected – because the use of probability assessments in psychiatric practice, is so common and the fact that their misuse can have such serious consequences – that some of the pitfalls associated with the making of such assessments, would be discussed. Jaspers held that delusion is the "*basic characteristic of madness*"<sup>55</sup> and assessments of probability are intrinsic to the definition of delusion.<sup>56</sup> Hence it is necessary that the prevalence of beliefs – of a type which commonly feature in psychiatric diagnosis – be rigorously established. As has been shown in Chapter 3, the survey results which showed a high prevalence, within the normal population, of paranoid beliefs and of 'hearing voices', came as a complete surprise to psychiatrists practising in these areas; yet such accurate estimates are the *sine qua non* of probabilistic assessments. In their

absence, common sense 'hunches' rather than science becomes the basis for diagnosis.

This also appears to be the standard in relation to assessments of dangerousness:

In clinical practice, assessments of the risk of dangerousness or violence in an individual are usually based solely on clinical judgment. The unstructured clinical

<sup>&</sup>lt;sup>54</sup> Radden (2004); Fulford (2006).

<sup>&</sup>lt;sup>55</sup> Jaspers (1997), p.93.

<sup>&</sup>lt;sup>56</sup> See, for example, Sedler (1995) *supra*.

judgment approach to risk assessment has been criticised on a number of grounds, including low interrater reliability, low validity, ...<sup>57</sup>

In that a psychiatric diagnosis and incorrect assessment of dangerousness may lead to the loss of liberty, 'common sense' – irrespective of the guise under which it shelters – is surely an inappropriate standard.

## F-4(ii): Magnitude of the errors involved

Dolan & Doyle's (2000) article had as its aims "*To review the current status of violence risk prediction research*"; in analysing this article, Szmukler (2001a) commented:

... they present only one half of the story. How well do the best instruments perform in the real clinical world where prediction leads to action, including restrictions on the liberty of patients regarded as dangerous? False positives are very serious from an ethical (including resource allocation) point of view. Here we encounter the 'base rate' problem that the authors inexplicably fail to mention. The rate at which violent acts occur in the population of interest is critical to the predictive abilities of any instrument.

Szmukler – who is Dean of the Institute of Psychiatry at King's College, London – is

being unduly kind; as will be seen from the following tables, Dolan & Doyle's (2000)

analysis is akin to describing an iceberg simply in terms of its tip whilst completely

ignoring the much larger, but hidden, problem underneath.

Szmukler examines the problem in terms of three possible base rates (*i.e.* the rates at which violence occurs in the general population): 20%, 6% and 1% concerning which he says:

Perhaps a base rate of 20% is appropriate to some forensic populations. In a community mental health service, even an inner-city one, the rate of violent acts, of any severity, over a 6-month period is more likely to be around 6%...., the prediction will be wrong almost nine times out of ten. For very serious violence, perhaps at a rate of 1%, the test will be wrong about 97 times out of a 100. For homicides, at around 1 in 10,000 per annum committed by patients with a psychosis, prediction is meaningless.

The following tables are constructed from the data given by Szmukler.<sup>58</sup>

Base rate 20%	(A): Violent	(B): Non-violent	Total
(I): Test Positive	140	240	380
(II): Test Negative	60	560	620
Total	200	800	1000
Table F-2: Predicting Violence with a base rate of 20%.			

Base rate 6%	(A): Violent	(B): Non-violent	Total
(I): Test Positive	42	282	324
(II): Test Negative	18	658	676
Total	60	940	1000

Table F-3: Predicting Violence with a base rate of 6%.

<sup>&</sup>lt;sup>57</sup> Dolan & Doyle (2000), p.304.

<sup>&</sup>lt;sup>58</sup> To facilitate comparison, the tables are in the same format as Table F-1 (*supra*).

Base rate 1%	(A): Violent	(B): Non-violent	Total
(I): Test Positive	7	297	304
(II): Test Negative	3	693	696
Total	10	990	1000

Table F-4: Predicting Violence with a base rate of 1%.

Dolan & Doyle's (2000) contention was that the tests were "*better than chance*" at picking out the violent from the total group of violent (*i.e.* their analysis focuses on column 'A' in each table). Szmukler's analysis examines row 'I' of each table and seeks to pick out the 'innocent' from all those who tested positive; the respective rates are 63% (240/280), 87% (282/324) and 98% (297/304); this last figure, for example, means that at a base rate of 1% [*i.e.* in the general population, 1 in every 100 is violent] whereas Dolan & Doyle believed that they were correctly identifying 7 out of every 10 violent individuals; they were actually correctly choosing 7 violent out of 304 as and wrongly identifying 297 'non-violent', as 'violent'.

Dolan & Doyle have not responded to Szmukler's criticism, and his analysis, though commented on, has not been challenged; indeed an editorial<sup>59</sup> in *Psychiatric Bulletin* written by Maden in response to criticisms such as Szmukler's, is dismissive and disingenuously asks "*Why all the fuss*?":

I have been surprised by the strength of feeling expressed by some opponents of standardised risk assessment. On the face of it, such opposition is a bizarre response to what amounts to nothing more than a special investigation. It is hard to imagine taking to the barricades in opposition to the Beck Depression Inventory, liver function tests or neuroimaging ... The best analogy is with intelligence quotient (IQ) testing. It is moderately useful to know that one's patient is a bit slow in copying a geometric design, but the true power of IQ tests lies in ranking his or her performance alongside that of his or her peers. The same is true of risk.

... The terminology of signal detection theory has been misused to argue that a 10% risk involves detaining nine false positives for every true one, resulting in the test having no value. But these instruments do not claim to identify offenders in advance, only to make statements of probability.

In that the tests have clearly high prejudicial value and little probative value the question surely is *"Why use them?"* unless the goal of the exercise is to hide prejudice under the mask of a spurious scientific respectability.

Whilst Maden might hold a certain scepticism towards IQ tests and tests of dangerousness, it is by no means clear that others who might have access to the results of such tests, will do so. Maden seems to show scant regard for the consequences of wrongfully labelling an individual as 'dangerous'. One wonders whether he would be equally sanguine if, say, some mandatory test was introduced for some rare but serious

<sup>&</sup>lt;sup>59</sup> Maden (2003a).

infectious disease: a test which might be hailed as picking up most of those who actually had the infectious disease but which (unfortunately) labelled over 90% of those tested as being infectious, when they were not.

Maden's argument also displays a certain artfulness:

Psychiatry has a bad record of detaining patients in excessive security. All those patients who are held inappropriately in high-security were put there by doctors exercising unfettered clinical judgement. Such patients deserve a proper, standardised assessment of risk. ... Similarly, forensic psychiatry has to take seriously the statistical over-representation of patients from ethnic minorities in all locked settings and the over-representation of women in high-security. Most of these patients were locked up by White male doctors and any objective evidence of risk should therefore be welcomed.

One can only urge that Maden take his own admonition ["Such patients deserve a

*proper, standardised assessment of risk*"] more seriously. Replacing a patently defective system of risk assessment with one which – unjustifiably – dons the cloak of scientific rigour, can hardly be termed an advance.

I wish to draw the following conclusion from the above discussion:

In that some eminent academic psychiatrists in discussing psychiatric risk assessment, appear to be unaware of the necessity to incorporate base rate calculations into their analysis and consequently are either unaware of, or dismissive of, the high possibility of many standard techniques of risk assessment generating false positives, their assessment of the level of dangerousness posed by any individual subject should not be assumed to be reliable.

## F-4(iii): Use as a diagnostic tool

In view of the seemingly widespread inability of medical and psychiatric professionals to correctly interpret estimates of probability or to apply Bayesian analysis, it is ironic to see the inability to apply probabilistic reasoning and '*deviations from optimal Bayesian inference*' being canvassed as possible diagnostic criteria for mental illness:

- Hemsley & Garety (1986) argue that their proposal "... makes it possible to classify delusional beliefs in terms of deviations from optimal Bayesian inference".
- Moritz (2006) reported that their research "... provide further evidence for the claim that schizophrenia patients make strong judgments based on little information."
- Davies & Coltheart (2000) summarise some recent research:

It is no part of Bentall's position that deluded subjects suffer from a gross and pervasive deficit in logical reasoning. But, he does draw attention to a body of experimental work that indicates that deluded patients perform differently, from normal subjects on probabilistic reasoning tasks. The basic finding from this research is that deluded subjects seek less information than normal controls do before reaching a judgement. In short, deluded subjects show a tendency to jump to conclusions. ... On the other hand, it may seem that this bias in probabilistic reasoning cannot be enough, by itself, to explain delusional beliefs. The performance deluded subjects is, on average closer to the Bayesian norms than the performance of normal subjects, who tend to be overly cautious.<sup>60</sup>

That deluded subjects perform better than do the (statistically) normal subjects in some areas echoes a finding by Mele<sup>61</sup> which he calls *'depressive realism'* and which is to the effect that depressed people tend to be significantly more accurate about their positive and negative attributes than do the (statistically) normal. One conclusion that might tentatively be drawn from both of these results is that (statistical) normalcy and pathology are not complementary concepts and that (statistical) normalcy should be clearly distinguished from normalcy (understood as an ideal).

<sup>&</sup>lt;sup>60</sup> Davies & Coltheart (2000) p.13.

<sup>&</sup>lt;sup>61</sup> Mele (2004).

## Appendix G: The Juklerød case

In the early 1970s, Arnold Juklerød was compulsorily detained in a Norwegian psychiatric hospital and forcibly medicated. His case became a *cause célèbre* and was the subject of intense media interest for the nearly thirty years for which it lay unresolved.

The case is exceptionally well documented: it has been discussed in the Norwegian parliament (where the central facts of the case were set forth) and in academic journals.<sup>1</sup> It has also been the focus of art exhibitions and films in which the psychiatrists have detailed the facts upon which they based their clinical decisions.

A factual outline is given in <u>Subsection G-1</u>. Juklerød's diagnosis and committal is examined in <u>Subsection G-2</u>. The diagnostic category '*paranoia querulans*' is discussed in <u>Subsection G-3</u>. Some observations are made in <u>Subsection G-4</u>.

## G-1: The Juklerød case: The factual background

[*The following account is drawn from a statements made in the Norwegian parliament,*<sup>2</sup> *transcripts of contemporaneous interviews with various lawyers, academics and psychiatrists, as shown in the Sandøy films*<sup>3</sup> *and a newspaper editorial.*<sup>4</sup>]

In 1968, as part of a wider programme of school amalgamation, the Norwegian

Department of Education decided to close a school at  $Holtane^5$  – a school to which a local man, Arnold Juklerød, had intended to send his daughter. Juklerød was elected by the local community to head their campaign against the decision. He maintained that the school closure was in breach of the law.

Following a family dispute<sup>6</sup> he was referred to Gaustad mental hospital<sup>7</sup> for examination where it was his manner of conducting the school protest – rather than any family dispute – that attracted psychiatric attention. He was forcibly committed, medicated, and diagnosed as suffering from *'kverulantparanoia'*.<sup>8</sup>

<sup>&</sup>lt;sup>1</sup> I have not been able to find any references to the case in the psychiatric literature.

<sup>&</sup>lt;sup>2</sup> Stortinget (1995).

<sup>&</sup>lt;sup>3</sup> Sandøy (1997), Sandøy (2001), both films have English subtitles.

<sup>&</sup>lt;sup>4</sup> Dag og Tid (1996). 'Redaksjonelt: Juklerød og Stortinget', Dag og Tid. 30 May. [online], available:

http://www.dagogtid.no/arkiv/1996/22/leiar.html [accessed: 11 July 2007 ]. Translated by Mette Roche. <sup>5</sup> A small costal town 150 km. south of Oslo.

 $<sup>^{6}</sup>_{-}$  Of no subsequent relevance.

<sup>&</sup>lt;sup>7</sup> Now part of Oslo University Hospital.

<sup>&</sup>lt;sup>8</sup> *I.e. paranoia querulans* also known as '*Litigious Delusions*' or '*Litigious Paranoia*'. See Munro (1999), p.130.

As described in the parliamentary submission:

This '*kverulantparanoia*' consisted in Juklerød having delusions, which he would not be dissuaded from, regarding the formal breach of the law he argued ... authorities had committed by closing Holtrane school.<sup>9</sup>

Juklerød was released after three months but continued to dispute his diagnosis and, to that end, maintained a protest outside the hospital which resulted in his re-committal for a further 11 years, during which time he was periodically held in isolation.<sup>10</sup> In a petition to Norwegian parliament, his predicament was identified: "*If a person protests against this diagnosis it strengthens it. But if he doesn't protest, he accepts that he is ill.*"<sup>11</sup> He was discharged in 1985<sup>12</sup> but renewed his protest and refused to leave the hospital. On being evicted he took up 'residence' first in an alcove outside the hospital, and later in a tent where he stayed for most of the next ten years.<sup>13</sup> Three months before his death<sup>14</sup> the Department of Education wrote to him acknowledging that their school closure policy had lacked proper legal authority. Juklerød decided to comment on the government apology.<sup>15</sup>

## G-2: Juklerød's diagnosis

Juklerød's diagnosis is examined from the perspective of his psychiatrists [G-2(i)]; external reviews [G-2(ii)] and some non-psychiatric academics [G-2(iii)].

## G-2(i): Juklerød's diagnosis: his psychiatrists

Three of Juklerød's psychiatrists were interviewed:<sup>16</sup> Nils Retterstøl,<sup>17</sup> Bård Brekke<sup>18</sup> and Ådel Grimsgaard.

Juklerød had described his diagnosis as being a stain on his character; Retterstøl

addressed himself to this issue:

We hold that getting mentally ill is not shameful. It can happen to the best, when problems come up that can't be managed. That is not shameful. Nor is it a shame

<sup>&</sup>lt;sup>9</sup> Stortinget (1995). Translated by Mette Roche.

<sup>&</sup>lt;sup>10</sup> One such period lasted 393 days.

<sup>&</sup>lt;sup>11</sup> Sandøy (2001).

*Cf.* a convict who protests his innocence and, on being offered parole on condition that he acknowledges his guilt, refuses to withdraw his protest.

<sup>&</sup>lt;sup>12</sup> Stortinget (1995): "... following an 'ad-hoc meeting' of lawyers ... only two months after he, according to the medical records, was characterised as "strongly in need of treatment"."

<sup>&</sup>lt;sup>13</sup> In winter temperatures as low as -13° C.

<sup>&</sup>lt;sup>14</sup> In 1996, aged 71.

<sup>&</sup>lt;sup>15</sup> Sandøy (2001).

<sup>&</sup>lt;sup>16</sup> All quotations in this subsection were transcribed from Sandøy (2001).

<sup>&</sup>lt;sup>17</sup> Director of Gaustad Hospital.

<sup>&</sup>lt;sup>18</sup> Chief Psychiatrist at Gaustad Hospital.

to have gone through it. This case gives the impression that this person has been stained. A stain on his reputation. This attitude is completely strange to us.

On being asked as to the nature of Juklerød's illness, Brekke stated:

He got a very detailed answer in court. It centres on his ideas relating to the school case. He thought that a number of ministers and civil servants conspired against him. They were trying to get rid of him to avoid publicity which would lead to impeachment and a colossal scandal. This was his basic delusion.

Retterstøl was more specific:

Well his diagnosis is "*paranoid psychosis*", a mental disease with delusions of a type called "*paranoia querulans*". A querulous and delusional disorder. ... No doubt about it, he had a cause which we can agree with. But what is important is lack of adaption. Everyone experiences injustice. Everyone is at times unreasonably and unjustly treated. Then we get sad and feel down, but life goes on.

To the interviewer's comment that Juklerød: "... seems so sound and in good health

when talking but is very critical about the psychiatric establishment." Retterstøl

replied: "Not just that. ... His aggression is directed against the superior authorities.

Psychiatry is just a part of it."

Asked as to why they would not revoke their diagnosis, Retterstøl commented:

No, then we would have to write a false declaration. That's like asking doctors at a cancer hospital to certify that the patient has never had cancer. That would be false.<sup>19</sup>

#### G-2(ii): Juklerød's diagnosis: external reviews

Juklerød had attempted to mount a legal challenge but, in the words of his lawyer:

... the judges put too much trust in the psychiatrists. When they declared Arnold had delusions the judges assumed that he had. Had the Ministry issued its admission prior to the trials the court's judgement would probably have been different. This shows that psychiatrists have too much power.<sup>20</sup>

Subsequent to his being evicted from hospital, the courts had requested a further

assessment:

This report concluded that at the time of committal in 1971 and 1974 "*it was not possible to confirm the basic symptoms of serious mental illness*". The Medical-Judicial Council, chaired by Gaustad's Chief Consultant Nils Retterstøl dissented from this report. A new commission was appointed. It included two of the three

<sup>&</sup>lt;sup>19</sup> A theme upon which Grimsgaard elaborated [Sandøy (1997)]:

As has been said several times there is no doubt about the diagnosis. It is quite typical. To use a comparison easier to understand you may compare it with a patient ill with cancer. A person with an advanced stomach cancer is being operated. He stipulates that he won't leave the hospital until he gets a declaration that he never had cancer. It's obvious that the doctors can't give him that. To us it is just as evident. We cannot give Juklerød a declaration about not having the diagnosis he has got.

<sup>&</sup>lt;sup>20</sup> Sandøy (2001).

psychiatrists from the first commission. The new report concluded .. that Arnold Juklerød suffered from a '*symptom-free mental illness*'.<sup>21</sup>

After Juklerød's death, a member of parliament proposed an official investigation,

however:

... the Judicial Committee concluded that"... even though the Juklerød case was special, the Committee is of the opinion that it would not be natural to suggest an extraordinary procedure such as the appointment of an investigative commission would be."<sup>22</sup>

## G-2(iii): Juklerød's diagnosis: academic critiques

Per Fugelli (Professor of Social Medicine at the University of Oslo):

Medicine is like an isolation ward in our democracy. It's practised behind closed doors. ... The doctors can also hide behind professional secrecy. There are weak traditions of democracy for the patients. Their influence is small. The medical doctor is the absolute expert. ... You may ask a medical doctor to make a diagnosis concerning a liver disease identified by a blood test. Concerning mental diagnosis, however, the boundaries towards social rebellion and political deviation become a grey zone ... <sup>23</sup>

Georg Høyer (Professor of Social Medicine at the University of Tromsø):

A forcible commitment is a major encroachment in a person's life. ... In Norway psychiatry confines more people than any other institution. The intentions of the psychiatrists might be good; the argument again is that they act for the patient's benefit, that they know better than the patients what are good for them. The problem is that there is no evidence supporting this.<sup>24</sup>

## G-3: The psychiatric diagnosis 'Paranoia Querulans'.

Though 'Paranoia Querulans' is not explicitly mentioned in the DSM-IV-TR (2000), it

is listed in the ICD-10 (2006) although its diagnostic criteria are rudimentary.<sup>25</sup>

Sullivan (1956) gives a case history:

He was litigious and he had, by means of lawsuits, made it extremely awkward for number of people, including at least one very high government official. Counsel for the people against whom he had brought actions were not at all inclined to minimize the skill with which he could build up very impressive claims on the basis of what a psychiatrist could regard only as paranoid formulations, but which a jury might easily regard as an instance of an extraordinarily capable person's

<sup>&</sup>lt;sup>21</sup> Stortinget (1995).

<sup>&</sup>lt;sup>22</sup> Editorial in *Dag og Tid* (1996); it continued:

And their reasoning is probably even more astonishing: "The committee points to [the fact] that there exists a large number of people in Norway who feel they have been badly treated by official bodies and it would be unsafe if the Parliament was to establish a practice whereby some of these cases would be followed up in the form of investigating commissions."

<sup>&</sup>lt;sup>23</sup> Sandøy (1997).

<sup>&</sup>lt;sup>24</sup> Sandøy (2001).

<sup>&</sup>lt;sup>25</sup> WHO (2006) p.97; F22.8 'Other persistent delusional disorders'; it states:

<sup>...</sup> The delusions are highly variable in content. Often they are persecutory, hypochondriacal, or grandiose, but they may be concerned with litigation or jealousy, or express a conviction that the individual's body is misshapen, or that others think that he or she smells or is homosexual. ...

seeing how he was being gypped by corporations, government officials, and various people.<sup>26</sup>

Munro (1999) describes the typical case:

What we are discussing here are people who have a profound and persistent sense of having been wronged and who ceaselessly and endlessly seek redress, ... Doubtless some of these individuals have suffered real grievances and have a strong sense of injustice which they are entitled to express, but it is inescapable that there are elements of psychiatric illness in at least a proportion of them ... Many patients with delusional disorder exhibit a peevish, complaintive quality but in querulous paranoia this is their most prominent feature, ... <sup>27</sup>

He cites a classification made by Goldstein (1987) ["who has had much forensic

psychiatric experience"]:

- '*the hypercompetent defendant*' (who knows the absolute letter of the law but nothing of the spirit);

- the '*paranoid party in a divorce proceedings*', who is often consumed ... a sense of having been wronged ...; and

- 'the paranoid complaining witness' who incessantly pursues grievances.

In each case, it may take a ling time to recognise that such individuals are ill, unless an experienced psychiatrist becomes involved.<sup>28</sup>

It is abundantly clear from the above descriptions that the diagnosis *'paranoia querulans'* is so ill defined as to be open to abuse.<sup>29</sup>

## G-4: The Juklerød Case: Some observations.

I wish to comment on the Juklerød case under the following headings: diagnosis [<u>*G*-4(*ii*)</u>]; misdiagnosis [<u>*G*-4(*ii*)</u>]; stigma [<u>*G*-4(*iii*)</u>]; the experience of psychotropic medication [<u>*G*-*IV*(*iv*)</u>] and, lastly, the choice of default presumptions concerning coercive psychiatric intervention [<u>*G*-4(*v*)</u>].

## G-4(i): Juklerød's diagnosis

To establish that Juklerød was delusional<sup>30</sup> it is necessary for the psychiatrists to establish , *inter alia*, the falsity<sup>31</sup> of Juklerød's belief that the school closure policy was not sanctioned by law and that those in authority wished, for whatever reason, to conceal this fact.

<sup>&</sup>lt;sup>26</sup> Sullivan (1956), p.306.

<sup>&</sup>lt;sup>27</sup> Munro (1999), p.132.

<sup>&</sup>lt;sup>28</sup> *Ibid.* p.133.

<sup>&</sup>lt;sup>29</sup> A conclusion with which Munro (1999) agrees:

There is also a realistic concern that over-ready willingness to diagnose paranoia in an excessively litigious person might lead to abuse of psychiatry, such as occurred in Russia in the past. (p.135).

<sup>&</sup>lt;sup>30</sup> As claimed by psychiatrist Brekke (*supra*).

<sup>&</sup>lt;sup>31</sup> *DSM-IV-TR* (2000); alternatively - if the 'falsity criterion' be replaced by the 'justifiability criterion' - to establish that Juklerød could not justify his belief. [See Chapter 3].

A disinterested observer might well ask as to what conceivable information might have been in the possession of the psychiatrists that would have been of such overwhelming force as to dispel any doubt that the schools were being closed contrary to law. Such behaviour is not unknown and – even in a democracy such as Norway – a belief that it might occur could hardly be judged, on *prima facie* grounds, to be manifestly false especially as the psychiatrists had no particular expertise in assessing the validity of legal claims. Indeed, as subsequent events demonstrated,<sup>32</sup> the belief was true.

However it seems that the acknowledgement of the truth of the claim of one diagnosed as having '*paranoia querulans*' does not dispose of the matter<sup>33</sup> in that the wrong at the heart of the litigious paranoiac complaint need not be imaginary but may well be valid. This suggests that Juklerød's diagnosis rested not so much on his belief but on the manner of asserting his belief;<sup>34</sup> not so much in a blind refusal to accept objective information but in a refusal to accept superior authority.<sup>35</sup>

The suggestion that Juklerød suffered from a "*symptom-free psychiatric illness*" raises considerable theoretical problems. Whereas it may be meaningful to speak of a 'symptom-free physical illness' (*i.e.* an illness such as cancer that, as yet, presents no symptoms perceivable to the subject) such an illness does present symptoms observable to the specialist (*i.e.* physical markers exist which are detectable by objective physical tests), to speak of 'symptom-free psychiatric illness' is something of an oxymoron<sup>36</sup> in that a psychiatric illness is defined *only* in terms of symptoms.<sup>37</sup>

The concept of 'symptom-free psychiatric illness' enables psychiatric diagnosis to become a self-authenticating procedure which clearly invalidates any possible claim to scientific status – how could one conceivably set about falsifying such a diagnosis?<sup>38</sup> In Juklerød's case the term was used in the context of an external review and appears designed – much as the '*Emperor's New Clothes*' – to hide that which is clear to a disinterested observer.

<sup>&</sup>lt;sup>32</sup> The subsequent apology from the Department of Education (*supra*).

<sup>&</sup>lt;sup>33</sup> Munro (1999) (supra): "Doubtless some of these individuals have suffered real grievances and have a strong sense of injustice which they are entitled to express ..."

<sup>&</sup>lt;sup>34</sup> See Retterstøl (*supra*): "*His aggression is directed against the superior authorities. Psychiatry is just a part of it.*"

<sup>&</sup>lt;sup>35</sup> See Per Fugelli (*supra*).

<sup>&</sup>lt;sup>36</sup> Though a 'symptom-free' psychiatric illness might be classified as a psychiatric illness 'in remission'; this solution however, is only apparent in that it only pushes the problem one level back: *i.e.* the problem then becomes how to distinguish between a 'psychiatric illness in remission'; a psychiatric illness which has been cured and a psychiatric misdiagnosis.

<sup>&</sup>lt;sup>37</sup> See *infra*.

<sup>&</sup>lt;sup>38</sup> See the discussion in Chapter 3 on the '*fallacy of the missing hippopotamus*' [Drury (1996)].

## G-4(ii): Juklerød's diagnosis – was it a misdiagnosis?

Assuming, for the sake of argument, that Juklerød's original diagnosis was a misdiagnosis, then it would seem that Juklerød's conduct of his campaign to establish this fact (as manifested in its extreme tenaciousness) provided grounds<sup>39</sup> for a further and independent diagnosis of *paranoia querulans*. This is an unsettling conclusion and suggests that the important question is not as might at first sight appear, '*Was Juklerød misdiagnosed?*' but rather '*How would one adjudge that Juklerød was misdiagnosed?*' The unwillingness of Juklerød's psychiatrists to accept even the possibility of misdiagnosis is striking; the comparison of Juklerød's diagnosis to that of a person with an advanced stomach cancer,<sup>40</sup> seeks to shelter the act of making a psychiatric diagnosis under the skirts of science; in that psychiatrists (unlike oncologists) have no access to definitive biological or other scientific tests<sup>41</sup> to validate their diagnostic findings – and *a fortiori* none to definitively diagnose *paranoia querulans* – the suggested comparison is fatuous.

Aside from the absence of definitive tests, the comparison is also misplaced because the factual circumstances which exist at the time of a psychiatric diagnosis cannot be frozen in time (unlike those which gave rise to a diagnosis of cancer where biopsy samples and X-rays may be preserved) and hence they cannot be revisited for the purposes of independent review. Except in the most unusual circumstances (as happened in the Manweiler case<sup>42</sup>) contemporaneous case notes which unequivocally imply that the original diagnosis was erroneous are unlikely to exist. Thus if psychiatrists treating an individual subject come to a consensual diagnosis is, for all practical purposes, impossible. A subsequent psychiatric review of the diagnosis can, at most, determine that *at the time of the review*, the subject does not manifest any symptoms of mental illness; this is what occurred in Juklerød's case.

<sup>&</sup>lt;sup>39</sup> See, for example, Retterstøl (*supra*):

No doubt about it, he had a cause which we can agree with. But what is important is lack of adaption. Everyone experiences injustice. Everyone is at times unreasonably and unjustly treated. Then we get sad and feel down, but life goes on.

<sup>&</sup>lt;sup>40</sup> Supra.

<sup>&</sup>lt;sup>41</sup> As stated in an editorial in the American Journal of Psychiatry [First & Zimmerman (2006) (supra)]: Despite widespread acceptance that most psychiatric disorders are "diseases of the brain", the field of psychiatry has thus far failed to identify a single neurobiological marker that is diagnostic of a mental disorder.

<sup>&</sup>lt;sup>42</sup> See Appendix H.

The topic of psychiatric misdiagnosis is discussed in Chapter 4 where some ambiguities in the term 'psychiatric misdiagnosis' are identified and some distinctions introduced. In the present context, the most important of these, involves distinguishing between:

- *'<u>radical misdiagnosis</u>'*: the misdiagnosis of (psychiatric) pathology sufficient to warrant a coercive intervention, and
- '*technical misdiagnosis*': the misdiagnosis of a specific psychiatric illness [*i.e.* misdiagnosing depression rather than bipolar disorder.]

The specification of the criteria appropriate to the definition of any particular psychiatric diagnostic category are matters that rightly fall to be decided by the psychiatric profession; it is they, for example, who decide that for a condition to be described as 'schizophrenia', certain criteria must be satisfied within a one month period rather than, say, a three month period,<sup>43</sup> but this is only part of the story: the informed public – whilst they may not be competent to adjudge on the specific diagnosis – is the rightful judge of whether the behaviour and beliefs manifested by a subject are so extreme as to warrant a coercive psychiatric intervention. I am suggesting that whilst the psychiatric profession is the rightful judge of technical misdiagnosis, the informed public – and not psychiatrists either individually or collectively – are the ultimate judges of whether an individual has been the subject of a radical psychiatric misdiagnosis.<sup>44</sup>

Lest such a proposal appears extreme, it should be remembered that the power that psychiatrists have to initiate a compulsory detention, is not theirs as of right but is given to them by the legislature in the name of the general citizenship and it is they who should be the final arbiters as to whether the power has been exercised appropriately. It was, after all the power of an informed public that ensured that many of the diagnostic categories of past eras – homosexuality being one such<sup>45</sup> – that had been used by psychiatrists to define mental illness should no longer be regarded as valid; it was the power of public opinion (in the face of psychiatric assurances to the contrary)<sup>46</sup> that ensured the abuse of psychiatry that occurred in the Soviet Union was finally acknowledged.

<sup>&</sup>lt;sup>43</sup> See *DSM-IV-TR* (2000), p.312.

<sup>&</sup>lt;sup>44</sup> Contra see Sullivan (1956) supra.

<sup>&</sup>lt;sup>45</sup> Time (1974).

<sup>&</sup>lt;sup>46</sup> The international psychiatric community had not only been reluctant to criticize their Soviet colleagues but, prior to being pressured to change their view, had been openly admiring of the practice of psychiatry in the USSR [See Chapter 4].

In relation to the Juklerød case, this implies that in order to adjudge that Juklerød was the subject of a radical psychiatric misdiagnosis, it is not necessary to find some psychiatric consensus, nor some legal judgement; the court of an informed public opinion is sufficient and the weight of informed comment appears to be that Juklerød was indeed subjected to a misdiagnosis.

## G-4(iii): Juklerød's forcible committal, was it a cause of stigma?

Retterstøl in stating that: "*This case gives the impression that this person has been stained. A stain on his reputation. This attitude is completely strange to us.*"<sup>47</sup> is conflating a number of issues:

- <u>a moral issue</u>: whether an individual should be blamed (or stigmatised) for becoming mentally ill.
- <u>a personal issue</u>: Retterstøl's personal belief that an individual should not be so blamed or stigmatised.
- <u>a factual issue</u>: whether, in point of fact, people who have been diagnosed as mentally ill are stigmatised.

Juklerød's concern was clearly with the third interpretation and it was this that fuelled his determination that his diagnosis be recognised as a misdiagnosis. The existence of such stigma is not the subject of contention<sup>48</sup> within academic psychiatry but is taken as a given and the focus is on how to minimise such stigma. Retterstøl was the Director of Norway's most prestigious mental hospital, he was widely published and the author of textbooks on psychiatry;<sup>49</sup> his (implied) denial of the existence of such stigma suggests a disingenuousness which ill serves him in relation to the credibility and reliability that should be accorded his testimony on other matters germane to the Juklerød case.

From Juklerød's perspective, the extreme intensity of the stigma to which he believed himself to have been subjected, is eloquently attested to by the persistence with which he pursued his campaign to have his diagnosis revoked.

## G-4(iv): Juklerød's experience of psychotropic medication

Juklerød remembered his first injection of neuroleptic medication:

... a paralysis entered my left side, an enemy that I couldn't fight. Together with the paralysis came a fear and restlessness completely new to me. I couldn't fight it, but made efforts to behave normally. [I had] no way to struggle against this enemy. The paralysis went up my left arm. My fingers stood out like this, unmovable. It went upwards and took my mouth and pulled it up in an awkward

<sup>47</sup> Sandøy (1997).

<sup>&</sup>lt;sup>48</sup> The literature on the stigma of psychiatric illness is extensive and is discussed in Chapter 6.

<sup>&</sup>lt;sup>49</sup> Munro (1999) cites 5 references including a textbook published in the US.

position. I couldn't speak. I could hardly talk. I was terrified and frightened. Eventually I got into the office of the section head. He saw how I had changed. I cried and begged them not to give me more shots. He called the man who had given me the shots but was then told to give me a shot against the side effects.<sup>50</sup>

The side effects of psychotropic medication are discussed in Chapter 5.

#### G-4(v): The Juklerød case and the choice of default presumptions

A distinction can be drawn between '*abuse of psychiatry*' and '*psychiatric abuse*',<sup>51</sup> based on the attitude adopted by the psychiatric profession when the facts underlying such cases become known: if an instance of professional wrongdoing is speedily condemned by the psychiatric profession then it remains an isolated instance of the abuse of psychiatry, however any unwillingness to remedy such abuse transforms the case into one of 'psychiatric abuse'.<sup>52</sup>

The attitude to the Juklerød case, of those outside professional psychiatry clearly classifies it as an abuse of psychiatry; however, the obfuscation and the obstructive attitude shown by the psychiatric profession towards attempts at resolution, suggest a case of 'psychiatric abuse'.

The prominence of the Juklerød case was achieved despite the efforts of the psychiatrists involved and was attributable primarily to the perseverance of the subject of the case, Arnold Juklerød. Without his efforts this case would have vanished into obscurity and the psychiatric misdiagnosis would have been undocumented. Instances of 'psychiatric abuse' – as distinct from 'abuse of psychiatry' – undoubtedly occur in modern Western psychiatry. The extreme difficulty faced by those attempting to highlight such cases render it difficult, if not impossible, to estimate their prevalence. If a strength of character and determination (such as exhibited by Juklerød) is required before incidents of alleged psychiatric abuse can seize the attention of the public then the dearth of detailed reports of psychiatric abuse in Western countries may be more indicative of the rarity of such individuals rather than the rarity of psychiatric abuse.

<sup>&</sup>lt;sup>50</sup> Sandøy (1997).

<sup>&</sup>lt;sup>51</sup> Professor Olofsson of the University of Växjö, Sweden makes a somewhat similar distinction between, what he terms, "*The 'bright side' of the professions*" and "*The 'dark side' of the professions*." He considers the use of lobotomy to be an example of the dark side of psychiatry. [See Olofsson (2007)]. <sup>52</sup> A similar distinction may be made in general medicine: *e.g.* the attempts by the medical profession in Ireland to prevent the facts underlying the Neary case becoming public (*supra*).

## Appendix H: The Manweiler case

The Manweiler case came before the Irish courts in 2005 and concerned the wrongful psychiatric confinement and treatment of a John Manweiler. It resulted in an award of Euro 3 million damages – the highest award of general damages in Irish legal history.<sup>1</sup> An outline of the factual background to the case prior to committal is given in <u>Subsection H-1</u>, and subsequent to committal in <u>Subsection H-2</u>. Some observations are made in <u>Subsection H-3</u>.

[The following account is based on media reports; a re-enactment of the court proceedings and commentaries by psychiatrists Drs. Barry (Clinical Director, Cluain Mhuire), Kennedy (Clinical Director, Central Mental Hospital) and Walsh (former Inspector of Mental Hospitals).]

## H-1: The factual background prior to committal

Manweiler entered St. Brendan's psychiatric hospital as a voluntarily patient in September 1984. He was subsequently certified as an involuntary patient and, in December 1984, he was released as an outpatient. Whilst in hospital his psychiatrist Dr. Burke, had prescribed antipsychotic medication which, on his release, was continued for a further eleven years.

At the time of his hospitalisation Manweiler, then aged 43, and had been living with his 83-year-old mother who suffered from dementia. His relationship with his married sister, Pauline, was poor.<sup>2</sup>

In September 1984 a verbal altercation occurred between Manweiler and his mother

which precipitated his later committal to a mental hospital. According to Manweiler:

I asked her if she had moved the tools and she said no, I got a bit annoyed.  $\dots$  I threw the tools into a flower bed. She was very surprised and said she was afraid, that she would report me to one of the family. I couldn't understand why she would be afraid. I never threatened her, I never threatened anyone.<sup>3</sup>

His mother complained to his sister Pauline who told Manweiler that unless he went voluntarily to a psychiatric hospital, he would be "*committed*"; he reluctantly agreed. His diagnosis, as recorded by the admitting psychiatrist, was: "*Chronic mild depression. Schizoid personality. Short stay only. Then day care.*"<sup>4</sup>

<sup>&</sup>lt;sup>1</sup> See O'Brien, C. (2005a). '€3m psychiatric detention award to be appealed'. *The Irish Times*, 6 June. The damages were subsequently reduced to Euro 500,000 in an out-of-court settlement. See O'Brien, C. (2005b). '€3m psychiatric award cut to €500,000'*The Irish Times*, 24 August.

<sup>&#</sup>x27;General damages' - in contrast to 'special damages' - compensates the claimant for non-monetary harm. <sup>2</sup> He had overheard a conversation between his mother, his sister and a solicitor on the redrawing of a will to make his sister sole beneficiary. See O'Brien, C. (2005c). 'Vindication for a solitary man'. *The Irish Times.* 21 May.

<sup>&</sup>lt;sup>3</sup> Ibid.

<sup>&</sup>lt;sup>4</sup> Ibid.

The Chief Psychiatrist, Dr. Burke, who had been on leave, returned a week later and changed Manweiler's status to 'involuntary'.

## H-2: The factual background subsequent to committal

The following aspects are examined:

- Manweiler's change of status [H-2(i)];
- his diagnosis [<u>*H*-2(*ii*)</u>];
- his medication [<u>*H*-2(*iii*)</u>];
- his experience of antipsychotic medication [H-2(iv)].

## H-2(i): Manweiler's change of status

Manweiler's counsel [John Rogers SC], questioned Burke as to why he changed

Manweiler's status to 'involuntary':

Burke:

He could have walked out giving 72 hours notice ... he was constantly grumbling about being there and was without enthusiasm.<sup>5</sup>

Rogers:

... There was nothing ... to show that he was anything but a very voluntary patient or that he would have left.

## Burke:

There was a serious history of violence that came from the evening before when his mother left the house. ... He was expressing his unwillingness but in his own ambivalent way he wouldn't make any fuss about it ... it was for safety's sake that this had to be done.

Burke was also questioned on the procedure used to change Manweiler's status as, in the circumstances obtaining, it was not legally permissible.

<u>Burke</u>

It was quite usual ... that was the practice and I believe that it still is.

## H-2(ii): Manweiler's diagnosis

Burke had spoken to Manweiler's family about him – but not about any family circumstances that might have precipitated the altercation – and had heard from a nurse colleague of Manweiler's sister as to the distress of Manweiler's mother on the day in question, but he had not spoken to Manweiler who had remained mute in his presence. He had diagnosed Manweiler as schizophrenic.

Rogers:

You decided this man was a schizophrenic just because he was silent?<sup>6</sup>

<sup>&</sup>lt;sup>5</sup> This and all subsequent exchanges between Rodgers and Burke, are transcribed from an archive recording of the Browne (2005b) except where stated otherwise.

<sup>&</sup>lt;sup>6</sup> Browne, V. (2005a). 'False imprisonment: The story of John Manweiler'. *The Village*. 5 May.

#### Burke:

I didn't decide then, I saw it as a possibility.

Rogers:

So what was the mental illness he had [then]?

#### Burke:

It was the same as he has now. He has a simple schizophrenia but it is very difficult to diagnose. ...

#### Rogers:

So you must have diagnosed it even though he didn't speak to you?...

#### Burke:

I admitted him for safety's sake and to investigate and prove he had a schizophrenic illness.

Rogers then asked Burke why, knowing of the existence of family problems, he had not

discussed these with Manweiler's family.

#### Burke:

Well I didn't think it appropriate for me to interfere in a family matter like that. ...

#### Rogers:

Why not?

<u>Burke</u>:

Because it has nothing to do with me and could be devised [*sic*] as being difficult, it is not something that I would do lightly. ... I wouldn't dream of doing that.

Manweiler described his first meeting with Burke:

"Early on in the meeting I was requested to leave the room ... I stood outside in the main entrance hall ... it would be an hour, that length. I remember Dr. Burke came out of the room ...[and] said to me '*You are in deep trouble*'. That's the word he used '*You are in deep trouble and there's a few other items we need to discuss of a delicate nature*'. That's about all he said to me." He said there was no further discussion then with Dr. Burke.

## <u>*H-2(iii)*</u>: Manweiler's medication

Manweiler (who had never been psychotic) had been prescribed the anti-psychotic

Clopixol – a drug which may have severe side effects. Shortly before this, a

psychologist's report on Manweiler - which made no mention of his being mentally ill

- saw poor family communication as being the root of the problem and recommended

the holding a family conference.

#### Burke:

... that was the psychologists view, that was not the cause of John Manweiler's illness, the illness was there anyway.

#### Rogers:

... it appears *Clopixol* is being prescribed in advance of the meeting the psychologist recommended?

Burke:

That was just a test dose...

In further cross-examination:<sup>7</sup>

#### Rogers:

In all the notes ... there is no note by anybody that he suffered from schizophrenia, including yourself?

#### Burke:

That's some oversight rather but that is my opinion, that is his illness.

#### Rogers:

Do you agree with me that a schizoid personality disorder is not treated with antipsychotic drugs?

#### Burke:

Probably not but I had to take into account his history of violence.

To counteract the side effects of the *Clopixol* Manweiler was given *Cojentin*<sup>8</sup> which caused further side effects.<sup>9</sup>

Manweiler was discharged on a "trial" basis in December 1984 and met Burke in early

January 1985. According to Manweiler:

... he said "you are suffering from something called nerves" and that there was no cure. Dr. Burke said he would need an injection called Clipoxil but it was too technical for him to understand the nature of that drug ... Dr. Burke said if he did not attend for the injections he could be detained in Unit 8 which is a lockup ward, and he would be forcibly administered these injections. In his evidence Dr. Burke vigorously denied this exchange occurred.<sup>10</sup>

In 1994, a different psychiatrist stopped Manweiler's antipsychotic medication and a

sympathetic nurse prompted him to make an official complaint about his earlier treatment.<sup>11</sup>

## H-2(iv): Manweiler: the effects of antipsychotic medication

Psychiatrists interviewed in Browne (2005a) were asked about the effect of antipsychotic medication such as *Clopixol*:

#### McKenna:

*Clopixol* is a tranquilising medication that will damp down psychotic thinking or disturbed behaviour consequent upon psychotic thinking ... ... were anybody here to ... take a dose, it would have a sedating effect.

<sup>&</sup>lt;sup>7</sup> Ibid.

<sup>&</sup>lt;sup>8</sup> A drug used in the treatment of Parkinson's disease.

<sup>&</sup>lt;sup>9</sup> Burke at first denied, but later accepted, the existence of such side effects.

<sup>&</sup>lt;sup>10</sup> Browne (2005a).

<sup>&</sup>lt;sup>11</sup> O'Brien (2005c).

[Questioned as to side effect] you were perhaps poorly motivated couldn't, you know, do a lot. Couldn't necessarily, you know, think in a creative way. It would have an overall damping down effect.

 $\ldots$  some of these symptoms would actually mimic chronic forms of schizophrenia  $\ldots$ 

#### Walsh:

... there is probably a group of individual psychiatrists ... who would be of the view that ... the possibility of it eventually moving over into florid, frank, symptomatic schizophrenia was so great that prophylactically – as a preventive measure – such individuals might be given an antipsychotic drug

They were also questioned<sup>12</sup> on its effects on Manweiler's quality of life:

#### Browne:

... when he came off the drug ... suddenly his life became very much better he was able to do things he hadn't been able to do on the ten years he was on the drug. He became interested in his own condition. He read extensively on the disorder that he was said to have had, on the schizophrenia that he was wrongly – that, it appears, wrongly – he was said to have had and on the drugs that were administered to him.

#### Barry:

But I think it is important equally just to say that people who suffer from schizophrenia or from mental illness in general can, you know, be interested in their condition.

#### Browne:

My point ... is that during the years that he was on this drug he was unable to do that. In other words, this drug blighted his life for ten years and when he came off it ... the quality of his life improved significantly.

#### Barry:

... in relation to major tranquilisers like *Clopixol*, if somebody takes the medication that might not have reason to do so then it is more likely to be ... quite profoundly sedated ...

Manweiler described the effects of the drug therapy which was administered by way of

injection every few weeks:

"One of the staff came along the ward and he had got a big medical tray with a large syringe on and he said 'I've got to give you this'. Needless to say I was a bit reluctant, sort of captive in there in my pyjamas and dressing gown along with the rest of them in there, most of the time. You had not much say in the matter. About an hour after the injection was administered I got a feeling of uncontrolled movements in the shoulders and neck area." He was kept on this drug for over 10 years and during that time suffered the side effect of uncontrolled movements, particularly of his legs. He also told the court he frequently felt like a "zombie".<sup>13</sup>

<sup>&</sup>lt;sup>12</sup> Browne (2005b).

<sup>&</sup>lt;sup>13</sup> Browne (2005a).

## H-3: Some observations on the Manweiler case

Observations are made under the following headings:

- the availability of legal redress [*H-3(i)*];
- the compliance by psychiatrists with their legal obligations [H-3(ii)];
- Manweiler's supposed 'dangerousness' [H-3(iii)]; and
- Manweiler's diminished personhood. [H-3(iv)].

## *H-3(i)*: The availability of legal redress

The *Freedom of Information Act* (1997) permitted Manweiler to seek access to his hospital file<sup>14</sup> which contained an explicit diagnosis for which *Clopixol* was not an appropriate treatment. The unequivocal nature of the note provided *prima facia* evidence of inappropriate psychiatric treatment and, presumably,<sup>15</sup> enabled Manweiler to surmount the obstacle placed by S. 260 of the *Mental Treatment Act* (1945).<sup>16</sup>

## H-3(ii): Compliance by psychiatrists with their legal obligations

The legal obligations placed on psychiatrists by mental health legislation, are far from onerous yet scant regard was paid to them:

- the method used by Burke to certify Manweiler as 'involuntary', was unlawful, yet it appears to have been common.
- some eminent psychiatrists defended<sup>17</sup> Burke on the ground that such technicalities interfered with psychiatrists acting in the best interests of their patients.<sup>18</sup>

A related legal matter concerns a patient's ability to refuse consent to treatment. Burke gave Manweiler's "*unwillingness*" and reluctance to consent as a reason<sup>19</sup> for changing Manweiler's status to involuntary. Kennedy gave similar reasons:

... the other [reason why involuntary committal procedures would be invoked] is expressing your general unhappiness or unwillingness to remain in hospital. I tend to listen to my patients and if they tell me that they are unhappy, I take it that they are not consenting.<sup>20</sup>

Such an interpretation eviscerates the doctrine of consent and renders it operative only in circumstances where the subject agrees with a proposed treatment; any hint of

<sup>&</sup>lt;sup>14</sup> Had Manweiler been treated in a private mental hospital this course of action would not have been open to him.

<sup>&</sup>lt;sup>15</sup> This is a surmise as I have been unable to access the court papers.

<sup>&</sup>lt;sup>16</sup> See Appendix A.

<sup>&</sup>lt;sup>17</sup> Browne (2005b).

<sup>&</sup>lt;sup>18</sup> There appears to be a widespread, but erroneous, belief amongst psychiatrists that to act 'in the best interests' of a patient, is an adequate defence to any ethical (or legal) challenge. [Based on my noting the views of psychiatrists whilst attending postgraduate conferences on the philosophy of psychiatry].
<sup>19</sup> The question of dangerousness is discussed below.

<sup>&</sup>lt;sup>20</sup> Browne (2005b).

disagreement becoming evidence of incapacity to consent.<sup>21</sup> In that Kennedy is an eminent psychiatrist<sup>22</sup> and did not appear to see himself as enunciating anything other than the general understanding of his professional colleagues, it shows a clear divergence between current psychiatric practice and the law which is set out by O'Neill (2005).<sup>23</sup>

## H-3(iii): Manweiler's supposed dangerousness

Under cross-examination, Burke stated: "There was a serious history of violence that came from the evening before when his mother left the house."

As pointed out by Rogers the only evidence for this assertion was that Manweiler had been "*aggressive in voice*" towards his mother.

In that the jury not only fully accepted Manweiler's account but also penalised the defendants for their manner of defence, it can be concluded that no violence had occurred. Yet in the absence of court proceedings, Manweiler's file containing the damning phrase that he had "*a serious history of violence*" would be unchallenged and unchallengeable and would constitute the basis on which a 'risk assessment' of Manweiler's level of dangerousness would be calculated.

Barry was of the opinion<sup>24</sup> that because of the *Freedom of Information Act* (1997), psychiatrists are more reluctant to commit sensitive information to paper; this would imply that similar erroneous 'assessments' could be operative yet be beyond challenge by the patient who would not necessarily even know of their existence.

If such is the case then vague hearsay and linguistic sleights-of-hand can constitute the 'raw data' on which risk assessments are based; although such assessments might be paraded in the raiments of science, they have little in common with that discipline.<sup>25</sup>

## H-3(iv): Manweiler: a diminished personhood?

The contrast in the attitudes adopted by Burke towards Manweiler, and towards his family is stark: Burke barely spoke to Manweiler yet had an extended discussion with Manweiler's family whilst avoiding matters that might appear to be intrusive. Yet, on

<sup>&</sup>lt;sup>21</sup> See the comment of the physician in Amy's case (*supra*):"... the current test of rationality was often concurrence with the opinions of one's physician".

<sup>&</sup>lt;sup>22</sup> Dr. Kennedy is Clinical Director of the Central Mental Hospital.

<sup>&</sup>lt;sup>23</sup> Op. cit., p.264:

A voluntary patient cannot as a general rule be treated without his/her consent. The only exception to this rule is in emergencies where the patient due to unconsciousness is unable to communicate

Where a voluntary patient is deemed incapable of giving consent by reason of mental disorder steps should be taken to admit him/her to hospital as an involuntary patient ...

<sup>&</sup>lt;sup>24</sup> Browne (2005b).

<sup>&</sup>lt;sup>25</sup> See Chapter 6.

the basis of such partial information, Burke felt able to precipitate an intervention which would have far reaching consequences for Manweiler. Clearly Manweiler's personhood was diminished to the extent that he did not merit the consideration which Burke readily extended to Manweiler's family.<sup>26</sup>

Furthermore, in discussing the events that had befallen Manweiler, the psychiatrists interviewed in Browne (2005b) were quite sanguine and – whilst one did acknowledge that the case had caused public concern – the only notes of regret expressed were in relation to the treatment of Burke in court: "One wonders about the charitableness or the fairness of such a cross examination of a man who is retired."

Of greater importance to the question of personhood is the fact that Manweiler – by virtue of the forcible administration of antipsychotics – had his mental capacities reduced to those of a "*zombie*" for close to ten years. Barry implicitly acknowledges<sup>27</sup> the possibility of such effects; yet Walsh – a former Inspector of Mental Hospitals – is cavalier about the use of such drugs *as a preventive measure*.

#### An aside: 'treatment' or 'damage'

The administration of such drugs falls under the broad rubric of '*treatment*'. Is this the appropriate terminology?

Harry Stack Sullivan, one of the founders of American psychiatry, described some psychiatric 'treatments' as causing a '*damage*' which may reduce the occurrence of troublesome symptoms:

... [the patients] are <u>reduced in human capabilities</u> and drop back from a world the complexities of which provoked some insoluble conflict of adaptive impulses to one simpler and within the range of their surviving human abilities. Mental disorder is thus rectified by acquiring a mental defect, a material alteration in functional capacity for living.<sup>28</sup>

Which term is more appropriate in relation to the use of neuroleptics? Barry's comments above and the existence of irreversible effects of long term use of such drugs<sup>29</sup> provides *prima facie* evidence that the question is at least worthy of further discussion.<sup>30</sup>

 $<sup>^{26}</sup>$  A possible explanation for this – and for Burke's dismissal of the psychologist's report – is that Burke saw himself as a scientist who saw Manweiler as having some 'brain defect' amenable only to chemical treatment, hence neither Manweiler's views nor family problems nor the psychologist's report, were of any relevance being, at best, a distraction. If this is indeed the case it presents a stark warning of the dangers lurking behind an unquestioning adherence to a scientistic perspective of psychiatry. See Chapter 4.

<sup>&</sup>lt;sup>27</sup> Supra: "[some of the side effects] actually mimic chronic forms of schizophrenia."

<sup>&</sup>lt;sup>28</sup> Sullivan (1964) at p.171. [Emphasis in original].

<sup>&</sup>lt;sup>29</sup> See Chapter 5.

<sup>&</sup>lt;sup>30</sup> Ibid.

In discussing the possible damage to Manweiler's personhood, the nature and intrusiveness of the harm that was done to him is of importance. Commenting on the quantum of damages awarded to Manweiler, the legal correspondent of *The Irish Times* contrasted it with the damages awarded to a Mr. Shortt for wrongful conviction and imprisonment: "... *involuntary detention in a psychiatric hospital is a very negative experience, it is arguably less onerous than detention in prison.*" <sup>31</sup> This ignores the forcible medication, the stigma and the damage to the sense of self consequent on an involuntary psychiatric committal.

The Manweiler award can be contrasted with that of a victim of rape.<sup>32</sup> The amount of damages awarded by a jury – in that it seeks to compensate the plaintiff for his injury – provides a rough guide to the level of harm suffered by the plaintiff, as perceived by the general public. It was suggested earlier that, in some circumstances, a coercive psychiatric intervention might – in its level of its intrusiveness – be compared to a rape; the respective jury awards supports such a comparison.

<sup>&</sup>lt;sup>31</sup> Coulter, C. (2005b). 'Unsatisfactory damages neither a deterrent nor a punishment'. *The Irish Times* 13 October; she continued:

Also, Mr. Manweiler was not branded a drug-dealer, deprived of his professional standing and generally subject to public odium, as was Mr Shortt, whose family was also severely affected by what occurred.

 <sup>&</sup>lt;sup>32</sup> The Irish Times, (2005a). 'Man awarded €3 million for unlawful detertion'. The Irish Times, 29 April:
 ...[the Manweiler award] is the highest made by a High Court jury and comes after a €1.7 million award made earlier this month to a woman who was sexually and physically abused by her father over a number of years.

# Appendix I: Iatrogenic harm and misdiagnosis in general medicine

The term 'iatrogenic illness' refers to illness or harm which has been (unintentionally) caused by a medical intervention. It includes cases of misdiagnosis if they occasion harm and cases where the original diagnosis was not mistaken but where subsequent interventions have an unforeseen<sup>1</sup> adverse effect on a subject.

As used in general medicine, the term 'iatrogenic harm' is usually restricted to physical harm and does not cover, for example, the psychological distress which may have resulted from a diagnosis of cancer which was incorrect, or the stigma which may befall one wrongly diagnosed as having an infectious disease such as AIDS. Thus, in so far as it is applied to the practice of psychiatry, 'iatrogenic harm' would generally be restricted to harm – other than foreseen but unintended 'side effects' – resulting from inappropriate pharmacological interventions<sup>2</sup> and would not cover any stigma or damage to personhood even if such stigma or damage flowed from an erroneous psychiatric diagnosis.

As discussed in Chapter 4, the term 'misdiagnosis' is – in the context of psychiatry – ambiguous; furthermore the incidence of that type of misdiagnosis which (erroneously) precipitates a coercive psychiatric intervention is, for reasons explained in the main body of the text, difficult to estimate, yet it is of considerable importance to the argument being proposed in this dissertation. The global level of misdiagnosis that occurs in general medicine provides a possible – albeit crude – estimate; hence the discussion in this appendix will focus not only on general estimates of iatrogenic harm but also on general estimates of misdiagnosis.

Contrary to what might be expected, iatrogenic harm is not restricted to those suffering from the most serious physical illnesses but extends throughout the medical health care system; estimates of this background level of iatrogenic harm are relevant to assessing the levels of iatrogenic harm that may be expected to flow from a psychiatric intervention. Furthermore, a substantial portion of the iatrogenic harm that occurs in general medicine is due to medication errors and – since pharmaceutical treatment

<sup>&</sup>lt;sup>1</sup> Thus excluding foreseen but unintended '*side effects*'.

<sup>&</sup>lt;sup>2</sup> Pharmacological interventions being the most common psychiatric treatment.

constitutes a major part of psychiatric treatment – levels of iatrogenic harm due to pharmaceutical intervention are of an especial relevance.<sup>3</sup>

The most influential studies on iatrogenic harm have been undertaken in the US and these will be discussed in *Subsection I-1;* some UK studies will be examined in *Subsection I-2* and some Irish sources, in *Subsection I-3*.

Some conclusions concerning the levels of iatrogenic harm and misdiagnosis occurring in general medicine are drawn in *Subsection I-4*; and concerning the levels of iatrogenic harm occasioned by psychiatric intervention,<sup>4</sup> in *Subsection I-5*.

## I-1: US estimates of iatrogenic harm and general misdiagnosis

The extent of misdiagnosis in general medicine is discussed in <u>*I*-1(*i*)</u>; that of iatrogenic harm, in <u>*I*-1(*ii*)</u>; that of iatrogenic harm occasioned by pharmacological intervention, <u>*I*-1(*ii*)</u>.

## I-1(i): Misdiagnosis (US)

In 1999 the Institute of Medicine issued a report entitled *To Err is Human: Building A Safer Health System<sup>5</sup>* and, although the primary focus of this report was on the level of iatrogenic harm, it did make one reference to misdiagnosis:

Unexpected findings at autopsy are an excellent way to refine clinical judgment and identify misdiagnosis. Lundberg<sup>6</sup> cites a 40% discrepancy between antemortem and postmortem diagnoses.<sup>7</sup>

Shojania (2003) was a meta-analysis of earlier international studies and had as its

objective: "To determine the rate at which autopsies detect important, clinically missed

diagnoses, and the extent to which this rate has changed over time."

It concluded that:

The median error rate was 23.5% ... for major errors<sup>8</sup> and 9.0% ... for class I errors<sup>9</sup>. ... we estimated that a contemporary US institution ... could observe a major error rate from 8.4% to 24.4% and a class I error rate from 4.1% to 6.7%.<sup>10</sup>

<sup>&</sup>lt;sup>3</sup> The nature, and extent, of the 'side effects' of pharmacological psychiatric treatments are discussed in Chapter 5.

<sup>&</sup>lt;sup>4</sup> Estimates of psychiatric misdiagnosis are discussed in Chapter 4.

<sup>&</sup>lt;sup>5</sup> Institute of Medicine (1999).

<sup>&</sup>lt;sup>6</sup> *I.e.* Lundberg (1998).

<sup>&</sup>lt;sup>7</sup> Institute of Medicine (1999), p.269.

<sup>&</sup>lt;sup>8</sup> '*Major errors*' were defined as clinically missed diagnoses involving a principal underlying disease or primary cause of death. [*Op. cit.*, p.2850.]

<sup>&</sup>lt;sup>9</sup> '*Class I errors*' were major errors that, had they been detected during life, "*would*," "*could*," "*possibly*," or "*might*" have affected patient prognosis or outcome (at a minimum, discharge from the hospital alive). [*Ibid.*, p.2850.]

<sup>&</sup>lt;sup>10</sup> *Ibid.*, p.2849; The authors noted (p. 2849) that the autopsy rate had decreased from 30-40% in the 1960's to 6% in 1994; they also noted that: "*For many physicians, interest in the autopsy as a means of detecting clinically missed diagnoses is undoubtedly offset by concerns over litigation.*" (p. 2855).

Dessmon (2001) examined the incidence of misdiagnosis in an ICU (Intensive Care

Unit), in all patients admitted over a two year period and concluded that:

The discordance between the clinical cause of death and postmortem diagnosis was 19.8%. In 44.4% of the discordant cases, knowledge of the correct diagnosis would have altered therapy.

## I-1(ii): Iatrogenic harm (US)

Steel (1981) estimated the incidence of iatrogenic harm at a university hospital and concluded that:

... 36% of 815 consecutive patients ... had an iatrogenic illness. In 9% of all persons admitted, the incident was considered major in that it threatened life or produced considerable disability. In 2% of the 815 patients, the iatrogenic illness was believed to contribute to the death of the patient. Exposure to drugs was a particularly important factor in determining which patients had complications.<sup>11</sup>

The study made a single reference to psychiatry:

If no documentation of any sort was available, no iatrogenic illness was recorded despite suspicions of the project staff that one had occurred. This problem was particularly common in cases of apparent psychiatric disturbances.<sup>12</sup>

This suggests:

- firstly, that the incidence of iatrogenic harm in relation to cases with a psychiatric dimension is much more opaque than in purely medical illness and,
- secondly, that the estimates of iatrogenic harm are underestimates.

Any attempt to extrapolate the study findings to psychiatric interventions is fraught with difficulties, the most obvious consideration being that the seriousness of the medical illness might be thought to have a direct bearing on the level of iatrogenic harm. On this point, the Steel (1981) study is of particular interest in that it excluded patients suffering from cancer;<sup>13</sup> commenting on the study, Morris (2004) noted that:

As expected, the intensive care settings accounted for more of the iatrogenic illness than did the others. However, when subjected to a logistic analysis, the unit in which the patient received care was not a determinant of iatrogenic illness; ... it is more likely that iatrogenic illness ... are linked to limitations in human decision making and to defects in the healthcare delivery system.

If the soundness of clinical decision making and the quality of health care management are indeed the crucial factors in determining the level of iatrogenic harm then a comparison of these factors between psychiatric and non-psychiatric medical facilities, might permit a tentative estimate of iatrogenic harm due to psychiatric intervention.

<sup>&</sup>lt;sup>11</sup> Op. cit., p.76.

<sup>&</sup>lt;sup>12</sup> *Ibid.*, p.77.

<sup>&</sup>lt;sup>13</sup> Op. cit. p.638: "... medical floor that is predominantly reserved for patients with cancer was excluded from the study because of the recognized high risk of iatrogenic complications in these patients."

The most cited<sup>14</sup> study dealing with iatrogenic harm is known as the *Harvard Medical Practice Study* which analysed hospitalisations in New York during 1984.

It was published in two parts (the first<sup>15</sup> concerned the incidence and the second<sup>16</sup> the cause, of the iatrogenic harm).

*I-1(ii)(a): Harvard Medical Practice Study: Incidence of iatrogenic harm* Brennan (1991) concluded that:

The Adverse events occurred in 3.7% of the hospitalizations ... and 27.6% of the adverse events were due to negligence ... Although 70.5% of the adverse events gave rise to disability lasting less than six months, 2.6% caused permanently disabling injuries and 13.6% led to death. ... There were significant differences in rates of adverse events among categories of clinical specialties but no differences in the percentage due to negligence.<sup>17</sup>

More recent reports from the US covering the years 2002-2007, found that the incidence

of iatrogenic harm had not decreased over time.<sup>18</sup>

## *I-1(ii)(b): Harvard Medical Practice Study: Type of intervention that caused iatrogenic harm*

Leape (1991) concluded that:

Drug complications were the most common type of adverse event (19%), ... The proportion of adverse events due to negligence was highest for diagnostic mishaps (75%), noninvasive therapeutic mishaps ("errors of omission") (77%), and events occurring in the emergency room (70%). Errors in management were

Furthermore when the rate of fatal iatrogenic harms as a percentage of admissions, is compared the apparent disparity vanishes [Harvard ( $0.037 \times 0.136 = 005$  which is 0.5%); Grady ( $0.18 \times 0.026 = 0.0047$  which is 0.47%)].

<sup>&</sup>lt;sup>14</sup> See BioInfoBank Library [online], available: http://lib.bioinfo.pl/meid:86786 [accessed: 24 March 2007].

<sup>&</sup>lt;sup>15</sup> Brennan (1991).

<sup>&</sup>lt;sup>16</sup> Leape (1991).

<sup>&</sup>lt;sup>17</sup> The figure of 13.6% causing death appears unduly high when compared with the figure of 2.4% reported by Grady (2010) *infra* and suggests that it might have been a typographical error for 1.36%. In the online HTML version of Brennan (1991), the figure 13.6% is omitted ["2.6 *percent caused permanently disabling injuries and percent led to death*"] whilst present in the online pdf version. An examination of the full text however, shows that there was no such typographical error:

However,  $2.6\pm0.4$  percent of the adverse events gave rise to permanent total disability, and  $13.6\pm1.7$  percent caused death. Extrapolating to the state of New York in 1984, we estimated that 2550 patients suffered permanent total disability and that 13,451 died at least in part as a result of adverse events. [*ibid.* p.371]

<sup>&</sup>lt;sup>18</sup> Grady (2010):

The study, conducted from 2002 to 2007 in 10 North Carolina hospitals, found that harm to patients was common and that the number of incidents did not decrease over time. ... It is one of the most rigorous efforts to collect data about patient safety since a landmark report in 1999 found that medical mistakes caused as many as 98,000 deaths and more than one million injuries a year in the United States. ... But instead of improvements, the researchers found a high rate of problems. About 18 percent of patients were harmed by medical care, some more than once, and 63.1 percent of the injuries were judged to be preventable. Most of the problems were temporary and treatable, but some were serious, and a few — 2.4 percent — caused or contributed to a patient's death, the study found.

Grady, D. (2010). 'Study Finds No Progress in Safety at Hospitals'. New York Times. 24 Nov.

identified for 58% of the adverse events, among which nearly half were attributed to negligence.

Of the interventions that caused iatrogenic harm, two – '*diagnostic mishaps*' and '*drug therapy*' – would appear to be of most relevance to psychiatry. Estimates of iatrogenic harm due to inappropriate use of drugs – whether incorrectly prescribed, dispensed or administered – are given later in this appendix.

The studies cited above, relate to the mid 1980's, the Institute of Medicine's report (*supra*) relates to the late 1990s and, whilst it did not explicitly advert to iatrogenic harm caused by psychiatric intervention, it did estimate the general level of iatrogenic harm based on two studies<sup>19</sup>:

In both of these studies, over half of these adverse events resulted from medical errors and could have been prevented. When extrapolated ... the results of the [first] study ... imply that at least 44,000 Americans die each year as a result of medical errors. The results of the [second] suggest the number may be as high as 98,000.

Even when using the lower estimate, deaths due to medical errors exceed the number attributable to the 8<sup>th</sup> leading cause of death. More people die in a given year as a result of medical errors than from motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516).<sup>20</sup>

The above estimates were garnered by the medical profession; patient groups provide an alternative – and possibly more authoritative<sup>21</sup> – perspective: a survey<sup>22</sup> conducted by the National Patient Safety Foundation – a group affiliated to the American Medical Association – on the public experience of patient safety issues, found that 33% of the respondents had personally experienced a medical<sup>23</sup> mistake, the most common being *'misdiagnosis/wrong treatment'* (40%) followed by *'medication error'* (28%). One in three respondents (32%) reported that the medical mistake had a permanent negative effect on their health.

<sup>&</sup>lt;sup>19</sup> Institute of Medicine (1999), p.1:

Two large studies, one conducted in Colorado and Utah and the other in New York, found that adverse events occurred in 2.9 and 3.7% of hospitalizations, respectively. In Colorado and Utah hospitals, 6.6% of adverse events led to death, as compared with 13.6% in New York hospitals.

<sup>&</sup>lt;sup>20</sup> *Ibid.* 

<sup>&</sup>lt;sup>21</sup> See Basch (2010):

The current drug-labeling practice for adverse events is based on the implicit assumption that an accurate portrait of patients' subjective experiences can be provided by clinicians' documentation alone. Yet a substantial body of evidence contradicts this assumption, showing that clinicians systematically downgrade the severity of patients' symptoms, that patients' self-reports frequently capture side effects that clinicians miss, and that clinicians' failure to note these symptoms results in the occurrence of preventable adverse events. (p.865)

<sup>...</sup> Patients' reports are more highly concordant with overall health status than clinicians' reports. (p.867)

<sup>&</sup>lt;sup>22</sup> NPSF (1997).

<sup>&</sup>lt;sup>23</sup> The survey made no reference to psychiatry or to mental illness.

## I-1(iii): Iatrogenic harm due to pharmacological intervention (US)

Lazarou (1998) was a meta-analysis of earlier studies on the incidence of adverse drug reactions (ADRs) in hospitalised patients; it found the level of ADRs to be "*extremely high*" and concluded that:

... the overall incidence of serious<sup>24</sup> ADRs was 6.7% and of fatal ADRs was 0.32% ... [it] estimated that in 1994 overall 2,216,000 ... hospitalized patients had serious ADRs and 106,000 ... had fatal ADRs, making these reactions between the fourth and sixth leading cause of death.

These are underestimates because the study "... excluded errors in drug administration,

noncompliance, overdose, drug abuse, therapeutic failures, and possible ADRs".

In 2006, following its earlier report on medical errors, the Institute of Medicine released

a study on medication errors in American hospitals; amongst its findings<sup>25</sup> were that:

- At least 1.5 million Americans are sickened, injured or killed each year by errors in prescribing, dispensing and taking medications ... drug errors cause at least 400,000 preventable injuries and deaths in hospitals each year, more than 800,000 in nursing homes ... and 530,000 ... in outpatient clinics.

- Mistakes in giving drugs are so prevalent in hospitals that, on average, a patient will be subjected to a medication error each day he or she occupies a hospital bed, ...

The report urged the adoption of computerised systems for prescribing drugs, a proposal

– which despite having been routinely made since 1999 – has been followed in less than 10% of hospitals.<sup>26</sup>

## I-2: The United Kingdom

The extent of misdiagnosis in general medical practice is discussed in <u>*I*-2(*i*)</u> and the extent of iatrogenic harm, in <u>*I*-2(*ii*)</u>.

## I-2(i): Misdiagnosis (UK)

Although I have been able to source statistics on the rate of misdiagnosis for various medical conditions, for example:

- epilepsy: estimates vary between 20-31%.<sup>27</sup>

- PVS: estimates vary between 18-43%.<sup>28</sup>

I have been unable to locate global estimates of medical misdiagnosis.

<sup>&</sup>lt;sup>24</sup> *I.e.* those that required hospitalization, were permanently disabling or resulted in death.

<sup>&</sup>lt;sup>25</sup> Kaufman, M., (2006). 'Medication Errors Harming Millions, Report Says'. *The Washington Post*, 21 July.

<sup>&</sup>lt;sup>26</sup> McNeil Jr., D. (2007), 'Medication Errors Are Studied', *The New York Times*, March 7.

<sup>&</sup>lt;sup>27</sup> NICE (2004b).

<sup>&</sup>lt;sup>28</sup> Andrews (1996) found a misdiagnosis rate of 43%; Tresch (1991) found that 18% of patients who were diagnosed as PVS, were aware; for a further discussion of these, and other, sources see Roche (2000).

In the UK, The National Patient Safety Agency (NPSA) is charged with monitoring and overseeing patient safety, a search of its online reports for 'misdiagnosis' elicits 4 results, none of which is relevant. The NPSA, however, does provide estimates of iatrogenic harm.

## I-2(ii): Iatrogenic harm (UK)

NPSA (2001) contained the following table:

Harvard (1991)	Australian (1995)	UK pilot
	16.5%	
3.7%	(8.25% preventable)	10%
314,000	1,414,000	850,000
Adverse Events	Adverse Events	Adverse Events
	3.7% 314,000	3.7%         16.5%           3.7%         (8.25% preventable)           314,000         1,414,000

Table I-1: Frequencies of adverse events in UK hospitals

NPSA (2001) also highlighted the statistic that for every major injury or death there are 10-50 minor injuries and 300-600 related near misses – a statistic which is of interest in that deaths due to pharmacological causes are recorded in Irish psychiatric hospitals and it may permit a tentative estimate of non-fatal adverse reactions; the statistic that 10% of hospital admissions lead to patient harm is also of interest.

A 2005 report by the National Audit Office found that 10.8% of patients experienced an

adverse event; it found that 2,081 deaths were attributed to the errors of staff, but said:

It is widely acknowledged there is significant under-reporting of deaths and serious incidents. Other estimates of deaths range from 840 to 34,000. In reality, the NHS simply does not know.<sup>29</sup>

The finding that, in a third of NHS hospitals, there is no requirement on clinicians to report unexpected complications or unexpected events, further emphasises the extent of underreporting.<sup>30</sup>

A 2006 report from the NPSA noted that :

International research suggests that there is significant under-reporting of incidents. ... [and] biases in what types of incident are reported. ... [though] reports from mental health ... services have increased rapidly.<sup>31</sup>

This report also noted that no reports from patients have been included in their analysis but that a system was being implemented to permit such reports.<sup>32</sup> This issue is of special importance in psychiatry because – as is the case in relation to the concept 'illness' – the defining, the measuring and the assessing of 'harm' is much more

<sup>&</sup>lt;sup>29</sup> Carvel, J., (2005). 'More than 1m patients fall victim to mistakes in NHS hospitals', *The Guardian*, 3 Nov.

<sup>&</sup>lt;sup>30</sup> NPSA (2001).

<sup>&</sup>lt;sup>31</sup> NPSA (2006a).

<sup>&</sup>lt;sup>32</sup> *Ibid.*, p.3.

problematic<sup>33</sup> than in general medicine. The ability of patients, ex-patients or *'survivors'*<sup>34</sup> to influence the perception of harm should – in the light of past practices such as lobotomy – be readily apparent.

In a further report<sup>35</sup> the NPSA specifically addressed the issue of patient safety in mental hospitals. It does not refer to misdiagnosis but is informative in relation to adverse reactions to psychotropic medications.

## I-3: Ireland

I have been unable to source specifically Irish statistics on general rates of misdiagnosis.

Some indicators as to the extent of iatrogenic harm occurring in Irish medical practice, are discussed in  $\underline{I-3(i)}$ ; and of iatrogenic harm occasioned by pharmacological intervention, in  $\underline{I-3(ii)}$ .

## I-3(i): Iatrogenic harm (Irl.)

In 2003, seeking to investigate the extent of iatrogenic harm occurring in Ireland, an RTE *Prime Time* programme,<sup>36</sup> found that research in this area was non-existent; it incorporated interviews with, amongst others, Professor Fitzgerald (Dean of Medicine, UCD) and Professor Leape (author of one<sup>37</sup> of the Harvard studies *supra*). Fitzgerald accepted that the result of the Harvard study applied to Ireland and that the problem was of a seriousness sufficient to warrant an independent investigation because the number of deaths due to iatrogenic harm exceeded, for example, those due to road accidents.

Leape, in discussing the estimate that should apply to Ireland, noted that the Harvard finding that iatrogenic harm occurred in 4% of hospitalisations related to the US and that estimates from other countries were considerably higher: 13% (Australia), 10% (UK) and 9% (Denmark). He suggested 10% as an initial estimate for Ireland however

<sup>&</sup>lt;sup>33</sup> See Chapter 4.

<sup>&</sup>lt;sup>34</sup> The term '*survivor*' is the preferred usage of those former patients who are critical of their experience at the hands of psychiatry. See, for example, Rissmiller & Rissmiller (2006) and a response by Emerick (2006):

<sup>...</sup> more than 60% of ex-patient groups support antipsychiatry beliefs and consider themselves to be "psychiatric survivors." Many in the "mad liberation" movement believe they are victims of psychiatric treatments that harmed them. ... Given the extensive critical literature on the concept of "mental illness" and the size of the ex-patient movement, the objective observer might conclude that psychiatry is less scientific and more political than the Rismillers (*sic*) suggest and that the expatient movement is more scientific, more antipsychiatry, and a more important social movement than most people understand it to be.

<sup>&</sup>lt;sup>35</sup> NPSA (2006b).

<sup>&</sup>lt;sup>36</sup> RTE (2003).

<sup>&</sup>lt;sup>37</sup> Leape (1991).

the informality of the discussion was such that the only conclusion that can reasonably be drawn is that the rate of iatrogenic harm in Ireland is at least comparable to that found in the United States.

The Deputy Chief Medical Officer for England was also interviewed; he emphasised the importance of first determining the extent of the problem because, in the absence of such information, the prevalence of iatrogenic harm is likely to be denied<sup>38</sup> – a response eloquently demonstrated by the response of the spokesman for the Irish Hospital Consultants Association who was also interviewed.

A spokesperson for Patient Focus (a patients' rights group) emphasised the importance of access to the courts in uncovering the extent of iatrogenic harm; in that, in Ireland, such access is effectively denied<sup>39</sup> to those who seek redress for harm caused by negligence psychiatric practice, it follows that an important avenue for estimating the prevalence of psychiatric iatrogenic harm, is not available.

#### I-3(ii): Iatrogenic harm due to pharmacological intervention (Irl.)

Interviewed on RTE (2003), the chief pharmacist of Tallaght Hospital described the effect of installing a system to monitor the extent of pharmacological errors occurring in the hospital. Prior to the introduction of this system<sup>40</sup> the extent of reporting amounted to 12 drug errors<sup>41</sup> per year; subsequent to the introduction, it rose to 500 per year.

Indicators to the extent of underreporting of ADRs can also be gleaned from the submissions<sup>42</sup> made to, and the report<sup>43</sup> of an Oireachtas Sub-Committee especially constituted to examine the adverse effects of pharmaceutical products.

## I-3(ii)(a): Submissions relating to the reporting of ADRs

The chairman of the Pharmaceutical Society of Ireland, stated:

The incidence of reporting of adverse events by all practitioners — medical, pharmaceutical, dental and nursing in the Republic — is low by European and international standards.

<sup>&</sup>lt;sup>38</sup> A spokesperson for a US patient group, also interviewed in the programme, stated "What gives us power is that we already have the data – if you don't have the information they will say what information? What evidence?"

<sup>&</sup>lt;sup>39</sup> See Mental Health Act (2001), S. 73.

<sup>&</sup>lt;sup>40</sup> The system sought to encourage rather than punish those who reported errors and which, in an Irish context, was novel.

<sup>&</sup>lt;sup>41</sup> This relates to errors missed by ward pharmacists who detect c.1,000 errors per month.

<sup>&</sup>lt;sup>42</sup> Oireachtas Sub-Committee on the Adverse Side Effects of Pharmaceuticals (2006).

<sup>&</sup>lt;sup>43</sup> Oireachtas Joint Committee on Health and Children (2007).

... Pharmacists ... do not currently have a legal obligation to report adverse effects.  $^{44}$ 

This picture was confirmed by the Medical Director of the Irish Pharmaceutical Healthcare Association, who stated that the annual number of reported ADRs was "... *approximately 2,500 ... of which more than 60% are reported by pharmaceutical companies.*" This implies that only 1,000 ADRs were reported by medical practitioners directly to the IMB.<sup>45</sup> In acknowledging the low level of reporting, he related his own experience:

... I did some research on this issue 14 or 15 years ago when I was working in St. James's Hospital. The junior hospital doctors ... were given a small financial incentive to report adverse events when they occurred. Within a three-month period doctors ... reported more adverse events than had been reported in the previous eight years.

As mentioned above, the Harvard estimates as applied to Ireland suggest that iatrogenic harm accounted for 4,000 deaths; of which 19% (*i.e.* 760) were attributable to pharmaceuticals. In relation to ADRs, the ratio of serious adverse events to fatal adverse events was in the ratio  $21:1^{46}$  which suggests that the total number of '*serious ADRs*'<sup>47</sup> occurring annually in Ireland is 15,906.<sup>48</sup> Whilst many of these ADRs are attributable to inappropriate prescription or administration of drugs, it is clear that a proportion are attributable to the side effects of medication. Given that knowledge of the nature and extent of ADRs is an obvious prerequisite to remedial action, it is difficult to comprehend why the Committee did not pursue the reasons for the low reportage of ADRs more forcefully.

#### I-3(ii)(b): The Report: Extent and Seriousness of ADRs

The Committee found that underreporting of ADRs was common and noted that whilst no comprehensive studies existed of the prevalence of ADRs in Ireland, some studies relating to individual hospitals, had been made:

[one such] study ... identified prescribing errors of 31.1% for in patients in a Dublin teaching hospital and another ... reported an error rate of 25% in the out patients department.

<sup>&</sup>lt;sup>44</sup> Oireachtas Sub-Committee on the Adverse Side Effects of Pharmaceuticals (2006), submissions of 10 Oct.

<sup>&</sup>lt;sup>45</sup> The Irish Medicines Board (IMB) is the competent authority.

Lexchin & O'Donovan (2010) report a possible conflict of interest between the IMB and the pharmaceutical industry.

<sup>&</sup>lt;sup>46</sup> Lazarou (1998) (supra) "...the overall incidence of serious ADRs was 6.7% and of fatal ADRs was 0.32%" [GR: 6.7/0.32=20.93]

<sup>&</sup>lt;sup>47</sup> 'Serious ADRs' were defined as those that required hospitalization, were permanently disabling, or resulted in death.

<sup>&</sup>lt;sup>48</sup> This figure relates to those ADRs deemed 'serious'; the total number of ADRs is clearly of a higher order of magnitude.

... two medical insurers calculated that 25% and 19% respectively of claims against GPs in Ireland were for medication errors.

... [ a study of] 600 geriatric patients ... at the Cork University Hospital found that 52% were given inappropriate medicines.<sup>49</sup>

#### I-3(ii)(c): The Report: The Role of Pharmaceutical Companies

The FDA ... points out that most drugs are approved on the basis of trials on subjects totaling not more than 1,500. ... the form of drug trials is such that ADRs are likely to be overlooked. Indeed, companies can structure tests with that objective in mind. Furthermore ... drug companies are not obliged, or do not, make available all studies to regulators.<sup>50</sup>

Some of the Report's strongest criticisms relate to psychiatric medication and these are discussed in Chapter 5.

## *I-4: Conclusions relating to the levels of iatrogenic harm and misdiagnosis in the practice of general medicine in Ireland.*

The conclusions relating to general medical practice, concerning levels of misdiagnosis are given in <u>Subsection I-4(i)</u>; those relating to iatrogenic harm, in <u>Subsection I-4(ii)</u>; and those relating to ADRs, in <u>Subsection I-4(iii)</u>.

#### I-4(i): Misdiagnosis

Leape (*supra*) suggested 10% as an initial estimate of the rate of iatrogenic harm in Ireland; a figure considerably in excess of the US rate at 4% however as stated earlier this was an estimate given informally and without accompanying evidence. The only conclusion that was drawn was that the rate of iatrogenic harm in Ireland is at least comparable to that found in the United States; similarly it would seem reasonable to conclude that, in the absence of authoritative studies, the rate of misdiagnosis in Ireland is at least as high that those found in the US which are summarised in <u>Table 1-2</u> (*infra*).

<u>Study</u>	<u>Rate</u>	<u>Type</u>
Lundberg (1998)	40%	Postmortem
Shojania, K. et al (2003)	Major error rate: 8.4% – 24.4%	Meta-analysis of autopsy
	Class I: 4.1% – 6.7%	studies on misdiagnosis
Dessmon, Y. et al (2001)	19.8%	Direct study of the rate of
		misdiagnosis in an ICU

#### Table I-2: Estimates of misdiagnosis in general medicine

Based on such considerations, it may be concluded<sup>51</sup> that a conservative estimate of the rate of misdiagnosis in general (*i.e.* non-psychiatric) medical practice in Ireland, is in the region of 25%.

<sup>&</sup>lt;sup>49</sup> *Op. cit.*, Para 3.5.

<sup>&</sup>lt;sup>50</sup> *Ibid.*, Para 4.4. See also Chapter 5.

<sup>&</sup>lt;sup>51</sup> The 'Precautionary Principle' (supra) adds independent support to this conclusion.

### I-4(ii):Iatrogenic harm

US and UK estimates of the rates of iatrogenic harm and 'major' or 'fatal' harm are shown in the following table:

<u>Study</u>	Rate	<u>Major or Fatal</u>	<u>Comments</u>	
Steel (1981)	36%	- of which 25%	Exposure to drugs was a particularly	
		major 5% fatal	important factor	
Harvard (1991)	3.7%	- of which 13.6%	Drug complications were the most common	
		fatal	type of adverse event (19%)	
Institute of	2.9% to	- of which 6.6% to		
Medicine (1991)	3.7%	13.6% fatal		
Australian (1995)	16.5%			
UK (2005)	10%		Significant under-reporting of deaths and	
			serious incidents.	
Table 1-3: Estimates of jatrogenic harm in general medicine				

<u>Estimates of iatrogenic harm in general medicine</u>

The studies summarised in *Table I-3*, suggest 10% as a tentative estimate of the proportion of iatrogenic harms that result in fatalities; inappropriate pharmaceutical treatments being a common source of such harms.<sup>52</sup>

### I-4(iii): Medication errors and level of reporting of ADRs in Ireland

The report of the Oireachtas sub-committee cited estimates of the levels of medication errors occurring in individual Irish hospitals ranging from 25% to 52%; in the absence of evidence to the contrary,<sup>53</sup> these can be taken as generally representative. Furthermore, based both on the evidence given to the sub-committee and on its own conclusions, ADRs are grossly underreported in Ireland.<sup>54</sup>

## I-5: Iatrogenic harm in Irish psychiatric practice<sup>55</sup>

Had the iatrogenic consequences of psychiatric interventions (including medication) received the same level of scrutiny as has non-psychiatric interventions, then the excursus into discussing the general levels of iatrogenic harm (such as has been undertaken in earlier sections of this chapter) would not have been necessary; but such studies do not exist and it is only by means of such a circuitous route that estimates of harm caused by psychiatric intervention can be made.

It is clear that the uncovering of iatrogenic harm due to drug errors can only occur in an environment where there is an obligation to maintain accurate and detailed records. As

<sup>&</sup>lt;sup>52</sup> Ibid.

<sup>&</sup>lt;sup>53</sup> Ibid.

<sup>&</sup>lt;sup>54</sup> In a letter to *The Irish Times* [22 October 2009] Dr. Orla O'Donovan of the Department of Applied Social Studies, University College Cork, stated: "In 2007, the IMB received only 206 ADR reports from GPs, indicating that fewer than one in 10 GPs on average submit one ADR report a year to this voluntary *reporting system.*"<sup>55</sup> The following discussion is restricted to pharmaceutical treatments [see *supra*].

evidenced by the reports of the Inspector of Mental Hospitals, Irish psychiatric practice is deeply remiss in this regard:

... drug prescribing in some locations is often arbitrary and made without regard to appropriate clinical diagnosis. ... In some instances, the prescriptions had not been reviewed for some considerable time. ... There appeared to be an increasing number of sudden deaths in psychiatric hospitals, some of which were attributed to drug-related effects.<sup>56</sup>

This raises the question as to the default presumptions that should be decreed in cases where full information on the level of harm consequent on psychiatric intervention, is unavailable: should examples of such harm be regarded as isolated [the "*few bad apples*" scenario] or as indicative of a considerably more extensive problem [the "*tip of the iceberg*" scenario]. The problem is discussed *infra*.

Two case histories are discussed [*Subsection I-5(i)*]; the first [the Cromer Case] provides a window into institutional attitudes towards the reporting of adverse patient events in a psychiatric institution; the second [the Neary Case] is indicative of the unwillingness of the medical professional bodies, at the highest levels, to actively uncover and resolve cases of serious and sustained iatrogenic harm. Some of the Oireachtas Sub-Committee's conclusions concerning psychiatric medications are discussed in *Subsection I-5(ii)*; and some conclusions are drawn in *Subsection I-5(iii*) concerning the extent of iatrogenic harm occurring in Irish psychiatric practice.

#### I-5(i): The Cromer and Neary cases

The Cromer case concerns an inquiry into the death of an elderly psychiatric patient, a Ms. Hannah Cromer, who, having been originally diagnosed as schizophrenic, had been hospitalised for 35 years. Ms. Cromer choked to death whilst restrained to a chair by a belt;<sup>57</sup> but was reported by hospital staff as having "*passed away*" and the information relating to the exact circumstances of the death was not recorded in case notes. Staff removed Ms Comber's body and "*dressed her in new clothes 'for her dignity*'."<sup>58</sup>

<sup>&</sup>lt;sup>56</sup> Walsh (1998), pp.3–4; and also:

The Inspectorate is concerned about the adequacy and quality of medical note taking in some mental health services. This relates particularly to consultant inputs both on, or shortly after, admission to hospital and subsequent clinical reviews and progress.

<sup>&</sup>lt;sup>57</sup> O'Riordan, S. (2007) "Gardaí 'made me change my statement on patient's death' " *The Irish Examiner*, 5 April.

Roche, B. (2007), 'Hospitals urged to examine rules on restraint', *The Irish Times*, 5 April. <sup>58</sup> O'Bi order (2007) (current)

<sup>58</sup> O'Riordan (2007) (supra).

Ms. Cromer's GP regarded the death as unexpected and reported it to the Garda Síochána. A post mortem "... was emphatic that Ms. Comber died from asphyxia as a result of her neck becoming entangled in the restraining belt of her chair."<sup>59</sup> In their initial statements to the guards, the two nursing staff who had been present, stated that Ms. Comber had slipped down in her chair and the belt became entangled around her neck and she became asphyxiated. These statement were withdrawn at the inquest with one nurse claiming that she had been coerced by the guards into making her statement. A verdict of misadventure was returned.

The Comber case is not an isolated example of the concealment of iatrogenic harm in Ireland:<sup>60</sup> the investigations<sup>61</sup> consequent on the disciplinary hearings relating to the obstetrician Dr. Neary<sup>62</sup> provide ample evidence to the existence in Ireland of a culture<sup>63</sup> amongst medical professionals – not only of unwillingness to highlight medical errors – but to actively conceal<sup>64</sup> such errors. (It should be noted that the Lourdes Inquiry found no evidence of bad faith on the part of Dr. Neary and – had the events in question occurred in a psychiatric setting – the absence of *male fides* would be a substantial bar<sup>65</sup> to a patient taking a civil action against Dr. Neary.)

<sup>&</sup>lt;sup>59</sup> Roche (2007) (*supra*).

<sup>&</sup>lt;sup>60</sup> See also Chapter 6 concerning a report [MHC (2009)] into allegations of ill-treatment of patients in two mental hospitals in County Tipperary. The inquiry had been prompted by reports of high levels of fractures being suffered by patients and this had led to suspicions of staff abuse of patients and calls for a Garda inquiry. The reports first came to light in 2004 and were not discussed by the regional authorities until 2005 and then not fully investigated.

<sup>&</sup>lt;sup>61</sup> Harding-Clarke (2006).

See also the reports of the Medical Council of Ireland investigation into the behaviour of Dr. John Murphy, Dr. Bernard Stuart and Professor Walter Prendiville who had, in an earlier inquiry, exonerated Dr. Neary. [Online], available:

https://www.medicalcouncil.ie/news/publicationsarticle.asp?NID=182&T=N [accessed: 9 April 2007 ]. <sup>62</sup> Harding-Clarke (2006). Dr. Neary had performed a number of caesarean hysterectomies on patients which were not justified on medical grounds and some of which had been performed against the patients' express wishes.

 $<sup>^{63}</sup>$  In that subsequent to events leading to the establishment of the Lourdes Inquiry becoming public, Dr. John Murphy – one of the three consultants who had exonerated Dr. Neary – was elected as President of The Royal College of Physicians in Ireland though he subsequently resigned this position.

See Wall, M. (2007) 'RCPI president resigns after Neary inquiry', *The Irish Times*, 22 February. <sup>64</sup> A report commissioned by the Medical Council of Ireland found that some complaints made to the Council against Neary, were not acknowledged or not recorded and investigations were subject to long delays.

See Bowers, F. 'Lessons from Neary controversy' Irish Health.com [online], available:

http://www.irishhealth.com/index.html?level=4&id=5111 [accessed: 9 April 2007 ].

One of the consultants who had exonerated Neary, did so with the words: "... *it is my view that the mothers of the North Eastern Health Board are fortunate in having the service of such an experienced and caring obstetrician.*" [See Harding-Clarke (2006) p.13].

<sup>&</sup>lt;sup>65</sup> See Appendix A.

### I-5(ii): Oireachtas Sub-Committee<sup>66</sup> on psychiatric medications<sup>67</sup>

#### - <u>Submissions</u>::

#### Executive Summary:

4. ... It was asserted that these medicines had dangerous, even fatal side effects, yet were prescribed extensively.

<u>4.1</u>... submissions made a number of points:

- ... the drugs are often prescribed on the basis of very limited observation of the patient;
- they generate side effects which are misdiagnosed as causal, leading to further medication;
- the side effects include, behavioural disorders, physical illness, dependence, suicidal ideation and even suicide;
- ... even where the risks of these side effects are well known they seem not to be fully appreciated or are ignored by prescribers;
- ... even setting aside the risk of side effects, some of the drugs are of doubtful benefit.

<u>4.12</u>. ADRs may arise because practitioners have an exaggerated view of the benefit of the drugs in relation to its drawbacks.

#### - <u>Conclusions</u>::

5.3... the influence of the pharmaceuticals industry ... is unhealthy and needs to be counterbalanced.

5.5. ... need to assign a higher priority to pharmacovigilance activities, including reporting of ADRs.

5.23.... the excessive use of medication prescribed by health care professionals and excessive use of psychiatric drug therapies in particular. Some of the responsibility for this lies in the promotional activities of the drug companies ...

## I-5(iii): Conclusions relating to the levels of iatrogenic harm in Irish psychiatric practice

The extent of iatrogenic harm in Ireland is being uncovered by a haphazard process -

the circumstances surrounding the death of Ms. Cromer were uncovered despite the

efforts of the psychiatric medical professionals, a series of fortuitous circumstances lead

to the uncovering of Dr. Neary's malpractice – other countries have adopted a much

more proactive stance.68

In the absence of such institutions in Ireland - and, therefore, in the absence of reliable, detailed statistics in relation to iatrogenic harm - how should the risk of such harm be

<sup>&</sup>lt;sup>66</sup> Oireachtas Joint Committee on Health and Children, (2007).

<sup>&</sup>lt;sup>67</sup> The Oireachtas subcommittee report did not consider errors in diagnosis. [Op. cit., Para. 4.10.]

<sup>&</sup>lt;sup>68</sup> For example:

<sup>-</sup> in the UK, the establishment of the NPSA (supra),

<sup>-</sup> in Sweden, the '*Lex Maria*' – which was enacted as early as 1937 – sought to ensure mandatory reporting of any serious patient injury, or even risk of serious injury, and extends to the psychiatric services. [See Ödegård (1998)].

incorporated into discussion of medical decision making? When it is known that iatrogenic harm does indeed occur, can any conclusions be drawn in relation to the prevalence of such harm? What should the 'default' presumption be? At the extremes, two conclusions are possible:

(i) that, cases such as the Neary, Cromer and other cases, are isolated cases; *i.e.* adverse events occur to an extent commensurate with their reporting [the "*few bad apples*" scenario].

(ii) that such cases are indicative of a pervasive laxity towards the reporting of adverse events in Irish hospitals and, in particular, Irish psychiatric hospitals; *i.e.* adverse events occur to an appreciably greater extent than is reported [the "*tip of the iceberg*" scenario].

The principles underlying the choice of default assumptions have been examined in Chapter 1 and the conclusion drawn that the Precautionary Principle is applicable and favours the adoption of the second option. Furthermore, the adoption of the first of the above options, would tend towards an acceptance of the *status quo* and its lax practices in relation to patient safety, whereas adopting the second create a momentum towards uncovering adverse events and consequently minimising harm; I suggest that the conclusion must be drawn that, in the absence of robust evidence to the contrary, the default presumption should be that adverse events occur in Irish Hospitals and, in particular, Irish psychiatric hospitals, to an extent appreciably greater than is reported.

As an indicator of the extent of underreporting, I will attempt (by using statistics discussed in earlier section of this chapter) to estimate the number of deaths that might by expected to occur in one year in Irish Psychiatric Hospitals because of iatrogenic effects of pharmaceutical treatments, and then compare it with the estimate made by the Inspector of Mental Hospitals.

[For the purposes of analysis I have taken the year 1998 as a base principally because statistics for the number of sudden deaths attributable to psychotropic medication have been made available by the Inspector of Mental Hospitals for that year.]

(i) The total number of admissions to Irish psychiatric hospitals in 1998 was 21.895.<sup>69</sup>

(ii) The Harvard Study (*supra*) estimated the number of adverse events for the US (as a percentage of total hospitalisations) as 3.7%;<sup>70</sup> Leape, one of the authors of the

<sup>&</sup>lt;sup>69</sup> Walsh (1998), Table 4.

<sup>&</sup>lt;sup>70</sup> Brennan (1991) (supra): "Adverse events occurred in 3.7% of the hospitalizations ..."

report, suggested 10% as an appropriate estimate for Ireland<sup>71</sup> however, as stated above, this was an estimate given in informal circumstances and the conclusion that was drawn (*supra*) was that the rate for Ireland was at least comparable to the United States.

(iii) Assuming the level of iatrogenic harm in psychiatric hospitals equates<sup>72</sup> with that of non-psychiatric hospitals, this suggests that 810 patents suffered iatrogenic harm in Irish psychiatric hospitals in 1998.

(iv) Removing all non-pharmacologically related iatrogenic harm<sup>73</sup> from consideration so that the focus is placed solely on '*drug complications*', permits the number of psychiatric admissions likely to suffer iatrogenic harm due to medication, to be estimated; this figure is 154.<sup>74</sup>

(v) Of these 154,<sup>75</sup> 15 would be expected to suffer fatal complications.

(vi) The Inspector of Mental Hospitals has only identified seven deaths in 1998 relating to the '*side-effect of psychotropic drug administration*';<sup>76</sup> in that the Inspector makes no reference to deaths due to incorrect administration or prescription of medications, it appears that this figure should be interpreted as being the total number of iatrogenic fatalities due medication.

I wish to draw the conclusion that the level of fatal iatrogenic harm caused to psychiatric inpatients by psychiatric medications exceeds, by orders of magnitude, that reported by the Inspector Of Mental Hospitals.

<sup>&</sup>lt;sup>71</sup> Supra

<sup>&</sup>lt;sup>72</sup> Because certain procedures - such as surgery – which may be thought to incur a higher risk of iatrogenic harm (though see the earlier discussion for an alternative point of view) are far more common in non-psychiatric hospitals than in psychiatric hospitals, this presumption may be questioned; though it should be noted that the estimate in the following paragraph omits 81% of such harm from consideration which may be thought to err in the opposite direction.

<sup>&</sup>lt;sup>73</sup> Which constitutes 81% of iatrogenic harm; see Leape (1991) (*supra*): "Drug complications were the most common type of adverse event (19%) ... "

<sup>&</sup>lt;sup>74</sup> 3.7% of 21,895 equals 810; 19% of 810 equals 154.

<sup>&</sup>lt;sup>75</sup> Institute of Medicine (1999), p.1. (supra): "In Colorado and Utah hospitals, 6.6% of adverse events led to death, as compared with 13.6% in New York hospitals."

I have taken the mean of 6.6% and 13.6% (*i.e.* 10.1%) as an estimate.

<sup>&</sup>lt;sup>76</sup> Walsh, D. (1999). 'Letters to the Editor: Deaths in Mental Hospitals.' *The Irish Times*. 26 Nov.

# Appendix J: Pharmaceutical company influence on psychiatric research

The economic importance of the pharmaceutical industry (and of psychiatry to the pharmaceutical industry) is sketched in <u>Subsection J-1</u>. Some methods of uncovering pharmaceutical company influence on research results are discussed in <u>Subsection J-2</u>; some studies on the pervasiveness of such influence are discussed in <u>Subsection J-3</u>. Conclusions are summarised in <u>Subsection J-4</u>.

## *J-1:The financial importance of psychiatry to the pharmaceutical industry*

The magnitude of global sales of pharmaceutical products [\$664 billion]<sup>1</sup> gives an indication both of the importance of the pharmaceutical industry to the global economy and of the importance of the key market leading drugs to individual pharmaceutical companies.

The importance of psychiatric pharmaceutical treatments to the global pharmaceutical industry is shown by the fact that of the ten top selling drugs, numbers six, seven and eight were psychiatric treatments; all were atypical antipsychotics<sup>2</sup> and these three accounted for 23% of the sales of top ten global pharmaceutical products.<sup>3</sup>

The importance of the pharmaceutical industry to the Irish economy is shown by the fact that it accounted for 40% of exports in 2006;<sup>4</sup> in that year only two Irish companies

<sup>4</sup> Irish Pharmaceutical Healthcare Association (2006), Press release, 19 July:

<sup>&</sup>lt;sup>1</sup> Total global sales of pharmaceutical products in 2007 amounted to \$664 billion of which the top ten products accounted for \$64 billion. IMS Global Healthcare, [online], available:

http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/Top\_Line\_Data/Top10GlobalProducts.pdf [accessed: 22 December, 2008].

<sup>&</sup>lt;sup>2</sup> Zyprexa (olanzapine), Risperdal (risperidone) and Seroquel (quetiapine).

<sup>&</sup>lt;sup>3</sup> See also Barber(2008):

And today's psychiatry really is corporate. A large proportion, arguably the largest portion, of the major pharmaceutical companies' extraordinary profits in recent decades has come from psychiatric drugs. The medical historian Carl Elliott has written that antidepressants were one of the most profitable products in the most profitable industry in the world over the course of the 1990s.

The industry has made a very significant contribution to the economy with corporate tax payments of over  $\in$ 3 billion annually. The high-value and knowledge-intensive nature of the industry is reflected in the level of exports, which now account for over 40% of total manufacturing exports from Ireland.

<sup>[</sup>online], available:

http://www.ipha.ie/htm/mediacentre/download/pressreleases/InnovationForfasReport.pdf [accessed: 9 February 2009].

were listed in the 'Forbes Global 500'<sup>5</sup>, one of which – Elan – was a pharmaceutical company.

These figures show the deep interconnection between the pharmaceutical industry and the finance and banking industries and helps explain why the development of new pharmaceutical treatments is often reported on the financial pages of newspapers rather than on those dealing with health.

Elan provides an example of the sensitivity of financial markets not only to the results of drug trials, but to the categorisation of individual adverse events occurring during those trials:

The makers of a promising new drug for multiple sclerosis abruptly pulled it off the market Monday after one patient died of a rare central nervous system disorder. Biogen Idec Inc. and Elan Corp. saw massive drops in their share prices and lost nearly \$18 billion in market value combined.<sup>6</sup>

That such extreme financial consequences could be precipitated by the clinical decision to categorise the death of a single patient as being due to the side effects of a drug rather than to some extraneous cause, clearly makes it difficult to prevent the values of the market place from intruding into clinical research. It is self evident that in the presence of such market volatility, the pharmaceutical industry will seek to exercise its influence both on the reporting of clinical trials (the precondition for drug sales) and on the prescribing of the drugs themselves.

### J-2: The uncovering of pharmaceutical company influence

The distortion of psychiatric research by pharmaceutical companies has been revealed principally<sup>7</sup> through litigation [J-2(i)] and the uncovering of previously undisclosed financial links to researchers [J-2(ii)].

#### J-2(i): Drug trial data uncovered during litigation

Of the trial data found to have been withheld, the most relevant to this dissertation concern antidepressants [J-2(i)(a)] and antipsychotics [J-2(i)(b)].

#### J-2(i)(a): Antidepressants

Documentation concerning the negative effects of the antidepressant *Paxil* came to light when the New York State attorney general, Eliot Spitzer, sued<sup>8</sup> the manufacturers

<sup>&</sup>lt;sup>5</sup> Finfacts Ireland (2007). 'R&D Scorecard Global Top 1,000 Companies'. 19 December. [online], available: http://www.finfacts.com/irelandbusinessnews/publish/article\_10003718.shtml [accessed: 9 February 2009].

<sup>&</sup>lt;sup>6</sup> Girion, L. & Gellene, D. (2005). 'Patient's Death Halts New MS Drug.' *Los Angeles Times*. 1 March. '*Tysabri*' was the drug being tested.

<sup>&</sup>lt;sup>7</sup> It has also been revealed by ex-employees and 'whistle-blowers'; see, for example, Fugh-Berman & Melnick (2008) and Kesselheim (2010).

(GlaxoSmithKline) for withholding data concerning its use in the treatment of adolescent depression. At the time Paxil was the second most widely prescribed antidepressant for children.<sup>9</sup>

The data which had been withheld, had shown that the drug had not only failed to confer any benefit over placebo treatment but had lead to an increase in suicidal ideation. The research paper which had originally been published<sup>10</sup> and which had advocated Paxil for the treatment of adolescent depression, had been 'ghostwritten'<sup>11</sup> and the data had been manipulated to give the impression of efficacy.<sup>12</sup>

#### J-2(i)(a): Antipsychotics

The documentation concerning the negative effects of the antipsychotic *Zyprexa* came to light during a civil action claiming that the drug's manufacturers – Lilly – had withheld information about the drugs links to obesity and diabetes.<sup>13</sup> The plaintiffs made the documents publically available in contravention to the order of the court.<sup>14</sup> Lilly who had been threatened with criminal proceedings, offered \$1billion in addition to \$1.2 billion already paid in settlement of 30,000 lawsuits.<sup>15</sup> The case also highlighted the use of 'off-label' marketing.<sup>16</sup>

#### - Antipsychotics prescribed for children

The number of American children and adolescents diagnosed with bipolar disorder increased 40-fold from 1994 to 2003. A report in the *New York Times* stated that:

The children's treatments almost always included medication. About half received antipsychotic drugs like Risperdal from Janssen or Seroquel from Astrazeneca, both developed to treat schizophrenia.

 $\dots$  The spread of the diagnosis is a boon to drug makers,  $\dots^{17}$ 

<sup>&</sup>lt;sup>8</sup> Harris, G. (2004). 'Spitzer Sues a Drug Maker, Saying It Hid Negative Data.' *The New York Times*. 3 June.

<sup>&</sup>lt;sup>9</sup> Friedman (2008).

<sup>&</sup>lt;sup>10</sup> Nine studies on the effectiveness of Paxil had been undertaken but only one had been published. [Keller (2001)].

<sup>&</sup>lt;sup>11</sup> That is it was originally written by the pharmaceutical company and then published under the names of the putative researchers.

<sup>&</sup>lt;sup>12</sup> Friedman (2008); Grohol (2008) provides links to the original documents.

<sup>&</sup>lt;sup>13</sup> See Walsh, M. (2008). 'Judge to Unseal Documents on the Eli Lilly Drug Zyprexa.' *The New York Times.* 5 September.

<sup>&</sup>lt;sup>14</sup> The Court, though giving access to the documents to the plaintiffs' lawyers, held that they were confidential to the pharmaceutical company and had ordered that they be withheld from the public. <sup>15</sup> Berenson, A. (2008a). 'Lilly Considers \$1 Billion Fine to Settle Case.' *The New York Times.* 31 January.

<sup>&</sup>lt;sup>16</sup> *Ibid.* Whereas 'off-label' prescribing by doctors is legal, off-label marketing by pharmaceutical companies is not.

<sup>&</sup>lt;sup>17</sup> Carey. B. (2007). 'Bipolar Illness Soars as a Diagnosis for the Young.' *The New York Times*. 4 September.

Harris (2008a) noted that: "More than a quarter of the prescriptions for Risperdal were for children and adolescents."

Harris, G. (2008a). 'Research Center Tied to Drug Company', The New York Times. 24 November

The health risks associated with the drug are considerable and had been poorly researched.<sup>18</sup>

The increase in the diagnoses of bipolar disorder in children is widely credited<sup>19</sup> to Dr. Joseph Biederman<sup>20</sup> of Harvard University and one of the most influential researchers in child psychiatry.<sup>21</sup> Biederman advocated Risperdal for the treatment of childhood bipolar disorder.

A court case between parents of children harmed by Risperdal and the drug's

manufacturers [Johnson & Johnson] resulted in the release of emails between

Biederman and the manufacturers concerning the financing of a proposed research center:

... with a goal to "move forward the commercial goals of J. & J."... "The rationale of this center," the message stated, "is to generate and disseminate data supporting the use of risperidone in" children and adolescents."<sup>22</sup>

Other emails concerned a study that was to be presented under the name of Biederman,

to the American Academy of Child and Adolescent Psychiatry; Dr. Pandina (a company

executive) wrote to Biederman:

"We have generated a review abstract but I must review this longer abstract before passing this along." One problem with the study, Dr. Pandina wrote, is that the children given placebos and those given Risperdal both improved significantly. "So, if you could," Dr. Pandina added, "please give some thought to how to handle this issue if it occurs."

The draft ... stated that only the children given Risperdal improved, while those given placebos did not.<sup>23</sup>

Commenting on these disclosures a *New York Times* editorial wondered whether Biederman was "... *a paid shill for the drug industry*."<sup>24</sup>

<sup>&</sup>lt;sup>18</sup> Harris (2008b):

From 1993 through the first three months of 2008, 1,207 children given Risperdal suffered serious problems, including 31 who died. Among the deaths was a 9-year-old with attention deficit problems who suffered a fatal stroke 12 days after starting therapy with Risperdal. At least 11 of the deaths were children whose treatment with Risperdal was unapproved by the F.D.A. Panel members said they had for years been concerned about the effects of Risperdal and similar medicines, but F.D.A. officials said no studies had been done to test the drugs' long-term safety.

Harris, G. (2008b) 'Use of Antipsychotics in Children Is Criticized.' *The New York Times*, 18 November. Also see Harris (2008a): "Although many of his studies are small and often financed by drug makers, Dr. Biederman has had a vast influence on the field largely because of his position at one of the most prestigious medical institutions."

<sup>&</sup>lt;sup>19</sup> See, for example, Harris (2008b).

<sup>&</sup>lt;sup>20</sup> The findings of the Senate subcommittee concerning undisclosed pharmaceutical company funding to Biederman is discussed *infra*.

<sup>&</sup>lt;sup>21</sup> Harris, G & Carey, B. (2008). 'Researchers Fail to Reveal Full Drug Pay.' *The New York Times.* 8 June.

<sup>&</sup>lt;sup>22</sup> Harris (2008a).

<sup>&</sup>lt;sup>23</sup> Ibid.

<sup>&</sup>lt;sup>24</sup> New York Times (2008). 'Editorial: Expert or Shill?'. The New York Times. 29 November.

## J-2(ii): Undisclosed financial links between psychiatrists and pharmaceutical companies

The extent of the financial links between psychiatrists and pharmaceutical companies – though long suspected – were uncovered, in the US, by virtue of the passing of the *Physician Payments Sunshine Act*  $(2007)^{25}$  sponsored by Senators Grassley and Kohl. Prior to these developments two states – Minnesota and Vermont – had required disclosure of pharmaceutical company payments to physicians and this provides an alternative source of data. No comparable system of disclosure exists in the UK<sup>26</sup> or Ireland.

Payments fall into two broad categories:<sup>27</sup>

- inducements offered to individual clinicians with a view to influencing their individual prescribing patterns [<u>J-2(ii)(a)</u>];
- payments to academics and researchers which may influence research results [<u>*J*</u>-<u>2(*ii*)(*b*)].</u>

#### *J*-2(*ii*)(*a*): Individual inducements

Although most physicians deny that receiving free lunches, subsidized trips, or other gifts from pharmaceutical companies has any effect on their practices, Campbell (2008) oppugns the validity of such claims, by asking:

After all, if these relationships didn't affect physician behavior in such a way as to increase sales, companies wouldn't spend \$19 billion each year establishing and maintaining them.<sup>28</sup>

In relation to psychiatry, the Senate subcommittee: "… *found an orchard of low-hanging fruit.*"<sup>29</sup> Though psychiatrists earn less in base salary than any other specialists, their total remuneration tops all others when consulting arrangements are taken into account.<sup>30</sup> In Vermont, for example:

<sup>&</sup>lt;sup>25</sup> So named because it aims to "... shine a much needed ray of sunlight on a situation that contributes to the exorbitant cost of health care". [Campbell (2007), p.1796]

<sup>&</sup>lt;sup>26</sup> Where pharmaceutical company payments to doctors have been described as being "... *far from transparent*." [See Boseley, S. & Evans, R. (2008). 'Drug giants accused over doctors' perks'. *The Guardian*. 23 August.].

<sup>&</sup>lt;sup>27</sup> Payment have also been made to patient advocacy groups, see, for example, Harris (2009): Earlier this year, Mr. Grassley sent a similar letter to the National Alliance on Mental Illness. In response, the group told the senator that more than two-thirds of its donations come from the pharmaceutical industry.

Harris, G. (2009). 'Senator Grassley Seeks Financial Details From Medical Groups.' *The New York Times.* 7 December.

<sup>&</sup>lt;sup>28</sup> Campbell (2007), p.1796.

<sup>&</sup>lt;sup>29</sup> Carey, B. & Harris, G. (2008) 'Psychiatric Group Faces Scrutiny Over Drug Industry Ties' *The New York Times.* 12 July.

<sup>&</sup>lt;sup>30</sup> Ibid.

... psychiatrists earn more money from drug makers than doctors in any other specialty. ... the more psychiatrists have earned from drug makers, the more they have prescribed a new class of powerful medicines known as atypical antipsychotics to children, for whom the drugs are especially risky and mostly unapproved.<sup>31</sup>

An analysis of data from Minnesota yielded similar conclusions.<sup>32</sup> An indicator of the amount of money involved can be gleaned from the fact that "... *more than 250 Minnesota psychiatrists together earned \$6.7 million in drug company money* — *more than any other specialty.*"<sup>33</sup> and from payments to a psychiatrist member of a Minnesota Drug Formulary Committee who had earned more than \$350,000 from Eli Lilly and AstraZeneca between 2004 and 2006 in honoraria, speaker's and consulting fees,<sup>34</sup> though he denied that his clinical decisions had been influenced.<sup>35</sup>

In assessing the effect of such undeclared payments, an analogy might be provided by considering the case of a judge, who having decided a court case, was found to have received payments from an interested party. An appropriate rule in such situations, is to the effect that even where there is an absence of direct evidence that gifts influenced a decision, the fact that a gift is undeclared is sufficient to 'shift the burden of proof' and to warrant the conclusion that verdicts are to be regarded as tainted unless the contrary be clearly proved.<sup>36</sup>

The application of such a rule to undeclared pharmaceutical contributions to clinical and research psychiatrists would imply that all such contributions should be regarded as tainting any research or other decision unless and until the contrary be proved.

#### J-2(ii)(b): Financial links to academics and researchers

The Senate subcommittee investigations proceeded by way of obtaining details from the pharmaceutical companies, as to their payments to individual psychiatrists and then comparing this data with the declarations of funding made by the psychiatrists themselves either to their universities or to academic journals when submitting articles for publication; two examples are given:

- Dr. Biederman (supra) a psychiatrist at Harvard University;

<sup>&</sup>lt;sup>31</sup> Harris, G. (2007). 'Psychiatrists Top List in Drug Maker Gifts.' *The New York Times*. 27 June. <sup>32</sup> *Ibid*.

<sup>&</sup>lt;sup>33</sup> Harris, G. & Roberts, J. (2007). 'Doctors' Ties to Drug Makers Are Put on Close View.' *The New York Times.* 21 March.

 <sup>&</sup>lt;sup>34</sup> Lohn, M. (2007). 'Minn. Law Sheds Light on Drug Companies.' *The Washington Post*. 21 August.
 <sup>35</sup> Yet, as noted by Lohn, (2007): "*The top drugs for Minnesota Medicaid patients covered by the panel's advice in recent years have been schizophrenia treatments from Eli Lilly & Co. and AstraZeneca ...*"
 <sup>36</sup> See, for example, Urbina, I. & Hamill, S. (2009). 'Judges Plead Guilty in Scheme to Jail Youths for Profit.' *The New York Times*. 12 February.

- Dr. Nemeroff, a psychiatrist at Emory University.

A further example concerns undeclared payments to a prominent media psychiatrist (Dr. Goodwin) and the final example details financial links between the pharmaceutical industry and the American Psychiatric Association.

- Biederman<sup>37</sup>

Since the mid 1990s Biederman (*supra*) promoted the aggressive diagnosis of childhood bipolar disorder and advocated the use of antipsychotics in its treatment. In 2008, Senator Grassley reported that:

Biederman, a renowned child psychiatrist at Harvard Medical School, and a colleague ... had reported to university officials earning several hundred thousand dollars each in consulting fees from drug makers from 2000 to 2007, when in fact they had earned at least \$1.6 million each. ... Another member of the Harvard group ... reported earning at least \$1 million after being pressed by Mr. Grassley's investigators.<sup>38</sup>

- <u>Nemeroff</u>

Nemeroff who has been described as "*one of the nation's most influential research psychiatrists*",<sup>39</sup> was editor of *Neuropsychopharmacology* which had printed a review of a device for the treatment for depression<sup>40</sup> but had omitted to reveal the financial ties of the reviewer – and of the editor – to the company (Cyberonics) marketing the device. Because the device's licensing by the FDA had been controversial:<sup>41</sup>

<sup>&</sup>lt;sup>37</sup> See the earlier discussion on documents released during litigation which evidenced the nature of the relationship between Biederman and the makers of an antipsychotic drug used in the treatment of childhood bipolar disorder.

<sup>&</sup>lt;sup>38</sup> Carey & Harris (2008) supra.

<sup>&</sup>lt;sup>39</sup> Carey, B. (2006). 'Correcting the Errors of Disclosure.' The New York Times. 25 July.

<sup>&</sup>lt;sup>40</sup> The '*vagus nerve stimulator*' is a device surgically implanted in the upper chest which stimulates a nerve leading to the brain.

<sup>&</sup>lt;sup>41</sup> Carey (2006):

The treatment ... was approved for depression in 2005 after intense debate over its effectiveness. ... In a bitter debate over the interpretation of these results, more than 20 experts at the Food and Drug Administration opposed the approval of the device for depression before being overruled by a senior official, according to a Senate Finance Committee investigation.

Even though the vagus nerve stimulator had been shown to be no more effective than a placebo as a treatment for depression, its proponents had urged that it should be licensed as a treatment for patients whose depression had previously proved intractable. An advisory panel having heard testimonials from a number of patients, approved the device; its chairwoman Dr. Kyra Becker stated *"The feeling was that anything that gives these people hope is potentially worthwhile."* 

<sup>[</sup>Carey, B. (2005) 'F.D.A. Considers Implant Device for Depression.' *The New York Times.* 21 May.]. A later report gives an indication of the magnitude of the financial interests involved:

<sup>...</sup> more than 550 Americans have undergone surgery to have a vagus nerve stimulator (VNS) implanted ... Another 7,000 people ... are seeking approval from their insurance companies for the \$25,000 operation. More than 3,700 psychiatrists ... have been trained in the use of VNS, ....

<sup>[</sup>Boodman S. (2006). 'Mood Machine: Now There's a Device to Treat Depression. If Only There Were Solid Evidence That It Works'. *Washington Post*, 21 March.]

The device begged for some more public analysis. But few if any outside experts knew the data well enough to raise questions. And the scientists who did know the science and the data were all on the company's payroll.<sup>42</sup>

The publication of the review was criticised by Emory University, its associate dean

stating: "I can't believe that anyone in the public or in academia would believe anything except that this paper was a piece of paid marketing."<sup>43</sup>

Letters written by Nemeroff to the university which surfaced during congressional

hearings shows that the university itself was not a disinterested party:

"Surely you remember that Smith-Kline Beecham Pharmaceuticals donated an endowed chair to the department and that there is some reasonable likelihood that Janssen Pharmaceuticals will do so as well," he wrote. "In addition, Wyeth-Ayerst Pharmaceuticals has funded [an] ... Award program in the department, and I have asked both AstraZeneca Pharmaceuticals and Bristol-Meyers [sic] Squibb to do the same."<sup>44</sup>

In 2008, Senator Grassley revealed that Nemeroff:

... earned more than \$2.8 million in consulting arrangements with drugmakers from 2000 to 2007, failed to report at least \$1.2 million of that income to his university and violated federal research rules.<sup>45</sup>

- <u>Goodwin</u>

Dr. Goodwin, a psychiatrist who had written an influential textbook on bipolar disorder

and was an adjunct professor at George Washington University, had hosted a

prestigious US National Public Radio programme<sup>46</sup> which had:

... more than one million listeners in more than 300 radio markets. The program has received major underwriting from the National Institutes of Health and the National Science Foundation ...<sup>47</sup>

Goodwin had earned at least \$1.3 million from 2000 to 2007 giving marketing lectures

for drugmakers, income not mentioned on the program, nor declared to his employers.<sup>48</sup>

His weekly radio programs had often touched on subjects important to the commercial

interests of the companies for which he consulted:

... he warned that children with bipolar disorder who were left untreated could suffer brain damage, a controversial view. "*But as we'll be hearing today*," Dr.

<sup>&</sup>lt;sup>42</sup> Carey (2006) *supra*.

<sup>&</sup>lt;sup>43</sup> Harris, G. (2008c). 'Top Psychiatrist Didn't Report Drug Makers' Pay.' *The New York Times*. 3 October.

<sup>&</sup>lt;sup>44</sup> Ibid.

<sup>&</sup>lt;sup>45</sup> Harris, G. (2008d). 'Drugmakers Paid Radio Host \$1.3 Million for Lectures.' *The New York Times*. 22 November.

<sup>&</sup>lt;sup>46</sup> Harris (2008d): "The Infinite Mind" has won more than 60 journalism awards over 10 years and bills itself as "public radio's most honored and listened to health and science program."
<sup>47</sup> Ibid.

<sup>&</sup>lt;sup>48</sup> *Ibid*: "The fact that he was out on the stump for pharmaceutical companies was not something we were aware of, ... It would have violated our agreements."

Goodwin told his audience, "modern treatments – mood stabilizers in particular – have been proven both safe and effective in bipolar children." That same day, GlaxoSmithKline paid Dr. Goodwin \$2,500 to give a promotional lecture for its mood stabilizer drug, Lamictal, ... In all, GlaxoSmithKline paid him more than \$329,000 that year for promoting Lamictal, records given to Congressional investigators show.<sup>49</sup>

#### - The American Psychiatric Association (APA)

The APA, in response to a request<sup>50</sup> from Senator Grassley's subcommittee, reported that pharmaceutical companies provided about 30% of its \$62.5 million in revenues in 2006, the most recent year for which financial data were available.<sup>51</sup> The APA is the publisher of the Diagnostic and Statistical Manual of Mental Disorders (the 'DSM') which is currently in its fourth edition with the fifth edition in the consultative stage.<sup>52</sup> The proposal of new categories of illness – e.g. 'hypersexuality', 'binge eating' – are clearly of interest to the pharmaceutical industry in that the treatment of such proposed categories may provide an additional use for an existing or planned pharmaceutical product; the term 'disease mongering' has been coined to describe the proactive role taken by pharmaceutical companies in the creation of diseases for which they anticipate being able to provide treatment.<sup>53</sup> In such circumstances, it is self-evident that the influence of the pharmaceutical companies on the consultative panels needs to be minimised<sup>54</sup> and to that end the psychiatrists working on such panels "agreed to limit their income from drug makers and other sources to \$10,000 a year for the duration of the job."<sup>55</sup> In view of the magnitude of the financial interests involved, this appears to be a less than onerous burden.

<sup>&</sup>lt;sup>49</sup> Ibid.

<sup>&</sup>lt;sup>50</sup> The request stated: "I have come to understand that money from the pharmaceutical industry can shape the practices of nonprofit organizations that purport to be independent ..." [Carey & Harris (2008) supra].

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<sup>&</sup>lt;sup>51</sup> *Ibid.* 

 $<sup>52^{52}</sup>$  See the discussion on the *DSM-V* [draft] in Chapter 4.

<sup>&</sup>lt;sup>53</sup> See, for example, Moynihan (2002) and Kumar (2006).

<sup>&</sup>lt;sup>54</sup> See, for example, *New York Times* editorial:

The pharmaceutical industry, in particular, doles out lots of money to doctors and academic experts in the form of speaking fees, consultancies, research grants and other financial benefits. And many of these recipients end up on federal advisory committees.

<sup>...</sup> In one egregious example, a panel that favored marketing the controversial painkillers Bextra and Vioxx would have made the opposite recommendation if the experts with industry ties had been excluded from voting.

The New York Times (2007) 'Editorial: A Cleaner Food and Drug Agency.' The New York Times. 23 March

<sup>&</sup>lt;sup>55</sup> Carey, B. (2008). 'Psychiatrists Revise the Book of Human Troubles.' *The New York Times*. 17 December.

Cosgrove (2006), noting that no earlier study had been made of the financial links between pharmaceutical companies and advisory panel members, examined the

financial links of panel members involved in the DSM-IV process and concluded that:

The connections are especially strong in those diagnostic areas where drugs are the first line of treatment for mental disorders. ... 100% of the members of the panels on 'Mood Disorders' and 'Schizophrenia and Other Psychotic Disorders' had financial ties to drug companies.<sup>56</sup>

It was not within the ambit of the study to determine whether these interests had been declared nor whether they had constituted a conflict of interest.

## *J-3:* The pervasiveness of pharmaceutical industry influence on medical research.

Lest it be imagined that the above examples were unrepresentative, editorials from leading medical journals also attest to the corrosive influence of the pharmaceutical industry on both medical research and its reporting: a *Journal of the American Medical Association* editorial is quoted in <u>J-3(i)</u>; a *New England Journal of Medicine*, in <u>J-3(ii)</u>; a *British Medical Journal <u>J-3(ii)</u>* and an *American Journal of Psychiatry, in <u>J-3(iv)</u>.* 

#### J-3(i): Journal of the American Medical Association

An editorial entitled "Impugning the Integrity of Medical Science: The Adverse Effects of Industry Influence" began:

The profession of medicine, in every aspect – clinical, education, and research – has been inundated with profound influence from the pharmaceutical and medical device industries. This has occurred because physicians have allowed it to happen, and it is time to stop.<sup>57</sup>

The editorial then discussed two articles published in that issue of the journal which detailed how in the marketing of its drug Vioxx, the manufacturers (Merck), in submissions to the FDA, misrepresented the mortality risk of the drug;<sup>58</sup> and how it "... *apparently manipulated dozens of publications to promote one of its products.*"<sup>59</sup> One of the articles illustrated how clinical trial articles and review articles had been 'ghost–written' and their authorship attributed: "... *to academically affiliated investigators who either had little to do with the study or review or who did not disclose financial support from the company.*"<sup>60</sup> The editorial clearly regards Merck's behaviour as not being

<sup>&</sup>lt;sup>56</sup> Cosgrove (2006), p.154.

<sup>&</sup>lt;sup>57</sup> DeAngelis & Fontanarosa (2008), p.1833.

<sup>&</sup>lt;sup>58</sup> Ibid.

<sup>&</sup>lt;sup>59</sup> Ibid.

<sup>60</sup> Ibid.

unusual: "But make no mistake – the manipulation of study results, authors, editors, and reviewers is not the sole purview of one company."<sup>61</sup>

#### J-3(ii): The New England Journal of Medicine

An editorial entitled "*Is Academic Medicine for Sale?*" recounts how the journal wished to commission an editorialist to review an article on antidepressants, but found very few who did not have a possible conflict of interest:

The ties between clinical researchers and industry include not only grant support, but also a host of other financial arrangements. Researchers serve as consultants to companies whose products they are studying, join advisory boards ... agree to be the listed authors of articles ghostwritten by interested companies, promote drugs and devices at company–sponsored symposiums, and allow themselves to be plied with expensive gifts and trips to luxurious settings. Many also have equity interest in the companies.<sup>62</sup>

The editorial went on to note that academic medical institutions are also compromised.

#### J-3(iii): British Medical Journal (BMJ)

The *BMJ* dedicated a full issue<sup>63</sup> to the topic of pharmaceutical industry influence with an editorial asking:

How did we reach the point where doctors expect their information, research, education, professional organisations, and attendance at conferences to be underwritten by drug companies?<sup>64</sup>

In support, it referred to research which found that "... studies sponsored by

pharmaceutical companies are four times as likely to have outcomes favouring the sponsor than are studies funded by other sources".<sup>65</sup>

A 2005 editorial revisited the same issues and referred to a House of Commons report<sup>66</sup>

on the influence of the pharmaceutical industry, which:

... found an industry that buys influence over doctors, charities, patient groups, journalists, and politicians, and whose regulation is sometimes weak or ambiguous. ... Over half of all postgraduate medical education in the UK, and

<sup>&</sup>lt;sup>61</sup> Ibid.

See also: Associated Press (2006). 'Medical Journal Says It Was Again Misled'. *The New York Times*. 13 July:

For the second time in two months, The *Journal of the American Medical Association* says it was misled by researchers who failed to reveal financial ties to drug companies. ... The latest incident ... involves a study showing that pregnant women who stop taking antidepressants risk slipping back into depression. Most of the 13 authors have financial ties to drug companies including antidepressant makers, but only two of them revealed their ties when the study was published in February. Antidepressant use during pregnancy is controversial, and some studies have suggested that the drugs could pose risks to the fetus.

<sup>&</sup>lt;sup>62</sup> Angell (2000), p.1516.

<sup>&</sup>lt;sup>63</sup> British Medical Journal (2003); 326: 7400, entitled "Time to untangle doctors from drug companies."

<sup>&</sup>lt;sup>64</sup> Abbasi & Smith (2003).

<sup>&</sup>lt;sup>65</sup> *Ibid.*, citing Lexchin (2003).

<sup>&</sup>lt;sup>66</sup> House of Commons Health Committee (2005).

much education of nurses, is funded by the pharmaceutical industry from its annual marketing budget of  $\pounds 1.65$  bn.<sup>67</sup>

The conclusions of the House of Commons report were mirrored those of an Oireachtas Joint Committee on Health and Children (2007) which also made some trenchant criticism of the pharmaceutical industry especially in relation to psychiatric drugs.<sup>68</sup>

#### J-3(iv): The American Journal of Psychiatry (AJP)

Although the *AJP* has published editorials<sup>69</sup> on conflicts of interest, which noted failures in relation to academic psychiatry, these were – in contrast to the journals discussed above – essentially aspirational in tenor and curiously reticent about other possible examples of misconduct of which there appeared to be no shortage in academic and research psychiatry: for example, a study<sup>70</sup> which had been published in the journal but a year earlier and which was "*one of the first recent examinations of conflict of interest specifically in the psychiatric literature*"<sup>71</sup> had found:

<u>*Results*</u>: Among 397 clinical trials identified, ...60% reported receiving funding from a pharmaceutical company ... and ... 47% included at least one author with a reported financial conflict of interest.

... those that reported conflict of interest were 4.9 times more likely to report positive results;

<u>*Conclusions*</u>: Author conflict of interest appears to be prevalent among psychiatric clinical trials and to be associated with a greater likelihood of reporting a drug to be superior to placebo.<sup>72</sup>

The reticence of the AJP stands in stark contrast to the observations of Tim Kendall,

deputy director of the Royal College of Psychiatrists' Research Unit:

In mental health 85% of all published trials are funded by the drug industry, ... Allowing for the unsuccessful trials the industry does not publish, the figure is probably nearer 95%.<sup>73</sup>

The above discussion related to the influence of the pharmaceutical industry on researchers and academics, but it has also been suggested that both academic journals themselves<sup>74</sup> and the FDA<sup>75</sup> have also been compromised.

<sup>&</sup>lt;sup>67</sup> Ferner (2005).

<sup>&</sup>lt;sup>68</sup> See Appendix I (*supra*).

<sup>&</sup>lt;sup>69</sup> For example, Lewis (2006) and Freedman (2006).

<sup>&</sup>lt;sup>70</sup> Perlis (2005).

<sup>&</sup>lt;sup>71</sup> *Ibid.*, p.1959.

<sup>&</sup>lt;sup>72</sup> *Op. cit.*, p.1957.

<sup>&</sup>lt;sup>73</sup> Quoted in Boseley, S. (2009). 'British doctor faces action over claims of 'ghost writing' for US drug company.' *The Guardian*. 18 September.

<sup>&</sup>lt;sup>74</sup> See Smith (2006); Smith, who was a former editor of the *British Medical Journal*, relates how the *New England Journal of Medicine* was compromised in its reporting of both the original Vioxx study and subsequent evidence that the original Vioxx data had been incomplete. He details how the owners of the journal had "… grown fat on the profits and is keen not only to keep the profits coming but also to exploit

### J-4: Summary of methods used to exert influence

Listed below is a summary of some of the mechanisms – many of which have been mentioned in earlier discussion – which have been used by the pharmaceutical industry to exert influence on both psychiatric research and academic and clinical psychiatry:

- design of drug tests;
- commissioning of drug tests;
- selective reporting of results of drug tests;
- 'targeting' of academic critics;<sup>76</sup>
- non-performance of follow-on tests;<sup>77</sup>
- non-proactive monitoring of side-effects;
- ghostwriting of journals articles;<sup>78</sup>
- influence of academic journals;<sup>79</sup>
- influence on diagnostic editorial committees;
- 'disease mongering';
- publication bias;
- influence on academics;

the brand." which lead to conflicts with two editors who resigned and subsequently "published books bemoaning the excessive influence of the drug industry".

<sup>75</sup> A report issued by the Institute of Medicine on the FDA stated:

"Some also have serious concerns that the regulator has been 'captured' by industry it regulates, that the agency is less willing to use the regulatory authority at its disposal," the report said, criticizing the agency's regulatory tools as "all-or-nothing."

See Harris, G. (2006). 'Study Condemns F.D.A.'s Handling of Drug Safety'. *The New York Times*. 23 September.

See also Shuchman (2007) who details the controversy surrounding the licensing by the FDA of the vagus nerve stimulator (*supra*).

<sup>76</sup> Marks & Verkaik (2010):

Merck also drew up a "hit list" of doctors and academics who needed to be "neutralised" or "discredited", according to company emails, because they had criticised the drug. It paid nurses to rifle patient records for potential candidates for Vioxx, and it persuaded the world's largest medical publisher, Elsevier, to produce several issues of what appeared to be an independent scientific journal, without disclosing that it was funded by Merck.

Marks K. & Verkaik, R. (2010). 'Vioxx ruling gives hope for payouts to British 'victims''. *The Independent*. 6 March.

 $^{77}$  *I.e.* further tests which had been requested by the regulator at the time of approval but which were never completed. See, for example, Perrone (2009):

The Food and Drug Administration ... has never pulled a drug off the market due to a lack of required follow-up about its actual benefits – even when such information is more than a decade overdue, according to a report due out Monday from the Government Accountability Office.

Perrone, M. (2009). 'GAO: FDA fails to follow up on unproven drugs.' *The Washington Times*. 26 October.

<sup>78</sup> See *supra* and also, for example, Boseley (2009):

The General Medical Council will call Professor Richard Eastell in front of a fitness to practice committee. Eastell, a bone expert at Sheffield University, has admitted he allowed his name to go forward as first author of a study on an osteoporosis drug even though he did not have access to all the data on which the study's conclusions were based. An employee of Proctor and Gamble, the US company making Actonel, was the only author who had all the figures.

<sup>79</sup> See, for example, Marks & Verkaik (2010) (*supra*).

- influence on academic institutions;
- sponsorship of undergraduate and postgraduate psychiatric education;
- influence on drug regulators;
- influence on formulary committees;
- influence on clinical psychiatrists;
- payments to clinical psychiatrists;<sup>80</sup>
- off-label promotion;<sup>81</sup>
- sponsorship of professional meetings;
- funding of patient advocacy groups;
- media consumer advertising;
- 'gag-orders' against disclosure;<sup>82</sup>
- other exercise of economic power.

Harris, G. (2009). 'Document Details Plan to Promote Costly Drug.' *The New York Times*. 1 September. A *New York Times* report details how a pharmaceutical company was fined \$81 million for illegally promoting an epilepsy drug for psychiatric uses:

<sup>&</sup>lt;sup>80</sup> Harris (2009) details a pharmaceutical company's antidepressant drug marketing plan which had been made public during Senate subcommittee investigations:

It is illegal to pay doctors to prescribe certain medicines to their patients. It is not illegal to pay doctors to educate their colleagues about a medicine. In recent years, federal prosecutors have accused many drug makers of deliberately crossing that line. ... Under "*Rep Promotional Programs*," the document said the company planned to spend \$34.7 million to pay 2,000 psychiatrists and primary care doctors to deliver 15,000 marketing lectures to their peers in one year. "*These meetings may be large-scale dinner programs with a slide presentation, small roundtable discussions or one-on-one advocate lunches*," the document states. ... Under "*Lunch and Learns*," the company intended to spend \$36 million providing lunch to doctors in their offices.

<sup>...</sup> under a program called Doctor-for-a-Day. The program hired outside physicians who joined sales representatives in visits to health care providers ... about prescribing Topamax for unapproved uses.

Associated Press (2010), 'Drug Makers to Pay Fine of \$81 Million.' *The New York Times*. 29 April. <sup>81</sup> The extent of the profits to be gained from off-label promotion are indicated by the fact that fines of

<sup>\$1.9</sup>billion levied of Pfizer were still not a sufficient deterrence: For this new felony, Pfizer paid the largest criminal fine in U.S. history: \$1.19 billion. On the same day, it paid \$1 billion to settle civil cases involving the off-label promotion of Bextra and three other drugs with the United States and 49 states. "At the very same time Pfizer was in our office negotiating and resolving the allegations of criminal conduct in 2004, Pfizer was itself in its other operations violating those very same laws," ...

The total of \$2.75 billion Pfizer has paid in off-label penalties since 2004 is a little more than 1% of the company's revenue of \$245 billion from 2004 to 2008.

Evans, D. (2010). 'When drug makers' profits outweigh penalties.' *The Washington Post*. 21 March. <sup>82</sup> Hari (2009):

In 1996, Dr. Nancy Olivieri was commissioned at her university to study a drug developed by Apotex Inc that treats a rare blood disorder. She discovered a serious side-effect. When she tried to inform her patients, the company brought the study to a sudden halt, and told Dr Olivieri that she could be sued.

Hari, J. (2009). 'Peter Mandelson's assault on science.' The Independent. 17 November.

Based on the preceding discussion the following conclusion can be drawn:

The influence of the pharmaceutical industry on the nature, conduct and reporting of psychiatric research is pervasive, often hidden, and is of such a magnitude as to cast doubt on the impartiality, objectivity and evidence base of much published research. Consequently individual psychiatric research studies on matters touching on the interests of the pharmaceutical industry and which purport to be objective and evidence-based, should not be regarded as such unless their independence from such interests, can be explicitly demonstrated.

# Appendix K: Problematic aspects of antidepressant research

<u>Note</u>: As mentioned at the commencement of Chapter 5, the discussion of psychiatric treatments in this Appendix is not intended to provide a comprehensive, objective and balanced overview of research into antidepressants. The goal is much more circumscribed: it is – by examining the published work of academic commentators and researchers in this area – to establish a *prima facie* case that clinical psychiatric practice in the use of antidepressants, often lacks (and, on occasion, conflicts with) a robust evidence-base.

Doubts as to the validity of clinical trials of antidepressants had, by the late 1990s,

become prevalent and led the American Journal of Psychiatry to commission a study

[Quitkin (2000)] to examine the evidence cited for assertions that:

... antidepressants are no better than placebo treatment and that their illusory superiority depends on methodologically flawed studies and biased clinical evaluations.

... that the blind in randomized trials is penetrable.<sup>1</sup>

The authors concluded that:

 $\dots$  studies cited as supporting the questionable validity of antidepressant trials fail upon closer examination to support assertions that these trials are invalid.<sup>2</sup>

A subsequent editorial in the British Journal of Psychiatry adopted a more nuanced

perspective:

Adverse physical effects of antidepressant treatment are well known, but the psychological effects are rarely discussed. The prescription of medication for depression conveys the powerful message that we are passive victims of our biology. ... The pharmaceutical industry is an obvious beneficiary of this situation and psychiatry must be wary of being swept along by this juggernaut. ... it is necessary at least to raise questions about the efficacy of antidepressants.<sup>3</sup>

A response was subsequently published which stated:

The efficacy argument at the head of her critique, based on individual, often old and poor-quality, studies flies in the face of consistent findings of antidepressant efficacy in systematic reviews and meta-analyses.<sup>4</sup>

Some clarity and focus was brought to the debate by Kirsch (2002) who under a

'Freedom of Information' request, obtained :

... the medical and statistical reviews of every placebo controlled clinical trial for depression reported to the FDA for initial approval of the six most widely used antidepressant drugs approved [between 1987 and 1999].

<sup>&</sup>lt;sup>1</sup> *Op. cit.*, p.327.

<sup>&</sup>lt;sup>2</sup> Quitkin (2000), p.327.

Quitkin appends no declaration of interests to his article, yet in a subsequent letter to the *British Medical Journal* [Quitkin (2005)] he declares numerous competing interests. These interests may, of course, have arisen post 2000.

<sup>&</sup>lt;sup>3</sup> Moncrieff (2002), p.194.

<sup>&</sup>lt;sup>4</sup> Anderson & Haddad (2003).

An analysis of the data revealed:

 $\dots$  a small but significant difference between antidepressant drug and inert placebo.  $\dots$  its clinical significance is dubious  $\dots^5$ 

Kirsch (2002) also noted that the criteria used by the FDA in approving antidepressant medications required "*positive findings from at least two controlled clinical trials, but the total number of trials can vary.*"<sup>6</sup> The implementation of this criterion had the surprising consequence that if two positive trials existed, other negative trials may be disregarded even if these had been more numerous.<sup>7</sup>

Antonuccio (2002), commenting on Kirsch (2002), posed a rhetorical question:

Does the small advantage of antidepressants over placebo justify the risks and side effects associated with these medications? How have we come to think of antidepressants as powerful, even "*life-saving*" treatments in the face of such weak outcome data?

The title to his article – "Antidepressants: A Triumph of Marketing Over Science?" – suggested his answer.<sup>8</sup>

Evidence subsequently began to emerge not only as to the lack of effectiveness of antidepressants, but as to their lack of safety. Parker (2003) opined that the then recent warnings that the dangers of treatment of adolescent depression with SSRI's<sup>9</sup> outweighed the benefits, "… should focus our minds on the evidence on which clinical practice is based." Noting that "about 50% of negative trials go unpublished," Parker (2003) wondered whether such clinical trials should be abandoned because they "are producing meaningless results." In view of studies such as Quitkin (2000) (*supra*), the simple posing of this question is worthy of note.

A further milestone occurred with the publication of Whittington (2004). Having noted inconsistencies between the published studies and the advice of regulatory agencies in relation to the use of SSRIs in the treatment of adolescent depression, Whittington (2004): "... contacted all the pharmaceutical companies who manufacture antidepressants requesting unpublished data. None was forthcoming."<sup>10</sup> The authors then obtained details of the trials which had been submitted to the regulatory agencies.

<sup>&</sup>lt;sup>5</sup> Kirsch (2002); the first usage of the term 'significant' refers to statistical significance.

<sup>&</sup>lt;sup>6</sup> Ibid.

<sup>&</sup>lt;sup>7</sup> Kirsch (2002) gives examples of such occurrences.

<sup>&</sup>lt;sup>8</sup> It should be noted that the Kirsch (2002) meta-analysis has been criticized on methodological grounds by Cipriani (2009) and that other meta-analyses – such as Melander (2008) and Khan & Khan (2008) – have reached conclusions different to Kirsch (2002).

 <sup>&</sup>lt;sup>9</sup> Selective Serotonin Reuptake Inhibitors [SSRIs] are antidepressants; examples are *Seroxat* and *Paxil*.
 <sup>10</sup> Op. cit., p.1345.

The authors concluded that, though the published studies indicated that the medications were safe and effective: "When we got the unpublished data and put it in with the published data, something happened. Instead of being safe and effective, the risk-benefit reversed."<sup>11</sup> An accompanying editorial commented:

The idea of that drug's use being based on the selective reporting of favourable research should be unimaginable. ... where evidence-based practice is seen as the gold standard for care, these failings are a disaster. ... This process is made entirely redundant if its results are so easily manipulated by those with potentially massive financial gains.<sup>12</sup>

The philosopher Simon Blackburn has spoken of how the pharmaceutical industry has

"... led to the institutional corruption of science by the billions involved in the

manufacture and selling of drugs."<sup>13</sup> In support, he cited the questioning of the FDA by

a US congressional sub-committee:

... who pointed out that nearly all studies of antidepressants in children and teenagers had failed to show that they were effective for depression. With no benefit to recommend them and a risk for suicidal behaviour the members said that they could not understand why the agency did not ban the drugs.<sup>14</sup>

The director of the FDA had responded:

... that just because the trials had failed to show an effect did not mean that the medications were not working. "*More than 50% of all trials in adults fail too*" he said. "*We don't know why*".<sup>15</sup>

To which Blackburn commented "I find that pretty scary as well."<sup>16</sup>

The focus was beginning to shift towards a scrutiny of the evidence base for the adult use of antidepressants.

<sup>12</sup> Lancet (2004) which commented:

<sup>&</sup>lt;sup>11</sup> Kendall, joint author of Whittington (2004) in an interview to the *New Scientist*. [online], available: http://www.newscientist.com/article/dn4920-unpublished-data-reverses-riskbenefit-of-drugs.html [accessed: 2 March 2009].

He also stated that:

Of the five SSRIs reviewed - fluoxetine, paroxetine, sertraline, citalopram, and venlafaxine, only fluoxetine (Prozac) offers more benefits than risks in children. Unpublished studies of venlafaxine, for example, suggested the drug increased suicide-related events such as suicidal thoughts or attempts by 14 times compared with placebo.

<sup>&</sup>quot;This data confirms what we found in adults with mild to moderate depression: SSRIs are no better than placebo, and there is no point in using something that increases the risk of suicide," says Kendall. "The key point is, can we trust the published evidence now?"

It is hard to imagine the anguish experienced by the parents, relatives, and friends of a child who has taken his or her own life. That such an event could be precipitated by a supposedly beneficial drug is a catastrophe.

<sup>&</sup>lt;sup>13</sup> Blackburn, S. (2004). Lecture entitled '*Trust me I'm a Scientist*' given to a Cambridge Philosophy Society on 23 September.

<sup>&</sup>lt;sup>14</sup> Harris, G. (2004). 'Warnings Called Likely On Drug Risk For Suicide.' *The New York Times*. 24 September.

<sup>&</sup>lt;sup>15</sup> *Îbid*.

<sup>&</sup>lt;sup>16</sup> *Op. cit.* 

In 2004 the National Institute for Clinical Excellence issued guidelines [NICE (2004a)] on the pharmaceutical treatment of adult depression and recommended that SSRIs be "first line treatment for moderate or severe depression."<sup>17</sup>

Moncrieff & Kirsch (2005) argued that the data on which the guidelines had been based, did not support the recommendation:

... methodological artefacts may account for the small effect seen. ... In children, the balance of benefits to risks is now recognised as unfavourable. We suggest this may also be the case for adults, given the continuing uncertainty about the possible risk of increased suicidality as well as other known adverse effects.<sup>18</sup>

The House of Commons Health Committee (2005) addressed the use of SSRIs as a treatment for adult depression; it found that – although there had been long-standing concerns that the drugs were addictive<sup>19</sup> and could induce "*suicidal and violent behaviour*"<sup>20</sup> – the clinical trials of SSRIs "... <u>were not adequately scrutinised</u> ... [and] <u>have been indiscriminately prescribed on a grand scale</u>."<sup>21</sup> The report stated that although SSRIs, had been licensed for 15 years and in spite of several earlier reviews of the same drug problems, the UK regulatory agency "*had received no convincing evidence*" relating to efficiency in mild depression nor or the incidence of withdrawal reactions.<sup>22</sup>

The poor reliability of published research into the efficacy of antidepressants was address by Turner  $(2008)^{23}$  who found that although an analysis of published data suggested that 94% of the trials conducted were positive, the inclusion of unpublished data, reduced this to 51%.

The Kirsch (2008) study was a meta-analysis of four new-generation antidepressants for which full datasets were available and found that:

<sup>&</sup>lt;sup>17</sup> Moncrieff & Kirsch (2005), p.155.

<sup>&</sup>lt;sup>18</sup> *Op. cit.*, p.157.

<sup>&</sup>lt;sup>19</sup> Op. cit., p.85: "...some users found it impossible to stop taking SSRIs because of severe withdrawal symptoms."

<sup>&</sup>lt;sup>20</sup> Ibid.

<sup>&</sup>lt;sup>21</sup> *Ibid.*, p.100. [Emphasis in original].

<sup>&</sup>lt;sup>22</sup> *Ibid.*, p.79.

The report quoted (p.83) evidence from Professor Healy that "In actual fact here in the UK we track the fate of parcels through the post one hundred times more accurately than you track the fate of people who have been killed by SSRI or other drugs."

It also quoted (p. 54) the evidence the editor of *The Lancet*:

<sup>...</sup> this whole story surrounding SSRIs ... is probably the best example where the companies have been very clever at seeding the literature with ghost-written editorials and review papers that promote off-label use of these drugs ... that is how you had two and a half million scripts a couple of years ago for SSRIs in under-18s with no licensed indication for it.

<sup>&</sup>lt;sup>23</sup> Appendix J supra.

 $\dots$  the researchers conclude that there is little reason to prescribe new-generation antidepressant medications to any but the most severely depressed patients unless alternative treatments have been ineffective.<sup>24</sup>

Mathew & Charney (2009) writing in the American Journal of Psychiatry, addressed

Kirsch's (2008) and Turner's (2008) conclusions:

The first study contends that publication bias ... results in an inaccurate characterization of antidepressant efficacy, while the second study argues that even when registration trials are positive, antidepressant efficacy is modest and of doubtful clinical significance. Although these reports offer a sober perspective on the benefit of our most commonly prescribed antidepressant medications, the trials suffer from poor generalizability to "real-world" patients.<sup>25</sup>

Mathew & Charney (2009) then discussed the results of the STAR\*D trial which had

been designed to have more clinical relevance than trials designed to satisfy the

requirements of licensing authorities:

... the landmark NIMH-funded STAR\*D trial examined the acute and longer-term effectiveness of antidepressants and augmentation strategies (including cognitive therapy) ... Although the acute and longer-term remission rates were disappointing, patients who completed all phases of the study had an overall cumulative remission rate of 67%.<sup>26</sup>

A summary of the results of the STAR\*D trial in *The Lancet* was more critical:

"STAR\*D showed that virtually all antidepressant strategies had low and similar

efficacy in major depression."<sup>27</sup> Cipriani (2009) [discussed supra] reviewed all trials of

second-generation antidepressants performed before 2007 and rated them as "...

adequate, unclear, or inadequate, according to the adequacy of the random allocation concealment and blinding."<sup>28</sup>

Of a total of 117 trials only 12 were rated as adequate.

At the beginning of this appendix a special article commissioned by the *American Journal of Psychiatry* was cited to the effect that criticisms of antidepressants trails could not be substantiated. Less than a decade later, a highly regarded<sup>29</sup> study [Cipriani(2009)] which was free of pharmaceutical industry funding, found that the methodology of more than 89.7% of all 117 trials on antidepressants conducted in the previous 16 years, to be less than adequate.

Cipriani (2009) also found that the design of the trials (being as they were of short duration) rendered the results of limited use in clinical psychiatric practice. The limited

<sup>&</sup>lt;sup>24</sup> Kirsch (2008), p.268.

<sup>&</sup>lt;sup>25</sup> *Op. cit.*, p.140.

<sup>&</sup>lt;sup>26</sup> Ibid.

<sup>&</sup>lt;sup>27</sup> Parikh (2009), p.700.

<sup>&</sup>lt;sup>28</sup> Cipriani (2009), p.747.

<sup>&</sup>lt;sup>29</sup> See Parikh (2009) (*supra*).

duration of trials would have the effect of minimising the perceived side effects of medications. Cipriani (2009) did not investigate either the nature or incidence of such harms.<sup>30</sup> Where clear evidence of harms did materialise – as in the case of the pharmaceutical treatment of adolescent depression (*supra*) – clinicians appear to have adopted a somewhat cavalier attitude to evidence of such harm as evidenced by the answer to a British parliamentary question which elicited the information that in 2006, one in three antidepressants prescribed for children are prescribed against the advice of the regulatory authority.<sup>31</sup>

Dr. Andrew Nierenberg, an associate professor of psychiatry at Harvard Medical School interviewed by the *New York Times* – and described as having "*consulted with drug makers*"<sup>32</sup> – was reported as responding to an FDA warning on the prescribing of antidepressants for adolescent depression:

... that he did not expect the findings to have any immediate effect on prescribing the medication. "You have to ask the question, 'What's the alternative for people who are depressed and in pain?"<sup>33</sup>

Nierenberg's response was reminiscent of that of the chairwoman of the FDA advisory panel which licensed the use of the vagus nerve stimulator<sup>34</sup> as a treatment for depression despite evidence both of its lack of efficacy and of its propensity to cause harm on the basis that "… *anything that gives these people hope is potentially worthwhile*."<sup>35</sup> A dissenting member of the panel, considered this argument to be specious:

Pancreatic cancer is a hopeless condition ... with a much higher death rate than chronic depression ... and we have as much evidence that this works for pancreatic cancer as it does for depression. Why not use it for that? ... This almost has a feel of 18th-century psychiatry ...<sup>36</sup>

The preceding discussion enables the following conclusions to be drawn:

1. Subsequent analyses of earlier research into the efficacy and safety of antidepressants which resulted in the uncovering of serious methodological flaws, in addition to disclosures concerning the influence of pharmaceutical industry on the publication of trial data, undermines – in the absence of compelling evidence

<sup>&</sup>lt;sup>30</sup> Cipriani (2009), p.753: "... we did not investigate important outcomes, such as side-effects, toxic effects, discontinuation symptoms, and social functioning."

<sup>&</sup>lt;sup>31</sup> In a response to a Parliamentary Question set down by the MP Paul Burstow, in February 2006. [online], available: http://paulburstow.org.uk/news/624.html?PHPSESSID=801ceb21 [accessed: 27 November 2006].

<sup>&</sup>lt;sup>32</sup> Carey, B. (2006). 'Antidepressants increase suicide risk in young adults, study finds.' *The New York Times.* 6 December.

<sup>&</sup>lt;sup>33</sup> *Ibid*.

<sup>&</sup>lt;sup>34</sup> See discussion in Appendix J.

 <sup>&</sup>lt;sup>35</sup> Carey, B. (2005) 'F.D.A. Considers Implant Device for Depression.' *The New York Times*. 21 May.
 <sup>36</sup> *Ibid*.

to the contrary – the claims of published research on antidepressants to being evidence-based and to being either efficacious or safe.

2. Some treatments for depression, despite lack of evidence as to their efficacy and despite concerns as to their safety, are administered on such spurious grounds as that "they give these people hope."

3. In that antidepressants are the most widely used psychiatric medication, doubts as to the efficacy or safety of such medications should by virtue of the 'Precautionary Principle' and in the absence of compelling evidence to the contrary, be regarded as being applicable to other pharmaceutical psychiatric treatments and, in particular, to those administered coercively.

## Appendix L: Problematic aspects of antipsychotic research

<u>Note</u>: As mentioned at the commencement of Chapter 5, the discussion of psychiatric treatments in this Appendix is not intended to provide a comprehensive, objective and balanced overview of research into antipsychotics. The goal is much more circumscribed: it is – by examining the published work of academic commentators and researchers in this area – to establish a *prima facie* case that clinical psychiatric practice in the use of antipsychotics, often lacks (and, on occasion, conflicts with) a robust evidence-base.

The goal of this appendix is to answer the following questions:

(i) Does robust evidence for the efficacy and safety of antipsychotics exist?

(ii) Do clinical psychiatrists manifest a sensitivity to the degree of harm sometimes occasioned by antipsychotics?

(iii) Do clinical psychiatrists show a responsiveness to changing evidence on the efficacy and safety of antipsychotics?

The distorting influence of the pharmaceutical industry on psychiatric research has been discussed in Appendix J ; consequently independently funded research into psychiatric pharmaceutical treatments attains a heightened importance; the CATIE Study (2005) and the CUtLASS 1 Study (2006) (*infra*) are examples of such independently funded studies.

Adopting the methodology used in discussing antidepressants (Appendix K), this appendix is in the nature of a decade-long 'timeline' showing how radical was the change in attitudes wrought by the advent of independently funded research; it is structured as follows:

- Some preliminary matters [Subsection L-1];
- Brief outline of the development of antipsychotics [Subsection L-2];
- Some research findings: 1998-2005 [Subsection L-3];
- The CATIE Study (2005) [*Subsection L-4*];
- A note on minimal drug treatment [Subsection L-5];
- The CUtLASS 1 Study (2006) [Subsection L-6];
- Interim conclusions [*Subsection L-7*];
- Some research findings from 2007 [*Subsection L-8*];
- Some research findings from 2008 [*Subsection L-9*];
- Antipsychotic use in the treatment of children [Subsection L-10];
- Some research findings from 2009 [Subsection L-11];
- Some examples of industry manipulation of test results [Subsection L-12];
- Conclusions [*Subsection L-13*].

#### *L–1: Some preliminary matters*

The Oxford dictionary considers the terms '*neuroleptic*', '*major tranquilliser*' and '*antipsychotic*' to be synonyms as does Webster's dictionary which also gives the speciality (health) definition of 'neuroleptic' as:

A term coined to refer to the effects on cognition and behaviour of antipsychotic drugs, which produce a state of apathy, lack of initiative, and limited range of emotion and in psychotic patients cause a reduction in confusion and agitation and normalization of psychomotor activity.<sup>1</sup>

Writing in the Lancet, Yawar (2009) sketches the history of these drugs:

In the 1950s, the chemical lobotomy, or "*hibernation therapy*" was introduced. Patients were given a drug that rendered them immobile and semiconscious for days, on the assumption that they would emerge improved. The drug was called a "neuroleptic", or brain restrainer. Its name? Chlorpromazine. Since marketed as an antipsychotic, it is used, at lower doses, today.

Yawar (2009) also discusses some of the side effects of neuroleptics:

Antipsychotics are, at times, cruel drugs. Some cause shaking, salivation, restlessness, infertility, stiffness, agitation, and frail bones; others cause obesity, somnolence, and increase the risk of heart attack, diabetes, and stroke.

The side effects of one of the older antipsychotics Haldol (haloperidol) were described

by Leonid Plyushch, a Soviet mathematician and dissident:

I was prescribed haloperidol in small doses. I became drowsy and apathetic. It became difficult to read books.

... I was horrified to see how I deteriorated intellectually, morally and emotionally from day to day. My interest in political problems quickly disappeared, then my interest in scientific problems, and then my interest in my wife and children. ... My speech became jerky, abrupt. My memory deteriorated sharply.<sup>2</sup>

Though Haldol is an older drug (a 'typical' antipsychotic) it is still in use both as an

antipsychotic and as a 'chemical cosh'.<sup>3</sup>

<sup>&</sup>lt;sup>1</sup> Online available at: http://www.websters-online-dictionary.org/ne/neuroleptic.html [accessed: 7 March 2009].

<sup>&</sup>lt;sup>2</sup> *The New York Times* (1976). 'Excerpts from statement by dissident on his detention in Soviet mental hospital'. *The New York Times*, 4 February.

See also Bloch & Reddaway (1984). In discussing Plyushch's case the authors attempt (p. 27-8) to distinguish the use of Haldol by western psychiatrists ["conscientious psychiatrist's caution ... scrupulous attention to .. dosage ... "] from that by Soviet psychiatrists ["... indiscriminate use of these drugs"]. It is of note that Plyushch's statement contradicts these assertions and makes reference to being given "small doses" of haloperidol. (Supra)

<sup>&</sup>lt;sup>3</sup> The term '*chemical cosh*' refers to the use of medications (especially antipsychotics) to subdue individuals where the primary purpose is not to advance the interests of the individual subject, but for the convenience of others; see, for example: Ballard (2005) which is entitled: "*Drugs used to relieve behavioral symptoms in people with dementia or an unacceptable chemical cosh*?". See also reports of the use of Haldol by the US immigration service:

Senate testimony last month revealed that 56 deportees were given psychotropic drugs ... between Oct. 1, 2006, and April 30, 2007. Thirty-three of them had no history of psychological problems, but were given the medicine because of "*combative behavior*," ... Soeoth's medical records show he received an injection of Haldol and Cogentin, a medicine given with the anti-psychotic drug to

Plyushch's description of the effects of antipsychotics is not unusual: John Manweiler<sup>4</sup> described the effects of such medication (administered over a period of ten years) as making him feel like a "*zombie*";<sup>5</sup> Arnold Juklerød<sup>6</sup> described his first injection of neuroleptic medication thus:

 $\dots$  a paralysis entered my left side  $\dots$  [then] came a fear and restlessness completely new to me.  $\dots$  The paralysis went  $\dots$  upwards and took my mouth and pulled it up in an awkward position. I couldn't speak. I could hardly talk. I was terrified and frightened.<sup>7</sup>

The harms occasioned by the use of psychiatric medications can be divided into two broad categories:

- those physical harms such as diabetes or tardive dyskinesia,<sup>8</sup>
- those harms which trespass deeply onto the psyche of an individual *e.g.* the harm done to Plyushch which has been described as being: "*a threat to 'the precious inner life of man'*."<sup>9</sup>

The harms caused by antipsychotics are of both types.

Harms of the first category will be discussed in this appendix.

Harms of the second type may occur with all psychoactive medications but in the case of antipsychotics – especially if they have been administered coercively – such harms may be of a level of invasiveness and intensity such that they dominate all other harms; they will be discussed in Chapter 7 where it will be argued that they constitute harms which may diminish or destroy the personhood of a subject.

## *L–2: Brief outline of the development of antipsychotics*<sup>10</sup>

Chlorpromazine (*supra*) came into clinical use as an antipsychotic in 1952 but within two years the severity of the side effects  $(EPS)^{11}$  became apparent. Although

reduce the facial spasms it can cause, said his attorney, Ahilan Arulanantham, of the American Civil Liberties Union. "*He has no history of violence of any kind, no disciplinary problems at all. He didn't resist in any way, whatsoever, ...*"

<sup>[</sup>Associated Press (2007). 'American Civil Liberties Union seeks to prevent forcible drugging of deportees.' *International Herald Tribune*. 10 October].

<sup>&</sup>lt;sup>4</sup> See Appendix H.

<sup>&</sup>lt;sup>5</sup> Browne (2005a).

<sup>&</sup>lt;sup>6</sup> See Appendix G.

<sup>&</sup>lt;sup>7</sup> Sandøy (1997).

<sup>&</sup>lt;sup>8</sup> US National Institute of Neurological Disorders and Stroke:

Tardive dyskinesia is a neurological syndrome caused by the long-term use of neuroleptic drugs. ... [it] is characterized by repetitive, involuntary, purposeless movements. Features of the disorder may include grimacing, tongue protrusion, lip smacking, puckering and pursing, ...

<sup>[</sup>online], available: http://www.ninds.nih.gov/disorders/tardive/tardive.htm [accessed: 7 March 2009]. <sup>9</sup> Campbell (1976).

<sup>&</sup>lt;sup>10</sup> The information in this subsection is drawn from Shen (1999).

chlorpromazine remained the most prescribed antipsychotic in the 1960s and 70s, a number of similar drugs (such as haloperidol) with different chemical and side-effect profiles, were introduced. The presence of EPS was originally regarded as an indicator of the efficacy of the antipsychotic medication but in 1971 a drug, Clozapine, which appeared to cause minimal EPS, was believed to be effective. Clozapine was introduced into the US market in 1990:

... and rapidly destroyed the general conviction that the efficacy and EPS profile were linked, and led to an emerging concept of "*atypical*" antipsychotic drugs. Although no precise definition of this concept has ever been established, a drug with the property of "*atypicality*" shows a clinical profile with a low propensity to induce EPS ...<sup>12</sup>

Clozapine's success quickly led to the development of other atypical antipsychotic drugs and by 1999 five others had been released onto the US market.

In the late 1990s, the possibility that the adverse effects of antipsychotics might be so serious as to cause death was known; a Dublin coroner's inquest, for example, was told that these drugs had been the cause of death and that: " ... there had been an increase in the number of 'sudden unexplained deaths' in previously healthy patients taking normal dosages of antipsychotic drugs ...<sup>"13</sup>

In the O'Donnell case [see *supra* Chapter 4], a year after having been convicted Brendan O'Donnell died from the side effects of an antipsychotic medication.<sup>14</sup>

#### *L–3: Research findings on antipsychotics: 1998-2005*

Thornley & Adams (1998) – noting that: "*Drug treatments are the bulwark of treatment* of schizophrenia"<sup>15</sup> – sought to evaluate the quality of studies supporting such treatments. It was a particularly comprehensive study in that it examined 3181

<sup>&</sup>lt;sup>11</sup> Acute Extrapyramidal Symptoms (EPS) including parkinsonism, dystonias, and akathisia and tardive dyskinesia.

<sup>&</sup>lt;sup>12</sup> Shen (1999), p.410.

<sup>&</sup>lt;sup>13</sup> Haughey, N. (1997). 'Woman died after reaction to drug.' *The Irish Times*. 11 November.

<sup>&</sup>lt;sup>14</sup> Haughey (1997):

Dr. Smith said O'Donnell's dosage of the anti-psychotic drug Thioridazine was "definitely within the known and accepted safety range". He had received the same drug six months before without any recorded side-effects.

Dr. Harbison said O'Donnell died of heart failure caused by the fatal intoxication of Thioridazine. The level of the drug in his blood during the post-mortem was just above the therapeutic range. Thioridazine had been found previously to have caused sudden unexplained deaths at levels below those detected in O'Donnell's blood. There was an element of "*idiosyncracy*" in the reaction of people to this type of drug.

Haughey, N. (1997) 'O'Donnell died of cardiac failure linked with drug, inquest jury says'. *The Irish Times*, 27 November.

<sup>&</sup>lt;sup>15</sup> *Op. cit.*, p.1183.

publications (c. 2500 trials); drug trials (involving 437 different drugs) predominated<sup>16</sup>

of which 1187 involved antipsychotics.<sup>17</sup>

The study concluded that:

The quality of reporting in this large sample of trials was poor  $\dots 1\%$  (20) of the 2000 trials achieved a maximum quality score of 5. Just under two thirds (1280) scored 2 or less,  $\dots$  We found little evidence that the quality of trial reporting improved with time.  $\dots$  As low quality scores are associated with an increased estimate of benefit, schizophrenia trials may well have consistently overestimated the effects of experimental interventions.<sup>18</sup>

The study also noted that the drug trials commonly used haloperidol as the control drug which has "*obvious side effects that render successful blinding difficult, if not impossible.*"<sup>19</sup>

The distortions caused by the use of haloperidol as the control, was confirmed by

Geddes (2000a) which was a meta-analysis of trials which compared atypical

antipsychotics with conventional antipsychotics. Geddes (2000a) found that:

The dose of haloperidol significantly affected outcome in the 23 trials in which it was used. ... The observed advantage in favour of the atypical drug disappeared as the dose of haloperidol decreased. ... suggesting that many of the perceived benefits of atypical antipsychotics are really due to excessive doses of the comparator drug used in the trial.<sup>20</sup>

Geddes (2000a) noted that the trials were of limited clinical value by virtue of, inter

alia, their short duration<sup>21</sup> and recommended the use of conventional antipsychotics

over atypical antipsychotics as a medication of first choice.<sup>22</sup> The data on adverse

effects of antipsychotics was so limited that it was not included in the report.<sup>23</sup>

Commenting on Geddes (2000a), an editorial<sup>24</sup> in *The Lancet* began by noting that:

An infectious optimism has infused the field of schizophrenia with the availability of the new "atypical" antipsychotics. ... prescription data suggest that atypical antipsychotics account for nearly three out of four new prescriptions for antipsychotics in North America. So, how can we reconcile this large shift in

<sup>&</sup>lt;sup>16</sup> Thornley & Adams (1998), p.1183: "Drug treatments are the bulwark of treatment of schizophrenia, so it is not surprising that drug trials dominate the sample."

<sup>&</sup>lt;sup>17</sup> *Ibid.*, p.1182.

<sup>&</sup>lt;sup>18</sup> Ibid.

<sup>&</sup>lt;sup>19</sup> *Ibid.*, p.1183 and continues:

<sup>...</sup> In addition, because haloperidol is also a potent cause of adverse effects, most drugs to which it is compared will have favourable side effect profiles. Therefore, so long as the new

experimental drug has moderate antipsychotic properties, favourable outcomes can be expected. <sup>20</sup> *Op. cit.*, pp.1373-4.

<sup>&</sup>lt;sup>21</sup> *Ibid.*, p.1375.

<sup>&</sup>lt;sup>22</sup> *Ibid.* 

<sup>&</sup>lt;sup>23</sup> *Ibid.*, p.1372: "*There were few data on quality of life, specific side effects, or cost effectiveness, and we have therefore not included these outcomes in this report.*"; see also (p.1375):

With the exception of extrapyramidal side effects, there is little consistent reporting of adverse events. There are few data on quality of life or clinically relevant functional outcomes and few reliable data on the cost effectiveness of atypical antipsychotics - none in the United Kingdom.

<sup>&</sup>lt;sup>24</sup> Kapur & Remington (2000).

prescribing practices ... with the sobering evidence provided by Geddes *et al*? Is this shift largely a victory of clinical hope and marketing hype over hard evidence, ...?

The editorial commented that whilst the atypical antipsychotics might have new side effects such as diabetes, the "gain on extrapyramidal effects is unequivocal"<sup>25</sup> – a considerably more robust conclusion than that drawn by Geddes (2000a).<sup>26</sup>

The *British Medical Journal* published a number of responses<sup>27</sup> to Geddes (2000a) many of which took issue with the fact that Geddes (2000a) felt enabled to draw such firm conclusions from what was admitted to be poor quality research; others were concerned with the intensity of EPS ["profoundly traumatic to be rendered rigid, trembling, unable to rest, or obese by drug treatment"] and with their underreporting. In reply, Geddes reiterated the view that "Unfortunately, the benefits on extrapyramidal side effects achieved by atypical antipsychotics are relatively modest."

The seriousness of some of the side effects associated with atypical antipsychotics had begun to emerge in the late 1990s; Hickey (1999) reported on a case of *'Neuroleptic Malignant Syndrome'* (NMS)<sup>28</sup> which the authors believe, had been exacerbated by the use of an atypical antipsychotic and which resolved within a day of the antipsychotics being discontinued.

Wieden & Miller (2001) discussed the rating scales used to assess the adverse effects of antipsychotics and noted that: "*Most research on the assessment of antipsychotic side effects has focused on EPS, ... Few scales assess for non-EPS side effects.*"<sup>29</sup> and that scales "*emphasize objective severity at the expense of subjective distress.*"<sup>30</sup> They urged caution in relation to assessing the severity of non–EPS side effects and noted that:

... the EPS caused by conventional antipsychotics were initially thought to be minor and that it took many years to fully understand the terrible burden caused by EPS.<sup>31</sup>

They cited research by one of the authors which found "*no significant correlation* between subjective distress ratings and concurrent objective findings on the ... [EPS Rating Scale]."<sup>32</sup> The implication of such research is that assessments of adverse effects of antipsychotics were limited in scope and that even within their restricted

<sup>&</sup>lt;sup>25</sup> *Ibid.*, p.1360.

<sup>&</sup>lt;sup>26</sup> Geddes (2000a), p.1374.

<sup>&</sup>lt;sup>27</sup> BMJ (2001).

<sup>&</sup>lt;sup>28</sup> Hickey (1999): "Neuroleptic malignant syndrome (NMS) is a serious adverse reaction to neuroleptic drugs. It is characterized by muscle rigidity and elevated temperature ..."

<sup>&</sup>lt;sup>29</sup> *Op. cit.*, p.41.

<sup>&</sup>lt;sup>30</sup> *Ibid*.

<sup>&</sup>lt;sup>31</sup>*Ibid.*, p.46.

<sup>&</sup>lt;sup>32</sup> *Ibid.*, p.43.

ambit, they were unreliable measures of the distress as experienced by the user of the

antipsychotics. Stalman (2002) gives an indication of the severity of EPS:

The extrapyramidal symptom of akathisia (internal restlessness) is the most difficult for patients to tolerate. Akathisia causes patients to stop their medication and <u>can clinically mimic psychosis</u>.<sup>33</sup>

An editorial in the *British Medical Journal* addressed some of the findings on non-EPS side effects of antipsychotics and, in particular, the question of whether they could be a cause of cardiac deaths:

... whether cardiac deaths are related to the illness itself or to the drugs used to treat it has remained unclear. Data from a very large American cohort of almost 100,000 outpatients with schizophrenia who were treated with antipsychotics were published recently and begin to suggest an answer: the drugs play a major part,  $...^{34}$ 

Mortimer (2005) – having studied the prescribing of antipsychotics in secondary care and found it "*unsatisfactory*" – examined antipsychotics prescribing in primary care and concluded:

... most is unsatisfactory. ... Half the regimes failed one or more audit criteria, leaving diagnosis aside. ... [and] adds to concerns regarding high levels of off–licence use of potentially harmful medication.

... community pharmacists reported insurmountable difficulty in establishing the diagnosis of patients prescribed antipsychotic drugs by their GPs even when case notes were scrutinized and personal enquiries made of the GPs.

They concluded:

Our patients' experience of worsening of symptoms and antipsychotic withdrawal syndromes is of particular concern. ... This excessive reliance on pharmacotherapy may bring with it irrational combinations of drugs<sup>35</sup> in inadequate doses for long periods: clearly contrary to the principles of rational evidence-based therapy.

Concerned about the lack of authoritative data on the safety and efficacy of atypical antipsychotics and the spiralling  $\cos^{36}$  and popularity of such drugs, the US National Institute of Mental Health (NIMH) published, in 2005, the results of a study [Lieberman (2005) – known as the CATIE<sup>37</sup> study] comparing the safety and efficacy of all existing

<sup>&</sup>lt;sup>33</sup> [Emphasis added]; thus hindering the uncovering of possible misdiagnosis.

<sup>&</sup>lt;sup>34</sup> Herxheimer & Healy (2002), p.1253.

<sup>&</sup>lt;sup>35</sup> Mortimer (2005):

For instance another primary care audit of 170 patients prescribed atypical antipsychotics drugs found nearly all were subject to psychotropic polypharmacy, over a third had no licensed indication.

<sup>&</sup>lt;sup>36</sup> Carey (2005): "*The new drugs account for \$10 billion in annual sales and 90 percent of the national market for antipsychotics*;" Carey also reported that a months supply of the conventional antipsychotic used in the study cost \$60 whereas the atypical antipsychotics cost between \$250 - \$520.

Carey, B. (2005). 'Little Difference Found in Schizophrenia Drugs.' *The New York Times*. 20 September. <sup>37</sup> Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE).

atypical antipsychotics with a conventional antipsychotic.<sup>38</sup> This study was regarded as a landmark study in that it was the most comprehensive comparative study into antipsychotics ever conducted and which, furthermore, had been funded by the US government independently of pharmaceutical industry finance.<sup>39</sup>

## L-4: The CATIE Study (2005) [Lieberman (2005)]

Because of the difficulty in specifying criteria for judging a treatment to be 'successful', the study adopted as its primary outcome measure 'duration to discontinuation of treatment for any cause'; hence the longer the subject continued on the treatment the more successful it was judged.<sup>40</sup> The main conclusion was that: "*The majority of patients in each group discontinued their assigned treatment owing to inefficacy or intolerable side effects or for other reasons*."<sup>41</sup>

Not only did the study find that the side effects of antipsychotics were sometimes so severe as to be "*intolerable*"<sup>42</sup> but it also found that, in relation to EPS, there were no significant differences between the atypical antipsychotics and the conventional antipsychotic.<sup>43</sup> Their final conclusion was that though one of the atypical antipsychotics (Olanzapine) was moderately superior to the other drugs in terms of the rates of discontinuation and rate of hospitalisation "*for an exacerbation of schizophrenia*",<sup>44</sup> it had more severe side effects; the results for the other atypical antipsychotics were similar to the conventional antipsychotic in most respects.<sup>45</sup> An editorial<sup>46</sup> accompanying the study noted that: "*The results could be viewed as discouraging. No drug provided the majority of patients a treatment that lasted the full 18 months of the study*."<sup>47</sup> and that whilst two atypical antipsychotics did appear to be more effective :

 <sup>&</sup>lt;sup>38</sup> Lieberman (2005), p.1215: "Although haloperidol is the first-generation agent most commonly used for comparison, we chose to use perphenazine because of its lower potency and moderate side-effect profile."
 <sup>39</sup> Vedantam, S. (2005b). 'New Antipsychotic Drugs Criticized; Federal Study Finds No Benefit Over Older, Cheaper Drug.' The Washington Post. 20 October; also:

<sup>&</sup>quot;The study has vital public health implications," said Thomas Insel, director of the National Institute of Mental Health, which funded the study. "It is the largest, longest and most comprehensive, independent trial ever done to examine existing therapies for this disease."

<sup>&</sup>lt;sup>40</sup> *Op. cit.*, p.1211.

<sup>&</sup>lt;sup>41</sup> *Ibid.*, p.1209.

<sup>&</sup>lt;sup>42</sup> *Ibid.*, p.1218: "*The times to discontinuation because of intolerable side effects were similar among the groups* …"

<sup>&</sup>lt;sup>43</sup> Ibid.:

In contrast to previous studies, the proportion of patients with extrapyramidal symptoms did not differ significantly among those who received first-generation and second-generation drugs in our study.

<sup>&</sup>lt;sup>44</sup> Ibid.

<sup>&</sup>lt;sup>45</sup> *Ibid.*, p.1209; p.1218.

<sup>&</sup>lt;sup>46</sup> Freedman (2005a).

<sup>&</sup>lt;sup>47</sup> *Ibid.*, p.1287.

 $\dots$  both drugs induce a significantly greater number of serious side effects. Even the most feared side effect of first-generation drugs, tardive dyskinesia, seems less troubling than potentially fatal metabolic problems.<sup>48</sup>

Interviewed subsequently, one of the authors of the study commented: "Many

psychiatrists, in fact, were so certain the new drugs were better that they questioned the need to pit the new medications against an older drug<sup>7,49</sup>

The lead author stated that:

Probably the biggest surprise of all was that the older medication produced about as good an effect as the newer medications, three of them anyway, and did not produce neurological side effects at greater rates than any of the other drugs,  $\dots$ <sup>50</sup>

The categorisation of the side effects of antipsychotics as being "*intolerable*" raises profound ethical questions in relation to the coercive administration of such drugs for extended periods of years to patients such as Manweiler or Juklerød (*supra*) who do not have the liberty to "*vote with their feet*". The seriousness of the side effects of antipsychotics in addition to their 'intolerability' raises the question as to whether a non– or minimal drug treatment for schizophrenia might not be preferable.

#### *L*–5: A note on non- or minimal drug treatment for schizophrenia

Davis (2006) which was an editorial in the *New England Journal of Medicine*, was adamant on the need for the lifetime use of drugs in the treatment of schizophrenia; it stated, *inter alia*, that:

(i) Schizophrenia is a serious chronic illness that requires lifelong medication.

(ii) We have known for 30 years that a delay in initiating treatment with antipsychotic medication may increase the need for hospitalization over the subsequent five years.

(iii) ... medication is typically needed for the rest of the patient's life. Patients who stop taking antipsychotic medications have a relapse rate of about 10 percent per month, until eventually almost all patients have a relapse.<sup>51</sup>

Of these three statements, authority is cited only for the second and in that case both of the studies cited<sup>52</sup> were *circa* 30 years old and had been primarily concerned with a comparison between drug therapy and psychotherapy. The author of the second study

<sup>&</sup>lt;sup>48</sup> Ibid.

<sup>&</sup>lt;sup>49</sup> See Vedantam, S. (2005). 'Psychiatric Drugs' Use Drops for Children.' *The Washington Post*. 8 October.

<sup>&</sup>lt;sup>50</sup> See Carey (2005) (*supra*).

<sup>&</sup>lt;sup>51</sup> Op. cit., p.520.

<sup>&</sup>lt;sup>52</sup> Davis (1978) and May (1976); the abstract of the latter states:

Patients who had been originally treated in hospital with psychotherapy alone stayed longer in hospital over the follow-up period than those who had received electroconvulsive therapy (ECT), drug alone, or drug plus psychotherapy. ...

summarised his findings in a later paper<sup>53</sup> which provide a less than adequate foundation for the unequivocal interpretation placed on them some thirty years later.

In view of the CATIE findings which showed that a previous near unanimity amongst the psychiatric profession on the superior efficacy and safety of atypical antipsychotics, was ill founded, the near unanimity on the necessity of drug treatment loses some of its authority.

Some months after the publication of Davis (2006), *The New York Times* reported<sup>54</sup> on responses to a then recently published study [Bola (2006a)]<sup>55</sup> which sought to directly examine the possibility of drug free treatment for schizophrenia and which "*exposes deep divisions in the field that are rarely discussed in public*":

 $\dots$  some doctors suspect that the wholesale push to early drug treatment has gone overboard and may be harming patients  $\dots$  Other experts warned that the new report's conclusions were dangerous, and represented only one interpretation of the evidence.<sup>56</sup>

Lieberman – lead author of the CATIE study (*supra*) – was reported as stating:

I am usually a pretty moderate person, but on this I am 110 percent emphatic: If the diagnosis is clear, not treating with medication is a huge mistake that risks the person's best chance at recovery. It's just flat-out nuts.<sup>57</sup>

Bola (2006a) – who had found that previous reviews concluding that drugs provided significant benefits included many studies that did not have a comparison group of people who were not on medication – reviewed six long–term studies involving 623 people who had symptoms of psychosis; in the studies, roughly half of the patients were promptly treated with antipsychotic drugs while the other half went without the medication for periods ranging from three weeks to more than six months. Two studies found that after a year or more, the patients on a full course of medication performed better on measures of social interaction, work success and the risk of rehospitalization

<sup>&</sup>lt;sup>53</sup> May (1981) the abstract of which states:

Two hundred twenty-eight first-admission schizophrenic patients were randomly assigned to the following five treatments: psychotherapy alone, drug alone, ... The drug alone and ECT groups tended to have the best outcome and the psychotherapy alone group the worst. The positive effect from prior drug treatment began to dissipate after three years postadmission. For the in-hospital treatment successes, the advantage from drug treatment and the disadvantage from psychotherapy were less apparent. Overall, the follow-up outcome is far from reassuring, ...

<sup>&</sup>lt;sup>54</sup> Carey, B. (2006a). 'Revisiting Schizophrenia: Are Drugs Always Needed?' *The New York Times*. 21 March.

<sup>&</sup>lt;sup>55</sup> The study found that [Carey (2006a)]:

<sup>...</sup> when some people first develop psychosis they can function without medication — or with far less than is typically prescribed — as well as they can with the drugs. And the long-term

advantage of treating first psychotic episodes with antipsychotics, the report found, was not clear. <sup>56</sup> *Ibid.* 

<sup>&</sup>lt;sup>57</sup> Ibid.

than those who were initially drug-free, whereas the other four studies found the

opposite. The most important conclusion, however, related to the lack of research:

The most striking observation in this review is the dearth of good-quality evidence that addresses the long-term effects of initial treatment with antipsychotic medication compared with short-term medication postponement in early episode schizophrenia research.<sup>58</sup>

Bola (2006b) discussed how the Declaration of Helsinki<sup>59</sup> had been interpreted to imply a categorical prohibition against research into the medication-free treatment of schizophrenia; he advocated that the prohibition be reconsidered; it also discussed how programmes in Finland and Sweden have helped subjects manage psychotic symptoms with either no, or minimal, use of medication. Due to methodological difficulties, the results of such programmes could not be incorporated into his results, nonetheless the results are worthy of note:

... researchers in Finland found that intensive family therapy helped more than 40% of patients with early symptoms of psychosis recover significantly without antipsychotics — and they have remained off the drugs, for more than two years. ... Another program, in Sweden, also has found that many people do well when treated with low doses of antipsychotic medications, or none at all, after their first psychotic break.<sup>60</sup>

Indirect support for the non or minimal use of antipsychotics in the treatment of schizophrenia may also be found from studies which have found that the course and outcome of schizophrenia is better in so-called 'third world' countries - where the use of antipsychotics is less prevalent – than in 'developed' countries.<sup>61</sup>

Kuipers (2007) also offers limited support for the use of psychological therapies in the treatment of schizophrenia.62

# L-6: The CUtLASS 1 Study<sup>63</sup> [Jones (2006)]

The CUtLASS 1 study was funded by the UK National Health Service with no financial support from the pharmaceutical industry; it sought to test the hypothesis that the use of

<sup>62</sup> Kuipers (2007) begins: "The present state of research provides sound evidence for the efficacy of *psychological therapy in the treatment of schizophrenia.*" <sup>63</sup> Cost Utility of the Latest Antipsychotic Drugs in Schizophrenia Study (CUtLASS 1).

<sup>&</sup>lt;sup>58</sup> Bola (2006a), p.292.

<sup>&</sup>lt;sup>59</sup> World Medical Association (2008).

<sup>&</sup>lt;sup>60</sup> Carey (2006a).

<sup>&</sup>lt;sup>61</sup> See Cohen (2008), p.229:

That schizophrenia has a better course and outcome in countries of the developing world has become an axiom in international psychiatry. This belief emerges from a long history of crossnational research, with the most often cited evidence coming from 3 studies by World Health Organization (WHO) ... These studies have been cited as "arguably the greatest achievements in psychiatric epidemiology," and their results as constituting "the single most important" finding in crosscultural psychiatry.

second generation atypical antipsychotic drugs ['*SGAs*'] in the treatment of schizophrenia, would lead to better quality of life<sup>64</sup> when compared with the older and cheaper first–generation drugs ['*FGAs*']. Despite the authors initial belief<sup>65</sup> that SGAs were superior,<sup>66</sup> their conclusion was a clear refutation of the hypothesis<sup>67</sup> with indications that the FGAs were actually the superior treatment.<sup>68</sup>

The study also noted the continuing emergence of information concerning the extent and seriousness of adverse effects caused by the use of antipsychotics.<sup>69</sup>

Two editorial commentaries accompanied the publication of Jones (2006). The first

[Lieberman (2006)] was by the lead author of the CATIE study who noted that the

results of the CUtLASS 1 were "*virtually identical*" to those obtained in the CATIE study and were:

 $\dots$  a conclusion that runs counter to the impressions of many clinicians and previous studies suggesting marked superiority of the SGAs and that belies the huge advantage in market share enjoyed by the SGAs in the United States and other parts of the world.<sup>70</sup>

Lieberman (2006) then asks as to how "the disconnect between the exuberant claims of

the superiority of the SGAs and their disappointing performance"<sup>71</sup> could have arisen.

He offers two reasons: the short-term nature of industry funded trials and secondly:

... by an overly expectant community of clinicians and patients eager to believe in the power of new medications. At the same time, the aggressive marketing of these drugs may have contributed to this enhanced perception of their effectiveness in the absence of empirical evidence.<sup>72</sup>

 <sup>&</sup>lt;sup>64</sup> In contrast to the CATIE study which used 'time to discontinuation' as its primary measure.
 <sup>65</sup> Vedantam (2006):

The results are causing consternation. The researchers who conducted the trial were so certain they would find exactly the opposite that they went back to make sure the research data had not been recorded backward.

Vedantam, S. (2006). 'In Antipsychotics, Newer Isn't Better. Drug Find Shocks Researchers.' *The Washington Post.* 3 October.

<sup>&</sup>lt;sup>66</sup> A belief that was widespread in clinical psychiatry [see *infra*].

<sup>&</sup>lt;sup>67</sup> Jones (2006), p.1085: "We emphasize that we do not present a null result; the hypothesis that SGAs are superior was clearly rejected."

 <sup>&</sup>lt;sup>68</sup> Ibid., p.1083: "Statistical precision was limited, but the ITT analysis indicated that true effects may have been in the opposite direction for this primary outcome and for the main symptom assessments".
 <sup>69</sup> Ibid., p.1086:

These trials provide benchmark data on adverse effect burden, but this may represent an underestimate. Furthermore, a range of adverse effects of FGAs and SGAs is emerging. Serious weight gain, diabetes mellitus, and hyperlipidemia may all adversely affect quality of life.

<sup>[</sup>GR: Hyperlipidemia is the presence of raised levels of lipids in the blood and is a risk factor for cardiovascular disease]

<sup>&</sup>lt;sup>70</sup> Lieberman (2006), p.1069.

<sup>&</sup>lt;sup>71</sup> Ibid.

<sup>&</sup>lt;sup>72</sup> *Ibid.*, p.1070.

He described the results as "sobering" especially as: "there were no differences in the rates of extrapyramidal symptoms and TD between FGAs and SGAs in CUtLASS 1 and CATIE."<sup>73</sup>

The second commentary [Rosenheck (2006)] noted that, in response to promises of reduced side effects:

... first-line use of SGAs has been advocated by guidelines from the American Psychiatric Association, the United Kingdom's National Institute for Health and Clinical Excellence, ... and the Expert Consensus Guideline Series in the Treatment of Schizophrenia, which observed as early as 1999 that SGAs were rendering conventional antipsychotics obsolete.<sup>74</sup>

Rosenheck (2006), in noting the extreme discordance between the results of the CATIE

and CUtLASS 1 studies and "previously held certainties",<sup>75</sup> commented:

A basic assumption of clinical research is that the results of carefully conducted clinical trials of the same agents in the same illness should not be grossly inconsistent.<sup>76</sup>

Rosenheck (2006) also noted that the risk of tardive dyskinesia with SGAs may have been underestimated.<sup>77</sup>

The lead author of CUtLASS 1 was asked to explain how, despite the evidence, the

prescribing of SGAs had become so prevalent:

"'Duped' is not right," he said. "We were beguiled."... "Why were we so convinced?" he asked, ... "I think pharmaceutical companies did a great job in selling their products. ... It became almost a moral issue on whether you would prescribe these dirty old drugs," he added.<sup>78</sup>

## L-7: Some interim conclusions

The question arises as to whether the results of the CATIE and CUtLASS 1 changed the prescribing habits of clinical psychiatrists. Rosenheck (one of the authors of the CATIE study) stated: "... the belief in the newer drugs was so ingrained that many psychiatrists insisted that the results could not be extrapolated to other old drugs,..."<sup>79</sup> – a belief which appears to have been shared by the Director of Research at the American Psychiatric Association who was reported<sup>80</sup> to have cautioned against drawing broad

<sup>&</sup>lt;sup>73</sup> *Ibid*.

<sup>&</sup>lt;sup>74</sup> Rosenheck (2006), p.1074.

<sup>&</sup>lt;sup>75</sup> Ibid., p.1075.

<sup>&</sup>lt;sup>76</sup> *Ibid*.

<sup>&</sup>lt;sup>77</sup> Ibid., p.1076: "... a meticulous replication of a 1985 study of TD at 1 community mental health center found no overall reduction in TD prevalence in 2003 in spite of widespread use of SGAs." [TD= Tardive Dyskinesia]

<sup>&</sup>lt;sup>78</sup> Vedantam (2006) (*supra*).

<sup>&</sup>lt;sup>79</sup> Ibid.

<sup>&</sup>lt;sup>80</sup> Ibid.

conclusions from the CUtLASS 1 findings, stating that "*a thoughtful and prolonged process*" is needed before treatment guidelines are changed.

The author of the Cutlass 1 study has responded to such beliefs by stating that "*educated clinicians as well as their patients should begin to take into account the results of such trials.*"<sup>81</sup> Urging the importance of trusting the data rather than clinical intuition and drawing on the analogy of his hobby of hill walking, he said:

Sometimes the compass tells you go straight in front of you, but you somehow know it is wrong and that north is behind you,... I have learned to follow the compass.<sup>82</sup>

Heres (2006) sought to determine if pharmaceutical industry funding of research could account for the extreme divergence in the research findings; he found:

... a clear link between sponsorship and study outcome ... as 90.0% of the abstracts were rated as showing an overall superiority of the sponsor's drug. ... different comparisons of the same two antipsychotic drugs led to contradictory overall conclusions, depending on the sponsor of the study.

... reporting of adverse events seems to be selective ... Information on side effects that are very likely to occur ... may be lacking.<sup>83</sup>

The underreporting of antipsychotic adverse effects was also discussed by Kane (2006) in an editorial in the *American Journal of Psychiatry*. The author had co-authored an earlier study which concluded that though tardive dyskinesia was still a risk with atypical antipsychotics it was substantially lower than with conventional antipsychotics. He sought to review these conclusions in light of the CATIE, and other findings. In the course of his editorial, Kane (2006) had noted that in relation to tardive dyskinesia:

... it took many years before its prevalence, incidence, and long-term course were well investigated. At first there was resistance and skepticism from many quarters as to the risk of this condition ... Some might argue that it was not until the threat of litigation became more and more a reality that clinical practice included adequate consideration of and monitoring for tardive dyskinesia.<sup>84</sup>

This conclusion has an especial relevance to Ireland in that the provisions of the *Mental Health Act (2001)* effectively preclude litigation in relation to, *inter alia*, harm cause by the negligent prescribing of antipsychotics.

The extreme seriousness of the possible side effects of antipsychotics was highlighted by Lehtinen (2006) which was a 17 year follow up study of Finnish subjects who had

<sup>&</sup>lt;sup>81</sup> Jones (2007).

<sup>&</sup>lt;sup>82</sup> Vedantam (2006).

<sup>&</sup>lt;sup>83</sup> Heres (2006), p.189.

<sup>&</sup>lt;sup>84</sup> Kane (2006), p.1316.

been diagnosed with schizophrenia and treated with antipsychotics. It found that such subjects were 2.5 times more likely to die and that this risk was proportionately related to the amount of neuroleptic that had been prescribed. Lehtinen (2006) concluded that:

There is an urgent need to ascertain whether the high mortality in schizophrenia is attributable to the disorder itself or the antipsychotic medication.<sup>85</sup>

The discordances between the results of independent and industry funded studies, the reluctance of clinical psychiatrists to change their beliefs in the face of new evidence, the underestimation of the harm caused by antipsychotics, are so great as to permit the drawing of some interim conclusions.<sup>86</sup>

(i) The incontrovertible conclusion to be drawn from the existence of grossly inconsistent results in relation to trials of first and second generation antipsychotics, is that many supposedly evidence-based studies supporting the psychiatric use of antipsychotics, are deeply flawed.

(ii) There is clear evidence of a reluctance amongst clinical psychiatrists to change their beliefs in relation to the appropriate prescribing of antipsychotics, in the face of authoritative, independently funded, studies such as CATIE and CUTLASS 1.

(iii) There are substantial grounds for holding that both the extent and the severity of harms associated with the use of both first and second generation antipsychotics, have been grossly underestimated both by researchers and by clinical psychiatrists.

#### *L*–8: Some research findings from 2007

Marder (2007) which was an editorial in the *American Journal of Psychiatry* spoke<sup>87</sup> of mild forms of extrapyramidal symptoms which, though difficult to detect for trial raters or treating psychiatrists, "*can be tormenting if a person experiences it all of his or her waking hours.*"<sup>88</sup> He suggested that: "*It would not be surprising if the raters from CATIE were not sensitive to these mild manifestations.*"<sup>89</sup> – a comment which, in itself, indicates both the underreporting of the adverse effects of antipsychotics and the extreme discordance between raters', and subjects', perceptions of the seriousness of side effects.<sup>90</sup>

Bick (2007) also revisited the CATIE study but from a different perspective – that of underlying, and possibly causative<sup>91</sup> – physical illness:

<sup>&</sup>lt;sup>85</sup> *Op. cit.*, p.122.

<sup>&</sup>lt;sup>86</sup> These conclusions will be revisited at the end of this appendix.

<sup>&</sup>lt;sup>87</sup> In discussing a CATIE follow-on trial which is not of interest in the present context.

<sup>&</sup>lt;sup>88</sup> Marder (2007), p.376.

<sup>&</sup>lt;sup>89</sup> Ibid.

<sup>&</sup>lt;sup>90</sup> Which should also be viewed in the light of a similar discordance found in early reports of tardive dyskinesia [See *supra*].

<sup>&</sup>lt;sup>91</sup> See Chapter 4.

The most stunning finding was that psychiatrists tend to ignore life-threatening, treatable medical conditions in patients presenting for treatment with schizophrenia. Of patients entering the study, 45% had untreated diabetes, 89% had untreated hyperlipidemias and 62% had untreated hypertension. ...
[CATIE] did expose a woeful standard in the medical management of schizophrenia offered by psychiatrists.<sup>92</sup>

#### *L*–9: Some research findings from 2008

Kahn (2008), which was industry funded, sought to compare the effectiveness of second-generation antipsychotic drugs with that of a low dose of haloperidol in first-episode schizophrenia. They found – in contrast to CATIE – that '*time to discontinuation*'<sup>93</sup> was greater for the second generation antipsychotics than for haloperidol,<sup>94</sup> but that:

... we cannot conclude that second-generation drugs are more efficacious than is haloperidol, since discontinuation rates are not necessarily consistent with symptomatic improvement.<sup>95</sup>

Kahn (2008) noted that even in short term studies of less than 8 weeks: "... fewer than

50–60% of patients continue to take their drugs before the study is complete."<sup>96</sup> –

eloquent testimony to either the ineffectiveness of the drugs or the severity of their side effects or both.

A more telling result concerning the side effects of antipsychotics was mentioned in an

interview with the psychiatrist Nancy Andreasen:97

The big finding is that people with schizophrenia are losing brain tissue at a more rapid rate than healthy people of comparable age. Some are losing as much as 1 percent per year. That's an awful lot over an 18-year period. And then we're trying to figure out why. Another thing we've discovered is that the more drugs you've been given, the more brain tissue you lose.<sup>98</sup>

Asked as to the implications of this finding she said:

<sup>&</sup>lt;sup>92</sup> Bick (2007), p.465.

<sup>&</sup>lt;sup>93</sup> The criterion used by CATIE.

<sup>&</sup>lt;sup>94</sup> Kahn (2008) suspected (p. 1095) that the distinctive side effects of haloperidol could have led to the *'breaking of the blind'*.

<sup>&</sup>lt;sup>95</sup> *Ibid.*, p.1085.

<sup>&</sup>lt;sup>96</sup> Ibid.

<sup>&</sup>lt;sup>97</sup> Andreasen is also a neuroscientist and was one of the first to use neuroimaging techniques in the study of psychiatric disorders.

<sup>&</sup>lt;sup>98</sup> Dreifus, C. (2008). 'A Conversation With Nancy C. Andreasen: Using Imaging to Look at Changes in the Brain.' *The New York Times.* 15 September.

<sup>(</sup>i) That these drugs have to be used at the lowest possible dose, which often doesn't happen now. There's huge economic pressure to medicate patients very rapidly and to get them out of the hospital right away.

<sup>(</sup>ii) We need to find other drugs that work on other systems and parts of the brain.

<sup>(</sup>iii) Whatever medications we use need to be combined with more nonmedication–oriented treatments, like cognitive or social therapies.

This interview drew a critical response from some other psychiatrists: "The fact that 'the more drugs you've been given, the more brain tissue you lose' may be explained by the fact that individuals with more

The May 2008 issue of the journal *Psychiatric Services* focused on the CATIE results and the implications that should be drawn from them. A number of the contributors argued for a preservation of the *status quo ante*.<sup>99</sup> However, the issue's editorial – in acknowledging that "*We professionals share the human tendency to embrace fads*" – argued that the appropriate response to CATIE was:

... we must share the uncertainties with our patients. Informed consent helps to ensure that patients are aware of their options for treatment, including no treatment, and of how their preferences and individual characteristics might influence their quality of life. Increasing patients' participation in informed decision making empowers both patients and their clinicians and respects patients' autonomy.<sup>100</sup>

Whilst the embracing of such uncertainties is to be welcomed, they are hardly compatible with the coercive use of such antipsychotics.

# *L*–10: Antipsychotic use in the treatment of children and adolescents

Further articles examined the ever widening 'consumer-base' for antipsychotics. Domino & Swartz (2008), for example, found that the substantial increase in the use of antipsychotics did not occur amongst individuals diagnosed with schizophrenia but for other conditions such as bipolar disorder and a "*a high, constant rate of off-label use.*" Their conclusion was that: "*The rapid diffusion of second-generation antipsychotic medications was achieved by large increases in the rate of use in certain subpopulations, most notably youths.*" Because of the limited efficiency and the risks associated with antipsychotics, "*the dramatic increase in use warrants attention.*"<sup>101</sup> The increase in the rate of antipsychotic prescribing for children and adolescents was also discussed in Kalverdijk (2008) who examined Dutch statistics and found that:

severe schizophrenia are given more drugs." [Torrey, E. & Chase, C. (2008). 'Letters: Schizophrenia's Toll'. *The New York Times*. 23 September.]

A later study by Andreasen *et al* [Ho (2011)] found that the progressive brain volume changes in those diagnosed with schizophrenia, that had been previously attributed to the disease, can, in part, be attributed to the use of antipsychotics. See also Goff (2011) who discusses how the brains of animals given antipsychotics for "*17 to 27 months lost roughly 10% of their total brain volume*".

<sup>&</sup>lt;sup>99</sup> Swartz (2008): "Although the CATIE results are controversial, they are broadly consistent with most previous antipsychotic drug trials and meta-analyses."

Owens (2008) concludes that CATIE's achievement lay in "... reinstating to physicians their key skill in expert, individualized prescribing."

Franks (2008) urges caution on use of CATIE as the cornerstone of new formulary policies. <sup>100</sup> Sutton (2008).

<sup>&</sup>lt;sup>101</sup> Domino & Swartz (2008), p.507.

From 1997 to 2005, prevalence increased from 3.0 to 6.8 per thousand. Prevalence was highest among ten-year-olds to 14-year-olds (11 per thousand), especially among boys (17 per thousand).<sup>102</sup>

A high and increasing level of antipsychotic prescribing for children and adolescents was also evident in the US where atypical antipsychotics prescriptions for children rose from 600 (per 100,000 doctor visits) in 1998 to 2,450 in 2004 with 80% of the prescriptions for conditions other than schizophrenia, 49% being for disruptive behaviour.<sup>103</sup> These levels of prescribing of atypical antipsychotics for children raised concerns about the increased risk of adverse effects. Two studies [Findling (2008), Sikich (2008)] in the *American Journal of Psychiatry* sought to address these concerns, which were also the focus of an editorial [Sikich (2008)].

Findling (2008) was a 6-week study of Aripiprazole<sup>104</sup> as a treatment for adolescent schizophrenia. Having commented that there was a "*paucity*" of other relevant studies,<sup>105</sup> it found that:

The most common adverse events associated with aripiprazole were extrapyramidal disorder, somnolence and tremor ... The rates of serious treatment-emergent adverse events were low for all groups  $\dots^{106}$ 

It concluded that: "Aripiprazole ... was more efficacious in ameliorating the symptoms of schizophrenia than was placebo ... Although considerable improvement was also observed with placebo, ..."<sup>107</sup> and recommended that longer-term trials were necessary to confirm the drugs efficacy and safety.<sup>108</sup>

Sikich (2008) – which was a publicly funded study (TEOSS)<sup>109</sup> – was designed to compare the safety and efficacy of two atypical antipsychotics [olanzapine (*Zyprexa*) and risperidone] with a first generation antipsychotic [molindone] in the treatment of children and adolescents. The authors noted that atypical antipsychotics are considered the "*standard treatment*" even though their superiority over first generation antipsychotics had never been demonstrated.<sup>110</sup> The belief in the superiority of atypical antipsychotics amongst clinical psychiatrists was so great as to raise "… *significant ethical concerns about utilizing any first-generation antipsychotic in comparison with* 

<sup>&</sup>lt;sup>102</sup> Kalverdijk (2008), p.554.

<sup>&</sup>lt;sup>103</sup> Carey, B. (2008). 'Risks Found for Youths in New Antipsychotics.' *The New York Times*. 15 September.

<sup>&</sup>lt;sup>104</sup> An atypical antipsychotic licensed for the treatment of adult schizophrenia and bipolar disorder.

<sup>&</sup>lt;sup>105</sup> Findling (2008) mention a 4-week study of 75 adolescents and an 8-week study of 107.

<sup>&</sup>lt;sup>106</sup> *Ibid.*, p.1438.

<sup>&</sup>lt;sup>107</sup> *Ibid.*, p.1439.

<sup>&</sup>lt;sup>108</sup> *Ibid.* 

<sup>&</sup>lt;sup>109</sup> Treatment of Early-Onset Schizophrenia Spectrum Disorders (TEOSS).

<sup>&</sup>lt;sup>110</sup> Sikich (2008), p.1420.

second-generation antipsychotics."<sup>111</sup> and to preclude using a drug-free arm which the

study authors had considered.<sup>112</sup>

In relation to efficacy the study concluded that:

... only small differences among treatments emerged, which was not what we predicted. We did not find any evidence of superiority of the two second-generation antipsychotics ... over the first-generation antipsychotic,<sup>113</sup>

However:

Across all three treatments, more than half the participants failed to achieve an adequate response after 8 weeks of therapy. The mean reductions in psychotic symptoms were modest, ... Furthermore, 10 participants (8%) required hospitalization during the acute trial, primarily as a result of increased psychotic symptoms.<sup>114</sup>

In relation to side effects:

Adverse effects led to premature treatment discontinuation in eight patients in the molindone group, six patients in the olanzapine group, and five patients in the risperidone group ... Frequent adverse events included sedation, irritability, and anxiety ... Youth treated with olanzapine gained an average of 6.1 kg.<sup>115</sup> ... those associated with olanzapine and risperidone are likely to have persistent effects on long-term physical health.<sup>116</sup>

The increases in cholesterol levels and other metabolic disruptions in the olanzapine

group were such that they may have become dangerous and prompted the safety review

board to stop the olanzapine arm of the study before it had been completed.<sup>117</sup>

The final conclusions were that:

These findings have broad public health implications. In the long term, the metabolic side effects of olanzapine and risperidone may place many youth at risk for diabetes and cardiovascular problems. Second-generation antipsychotics are now widely used to treat nonpsychotic mood and behavioral disorders in youth. The balance between potential therapeutic benefits and risk of adverse events needs to be carefully considered in this age group.<sup>118</sup>

The editorial which accompanied the publication of both studies, noted the limited efficacy of all the antipsychotics that had been tested, particularly when contrasted with placebo treatment:

<sup>&</sup>lt;sup>111</sup> *Ibid*.

<sup>&</sup>lt;sup>112</sup> Ibid., p.1427.

<sup>&</sup>lt;sup>113</sup> Ibid.

<sup>&</sup>lt;sup>114</sup> *Ibid.*, p.1425.

<sup>&</sup>lt;sup>115</sup> Ibid., p.1424.

<sup>&</sup>lt;sup>116</sup> Ibid., p.1425.

<sup>&</sup>lt;sup>117</sup> Press release from *National Institute for Mental Health* [online], available:

http://www.nih.gov/news/health/sep2008/nimh-15.htm [accessed: 20 March 2009].

<sup>&</sup>lt;sup>118</sup> Sikich (2008), p.1428–9.

For both studies, the target mean dose was reached within 2 weeks of study onset. All treatment arms (including placebo) demonstrated a 12%-16% decrease in symptoms over the first 2 weeks of treatment. By 6 weeks, the <u>placebo arm had a symptom decrease of 22%</u>, while the active treatment arms had decreases of 23%-30%.<sup>119</sup>

The widespread – and often off-label – use of atypical antipsychotics as shown by, for example, Kalverdijk (2008) (*supra*), in conjunction with extremely limited evidence as to their efficacy and the seriousness of the side effects is striking and provides little comfort for those who argue that clinical paediatric psychiatry is an evidence-based discipline. Furthermore, the ethical concerns raised by psychiatrists on the use of conventional antipsychotics in place of atypical antipsychotics was shown to be deeply misplaced in that it effected an interdict against seeking supporting evidence, yet when the evidence was obtained it showed that the use of atypical antipsychotics in adolescents was likely to cause "*persistent effects on long-term physical health*" (*supra*). This provides a cautionary tale against yielding to the similar concerns which have been raised against examining the evidence for non-drug treatment of schizophrenia.

Further evidence on the extent and severity of the adverse effects of the adult use of antipsychotics emerged in Douglas & Smeeth (2008) which sought to determine whether the adult use of antipsychotics increased the risk of stroke. The study had been based on the General Practice Research Database and thus had access to the records of over 6 million patients; this allowed the authors to conclude that the study was: "… *large and statistically powerful … largely representative of the population of the UK and so the results are likely to be highly generalisable.*"

The study concluded that:

All antipsychotics are associated with an increased risk of stroke, and the risk might be higher in patients receiving atypical antipsychotics than those receiving typical antipsychotics. ... During the periods after treatment the rate ratio fell towards unity.

The increased risk of stroke was further analysed according as to whether dementia was present; the data is summarised in the following table:

<sup>&</sup>lt;sup>119</sup> Ross (2008), p.1371 [Emphasis added]

	No Dementia Present	Dementia Present
Typical Antipsychotics	140%	326%
Atypical Antipsychotics	190%	586%

Table L-1: Increased risk of stroke associated with antipsychotics use

Evidence that the use of atypical antipsychotics can nearly double the risk of stroke gives an added emphasis to the warnings of psychiatrists such as Moncrieff (2007) who berates her fellow psychiatrists for ignoring the evidence of the harm caused by antipsychotics thereby risking "*an epidemic of iatrogenic brain damage*."<sup>120</sup> It gives an additional urgency to addressing Lehtinen's (2006) concern (*supra*) that the high mortality in schizophrenia is attributable to the use of antipsychotics; some of these concerns were addressed by Ray (2009) which is discussed in the following subsection.

## L-11: Some research findings from 2009

Ray (2009), which was an analysis of more than 250,000 Medicaid records, was the first study to rigorously document the risk of cardiac harm attributable to the adult use of atypical antipsychotics.<sup>121</sup> The study concluded that:

Current users of typical antipsychotic drugs had an adjusted rate of sudden cardiac death that was twice that for nonusers ... A similar increased risk was seen for current users of atypical antipsychotic drugs, who had a rate of sudden cardiac death that was more than twice that for nonusers ... The risk of sudden cardiac death increased with an increasing dose ... <sup>122</sup>

By using a parallel secondary analysis of those subjects who had not been diagnosed with schizophrenia they were able to answer the concern raised by Lehtinen (2006) (supra) – in so far as it related to deaths due to cardiac arrest – and to conclude that the increased risk was attributable to antipsychotic use rather than any underlying psychiatric condition.

An accompanying editorial<sup>123</sup> noted, without comment, that:

It is striking that it took so long to establish the elevated risk associated with atypical antipsychotic medications given that the first agent in this class  $\dots$  entered the U.S. market in 1989.<sup>124</sup>

Given the increased risk, it is important to judge it in context and to ask 'how common is sudden cardiac death among adults treated with antipsychotic medications?' Ray

<sup>&</sup>lt;sup>120</sup> James, A. (2008). 'Myth of the antipsychotic'. *The Guardian*. 2 March: "'*It is as if the psychiatric community can not bear to acknowledge its own published findings,' she writes.*"

<sup>&</sup>lt;sup>121</sup> Carey, B. & Rabin, R. (2009). 'Study Finds Drug Risks With Newer Antipsychotics.' *The New York Times.* 14 January.

<sup>&</sup>lt;sup>122</sup> Ray (2009), p.225.

<sup>&</sup>lt;sup>123</sup> Schneeweiss & Avorn (2009).

<sup>&</sup>lt;sup>124</sup> *Ibid.* and noted that three of the antipsychotics: "Zyprexa, ... Risperdal, ... Seroquel, are among the 10 top-selling drugs worldwide, with a combined sales volume of \$14.5 billion in 2007."

(2009) estimated the prevalence at 2.9 events per 1000 patient-years. A commentary on this stated: "*The risk of death from the drugs is not high, on average about 3 percent in a person being treated at least 10 years.*"<sup>125</sup>

Such a perspective must be viewed against an earlier editorial in the *New England Journal of Medicine*<sup>126</sup> which advocated a life time use of antipsychotics in the treatment of schizophrenia; within such a context and analysing the risk-profile of ten subjects diagnosed with schizophrenia and using antipsychotics for a period of 30 years, Ray (2009) implies that 1 will die from cardiac arrest. Seen in the context of a lifetime use of antipsychotics, the risk of death due to cardiac arrest cannot – at 10% – be described as being "*not high*".

Leucht (2009) was a meta-analysis of 150 double-blind randomised controlled trials of antipsychotics. Its goal was to compare the effects of conventional antipsychotics and atypical antipsychotics in the treatment of patients with schizophrenia; it was funded by the National Institute of Mental Health. It differed from earlier studies such as Geddes (2000a) (*supra*) which analysed only one efficiency outcome; it differed from *CATIE* and *CUtLASS* in that they used comparator drugs that are less potent than haloperidol whereas according to Leucht (2009): "A major limitation of our meta-analysis is that haloperidol was the comparator drug in most of the studies."<sup>127</sup>

Leucht (2009) concluded that:

Four of these<sup>128</sup> drugs were better than first-generation antipsychotic drugs for overall efficacy, with small to medium effect sizes ... The other second-generation drugs were not more efficacious than the first-generation drugs, even for negative symptoms. ...

Only a few have been shown to induce fewer extrapyramidal side-effects than low-potency first-generation antipsychotic drugs.<sup>129</sup>

The study noted that of the 150 studies, only 14 reported on the rate of relapse and 17 on the quality of life of medicated subjects and that "*In previous meta-analyses* … *side-effects were not assessed thoroughly*."<sup>130</sup> Their final conclusion was to the effect that because atypical antipsychotics differ in many of their properties:

... they do not form a homogeneous class and neither do first-generation antipsychotic drugs. Improper generalisation creates confusion and as a result the classification might be abandoned. ...

The second-generation drugs are expensive, and cost-effectiveness has not been

<sup>&</sup>lt;sup>125</sup> Carey & Rabin (2009).

<sup>&</sup>lt;sup>126</sup> Davis (2006) (*supra*).

<sup>&</sup>lt;sup>127</sup> *Op. cit.*, p.40.

<sup>&</sup>lt;sup>128</sup> *I.e.* atypical antipsychotics.

<sup>&</sup>lt;sup>129</sup> *Op. cit.*, p.31.

<sup>&</sup>lt;sup>130</sup> *Ibid*.

proven. Public institutions could save costs by funding studies to accurately define selected old compounds, because they were not rigorously studied at the time they were introduced.<sup>131</sup>

Tyrer & Kendall (2009) in an editorial accompanying Leucht (2009), comment that:

... what was seen as an advance 20 years ago ... is now, and only now, seen as a chimera that has passed spectacularly before our eyes before disappearing and leaving puzzlement and many questions in its wake. ... The spurious invention of the atypicals can now be regarded as invention only, cleverly manipulated by the drug industry for marketing purposes and only now

cleverly manipulated by the drug industry for marketing purposes and only now being exposed.  $^{\rm 132}$ 

In an echo of the comment by the lead author of Jones (2006) (*supra*), they ask: "*But how is it that for nearly two decades we have … 'been beguiled' into thinking they were superior?*"<sup>133</sup> A rhetorical question that eloquently reflects the woeful standard of evidence which had been used by clinical psychiatrists for over a decade, to justify their belief in the superiority of atypical antipsychotics.

#### L-12: Examples of industry manipulation of test results

Sketched below are three examples – Zyprexa [L–12(i)], Seroquel [L–12(ii)] and Neurontin<sup>134</sup> [L–12(iii)] – where either negative test data was withheld or where the pharmaceutical company engaged in illegal practices such as off-label marketing, which were uncovered in litigation undertaken in US courts.

There is a more complete discussion of such practices in Appendix J.

#### L-12(i): Zyprexa

Eli Lilly (the manufactures of Zyprexa) had been found by the courts to have withheld data which had shown that the antipsychotic caused obesity and diabetes. Under threat of criminal proceedings the company had offered \$1 billion as payment of a fine in addition to \$1.2 billion already paid in settlement of civil actions. Eli Lilly sales material encouraged representatives to engage in off-label marketing and to promote Zyprexa as a "*safe, gentle psychotropic*" suitable for people with mild mental illness.<sup>135</sup>

<sup>&</sup>lt;sup>131</sup> *Ibid.*, p.40.

 $<sup>^{132}</sup>$  Op. cit., p.4. They also note some of the methods whereby this sleight of hand has been achieved (e.g. high doses of haloperidol as a comparator; selective publication).

<sup>&</sup>lt;sup>133</sup> *Ibid*.

<sup>&</sup>lt;sup>134</sup> Though Neurontin is not strictly an antipsychotic, it has been used as a treatment for tardive dyskinesia and is thus associated with the use of antipsychotics. [See Hardoy (2003)].

<sup>&</sup>lt;sup>135</sup> Berenson, A. (2006). 'Eli Lilly Said to Play Down Risk of Top Pill'. *The New York Times*. 17 December.

## L-12(ii): Seroquel<sup>136</sup>

AstraZeneca (the manufacturers of Seroquel) were sued in a class action comprising 9,200 patients who alleged that their diabetes was caused by their use of Seroquel. Details of a research study known as '*Study 15*' emerged during proceedings; it had been completed in 1997 but never made public nor made known to clinicians though provided to the FDA.<sup>137</sup>

The drug was approved by the FDA in 1997, was widely prescribed and "*has earned billions for* … *AstraZeneca* … *including nearly* \$12 *billion in the past three years*." Study 15 showed that the test subjects gained an average of 11 pounds a year – a result which precipitated an exchange of e-mails between company executives:

- [X] reported that across all patient groups and treatment regimens, regardless of how numbers were crunched, patients taking Seroquel gained weight: "*I'm not sure there is yet any type of competitive opportunity no matter how weak.*" ...

- [Y] praised AstraZeneca's efforts to put a "positive spin" on "this cursed study" and said of Arvanitis: "Lisa has done a great 'smoke and mirrors' job!" "Thus far, we have buried Trials 15, 31, 56 and are now considering COSTAR."

In 1999, two years after those exchanges, the company presented different data at an American Psychiatric Association conference, to the effect that Seroquel helped psychotic patients lose weight – a claim which was based on a company-sponsored study by a psychiatrist who had reviewed the records of 65 patients who had switched their medication to Seroquel.

## L-12(iii): Neurontin<sup>138</sup>

Neurontin had been approved by the FDA for a very narrow use in the controlling of seizures in epileptics but had been widely prescribed off-label.

Under a so-called 'shadowing' programme which came to light during a civil and criminal investigation of the drug's manufactures (Pfizer):

... physicians, in exchange for money, have allowed pharmaceutical sales representatives into their examining rooms to meet with patients, review medical charts and recommend what medicines to prescribe.

Pfizer tracked whether doctors prescribed Neurontin, "*rewarding those who were considered high-volume prescribers by paying them as speakers and consultants*"

<sup>&</sup>lt;sup>136</sup> The information below has been drawn from Vedantam (2009) except where otherwise stated. Vedantam, S. (2009). 'A Silenced Drug Study Creates An Uproar.' *The Washington Post*. 18 March.

<sup>&</sup>lt;sup>137</sup> Though "the agency has strenuously maintained that it does not have the authority to place such studies in the public domain."

<sup>&</sup>lt;sup>138</sup> The information below has been drawn from Peterson (2002) except where otherwise stated. Peterson, M. (2002). 'Suit Says Company Promoted Drug in Exam Rooms.' *The New York Times.* 15 May.

In 2000, more than 78% of Neurontin prescriptions were written for off-label uses.

However, some psychiatrists had found that:

... some patients taking Neurontin for schizophrenia or bipolar disorder appeared to become more aggressive after starting on the drug. ... "Neurontin is being used like water for disorders where there is not much evidence it is effective, ..."

Pfizer pleaded guilty to criminal charges and was fined \$430 million;<sup>139</sup> it was also found to have manipulated test data, suppressed negative test results and fraudulently manipulated the drug's supposed benefits.<sup>140</sup>

# *L*–13: Some conclusions concerning the safety and efficacy of antipsychotics

Having discussed the CATIE and CUtLASS 1 findings (*supra*) three interim conclusions were drawn [L–7 *supra*]. The goal of this final subsection is to see whether the studies published between 2006 and 2009 necessitate a revision of these interim conclusions.

The first interim conclusion was to the effect that the existence of grossly inconsistent results regarding the safety and efficacy of atypical antipsychotics implied that some earlier studies were deeply flawed. The statement by a *Lancet* editorial<sup>141</sup> that the advent of the supposedly safer and more efficacious atypical antipsychotics: "... *is now, and only now, seen as a chimera that has passed spectacularly before our eyes* ...", in addition to evidence of the manipulation of test results in published studies, adds further strength to that interim conclusion and allows it to be stated without reservation:

1. The inference to be drawn from the existence of grossly inconsistent results in relation to trials of first and second generation antipsychotics, is that some supposedly evidence-based studies supporting the psychiatric use of antipsychotics, are deeply flawed.

The second interim conclusion concerned the reluctance of clinical psychiatrists to change their beliefs concerning the safety and efficacy of atypical antipsychotics in the light of new and authoritative disconfirmatory evidence.

The continuously increasing use of atypical antipsychotics (including evidence of extreme levels<sup>142</sup> of off-label use), especially in the treatment of children and young adults,<sup>143</sup> in the face of mounting evidence<sup>144</sup> as to risk of serious adverse effects such

<sup>&</sup>lt;sup>139</sup> Harris, G. (2004). 'Pfizer to Pay \$430 Million Over Promoting Drug to Doctors.' *The New York Times*. 14 May.

<sup>&</sup>lt;sup>140</sup> Saul. S. (2008). 'Experts Conclude Pfizer Manipulated Studies.' *The New York Times.* 8 October.

<sup>&</sup>lt;sup>141</sup> Tyrer & Kendall (2009) (*supra*).

<sup>&</sup>lt;sup>142</sup> See, for example, (*supra*) 78% of Neurontin prescriptions were for off-label use.

<sup>&</sup>lt;sup>143</sup> As shown by, for example, Kalverdijk (2008) (supra).

<sup>&</sup>lt;sup>144</sup> See, for example, Sikich (2008) (*supra*).

as EPS and diabetes and "persistent effects on long-term physical health" (supra), suggests that the beliefs of clinical psychiatrists in relation to the use of atypical antipsychotics is relatively immune from readily available disconfirming evidence. In that the reluctance to adjust robustly held views in the face of disconfirming evidence is one of the criteria used by psychiatrists in the definition of delusional behaviour,<sup>145</sup> this conclusion is disconcerting. In these circumstances, the second interim conclusion can only be strengthened:

2. There is a manifest reluctance amongst clinical psychiatrists to changing their beliefs in relation to the appropriate prescribing of antipsychotics, in the face of authoritative disconfirming evidence relating to the safety and efficacy of atypical antipsychotics.

The third interim conclusion was to the effect that both the extent and severity of harms associated with antipsychotics use had been underestimated. Results published in the years between 2006 and 2009:

- as to the risk of diabetes and EPS,
- long term and extensive brain damage,<sup>146</sup> \_
- the doubling of the risk of stroke.<sup>147</sup> -
- the limited duration of drug trials (6 -8 weeks) when compared to a possible lifetime use of such drugs,
- the lack of attention paid to possible adverse effects and to the subjective effect of such adverse effects,<sup>148</sup>
- the reluctance of clinical psychiatry to acknowledge the seriousness of the adverse effects of antipsychotics as evidenced by its earlier attitude towards the emergent risk of tardive dyskinesia,149

suggest not only a stronger conclusion in relation to the underestimation of harm, but also the conclusion that clinical psychiatry appears to be somewhat inured to the possibility of such harm.

Kane (2006) (supra) had suggested that it was the threat of litigation that forced clinical psychiatry to confront the risk of tardive dyskinesia. If this is correct, the effective absence of legal recourse under Irish Law in respect of harm occasioned by coercive treatment with antipsychotics, is in need of urgent redress.

<sup>&</sup>lt;sup>145</sup> See Chapter 2 (*supra*).

<sup>&</sup>lt;sup>146</sup> See Andreasen (*supra*).

<sup>&</sup>lt;sup>147</sup> See Douglas & Smeeth (2008) (*supra*).

<sup>&</sup>lt;sup>148</sup> See Leucht (2009) (*supra*) who noted that of the 150 studies examined, only 14 reported on the rate of relapse and 17 on the quality of life of medicated subjects and that "In previous meta-analyses ... sideeffects were not assessed thoroughly." <sup>149</sup> Kane (2006) (supra).

3. There are substantial grounds for holding not only that the extent and the severity of harms associated with the use of antipsychotics have been grossly underestimated both by researchers and by clinical psychiatrists, but that even when the magnitude of such harms has been conclusively established, it has not informed the beliefs of psychiatrists as reflected in their prescribing habits. The implementation of an effective means for seeking legal redress for those harmed by coercive treatment with psychotropic medication, is a precondition for the minimising of iatrogenic harm consequent on psychiatric intervention.

# Appendix M: Journal searches for rates of psychiatric misdiagnosis

In an attempt to locate estimates of the rates of psychiatric misdiagnosis, journal searches were undertaken; these searches were of two types:

- searches of journals which were not specific to psychiatry for occurrence of the phrase 'psychiatric misdiagnosis' anywhere in the text *i.e.* in the title, abstract or body of the journal article. [Subsection M-1]
  - Contrary to expectations these searches elicited so few results that a further search was undertaken for articles which contained both the terms 'psychiatric' and *'misdiagnosis'* but not necessarily adjacent nor in the same context.<sup>1</sup>
- searches of psychiatric journals for occurrences of the term 'misdiagnosis' firstly in the title or abstract, and secondly, anywhere in the text. [Subsection M-2] Within these results, a further search was undertaken for 'compulsory admission' in an attempt to find estimates of the proportion of coercive psychiatric interventions that had been grounded in a misdiagnosis.

The conclusions drawn from these searches are discussed in Chapter 4, Section D.

## M-1: Searches of non-psychiatric journals<sup>2</sup>

The search was first undertaken within some individual medical journals:

- (i) The British Medical Journal [M-1(i)];
- (ii) The Lancet  $[\underline{M-1(ii)}]$ ; and
- (iii) The New England Journal of Medicine [M–1(iii)].

And then within medical databases:

- (iv) PubMed [M-1(iv)]; and
- (v) MEDLINE [ $\underline{M}-\underline{l(v)}$ ].

#### M-1(i): The British Medical Journal

A search of the British Medical Journal between January 1994 and July 2008, for the term 'psychiatric misdiagnosis' occurring anywhere in a journal article, retrieved just one article;<sup>3</sup> it concerned the misdiagnosis of '*conversion symptoms*'<sup>4</sup>.

<sup>&</sup>lt;sup>1</sup> I.e. the search term was "psychiatric AND misdiagnosis".

<sup>&</sup>lt;sup>2</sup> Searches were conducted between 3 and 10 September 2008.

<sup>&</sup>lt;sup>3</sup> Stone (2005).

Searches for the terms "psychiatric mis-diagnosis"; "psychiatric under-diagnosis"; "psychiatric underdiagnosis"; "psychiatric over-diagnosis" or "psychiatric overdiagnosis" retrieved no results.

<sup>&</sup>lt;sup>4</sup> *I.e.* physical symptoms diagnosed as being of psychiatric origin.

A search for "*psychiatric AND misdiagnosis*" retrieved 24 results; of those results which had some relevance to psychiatric misdiagnosis:

- 8 concerned the misdiagnosis of conversion symptoms;
- 3 discussed the misdiagnosis of physical illness (*e.g.* epilepsy) as psychiatric;
- 1 discussed whether the high diagnosis of psychiatric illness amongst immigrant communities, could be attributed to misdiagnosis;
- 2 were news items reporting the rapid increase ("40-fold from 1994 to 2003")<sup>5</sup> in the diagnosis of bipolar disorder and whether this indicated extensive misdiagnosis.

## <u>M-1(ii): The Lancet</u>

A full text search of the *Lancet* series of journals for use of the term '*psychiatric misdiagnosis*' between January 1996 and January 2008 retrieved no results.

A full text search for '*psychiatric AND misdiagnosis*' over the same period retrieved 26 results, the most common topic being epilepsy (3 results) followed by chronic fatigue syndrome (2 results). Only one result had a general relevance to psychiatric misdiagnosis and its author (a consultant psychiatrist who had worked at Ashworth Maximum Security Hospital) detailed how his attempt to introduce non-pharmacological psychiatric treatments had been frustrated by other psychiatrists:<sup>6</sup>

... [these] psychiatrists are not alone in misdiagnosing all mental disease – contemporary psychiatry takes its cue from DSM-IV, bizarrely presuming, against all the evidence, that social and emotional stress, even the death of a loved one, have no impact on mental disease. The horrors from this misdiagnosis exceed even those from the Ashworth variety – and are harder to remedy, given the level of support for it among government departments and medical editors.<sup>7</sup>

## *M*–1(*iii*): The New England Journal of Medicine

A full text search for occurrences of the term '*psychiatric misdiagnosis*' in articles published between September 1993 and September 2008, retrieved no results.

A full text search for "*psychiatric AND misdiagnosis*" retrieved 9 results the most common topic being ADHD (2 results); none were relevant to estimating levels of psychiatric misdiagnosis.

<sup>&</sup>lt;sup>5</sup> Tanne (2007).

<sup>&</sup>lt;sup>6</sup> Johnson (1999):

The 15 consultant psychiatrists showed their managerial power by having us both removed ... It was only when the so-called treatment-resistant patients insisted on attending every group session, as did the Head of Psychology herself, that the consultant staff cited General Medical Council guidelines and the Mental Health Acts to expel me. The consultants deflected patients from the very door of the group therapy sessions, denying them entrance.

## M-1(iv): PubMed

A full text search for '*psychiatric misdiagnosis*' retrieved 12 results, the most relevant were:

- the misdiagnosis of physical or neurological illness as psychiatric (5 results); \_
- analyses of cases of psychiatric misdiagnosis (4 results);<sup>8</sup>
- misdiagnosis of Black patients (1 result). \_

A search for 'psychiatric AND misdiagnosis' retrieved a further 270 results of which 42 had some relevance to psychiatric misdiagnosis. Of these results,

- 8 related to technical misdiagnosis:<sup>9</sup> -
- 7 related to the misdiagnosis of physical illness as psychiatric;<sup>10</sup> \_
- 1 concerned deliberate misdiagnosis of depression. -
- 12 examined race as a cause of misdiagnosis<sup>11</sup> and \_
- 13 examined other causes, some of which have already been discussed.<sup>12</sup> \_

Of the remaining relevant studies, one argued that:

Recent research has raised concerns about the adequacy of psychiatric diagnostic evaluations conducted in routine clinical practice. Semistructured diagnostic interviews have been considered the diagnostic gold standard. Judged against this standard, studies comparing unstructured clinical evaluations with semistructured interviews have found that there is a high rate of missed diagnoses and misdiagnosis using the usual clinical assessment. Whether this is clinically significant is uncertain because there are no studies that have examined whether the use of standardized research interviews improves clinical outcome.<sup>13</sup>

A second examined the social causes of psychosis and concluded that:

The relation between the etiology of psychosis and such social factors as poverty, migration, and racial discrimination has been neglected in the North American psychiatric literature for the last 40 years. ... the study of social causes of psychosis has been replaced by a focus on the clinical encounter, in which

 $<sup>^{8}</sup>$  Khan & Shaikh (2008) examined four case reports in an attempt to isolate the factors contributing to psychiatric misdiagnosis; one such factor was the "excessive reliance on the expertise of specialists." The authors emphasised "the need to challenge and correct erroneous diagnoses to avoid inadequate response".

The other three papers were by Israeli researchers on psychiatric misdiagnosis: Witztum (1992), Margolin (1995) and Witztum (1995a). (See supra)

<sup>&</sup>lt;sup>9</sup> E.g. bipolar disorder misdiagnosed as unipolar depression.

Instances of misdiagnosis of schizophrenia in place of affective disorders, have not been classified as 'technical' because the diagnoses are qualitatively different when viewed from the perspective of assessing the risk of stigma, dangerousness or coercive intervention. [See infra and Chapter 4].

<sup>&</sup>lt;sup>10</sup> E.g. Reeves (2000) who examined the cases of 64 patients with unrecognized medical emergencies who were inappropriately admitted to psychiatric units, concluded that:

In none of the cases (0%) was an appropriate mental status examination performed. Other common causes of misdiagnosis included inadequate physical examination (43.8%), failure to obtain indicated laboratory studies (34.4%), and failure to obtain available history (34.4%).

<sup>&</sup>lt;sup>11</sup> The existence of a possible link between race and misdiagnosis is contentious [see *infra*].

 <sup>&</sup>lt;sup>12</sup> E.g. Witztum (1995a).
 <sup>13</sup> Zimmerman (2003).

clinician bias is presumed to be responsible for widespread misdiagnosis of psychosis in minority ... populations.<sup>14</sup>

A standpoint which if adopted, might help dispel some of the confusion that surrounds the debate on race and psychiatric misdiagnosis (*supra*).

#### <u>M-1(v): MEDLINE</u>

A full text search for the term '*psychiatric misdiagnosis*' between 1979 and 2007 yielded 9 results;<sup>15</sup> these added little to the results already obtained.

The search for '*psychiatric AND misdiagnosis*' between 1996 and 2007 yielded 129 results; as an analysis of these added little to earlier results, no searches were made prior to 1996.

## M-2: Searches of psychiatric journals<sup>16</sup>

Searches were made of two authoritative journals:

- The American Journal of Psychiatry [M-2(i)]; and
- The British Journal of Psychiatry [<u>M-2(ii)</u>].

for occurrences of the term '*misdiagnosis*'<sup>17</sup> firstly in the title or abstract, and secondly, anywhere in the text.

#### <u>M–2(i): The American Journal of Psychiatry</u>

A title or abstract, search for '*misdiagnosis*' between 1844 and 2008, yielded 19 results.<sup>18</sup> Though none of the studies yielded information sufficient to estimate rates of misdiagnosis (whether general or specific) some did give an insight into the misdiagnosis of schizophrenia:

- 1996-1999: 1 [racism];
- 2000-2002: none;
- 2003-2007: 2 [racism].

<sup>&</sup>lt;sup>14</sup> Jarvis (2007).

<sup>&</sup>lt;sup>15</sup> More accurately:

<sup>1975-1979:</sup> none;

<sup>1980-1984: 1 [</sup>racism];

<sup>1985–1988: 1 [</sup>psychiatric misdiagnosis of myasthenia gravis (muscle weakness)];

<sup>1989–1990:</sup> none;

<sup>1991–1995: 5 [3</sup> Witztum papers (supra), misdiagnosis of myasthenia gravis and of cystitis];

<sup>&</sup>lt;sup>16</sup> Searches were conducted on 11 September 2008.

<sup>&</sup>lt;sup>17</sup> Being psychiatry journals, a search for '*misdiagnosis*' was considered to be more appropriate that one for '*psychiatric misdiagnosis*'.

<sup>&</sup>lt;sup>18</sup> Of which:

<sup>3</sup> were 'Letters to the Editor';

<sup>3</sup> were book reviews;

<sup>4</sup> concerned technical misdiagnosis;

<sup>2</sup> discussed misdiagnosis and race;

<sup>7</sup> concerned the misdiagnosis of schizophrenia.

<u>Example (i)</u>: It appears from these data that black and Hispanic ... bipolar patients may be at a higher risk than whites for misdiagnosis as schizophrenic ... <sup>19</sup>

*Example (ii)*: Two groups of inpatients who were initially misdiagnosed are described. The pseudoschizophrenics showed little affect and had histories of exotic and sensational behavior; the initial misdiagnosis of schizophrenia appeared to be a moral censure.

The pseudoneurotic schizophrenics (mistakenly diagnosed at admission as nonschizophrenic) had more affect and were frequently pregnant, affiliated with the medical profession, or twins; these diagnostic mistakes appeared to be attempts to protect someone from the label of schizophrenia.<sup>20</sup>

*Example (iii)*: In the Amish Study of affective disorders, 79% of the 28 active bipolar I patients, ... previously had received hospital record diagnoses of schizophrenia.<sup>21</sup>

A full text search for 'misdiagnosis' yielded no additional results.

A full text search for '*misdiagnosis AND* "*compulsory admission*" ' yielded 3 results of which 1 had no relevance,<sup>22</sup> both of the remaining concerned race; of these, one discussed the advisability of "*matching clients from a minority group with clinicians from the same ethnic background*"<sup>23</sup>; the second<sup>24</sup> was a meta-analysis which found that the relative risk of schizophrenia in immigrant communities was 4.8 times that of non-immigrants; it did not, however, give credence to the possibility of misdiagnosis as being a possible cause.<sup>25</sup>

#### <u>M-2(ii): The British Journal of Psychiatry</u>

A title or abstract search for 'misdiagnosis' yielded 13 results;<sup>26</sup> of most interest in the present context was an especially authoritative<sup>27</sup> survey of UK psychiatrists as to whether they believed that race contributed to psychiatric misdiagnosis.<sup>28</sup> It concluded that:

<sup>25</sup> *Ibid.*, p.20:

schizophrenia, seriously affects their lives by its effects, for example on job prospects and relationships." [*Ibid.*, p.401] provides some justification for the decision taken earlier in this discussion to distinguish between a 'technical misdiagnosis' and the misdiagnosis of schizophrenia.

<sup>&</sup>lt;sup>19</sup> Mukherjee (1983).

<sup>&</sup>lt;sup>20</sup> Schorer (1968).

<sup>&</sup>lt;sup>21</sup> Egeland (1983).

<sup>&</sup>lt;sup>22</sup> The context was: "This interview was compulsory for all potential living kidney and kidney/pancreas recipients."

<sup>&</sup>lt;sup>23</sup> Ziguras (2003).

<sup>&</sup>lt;sup>24</sup> Cantor-Graae (2005).

Some researchers have argued that migrants preferentially receive schizophrenia diagnoses because of cultural misunderstanding and/or language difficulties ... Nevertheless, evidence in support of this notion is not convincing.

It did, however, canvass the possibility that the experience of racial discrimination possibly "facilitates the development of psychotic symptoms". (p.21).

<sup>&</sup>lt;sup>26</sup> Of these results, 4 discussed the possible link between misdiagnosis and race; 4 examined the misdiagnosis of a physical illness as psychiatric; 1 discussed a technical misdiagnosis.

 <sup>&</sup>lt;sup>27</sup> Each member of the Royal College of Psychiatrists in the UK was canvassed and 43% participated.
 <sup>28</sup> The opening sentence of the report: "Stigmatisation of people with mental illness, especially

Misdiagnosis of schizophrenia in Black people is believed to be  $common^{29}$ ... This may be surprising in view of research studies, which have suggested such misdiagnosis to be uncommon (Harrison *et al*, 1988), but accords with the views of many patient groups and some recent research (Hickling *et al*, 1999). It is possible that such studies using standardised instruments are seen by psychiatrists as not being typical of 'normal' clinical practice where such misdiagnosis may be more common.<sup>30</sup>

The dichotomy noted between research findings and clinical perceptions of misdiagnosis, raises the question – particularly because the survey was so authoritative – as to whether other research findings on psychiatric misdiagnosis underestimate the phenomenon.

A full text search for '*misdiagnosis*' yielded 172 results; whilst some discussed instances of physical disorders misdiagnosed as psychiatric (*e.g.* Huntington's Chorea) and some examined small studies of technical misdiagnosis, none – with the exception of 25 results which discussed racial factors – had any immediate relevance to the problem of estimating general rates of psychiatric misdiagnosis. The studies on misdiagnosis and race focused mainly on whether the high rates of diagnosis of schizophrenia found in the Afro-Caribbean population in the UK, was evidence of misdiagnosis.

Searching within these 172 results for those which discussed '*compulsory admission*' yielded 9 results, 6 of which<sup>31</sup> concerned race as a cause of psychiatric misdiagnosis. Amongst these papers there is broad agreement on a number of propositions:

1. The existence of disproportionately high rates of compulsory admission amongst

Afro-Caribbeans and Blacks when compared to Whites.<sup>32</sup>

2. The existence of disproportionately high rates of schizophrenia amongst Afro-

Caribbeans and Blacks when compared to Whites.<sup>33</sup>

<sup>&</sup>lt;sup>29</sup> 47.9% of respondents '*strongly agreed/agreed*' that misdiagnosis of schizophrenia in Black people is common whereas 25.1% '*strongly disagreed/disagreed*'.

<sup>&</sup>lt;sup>30</sup> Kingdon (2004).

<sup>&</sup>lt;sup>31</sup> The remaining 3 were:

<sup>(</sup>i) Porter (2001) which concerned non-pharmacological treatment of depression;

<sup>(</sup>ii) Clark (2001) which examined the treatment of adolescent psychosis; and

<sup>(</sup>iii) Davison (2002) which discussed managing patients with personality disorder.

<sup>&</sup>lt;sup>32</sup> Singh (2007): "Black patients were 3.83 times ... more likely to be detained."

<sup>&</sup>lt;sup>33</sup> Bhugra (2001) cites studies showing rates of schizophrenia amongst African–Carribeans as between 2 and 14.6 times that of their White counterparts. (p.286).

See also De Vries (1995) who in discussing South Africa, stated:

Audit of community psychiatric clinics, however, showed strange figures: "Schizophrenia was diagnosed in 68% of black patients compared with 19% of white patients; mood disorders were diagnosed in 9% of black patients compared with 41% of white patients."

He also posed the following questions:

What criteria have been used to make the diagnosis? By whom were the diagnoses made? ... Is it not a sign of wisdom for rural black people to "hear voices" or "see vision" of their forefathers?

3. The raised rates of compulsory admission were largely attributable to increased rates of schizophrenia.<sup>34</sup>

The question of whether the disproportionately high rates of diagnoses of schizophrenia amongst Afro-Caribbeans and Blacks (and the corresponding high rates of compulsory admission) could be accounted for by misdiagnosis due to an (unconscious) racial prejudice amongst psychiatrists,<sup>35</sup> was generally discounted:

(i): Bebbington (1994) concluded: "*Ethnicity did not appear to be of outstanding importance in decisions to use the Mental Health Act.*"

(ii): Singh (2007) concluded: Although BME<sup>36</sup> status predicts psychiatric detention in the UK, most explanations offered for the excess detention of BME patients are largely unsupported."

(iii): Harvey (1990): "... [this study] does not support the hypothesis that misdiagnosis within the psychoses can explain the higher admission rates of schizophrenia calculated for Afro-Caribbean populations."

(iv): Sharpley (2001): "No simple hypothesis explains these findings."

(v): Bhugra (2001): "However, misdiagnosis alone cannot explain all the findings in both the USA and the UK."<sup>37</sup>

The conclusions that might be drawn from these search results are discussed in Chapter 4, Section D.

<sup>&</sup>lt;sup>34</sup> Thomas (1993):

In the Afro-Caribbean group, the raised rates of admission were largely attributable to increased rates of schizophrenia. The highest rate occurred in second-generation (UK-born) Afro-Caribbeans and was nine times that among Europeans.

See also Bebbington (1994): "... admission under the Act was strongly associated with challenging behaviour and diagnosis of schizophrenia."...

<sup>&</sup>lt;sup>35</sup> See Luhrmann (2010) who notes that in the 1980s:

African American men came to represent the problem of schizophrenia in popular culture and, arguably, in psychiatry. Advertisements for antipsychotic medications in the psychiatric journals showed angry black men or even just African tribal symbols. (p.479)

<sup>&</sup>lt;sup>36</sup> *I.e.* Black and minority ethnic groups

<sup>&</sup>lt;sup>37</sup> Op. cit., p.285.

### Appendix N: Journal searches for occurrences of 'irrational(ity)'

Of the various journal searches for occurrences of the term 'irrational' (which have been detailed in Chapter 2, Section B) the smallest set of search results (6) was for the *British Journal of Psychiatry* and – in order to convey a 'flavour' of the general results – this complete set is listed in <u>Subsection N-1</u>.

<u>Subsection N-2</u> contains an analysis of the aggregated results of all the journals which were searched.

## *N–1: The British Journal of Psychiatry: complete listing*

A search for occurrences of either 'irrational' or' irrationality' in title or abstract<sup>38</sup> between October 1855 to December 2009, yielded 6 results:<sup>39</sup>

[In the interests of readability, occurrences of 'irrational' or 'irrationality' are underlined.]

1. Philpot, M. *et al* (2001). 'The use of operationalised criteria for inclusion on a Care Programme.' *Psychiatr. Bull.* 25: 172 – 174.

Health service policies exist to reduce variation in clinical practice and to ensure minimum standards. Clinical audit may be a useful tool in identifying <u>irrational</u> variation within the framework of clinical governance.

2. Anderson, D. (1989). 'A comparison of in-patient and out-patient prescribing.' *The British Journal of Psychiatry*. 154: 644 – 649.

This suggests that psychiatrists do not adopt intransigent stances in favour of polypharmacy and <u>irrational</u> psychotropic prescribing, as previous studies have implied. Caution is advised before attributing apparently <u>irrational</u> prescribing to bad clinical practice, or advocating remedial action aimed at changing the habits of prescribers.

3. McKerracher, D. *et al* (1968). 'Self-Mutilation in Female Psychopaths.' *The British Journal of Psychiatry*. 114: 829 – 832.

It may be that the acts of self-mutilation and window-smashing have a ceremonial quality. There would certainly seem to be a compulsive element in the repetitive and <u>irrational</u> manner of their perpetration ...

4. Kräupl, F. (1948). 'Some Observations on the Analytical Group Treatment of a Phobic Patient.' *Journal of Mental Science*. 94: 77 – 88.

The psychosexual constitution of the patient and his response to the group were unusually transparent. He showed marked anal-erotic, sado-masochistic, and bi-sexual trends with repressed passive homo-erotic impulses. The result of group treatment was mainly limited to a correction of <u>irrational</u> social fears through the reduction of guilt feelings and the gradual acceptance of his passive-feminine and masochistic leanings.

5. Stengel, E. (1941). 'On the Aetiology of the Fugue States.' Journal of Mental Science. 87: 572 – 599.

<sup>&</sup>lt;sup>38</sup> Full text searches over the same period, yielded 652 results for 'irrational' and 87 for 'irrationality'.

<sup>&</sup>lt;sup>39</sup> The results are listed in reverse chronological order.

Certain types of behaviour akin to wandering states occur in children in whom there is a disturbance of home conditions similar to what has been noted in this paper. A tendency towards rationalization and sublimation indicates in some cases the effort to oppose the irrational urge. ... to find a compromise between the irrational impulse and rational strivings.

6. Unsigned (1902). 'Epidemic Irrationality: an American City of Unreason.' Journal of Mental Science. 48: 542-543

... such an extensive outburst of <u>irrationality</u>, that it really calls for grave consideration.

In that these results comprise the complete listing of all 'Title/Abstract' occurrences (over a period of 154 years) of the term 'irrational', in the leading UK clinical psychiatric journal, they clearly exhibit a less than full understanding of the nuances of the term and a lack of precision in its usage. The following analysis will help determine the generalizability of this conclusion.

## *N*–2: Analysis of the aggregated search results of all journals

The aggregated search results were analysed under a number of headings as shown in the tables in N-2(i). Examples of individual search results as categorised under the various headings are given in <u>N-2(ii)</u>.

## N-2(i): Tables

The headings were suggested by a preliminary scrutiny of the search results; the examples given in N-2(ii) (*infra*) will give an indication of the meanings of the various categories that were adopted.

<u>Category</u>	<u>Number</u>
Colloquial	41
Emotion	12
Management	10
Philosophy (General)	12
Philosophy (Psychiatry)	23
Phobia / Fear	8
Polypharmacy	7
Psychiatric	9
Psychotherapy	8
Society	18
Suicide	15
Treatment Refusal	1
Treatments	17
Total:	181

Table N-1: Analysis of jou

105
42
15
16
3
181

Table N-2: Analysis of journal search results by precision

Coercion indicated	<u>Number</u>
Yes	12
No	169
Total:	181

Table N-3: Analysis of journal search results by coercive context

## N-2(ii): Examples<sup>40</sup>

Examples of categorisation are given in N-2(ii)(a); examples of precision rankings are given in N-2(ii)(b) and examples of coercion rankings are given in N-2(ii)(c). Two examples are given of all categories and rankings.<sup>41</sup>

#### N-2(ii)(a): Examples of categorisation

- Colloquial

<u>Example (i)</u>: Thomas Kuhn was criticized for allegedly suggesting ... that scientific decisions regarding theory choice, interpretation of data, and the like were determined by "mob psychology" or similar <u>irrational</u> sources.<sup>42</sup>

<u>Example (ii)</u>: One autumn evening when the university corridors were deserted, an <u>irrational</u>-seeming male student whom I did not recall having seen before, asked if he could speak to me.<sup>43</sup>

- Emotion

<u>Example (i)</u>: French sociologist who viewed punishment as an <u>irrational</u> emotional reaction driven by a culture's desire to maintain ...  $^{44}$ 

<u>Example (ii)</u>: ... a mother crazed with the stressors of incomprehensible behaviors, controversial professional advice, minimal support, and <u>irrational</u> guilt.<sup>45</sup>

<u>Management</u>

<u>Example (i)</u>: There is much that is inconsistent and <u>irrational</u> in the present methods of training surgeons.<sup>46</sup>

<sup>&</sup>lt;sup>40</sup> Page numbers for some examples could not be readily determined from the search results.

<sup>&</sup>lt;sup>41</sup> Except for 'Treatment Refusal' for which only one example was found

<sup>&</sup>lt;sup>42</sup> Sadler (1996).

<sup>&</sup>lt;sup>43</sup> Code (1996).

<sup>&</sup>lt;sup>44</sup> Kaempf (2009).

<sup>&</sup>lt;sup>45</sup> Lefley (2006).

<sup>&</sup>lt;sup>46</sup> Ravdin (1957).

*Example (ii)*: The authors believe this experience demonstrates that political factors can overwhelm standard clinical practice and reasoned health planning to force <u>irrational</u> change on health care delivery.<sup>47</sup>

- Philosophy (General)

<u>Example (i)</u>: ... arguments based on Kantian conceptions of autonomy are rejected as confused, and preference is given to Millian arguments based on the right to make decisions about one's own life, however <u>irrational</u>, as long as they do not harm others. In light of this discussion, it is argued that mentally disordered people cannot be denied this right on grounds of their <u>'irrationality</u>', which is anyway a vague concept with several meanings.<sup>48</sup>

<u>Example (ii)</u>: The problem shows up very clearly, interestingly enough given the present context, in Davidson's application of the theory to the phenomena of <u>irrationality</u>. <u>Irrationality</u> is explicated in terms of the causal efficacy of a reason overriding rational principles ...<sup>49</sup>

Philosophy (Psychiatry)

<u>Example (i)</u>: He tackles the crucially important issue of how practical rationality is related to mental health and of how certain forms of <u>irrationality</u> are connected with mental illness.<sup>50</sup>

<u>Example (ii)</u>: The history and present practice of psychiatry, as well as much ordinary moral thinking, is replete with examples of discounting some desires of patients on grounds of their supposed <u>irrationality</u>, a discounting which often, upon inspection, comes to little more than the evaluator disagreeing with the patient about what should be desired in the circumstances in question. Grounds for judging desires as intrinsically <u>irrational</u>, or as intrinsically less rational than other desires (as opposed to instrumentally <u>irrational</u> in achieving agreed upon ends), are notoriously unclear and controversial.<sup>51</sup>

- <u>Phobia / Fear</u>

<u>Example (i)</u>: Such a model will need to take account of the intuition that, for example, people who are paralyzed by <u>irrational</u> fear, ... may not be in the ideal position to make medical decisions ...  $52^{52}$ 

<u>Example (ii)</u>: A lasting psychological result from the accident is an <u>irrational</u> fear that while driving or bicycling, a car or truck will suddenly swerve into my path.<sup>53</sup>

**Polypharmacy** 

<u>*Example (i)*</u>: We are all aware that polypharmacy is a common practice – eminently rational when we engage in it but blatantly <u>irrational</u> in the hands of others.<sup>54</sup>

<sup>&</sup>lt;sup>47</sup> Hogben (1979).

<sup>&</sup>lt;sup>48</sup> Matthews (2000).

<sup>&</sup>lt;sup>49</sup> Bolton & Hill (1997).

<sup>&</sup>lt;sup>50</sup> Fields (1996a).

<sup>&</sup>lt;sup>51</sup> Brock (1998).

<sup>&</sup>lt;sup>52</sup> Elliot (1998).

<sup>&</sup>lt;sup>53</sup> Ship (2004).

<sup>&</sup>lt;sup>54</sup> Jefferson (2003).

<u>Example (ii)</u>: However, <u>irrational</u> polypharmacy occurs too frequently. Examples include the use of several benzodiazepines or several antipsychotics at the same time.<sup>55</sup>

- Psychiatric

<u>*Example (i)*</u>: The authors conclude that the experience of volitional control in patients with OCD [obsessive-compulsive disorder] is not significantly related to the level of insight they have into the <u>irrationality</u> of their behavior.<sup>56</sup>

<u>Example (ii)</u>: During the last decade there has been increasing pressure to legislate legal rights for psychiatric patients especially in relation to consent to treatment. The attempt to subject the <u>irrationality</u> of psychotic illness to the due process of rational laws has caused problems.<sup>57</sup>

<u>Psychotherapy</u>

<u>*Example (i)*</u>: Discussion groups of various kinds have been called "group psychotherapy." This <u>irrational</u> practice is illustrated and discussed.<sup>58</sup>

<u>*Example (ii)*</u>: ... very concept of therapeutic alliance involves contradiction – namely, the expectation that the patient is motivated to be rational about his or her own <u>irrationality</u>.<sup>59</sup>

Society

<u>Example (i)</u>: Belief systems which may be just as <u>irrational</u> but which are shared by millions are called world religions.<sup>60</sup>

<u>Example (ii)</u>: ... notion that climate change is an impending problem, the fear of nuclear power and radiation is perhaps based on ignorance and irrationality.<sup>61</sup>

<u>Suicide</u>

<u>Example (i)</u>: And the law in England makes clear that a person can refuse treatment for no reason or for an <u>irrational</u> reason ... But perhaps in practice, one reason why physicians do not respect the preferences of people like John and Ron is that they believe that such patients are <u>irrational</u> in desiring to die. Are such preferences <u>irrational</u>? In philosophy and economics, a dominant school maintains that there is only one form of rationality: instrumental rationality. According to this school, we are only <u>irrational</u> if we choose means which are inappropriate to our ends. Neither John nor Ron is <u>irrational</u> in this sense. Is John's choice intrinsically <u>irrational</u>?

*Example (ii)*: The author's literature survey suggests that the incidence of suicide among psychiatric residents ... During their residencies psychiatrists

<sup>&</sup>lt;sup>55</sup> Kingsbury (2002).

<sup>&</sup>lt;sup>56</sup> Rotter & Goodman (1993).

<sup>&</sup>lt;sup>57</sup> Draper & Dawson (1990).

<sup>&</sup>lt;sup>58</sup> Pinney (1965).

<sup>&</sup>lt;sup>59</sup> Lindy (2000).

<sup>&</sup>lt;sup>60</sup> Storr (1997).

<sup>&</sup>lt;sup>61</sup> Kotchen (2008).

<sup>&</sup>lt;sup>62</sup> Savulescu & Dickenson (1998a).

should be helped to prepare themselves to endure the <u>irrationalities</u> of their patients and the burden of isolation in their professional practice.<sup>63</sup>

- <u>Treatment Refusal</u>

<u>Example (i)</u>: Twelve renal homotransplantation donors were interviewed in depth between five weeks and 18 months after surgery. Unexpected findings were (1) the decision-making process about donorship did not at all follow a pattern compatible with the concept of "informed consent" but occurred as an instantaneous, <u>irrational</u> response which subsequently was justified and maintained with the aid of a number of defensive techniques;  $\dots^{64}$ 

*Example (i)*: Contemporary biological psychiatry is in a seemingly inchoate state. I assert that this state of biological psychiatry is due to its violation of an epistemological criterion of rationality, *i.e.*, the relevance criterion; that is, contemporary biological psychiatry is <u>irrational</u> as it adopts a conception irrelevant to the psychobiological domain. This conception is mechanistic. The <u>irrationality</u> of biological psychiatry is manifest as the dominance of neurochemical explanations of psychopharmacological correlations, resulting in predictive sterility and, correspondingly, in the dominance of serendipity.<sup>65</sup>

<u>Example (ii)</u>: Meprobamate: A Study of <u>Irrational</u> Drug Use. The history of the tranquilizer meprobamate illustrates how factors other than scientific evidence may determine physicians' patterns of drug use. Forceful advertising and publicity, an attitude of general optimism, and uncontrolled studies with favorable results combined to elevate meprobamate to the position of America's magical cure-all tranquilizer. This drug remains in wide use despite a large body of sound scientific data that questions its efficacy.

#### *N*–2(*ii*)(*b*): Examples of precision rankings [\* (low) to \*\*\*\*\* (high)]

\*

<u>Example (i)</u>: When a group therapy program is instituted on a psychiatric service ... It exposes as diversionary maneuvers by various group members <u>irrational</u> distortions of the administrative physician as a surrogate authority.<sup>66</sup>

<u>Example (ii)</u>: Some psychiatrists allege that the death fear (whether on the battlefield or in the death house) serves as an <u>irrational</u> surrogate for some other fear – such as castration.<sup>67</sup>

\*\*

<u>Example (i)</u>: Hence, I can accommodate eccentric, <u>irrational</u> or even "crazy" moral beliefs like that of Duff's split-infinitive fanatic. A person can have <u>irrational</u> factual beliefs; why not <u>irrational</u> moral beliefs?<sup>68</sup>

<sup>&</sup>lt;u>Treatments</u>

<sup>&</sup>lt;sup>63</sup> Kelly (1973).

<sup>&</sup>lt;sup>64</sup> Fellner & Marshall (1968).

<sup>&</sup>lt;sup>65</sup> Rudnick (1990).

<sup>&</sup>lt;sup>66</sup> Cruvant (1953).

<sup>&</sup>lt;sup>67</sup> Bluestone & McGahee (1962).

<u>Example (ii)</u>: The clinical manifestations of PD [Parkinson's disease] depression include apathy, psychomotor retardation, memory impairment, pessimism, <u>irrationality</u>, and suicidal ideation without suicidal behavior.<sup>69</sup>

\*\*\*

<u>Example (i)</u>: The definitions seem to be stating the degree of <u>irrationality</u> or abnormality necessary to invalidate deeds or to require action by society.<sup>70</sup>

<u>*Example (ii)*</u>: He tackles the crucially important issue of how practical rationality is related to mental health and of how certain forms of <u>irrationality</u> are connected with mental illness.<sup>71</sup>

\*\*\*\*

<u>Example (i)</u>: Delusion, then, has traditionally been presented as synonymous with <u>irrationality</u> (absurdity, groundlessness, error, chaos), whereas by contrast its mirror image, reason, has been defined in terms of evidence, demonstrability, truth and order. I will analyse and contrast their paradoxical definitions.<sup>72</sup>

<u>Example (ii)</u>: The ubiquitous nature of <u>irrational</u> thought in nonpathological states is acknowledged; "We are all—even the most insightful among us holding a great many false beliefs at any moment." <u>Irrationality</u> is defined as pathological only when it obstructs an individual's ability to realize important life goals.<sup>73</sup>

\*\*\*\*

<u>Example (i)</u>: As he points out, the paradox of <u>irrational</u> actions or beliefs is that they are failures within the space of reasons. If they were simply non-rational they would lie outside the sphere of rationality completely and would not be paradoxical. But <u>irrational</u> acting or thinking is subject to reason explanation and thus subject to the in-built rationality that that form of explanation carries. They are, however, subject to merely partial reason explanations, reason explanations which fail to be fully rational. The philosophical difficulty is to account for this half way house.<sup>74</sup>

<u>Example (ii)</u>: I do have reservations about the way in which Bolton and Hill use intentional predicates and whether the intentional stance is as successful for <u>irrational</u> behavior as they need it to be. Once they have used the intentional stance for <u>irrational</u> behavior, does it still have the predictive force that it is supposed to? Bolton and Hill state, "*If a person believes such-and-such, then she must, in appropriate circumstances, act in a way that accords with that belief*" ... They note, correctly, that the force of the word must derives (if it does at all) from the assumption of rationality. They suggest that <u>irrational</u> behavior may likewise be predicted by adding *ceteris paribus* clauses that account for variation away from the norm.<sup>75</sup>

<sup>&</sup>lt;sup>68</sup> Fields (1996b).

<sup>&</sup>lt;sup>69</sup> Slaughter (2001).

<sup>&</sup>lt;sup>70</sup> Mezer & Rheingold (1962).

<sup>&</sup>lt;sup>71</sup> Fields (1996a).

<sup>&</sup>lt;sup>72</sup> Bodei (2005).

<sup>&</sup>lt;sup>73</sup> Trevino (2008).

<sup>&</sup>lt;sup>74</sup> Thornton (1997).

<sup>&</sup>lt;sup>75</sup> McMillan (1999).

- <u>Yes</u>

<u>Example (i)</u>: John Burnside considers that suicidal intent is "*prima facie evidence of disease of the mind*," and that "*irrationality with intent to kill the self*" justifies the force of the law and an ethical duty of psychiatrists to prevent suicide ... <sup>76</sup>

<u>Example (ii)</u>: My contention of *prima facie* status extends to their discussion about competence and autonomy. <u>Irrationality</u>, I agree, does not amount to incompetence, but <u>irrationality</u> with the intent to kill a self justifies the force of law and the maximum requirements of psychiatrists ...<sup>77</sup>

- <u>No</u>

<u>*Example (i)*</u>: ... insistence on all possibly beneficial care worsens this toxicity. Good mediation technique can help to clarify misunderstandings, soften anger, and ease <u>irrational</u> distrust.<sup>78</sup>

<u>Example (ii)</u>: So when Halpern explains repeatedly that emotions are <u>irrational</u> – a common view dating back to Plato – it is not very useful.<sup>79</sup>

<sup>&</sup>lt;sup>76</sup> Burgess & Hawton (1998b).

<sup>&</sup>lt;sup>77</sup> Burnside (1998).

 $<sup>^{78}</sup>_{70}$  Bloche (2005).

<sup>&</sup>lt;sup>79</sup> Cassell (2002).

# *Bibliography*<sup>1</sup>

# Books/Articles<sup>2</sup>

- Abbasi, K. & Smith, R. (2003). 'No more free lunches.' *British Medical Journal*. 326:1155-1156.
- Acharya, H. (2004). 'The Rise and Fall of the Frontal Lobotomy'. *The Proceedings of the 13<sup>th</sup> Annual History Of Medicine Days*. University of Calgary. [online], available: http://www.hom.ucalgary.ca/Proceedings-2004.pdf#page=44 [accessed: 15 January 2008].
- Adebimpe, V. (1981). 'Overview: White norms and psychiatric diagnosis of black patients.' *American Journal of Psychiatry*. 138 (3), 279-285.
- Amador, X. & Strauss, D. (1993). 'Poor Insight in Schizophrenia.' *Psychiatric Quarterly* 64(4). 305-318.
- Amador, X. (2006) 'Poor Insight in Schizophrenia: Overview and Impact on Medication Compliance' [online], available: http://www.psychlaws.org/medicalresources/documents/AmadoronInsightfo rCNSReview.pdf [accessed: 1 September 2008].
- Anaf, G. & Halasz, G. (2002). National Association of Practising Psychiatrists Submission to the New South Wales Parliamentary Joint Committee on Children and Young People: Inquiry into the use of prescription drugs and medications in children and young people. Attention Deficit Hyperactivity Disorder. [online], available: http://www.napp.org.au/downloads/submissions/to\_NSW\_JPCCYP\_Inquiry .pdf [accessed: 20 August 2008].
- Andrews, K. *et al* (1996). 'Misdiagnosis of the vegetative state: retrospective study in a rehabilitation unit.' *British Medical Journal*, 313, 13-16.
- Andrews, P. *et al* (2008). 'Sex Differences in Detecting Sexual Infidelity: Results of a Maximum Likelihood Method for Analyzing the Sensitivity of Sex Differences to Underreporting.' *Human Nature*. 19:347–373.
- Angell, M. (2000). 'Is Academic Medicine for Sale?' *New England Journal of Medicine*. 342: 1516-1518.
- Angell, M. (2011a). 'The Epidemic of Mental Illness: Why?'. *The New York Review of Books*. June 23.
- Angell, M. (2011b). 'The Illusions of Psychiatry'. *The New York Review of Books*. July 14.
- Annas, G. (1999). 'The Last Resort The Use of Physical Restraints in Medical Emergencies.' *New England Journal of Medicine*. 341(18): 1408-1412.
- Annas, G. (2000). 'Correspondence: The Use of Physical Restraints in Medical Emergencies.' *New England Journal of Medicine*. 342 (10):742-744.
- Annas, G. 'Review: Force-feeding prisoners and the role of physicians.' *The Lancet*. 374:1737-8.
- Antonuccio, D. *et al* (2002). 'Antidepressants: A Triumph of Marketing Over Science?' *Prevention & Treatment*. 5(1) ArtID 25. [online], available: http://psycnet.apa.org. [accessed: 3 February 2009].

<sup>&</sup>lt;sup>1</sup> References are cited using the Harvard Style.

 $<sup>^{2}</sup>$  Source details of newspaper articles are not included in the bibliography but are given in the first footnote reference to the article in the main text.

- Appelbaum, P. & Grisso, T. (1998). Assessing Competence To Consent To Treatment. Oxford: Oxford University Press.
- Appelbaum, P. (2006). 'Editorial: Violence and Mental Disorders: Data and Public Policy.' *Am J Psychiatry*. 163:1319-1321.
- Appelbaum, P. (2007). 'Assessment of Patients' Competence to Consent to Treatment'. *The New England Journal of Medicine*. 357:1834-1840.
- Austin, JL. (1962). G. J. Warnock (ed.). *Sense and Sensibilia*. Oxford. Clarendon Press.
- Ayton, P. (1995). 'Correspondence: Risk measures expressed as frequencies may have a more rational response.' *British Medical Journal*.
- Bacon, F. (1620). The New Organon Or True Directions Concerning The Interpretation Of Nature [online], available: <u>http://www.constitution.org/bacon/nov\_org.htm</u>, [accessed 1 August 2006].
- Baker, F. (1995). 'Misdiagnosis among older psychiatric patients'. *Journal of the National Medical Association.* 87(12): 872-876.
- Ballard, C. *et al* (2005). 'Drugs used to relieve behavioral symptoms in people with dementia or an unacceptable chemical cosh?'. *International Psychogeriatrics*, 17: 4-12.
- Ballard, C. *et al* (2009). 'The dementia antipsychotic withdrawal trial (DART-AD):long-term follow-up of a randomised placebo-controlled trial.' *Lancet Neurology*. 8(2):151-7.
- Barber, C. (2008). 'The Brain: A Mindless Obsession.' *WilsonQuarterly*. Winter. [online], available: http://www.wilsonquarterly.com/article.cfm?aid=1131 [accessed: 22 September 2008].
- Basch, E. (2010). 'The Missing Voice of Patients in Drug-Safety Reporting.' *The New England Journal of Medicine*. 362(10):865-869.
- Bassman, R. (2000). 'Agents, not objects : Our fights to be.' *Journal of Clinical Psychology*. 25(11):1395-1411.
- Bassman, R. (2001). 'Overcoming the Impossible: My Journey Through Schizophrenia.' *Psychology Today*. February. [online], available: http://www.psychologytoday.com/articles/200101/overcoming-theimpossible [accessed: 18 September 2009].
- Bassman, R. (2007). A Fight to Be: A Psychologist's Experience from Both Sides of the Locked Door. Albany: Tantamount Press.
- Beattie, N. *et al* (2009). 'Predictors of PTSD Symptoms in Response to Psychosis and Psychiatric Admission.' *Journal of Nervous & Mental Disease*. 197(1):56-60.
- Bebbington, P. *et al* (1994). 'Inner London collaborative audit of admissions in two health districts. II: Ethnicity and the use of the Mental Health Act'. *The British Journal of Psychiatry*. 165: 743-749.
- Bell, C. (2005). 'Racism and Mental Disorders'. *Psychiatr Serv*. 56:220-221. [online], available: http://psychservices.psychiatryonline.org/cgi/content/full/56/2/220-a [accessed: 18 July 2008].
- Bell, V. et al (2003). 'Belief about delusions'. The Psychologist, 16 (8), 418-423.
- Bentall, R. (2003). *Madness Explained*. London: Allen Lane.
- Bentall, R. (2009). *Doctoring the Mind: Is Our Current Treatment of Mental Illness Really Any Good?* London: Allen Lane.
- Berrios, G. (1991). 'Delusions as "wrong beliefs": A conceptual history'. *British Journal of Psychiatry* 159 (suppl. 14):6-13.

- Bhugra, D. & Bhui, K, (2001). 'African–Caribbeans and schizophrenia: contributing factors.' *Advances in Psychiatric Treatment*. 7: 283-291.
- Bick, P. *et al* (2007). 'Clinical implications of the CATIE schizophrenia trials: day-to-day management.' *Australasian Psychiatry*. 15(6): 465-9.
- Blackburn, S. (1999). *Think: A Compelling Introduction to Philosophy*. Oxford: Oxford Paperbacks.
- Blankenburg, W. (2001). 'First Steps Toward a Psychopathology of "Common Sense". [Mishara, A. (tr)]. *Philosophy, Psychiatry, & Psychology.* 8(4): 303-315.
- Bloch, S. & Reddaway, P. (1984). Soviet Psychiatric Abuse. London: Gollancz.
- Bloch. S. *et al* (eds.) (1999). *Psychiatric Ethics*. (3<sup>rd</sup> ed.). Oxford: Oxford University Press.
- Boissier, M-C. (2003). 'Pondering the precautionary principle'. *Joint Bone Spine*. 70(5), 318-320.
- Bola, J. (2006a). 'Medication-Free Research in Early Episode Schizophrenia: Evidence of Long-Term Harm?' *Schizophrenia Bulletin.* 32(2):288-296.
- Bola, J. *et al* (2006b). 'Predicting Medication-Free Treatment Response in Acute Psychosis: Cross-Validation From the Finnish Need-Adapted Project.' *The Journal of Nervous and Mental Disease*. 194(10): 732-739.
- Bourdouxhe, M. (1992). (Evans F. tr.). *La Femme de Gilles*. London: Lime Tree.
- Brakel, J. (2010). 'Psychiatrists and Law .' *Psychiatric Times*. 19 Nov.
- Brandom, R. (1988). 'Insights and blindspots of realism'. *The Monist*. 81: 371-392.
- Breggin, P. (1993). *Toxic Psychiatry*. London: Fontana.
- Brennan, T. *et al* (1991). 'Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I', *New England Journal of Medicine*. 324, 370-6.
- Briesacher, B. *et al* (2005). 'The Quality of Antipsychotic Drug Prescribing in Nursing Homes.' *Arch Intern Med.* 2005;165:1280-1285.
- British Psychological Society. (2000) '*Recent advances in understanding mental illness and psychotic experiences*'. [online], available: http://www.mentalhealthcare.org.uk/download/psychosis/Understanding\_M ental\_Illness.pdf [accessed: 4 August 2006].
- Browne, I. (2008). *Music and Madness*. Cork: Atrium.
- Brülde, B. (2008). 'Mental Disorder and Values'. *Philosophy, Psychiatry, & Psychology.* 14 (2):93-102.
- Buchanan, A. (2008). 'Risk of Violence by Psychiatric Patients: Beyond the "Actuarial Versus Clinical" Assessment Debate.' *Psychiatr Serv* 59:184-190.
- Burgess, S. & Hawton, K. (1998b). 'Response to the Commentaries.' *Philosophy*, *Psychiatry*, & *Psychology*. 5(2), 151-152.
- Burnside, J. (1998). 'Commentary on "Suicide, Euthanasia, and the Psychiatrist".' *Philosophy, Psychiatry, & Psychology.* 5(2), 141-143.
- Burton, N. & Fulford, B. (2006). *Psychiatry*. Chichester: Wiley-Blackwell.
- Buss, D. & Shackelford, T. (1997) 'Susceptibility to Infidelity in the First Year of Marriage' *Journal Of Research In Personality*. 31:193–221.
- Butcher, J. (2007). 'Controversial Mental Health Bill reaches the finishing line.' *The Lancet*. 370(9582):117-118.
- Byrne, P. (2000). 'Stigma of mental illness and ways of diminishing it.' *Advances in Psychiatric Treatment*. 6: 65-72.

- Byrne, P. (2001). 'Psychiatric stigma'. *The British Journal of Psychiatry*. 178:281-284.
- Cabot, M. (1990). 'The Incidence and prevalence of schizophrenia in the Republic of Ireland'. *Social Psychiatry and Psychiatric Epidemiology*. 210-215.
- Cameron S. (1997a). 'Learning from Amy: A remarkable patient provokes anguished debate about rationality, autonomy and the right to die.' *Can Med Assoc J*, 156(2), 229-31.
- Cameron S. (1997b). 'Lessons from Amy the author responds'. *Can Med Assoc J.* 157(1), 14.
- Campbell, A. (1976). 'The Case of Leonid Plyushch.' J. Med. Ethics. 2: 211.
- Campbell, E. (2007). 'Doctors and Drug Companies Scrutinizing Influential Relationships.' *New England Journal of Medicine*. 357:1796-1797.
- Campbell, I. *et al* (2006). 'Polypharmacy and psychotropic drug usage in those awaiting long term care.' *Irish Journal Of Medical Science*. 175(3.2):71.
- Campbell, P. (2005). 'Edvard Munch's At the Royal Academy'. *London Review* of *Books*. 20 October.
- Cantor-Graae, E. & Selten, J-P. (2005). 'Schizophrenia and Migration: A Meta-Analysis and Review'. *Am J Psychiatry*. 162:12-24.
- Caplan, P. & Cosgrove, L. (eds.) (2004). *Bias in psychiatric diagnosis*. Oxford: Jason Aronson.
- Carmel, H. (1999). 'Letters: A misleading review?: In Reply'. *Psychiatric Services*. 50(6):835.
- Carroll, L. (2010). *Alice's Adventures in Wonderland and Through the Looking-Glass*. Madison: Cricket House Books, LLC.
- Cassell, E. (2002). 'From Detached Concern to Empathy: Humanizing Medical Practice.' *The New England Journal of Medicine*. 347:1628.
- Chadwick, R. & Aindow, G. (2004). 'Treatment and Research Ethics' in Radden (2004): 282-295.
- Chalmers, I. (2006). 'From optimism to disillusion about commitment to transparency in the medico-industrial complex'. *J R Soc Med.* 99, 337–341.
- Chamberlin, J. (2006): Foreword to Thornicroft, G. (2006). *Shunned: Discrimination against People with Mental Illness*. Oxford: Oxford University Press.
- Chan, A. (2008). 'Bias, Spin, and Misreporting: Time for Full Access to Trial Protocols and Results'. *PLoS Med.* 5(110) e230 [online], available: www.plosmedicine.org [accessed: 4 February 2009].
- Channel 4 (2006). Dispatches: Muslim Survey: Attitudes to Living in Britain, [online], available: http://www.channel4.com/news/microsites/D/dispatches2006/muslim\_surve y/index.html# [accessed: 17 August 2006].
- Chaplin, R. (2000) 'Correspondence: Psychiatrists can cause stigma too.' *The British Journal of Psychiatry*. 177:467.
- Chaudry, R. (2008). 'The Precautionary Principle, public health, and public health nursing.' *Public Health Nurs*. 25(3):261-8.
- Chekhov, A. (2003). (tr. R. Wilks). *Ward No. 6 and Other Stories, 1892-1895*. London: Penguin.
- Cheyette, B. & Marcus, L. (1998) (eds). *Modernity, Culture and the Jew.* Stanford: Stanford University Press.
- Chiswick, D. (1999). 'Editorial: Preventive detention exhumed and enhanced.' *Psychiatric Bulletin.* 23:703-704.
- Christie, N. (1981). *Limits to Pain*. Oslo: Aschehoug AS.

- Cipriani, A. *et al* (2009). 'Comparative efficacy and acceptability of 12 newgeneration antidepressants: a multiple-treatments meta-analysis.' *The Lancet.* 373 (9665): 746-758.
- Clare, A. (1980). *Psychiatry in Dissent: Controversial Issues in thought and practice.* (2<sup>nd</sup> ed.). Cambridge: Routledge.
- Clark, A. (2001). 'Proposed treatment for adolescent psychosis. 2: Bipolar illness'. *Advances in Psychiatric Treatment*. 7: 143-149.
- Clarke, T. & Rowe, R. (2006). 'Violence, stigma and psychiatric diagnosis: the effects of a history of violence on psychiatric diagnosis.' *Psychiatric Bulletin.* 30: 254-256.
- Code, L. (1996). 'Commentary on "Loopholes, Gaps, and What Is Held Fast"' *Philosophy, Psychiatry, & Psychology.* 3(4), 255-260.
- Cohen, A. *et al* (2008). 'Questioning an Axiom: Better Prognosis for Schizophrenia in the Developing World?' *Schizophrenia Bulletin*. 34(2):229-244.
- Coker, R. (1999a). 'Editorial: Carrots, sticks and tuberculosis'. *Thorax*, 54:95-6.
- Coker, R. (1999b). 'Editorial: Public health, civil liberties, and tuberculosis'. *British Medical Journal.* 318:1434-35.
- Committee on Human Resources. (1977). *Human Drug Testing by the CIA*. Washington: U.S. Government Printing Office. [online], available: http://graphics.nytimes.com/packages/pdf/national/13inmate\_HumanDrug.p df [accessed: 16 July 2009].
- Cooper, J. (2003). 'Editorial: Remembering Robert Kendell'. *The British Journal* of Psychiatry. 182: 279-280.
- Corrigan, P. *et al* (2005). 'Newspaper stories as measures of structural stigma.' *Psychiatr Serv.* 56(5):551-556.
- Cosgrove L. *et al* (2006). 'Financial Ties between DSM-IV Panel Members and the Pharmaceutical Industry'. *Psychotherapy and Psychosomatics*.75:154-160.
- Council of Europe (2008). Report to the Danish Government on the visit to Denmark carried out by the European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (CPT). Council of Europe. Strasburg. [online], available: http://www.unhcr.org/refworld/docid/48db4e5f2.html [accessed: 24 June 2009].
- Coverdale, I. *et al* (2002). 'Depictions of mental illness in print media: a prospective national sample.' *Aust NZ J Psychiatry*. 36(5):697-700.
- Crawford, M. (2000). 'Correspondence: Homicide is impossible to predict.' *Psychiatric Bulletin.* 24: 152.
- Crisp, A. (2001). 'Editorial: the tendency to stigmatise.' *The British Journal of Psychiatry*. 178:197-199.
- Crisp, A. *et al* (2000). 'Stigmatisation of people with mental illnesses.' *The British Journal of Psychiatry*. 177: 4-7.
- Cruvant, B. (1953). 'The Function Of The "Administrative Group" In A Mental Hospital Group Therapy Program.' *Am J Psychiatry*. 110:342-346.
- Culver, C. & Gert, B. (2004). 'Competence'. in Radden (2004): 258-270.
- Culver. M. & Gert, B. (1982). *Philosophy in Medicine: Conceptual and Ethical Issues in Medicine and Psychiatry*. Oxford: Oxford University Press.
- Currier, G. & Allen, M. (2000). 'Emergency Psychiatry: Physical and Chemical Restraint in the Psychiatric Emergency Service.' *Psychiatric Services*. 51:717-719.

- Dalrymple, T. (2006). 'Why New Vaccines Are Scarce'. *City Journal*. 16(3), [online], available: http://www.city-journal.org/html/rev2006-03-06td.html [accessed: 21 August 2006].
- Dalrymple, T. (2007). 'A Drinker of Infinity.' *City Journal*. [online], available: http://www.city-journal.org/html/17\_2\_oh\_to\_be.html [accessed: 16 July 2009].
- David, A. (1999) 'On the Impossibility of Defining Delusions'. *Philosophy, Psychiatry, & Psychology.* 6(1), 17-20.
- Davies, M. & Coltheart, M. (2000) (eds.) *Pathologies of Belief*. Oxford: Blackwell.
- Davis, J. (2006). 'Editorial: The Choice of Drugs for Schizophrenia.' *New England Journal of Medicine*. 354(5): 518-520.
- Davis, J. *et al* (1978). 'Does psychotherapy alter the course of schizophrenia?' In: Brady, J. & Brodie, H. (eds.) (1978). *Controversy in psychiatry*. Philadelphia: W.B. Saunders, 595-620.
- Davison, S. (2002). 'Principles of managing patients with personality disorder'. *Advances in Psychiatric Treatment.* 8: 1-9.
- Dawkins, R. (1995). 'Where d'you get those peepers?' *New Statesman & Society*, 16 June.
- de Montaigne, M. (1991). [Screech M. (tr)]. *The Essays of Michael de Montaigne*. London: Allen Lane.
- De Vries, P. (1995). 'Letters: Psychiatric data are questionable.' *British Medical Journal*. 311:947.
- Deane, W. (1961). 'The reactions of a nonpatient to a stay on a mental hospital ward.' *Psychiatry*. 24: 61-68.
- DeAngelis, C. & Flanagin, A. (2005). 'Editorial: Tuberculosis—A Global Problem Requiring a Global Solution'. *Journal of the American Medical Association*. 293, 2793-2794.
- DeAngelis, C. & Fontanarosa, P. (2008). 'Impugning the Integrity of Medical Science: The Adverse Effects of Industry Influence.' *Journal of the American Medical Association*. 299(15):1833-5.
- deFur P., & Kaszuba, M. (2002). 'Implementing the precautionary principle.' *Sci Total Environ.* 288(1-2):155-65.
- Dennett, D. (1997). *Brainstorms*. London: Penguin.
- Department of Health and Children. (2002), Fottrell, P. (Chair). *Report of the Forum on Fluoridation*. [Online], available: http://www.dohc.ie/publications/fluoridation\_forum.html [accessed: 21 August 2006].
- Dessmon, Y. *et al* (2001). 'A Study of Consecutive Autopsies in a Medical ICU

   A Comparison of Clinical Cause of Death and Autopsy Diagnosis', Chest. 2001;119:530-536.
- Dickinson, E. [McNeil, H. (ed.)] (1997). *Everyman Poetry: Emily Dickinson*. London: Dent.
- Dolan, M. & Doyle, M. (2000). 'Violence risk prediction'. *British Journal of Psychiatry*. 177: 303-11.
- Domino, M. & Swartz, M. (2008). 'Who Are the New Users of Antipsychotic Medications?' *Psychiatr Serv*. 59: 507-514.
- Douglas, I. & Smeeth, L. (2008). 'Exposure to antipsychotics and risk of stroke: self controlled case series study.' *British Medical Journal*. 337:a1227.
- Dovidio, R. & Fazio, R.(1991). 'New technologies for the direct and indirect assessment of attitudes' Tanur, J.(1991). (ed.). *Questions about questions:*

*inquiries into the cognitive bases of surveys.* New York: Russell Sage Foundation.

- Dowie, J. & Elstein, A. (1988). *Professional Judgment: A Reader in Clinical Decision Making*. Cambridge: Cambridge University Press.
- Downie, R. & Telfer, E. (1969). *Respect for Persons*. London: Allen and Unwin.
- Drane, J. (1994). *Clinical Bioethics*. Wisconsin: Sheed & Ward.
- Draper, R. & Dawson, D. (1990). 'Competence to consent to treatment: a guide for the psychiatrist.' *Can J Psychiatry*. 35(4), 285-9.
- Drury, O'C. (1996). (Berman, D. Fitzgerald, M. and Hayes, J. (eds.)). *The Danger* of Words and writings on Wittgenstein. Bristol: Thoemmes.
- DSM-III (1980). American Psychiatric Association, DSM-III: Diagnostic and Statistical Manual of Mental Disorders, Washington: American Psychiatric Association [Cited as DSM-III (1980)]
- DSM-III-R (1987): American Psychiatric Association (1987). DSM-III-R: Diagnostic and Statistical Manual of Mental Disorders, Washington: American Psychiatric Association [Cited as DSM-III-R (1987)]
- DSM-IV (1994): American Psychiatric Association (1994). DSM-IV: Diagnostic and Statistical Manual of Mental Disorders, Washington: American Psychiatric Association [Cited as DSM-IV (1994)]
- DSM-IV-TR (2000): American Psychiatric Association (2000). DSM-IV-TR: Diagnostic and Statistical Manual of Mental Disorders. Washington: American Psychiatric Association [Cited as DSM-IV (2000)]
- DSM-V [draft] (2010): American Psychiatric Association (2010). *DSM-5 Development*. [online], available: www.dsm5.org. [accessed: 22 March 2010].
- Dyer, C. (1994). 'Colleges say no to forced caesarean sections.' *British Medical Journal.* 308, 224.
- Dyer, C. (1998a). 'Judge misled over call for caesarean operation.' *British Medical Journal.* 316, 571.
- Dyer, C. (1998b). 'Trusts face damages after forcing women to have caesareans.' *British Medical Journal*. 316, 1477.
- Eastman, N. (1998). 'Commentary on "The Time Frame of Preferences, Dispositions, and the Validity of Advance Directives for the Mentally III".' *Philosophy, Psychiatry, & Psychology.* 5(3), 259-261.
- Eddy, D. (1982). 'Probabilistic reasoning in clinical medicine: problems and opportunities'. In: Kahneman D, Slovic P, Tversky A, (eds). *Judgement under uncertainty: heuristics and biases*. Cambridge: Cambridge University Press, 1982:249-67.
- Edge Annual Question of 2005, (2005). '*What Do You Believe Is True Even Though You Cannot Prove It?*' [online], available: http://www.edge.org/q2005/q05\_print.html [accessed 29 July 2006].
- Egeland, J. *et al* (1983). 'Amish Study, III: the impact of cultural factors on diagnosis of bipolar illness'. *Am J Psychiatry*. 140: 67-71.
- Eisenberg, L. (1998). 'Last Resort: Psychosurgery and the limits of medicine'. *New England Journal of Medicine*. 339:1719-1720.
- Eisenberg, L. (2000). 'Editorial: Is psychiatry more mindful or brainier than it was a decade ago?'. *The British Journal of Psychiatry*. 176: 1-5.
- Elbogen, E. & Johnson, S. (2009). 'The Intricate Link Between Violence and Mental Disorder.' *Arch Gen Psychiatry*. 66(2):152-161.
- El-Hai, J. (2005). The Lobotomist: A Maverick Medical Genius and his Tragic Quest to Rid the World of Mental Illness. New Jersey: John Wiley & Sons..

- Eliot, T. (1944). *Four Quartets*. London: Faber.
- Eliot, T. (1961). *Selected Poems*. London: Faber.
- Elliot, C. (1998). 'Commentary on "Is Mr. Spock Mentally Competent?"' *Philosophy, Psychiatry, & Psychology*. 5(1):87-88.
- Emerick, R. (2006). 'Letter: "Antipsychiatry" and "Consumerism": Perspectives and Definitions.' *Psychiatr Serv.* 57:1514-1515.
- Emory University(2006); 'Emory Study Lights Up the Political Brain' 24 January [online], available: http://news.emory.edu/Releases/PoliticalBrain1138113163.html [accessed: 3 August 2006].
- Englander, E. (1997). *Understanding Violence*. Mahwah: Lawrence Erlbaum Associates.
- Englander, E. (1999). 'Letters: A misleading review?' *Psychiatric Services*. 50(6): 835.
- Enoch M. *et al* (1967). *Some Uncommon Psychiatric Syndromes*. Bristol: John Wright and Sons.
- Erickson, C.D. *et al* (1991). 'On Thinking and Feeling Bad: Do Client Problems Derive From a Common Irrationality Or Specific Irrational Beliefs?' Paper presented at the annual meeting of the American Psychological Association, August 18, 1991. [online], available: http://horan.asu.edu/d-ce-apa.htm [accessed: 12 February 2008].
- Essex C. (1997) 'The death of childhood'. *British Medical Journal*. 314:1839.
- European Commission: Health & Consumer Protection Directorate-General (2002). Compulsory Admission and Involuntary Treatment of Mentally Ill Patients Legislation and Practice in EU-Member States. Mannheim: European Commission.
- Evans, J. (1989). *Bias in human reasoning: Causes and consequences*. Hillsdale, NJ: Erlbaum.
- Ewing, W. & Ewing, J. (2002). 'Correspondence: Arthroscopic Surgery for Osteoarthritis of the Knee.' *New England Journal of Medicine*. 347(21): 1717.
- Fahrenberg, J. & Cheetham, M. (2007). 'Assumptions About Human Nature and the Impact of Philosophical Concepts on Professional Issues: A Questionnaire Based Study With 800 Students From Psychology, Philosophy, and Science.' *Philosophy, Psychiatry & Psychology*. 14(3):183-201.
- Fazel, S. *et al* (2006). 'The Population Impact of Severe Mental Illness on Violent Crime.' *Am J Psychiatry*. 163:1397-1403.
- Fellner, C. & Marshall, J. (1968). 'Twelve Kidney Donors.' *Journal of the American Medical Association*. 206:2703-7.
- Ferner, R. (2005). 'The influence of big pharma.' *British Medical Journal*. 330: 855-856.
- Fields, L. (1996a). 'Commentary on "Sanity and Irresponsibility".' *Philosophy*, *Psychiatry*, & *Psychology*. 3(4): 303-4.
- Fields, L. (1996b), 'Response to the Commentaries.' *Philosophy, Psychiatry, & Psychology*. 3(4), 291-2.
- Findling, R. *et al* (2008). 'A multiple-center, randomized, double-blind, placebocontrolled study of oral aripiprazole for treatment of adolescents with schizophrenia.' *American Journal of Psychiatry*. 165(11):1432-41.
- First, M. &. Zimmerman, M. (2006). 'Including Laboratory Tests in DSM-V Diagnostic Criteria'. *American Journal of Psychiatry*. 163:2041-2.

- Fitzpatrick, M. (2003). 'Therapeutic pi: Why is 'one in four' people considered mentally ill?'. *Spiked-Health*. 18 February. [online], available: http://www.spiked-online.com/articles/00000006DC63.htm [accessed: 22 March 2010].
- Flanagan, E. (2007) 'Issues for DSM-V: Incorporating Patients' Subjective Experiences'. *American Journal of Psychiatry*. 164:391-2.
- Flanagan, O. (1991). *Varieties of Moral Personality*. Cambridge, Mass.: Harvard University Press.
- Fletcher, J. (1979). *Humanhood: Essays in Biomedical Ethics*. New York: Prometheus.
- Foot, P. (1977). 'Euthanasia'. *Philosophy and Public Affairs*. 6(2): 85-112.
- Foot, P. (1978). Virtues and Vices. Oxford: Basil Blackwell.
- Foucault, M. (1976). 'I, Pierre Rivière... An Interview with Michel Foucault.' From Sylvère Lotringer (ed) (1996) Foucault Live: Collected Interviews, 1961-1984. USA: SEMIOTEXT[E]. (pp. 203-206). (John Johnston trans.). [online], available: http://foucault.info/documents/pierreRiviere/foucault.pierreRiviere.intervie w.en.html [accessed: 18 May 2011].
- Foucault, M. (1978). 'About the Concept of the "Dangerous Individual" in 19<sup>th</sup>– Century Legal Psychiatry.' [Baudot, A. & Couchman, J. (trans.)]. *International Journal of Law and Psychiatry*. 1: 1–18.
- Foucault, M. (1984). 'Foucault'. A text written by Foucault (under the pseudonym 'Maurice Florence') as the entry 'Foucault' in *Dictionnaire des philosophes* (1984), pp 942-944, [online], available: http://foucault.info/foucault/biography.html [accessed: 7 June 2011].
- Foucault, M. (2003). [Burchell, G. (trans.)]. *Abnormal: Lectures at the College de France 1974-1975.* New York: Picador.
- Foucault, M. (2004) 'Je suis un artificier'. In Roger-Pol Droit (ed.), *Michel Foucault, entretiens*. Paris: Odile Jacob.
- Frances, A. & Spitzer, R. (2009). 'Letter to APA Board of Trustees July 7. [online], available: http://www.scribd.com/doc/17172432/Letter-to-APA-Board-of-Trustees-July-7-2009-From-Allen-Frances-and-Robert-Spitzer [accessed: 24 March 2010].
- Frances, A. (2009a). 'Frances Responds to APA: "Important Questions Need Answering"' *Psychiatric Times*. [online], available: http://www.psychiatrictimes.com/dsm-v/content/article/10168/1427728 [accessed:24 March 2010].
- Frances, A. (2009b). 'Editorial: Issues for DSM-V: The Limitations of Field Trials: A Lesson From DSM-IV.' *American Journal of Psychiatry*. 166:1322.
- Frances, A. (2010). 'Opening Pandora's Box: The 19 Worst Suggestions For DSM5.' *Psychiatric Times*. 11 February. [online], available: http://www.psychiatrictimes.com/dsmv/content/article/10168/1522341?pageNumber=1 [accessed: 22 March 2010].
- Franks, R. (2008). 'Policy Toward Second-Generation Antipsychotic Drugs: A Cautionary Note'. *Psychiatr Serv.* 59: 521-522.
- Freedman, K. (2007a). 'Traumatic Blocking and Brandom's Oversight.' *Philosophy, Psychiatry, & Psychology.* 14 (1):1-12.
- Freedman, K. (2007b). 'Knowledge Without Citable Reasons'. *Philosophy*, *Psychiatry*, & *Psychology*. 14 (1):25-28.

- Freedman, R. (2005a). 'Editorial: The Choice of Antipsychotic Drugs for Schizophrenia.' *New England Journal of Medicine*. 353(12): 1286-1288.
- Freedman, R. *et al* (2006). 'Editorial: Conflict of Interest; Round 2.' *American Journal of Psychiatry.* 163: 1481-3.
- Freeman, D. *et al* (2005b). 'Psychological investigation of the structure of paranoia in a non-clinical population'. *British Journal of Psychiatry*. 186:427-35.
- Frie, R. (2000). 'The Existential and the Interpersonal: Ludwig Binswanger and Harry Stack Sullivan.' *Journal of Humanistic Psychology*. 40:108.
- Friedman, C. (2005) *et al* 'Do Physicians Know When Their Diagnoses Are Correct?'. J *Gen Intern Med*. 20(4):334-339. [online], available: http://www.medscape.com/viewarticle/503826\_print [accessed: 23 May 2007 ].
- Friedman, R. (2008). 'Review: Side Effects: A Prosecutor, a Whistleblower, and a Bestselling Antidepressant on Trial'. *New England Journal of Medicine*. 358:2852.
- Fugh-Berman, A. & Melnick, D. (2008). 'Off-Label Promotion, On-Target Sales'. *PLoS Med.* 5(10): e210 doi:10.1371/journal.pmed.0050210.
- Fulford, K. (1989). *Moral Theory and Medical Practice*. Cambridge: Cambridge University Press.
- Fulford, K. *et al* (2004). 'What can philosophy do for psychiatry?' *World Psychiatry* 3(3) [online], available: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1414692 [accessed 6 July 2006].
- Fulford, K. *et al* (2006). *Oxford Textbook of Philosophy and Psychiatry*. Oxford: Oxford University Press.
- Gadamer, H–G. (1996). [Gaiger, J. & Walker, N. (trans.)]. *The Enigma of Health: The Art of Healing in a Scientific Age*. Stanford: Stanford University Press.
- Gallup (2005). *Three in Four Americans Believe in Paranormal*. [Online], available: http://poll.gallup.com/content/default.aspx?ci=16915&pg=1 [accessed 31 July06]; also available: http://home.sandiego.edu/~baber/logic/gallup.html [accessed 31 July06].
- Geddes, J. & Wessely, S. (2000b). 'Clinical standards in psychiatry. How much evidence is required and how good is the evidence base?' *Psychiatric Bulletin.* 24: 83-84.
- Geddes, J. *et al* (1996). 'What proportion of primary psychiatric interventions are based on evidence from randomised controlled trials?' *Quality in Health Care.* 5(4): 215–217.
- Geddes, J. *et al* (2000a). 'Atypical antipsychotics in the treatment of schizophrenia: systematic overview and meta-regression analysis' *British Medical Journal*. 321: 1371-1376.
- Genova, P. (2002). *The Thaw: Reclaiming the Person for Psychiatry*. London: Routledge.
- Genova, P. (2003) 'Dump the DSM>!'. *Psychiatric Times*. 20(4). [online], available: http://www.psychiatrictimes.com/display/article/10168/47316 [accessed: 22 July 2008].
- Gervais L. (1997). 'Correspondence: Lessons from Amy'. *Can Med Assoc J.* 157(1):14.
- Gettier, E. (1963). 'Is Justified True Belief Knowledge?' *Analysis* 23:121-123.
- Gillett, G. (2004). 'Cognition: Brain Pain: Psychotic Cognition, Hallucination and Delusions.' in Radden (2004):21-35.

- Glantz, L. (1983). 'The Role of Personhood in Treatment Decisions Made by Courts'. *Milbank Memorial Fund Quarterly, Health and Society*. 61(1):76-100.
- Goff, D. (2011). 'Antipsychotics and the Shrinking Brain.' *Psychiatric Times*. 28(4).
- Goffman, E. (1968). Asylums: Essays on the Social Situation of Mental Patients and Other Inmates. Middlesex: Penguin Books.
- Goldbeck-Wood, S. (1996) 'Norway compensates lobotomy victims.' *British Medical Journal.* 313:708.
- Goldbeck-Wood, S. (1997). 'Editorial: Women's autonomy in childbirth'. *British Medical Journal*, 314.
- Goldstein, R., (1987). 'Litigious paranoids and the legal system: the role of the forensic psychiatrist.' *J. Forens. Sci. JFSCA* 32:1009-1115.
- Goodman, W. (2011). 'Electroconvulsive Therapy in the Spotlight.' *The New England Journal of Medicine*. 364:1785.
- Gould, S. (1985). '*The Median Isn't the Message*' [online], available: http://www.phoenix5.org/articles/GouldMessage.html [accessed: 16 August 2006 ].
- Greally, H.(1971). *Birds' Nest Soup*. Dublin: Allen Figgis.
- Grohol, J. (2008). 'More on Infamous Paxil Study'. *PsychCentral* [online], available: http://psychcentral.com/blog/archives/2008/04/30/more-oninfamous-paxil-study-329/ [accessed: 10 February 2009].
- Grubb. A. (2004). 'Medical Negligence: Duties in Contract and Tort' in Laing, J. & Grubb, A. (2004). *Principles of Medical Law*. (2<sup>nd</sup> ed.). Oxford: Oxford University Press; 313-368.
- Gutting, G. (2005). (ed.). *The Cambridge Companion to Foucault*. 2<sup>nd</sup> ed. Cambridge: Cambridge University Press.
- Gutting, G. (2005a). 'Foucault and the History of Madness.' in Gutting, G. (2005). pp.49–73.
- Habermas J. (1986). *The Theory of Communicative Action: Reason and the Rationalization of Society.* Cambridge: Polity Press.
- Hacking, I. (1999). *Mad Travellers: Reflections on the reality of transient mental illness*. London: Free Association Books.
- Hagen, B. *et al* (2005). 'Antipsychotic drug use in Canadian long-term care facilities: prevalence, and patterns following resident relocation'. *International Psychogeriatrics*, 17: 179-193.
- Haghighat, R. (2001). 'A unitary theory of stigmatisation.' *The British Journal of Psychiatry*. 178: 207-215.
- Hall, R. *et al* (1980). 'Physical illness manifesting as psychiatric disease. II. Analysis of a state hospital inpatient population.' *Arch Gen Psychiatry*. 37(9):989-95.
- Hansard (2007). *House of Commons Debates*. 463 (124): Column 116-117. 16 April.
- Hansen, J. (2007). 'There Are No Philosophers in Foxholes! But Maybe There Should Be . . .' Association for the Advancement of Philosophy and Psychiatry Bulletin. 14(1): 2-5.
- Hansen-Flaschen, J. (2000). 'Correspondence: The Use of Physical Restraints in Medical Emergencies.' *New England Journal of Medicine*. 342 (10): 742-744

- Hansson, L. *et al* (1999). 'The Nordic comparative study on sectorized psychiatry: rates of compulsory care and use of compulsory admissions during a 1-year follow-up.' *Social psychiatry and psychiatric epidemiology*. 34(2): 99-104.
- Harding-Clarke, M. (2006) *The Lourdes Hospital Inquiry*, [online], available: http://www.dohc.ie/publications/lourdes.html [accessed: 9 April 2007].
- Hardoy, M. *et al* (2003) 'Gabapentin in antipsychotic-induced tardive dyskinesia: results of 1-year follow'. *Journal Of Affective Disorders*. 75(2):125-130.
- Hargrave, T. (2000). *The Essential Humility of Marriage: Honoring the Third Identity in Couple Therapy*. Phoenix: Zeig, Tucker & Theisen.
- Harris (2003). *The Religious and Other Beliefs of Americans 2003*. [online], available: http://www.harrisinteractive.com/harris\_poll/index.asp?PID=359 [accessed 31 July 2006].
- Harris, J. (1994). *The Value of Life*. London: Routledge.
- Harvey, I. (1990). 'The functional psychoses in Afro-Caribbeans.' *Br J Psychiatry*. 157:515-22.
- Hatling T. *et al* (2002). 'Compulsory admissions to psychiatric hospitals in Norway international comparisons and regional variations'. *Journal of Mental Health.* 11(6): 623-634.
- Hayakawa, S. (1956). 'The Fully Functioning Personality'. A Review Of General Semantics. XIII(3):169-181.
- Healy, D. (2002). *The Creation of Psychopharmacology*. Cambridge: Harvard University Press.
- Hemsley, D. & Garety, P. (1986). 'The formation of maintenance of delusions: a Bayesian analysis'. *British Journal of Psychiatry*. 149:51-6.
- Heres, S. *et al* (2006). 'Why Olanzapine Beats Risperidone, Risperidone Beats Quetiapine, and Quetiapine Beats Olanzapine: An Exploratory Analysis of Head-to-Head Comparison Studies of Second-Generation Antipsychotics.' *American Journal of Psychiatry*.163:185-194.
- Herxheimer, A. & Healy, D. (2002). 'Arrhythmias and sudden death in patients taking antipsychotic drugs'. *British Medical Journal*. 325:1253-1254.
- Hickey, C. *et al* (1999). 'Letters: Olanzapine and NMS'. *Psychiatric Services*. 50(6). 836-7.
- Hickling, F. (2005). 'The epidemiology of schizophrenia and other common mental health disorders in the English-speaking Caribbean.' *Rev Panam Salud Publica*. 18(4-5):256-62.
- Hickling, F. *et al* (1999). 'A Jamaican psychiatrist evaluates diagnoses at a London psychiatric hospital'. *The British Journal of Psychiatr.* 175: 283-285.
- Higgins, N. *et al* (2005). 'Assessing violence risk in general adult psychiatry.' *Psychiatric Bulletin.* 29:131-133.
- Hinshelwood, R. (1997). 'Primitive Mental Processes: Psychoanalysis and the Ethics of Integration.' *Philosophy, Psychiatry, & Psychology*. 4(2):121-143.
- Hjertaas, T. (2004). 'Adler and Binswanger: Individual Psychology and Existentialism'. *Journal of Individual Psychology*. 60(4):396–407.
- Ho, B. *et al.* (2011). 'Long-term antipsychotic treatment and brain volumes: a longitudinal study of first-episode schizophrenia.' *Arch Gen Psychiatry*. 68:128-137.
- Hoffman, E. (1989). *The Right to Be Human: The Biography of Abraham Maslow*. Los Angeles: JP Tarcher.
- Hoffrage, U. & Gigerenzer, G. (1998). 'Using natural frequencies to improve diagnostic inferences'. *Academic Medicine*. 73(5):538-40.

- Hogben, G. *et al* (1979). 'The impact of political process on hospital psychiatry.' *Am J Psychiatry*. 136:201-204.
- Hoggett, B. (1990). *Mental Health Law*. (3<sup>rd</sup> Ed) London: Sweet and Maxwell.
- Holt, C. & Anderson, L. (1996). 'Understanding Bayes' Rule'. *Journal of Economic Perspectives*. 10(2):179-183.
- Holt, J. (2006). 'Code-Breaker: The life and death of Alan Turing'. *The New Yorker*. 6 February.
- Honderich, T. (1995). *The Oxford Companion to Philosophy*. Oxford: OUP.
- Horng, S. & Miller F. (2002). 'Is Placebo Surgery Unethical?' *New England Journal of Medicine*. 347:137-9.
- House of Commons Health Committee (2005). *The influence of the pharmaceutical industry*. London: The Stationery Office.
- Huff, D. & Geis, I. (1959). *How to take a chance*. New York: Norton.
- Iacopino V. & Xenakis S. (2011). 'Neglect of medical evidence of torture in Guantánamo Bay: A case series.' *PLoS Med 8(4)*: e1001027. doi:10.1371/journal.pmed.1001027.
- ICD-10 (2006): World Health Organisation (2006). *International Statistical Classification of Diseases and Related Health Problems 10<sup>th</sup> Revision*. [online]; available: http://www3.who.int/icd/currentversion/fr-icd.htm: [accessed 27 June 2006]
- Institute of Medicine (1999). *To Err is Human: Building A Safer Health System*, [online], available: http://www.nap.edu/books/0309068371/html/ [accessed: 23 March 2007].
- Institute of Medicine (2009). Report Brief: Initial National Priorities for Comparative Effectiveness Research. [online], available: http://ctsi.ucsf.edu/files/Retreat09/IOM\_CER\_Brief\_Report.pdf [accessed: 17 April 2010].
- Interdepartmental Liaison Group On Risk Assessment, The(UK). (2002). *The Precautionary Principle: Policy and Application*, [online], available: http://www.hse.gov.uk/aboutus/meetings/ilgra/pppa.pdf [accessed: 5 April 2007].
- Irish Prison Service (2004). Annual Report 2004. Dublin: Irish Prison Service.
- Irish Prison Service (2009). Annual Report 2009. Dublin: Irish Prison Service
- Iversen, K. *et al* (2002). 'Perceived coercion among patients admitted to acute wards in Norway.' *Nordic Journal of Psychiatry*. 56(6):433-439.
- Janofsky, J. (2000). 'Correspondence: The Use of Physical Restraints in Medical Emergencies.' *New England Journal of Medicine*. 342(10):742-744.
- Jansson, B. (1998). 'Controversial Psychosurgery Resulted in a Nobel Prize' [online], available: http://nobelprize.org/nobel\_prizes/medicine/articles/moniz/ [accessed: 15 December 2008]
- Jarvis, G. (2007). 'The social causes of psychosis in North American psychiatry: a review of a disappearing literature.' *Can J Psychiatry*. 52(5):287-94.
- Jaspers, K. (1997). [Hoenig, J. & Hamilton, M. (trans.)]. *General Psychopathology*. Volumes 1 and 2. London: John Hopkins University Press.
- Jaynes, E. (1994). Probability Theory: the Logic of Science. [Online], available: http://omega.albany.edu:8008/JaynesBook.html and http://wwwbiba.inrialpes.fr/Jaynes/cc15b.pdf#search=%22jaynes%20Chapter%2015%2 0%20%20PARADOXES%20%20%20OF%20%20%20PROBABILITY%2 0%20%20THEORY%20%22 [accessed: 17 August 2006].

- Jefferson, J. (2003). 'Review: Polypharmacy in Psychiatry.' *Am J Psychiatry*. 160:1198-1199.
- Jenicek, M. (2003). 'Evidence-Based Psychiatry in clinical care and community mental health programs and policies – Misconceptions, achievements and future directions.' *XLIII Congresso Nazionale della Societa' Italiana di Psichiatria*. [online], available: http://www.pol-it.org/ital/sipbologna/2410inter1.htm [accessed: 17 March 2008].
- Johnson, B. (1999). 'The horrors of Ashworth: misdiagnosis'. *The Lancet*. 353(9156):931.
- Johnstone, L. (2000). Users and Abusers of Psychiatry: A critical look at psychiatric practice. (2<sup>nd</sup> Ed). London: Routledge.
- Joint Tuberculosis Committee of the British Thoracic Society (2000). 'Control and prevention of tuberculosis in the United Kingdom: Code of Practice 2000.' *Thorax.* 55:887-901.
- Jones, P. *et al* (2006). 'Randomized controlled trial of the effect on quality of life of second- *vs*. first-generation antipsychotic drugs in schizophrenia: Cost Utility of the Latest Antipsychotic Drugs in Schizophrenia Study (CUtLASS 1).' *Arch Gen Psychiatry*. 63:1079-1087.
- Jones, P. *et al* (2007). 'First- *vs*. Second-Generation Antipsychotic Drugs in Schizophrenia Reply.' *Arch Gen Psychiatry*. 64:1074-1076.
- Kaempf, A. (2009). 'Review: Punishment and Culture.' *Psychiatr Serv.* 60: 852.
- Kahn, R. *et al* (2008). 'Effectiveness of antipsychotic drugs in first-episode schizophrenia and schizophreniform disorder: an open randomised clinical trial'. *The Lancet.* 371:1085-1097.
- Kaiser R. (2002). *Clerical Error: A True Story*. New York: Continuum.
- Kales, H. *et al* (2007). 'Mortality Risk in Patients With Dementia Treated With Antipsychotics *Versus* Other Psychiatric Medications.' *American Journal of Psychiatry*. 164:1568-1576.
- Kallert, W. et al (eds.) (2011). Coercive Treatment in Psychiatry: Clinical, Legal and Ethical Aspects. Malden: Wiley.
- Kalverdijk, L. *et al* (2008). 'Use of Antipsychotic Drugs Among Dutch Youths Between 1997 and 2005.' *Psychiatr Serv.* 59:554-560.
- Kane, J. (2006). 'Editorial: Tardive Dyskinesia Circa 2006.' *American Journal of Psychiatry*. 163:1316-1318.
- Kaplan, B. & Sadock, V. (2009). *Comprehensive Textbook of Psychiatry*. [9<sup>th</sup> edition]. Philadelphia: Lippincott Williams and Wilkins.
- Kaptchuk, T. (2003). 'Effect of interpretive bias on research evidence.' *British Medical Journal.* 326:1453-1455.
- Kapur, S. & Remington, G. (2000). 'Editorial: Atypical antipsychotics.' *British Medical Journal*. 321:1360-61.
- Katsakou, C. *et al* (2010). 'Coercion and Treatment Satisfaction Among Involuntary Patients'. *Psychiatric Services*. 61(3).
- Keller. B. *et al* (2001). 'Efficacy of Paroxetine in the Treatment of Adolescent Major Depression: A Randomized, Controlled Trial.' *Journal of Amer Academy of Child & Adolescent Psychiatry*. 40(7):762-772.
- Kelly, W. (1973). 'Suicide and Psychiatric Education.' *American Journal of Psychiatry*. 130:463-468.
- Kendell, R. & Jablensky, A. (2003). 'Distinguishing Between the Validity and Utility of Psychiatric Diagnoses'. *American Journal of Psychiatry*. 160(1):4-12.

- Kennedy, H. (2001). 'Risk assessment is inseparable from risk management'. *Psychiatric Bulletin.* 25: 208-211.
- Kenny, A. (1969). 'Mental Health in Plato's Republic.' *Proceedings of the British Academy*. 55:229-253.
- Kesselheim, A. *et al* (2010). 'Whistle-Blowers' Experiences in Fraud Litigation against Pharmaceutical Companies.' *The New England Journal of Medicine*. 362:1832-1839.
- Keys, M. (1999). *Mental Health Law in Ireland*. Unpublished LL.M Thesis. University College, Galway.
- Keys, M. (2002). 'Challenging the Lawfulness of Psychiatric Detention under Habeas Corpus in Ireland'. *Dublin University Law Journal*. 24:26-56.
- Khan, A,. & Khan, S. (2008). 'Placebo response in depression: a perspective for clinical practice.' *Psychopharmacol Bull.* 41: 91-98.
- Khan, A. & Shaikh, M. (2008). 'Challenging the established diagnosis in psychiatric practice: is it worth it?' *J Psychiatr Pract*. 14(1):67-72.
- Kingdon, D. (2004). 'What attitudes do psychiatrists hold towards people with mental illness?'. *Psychiatric Bulletin.* 28:401-406.
- Kingham, M. & Gordon, H. (2004). 'Aspects of morbid jealousy'. Advances in *Psychiatric Treatment*. 10:207-215.
- Kingsbury, S. *et al* (2002). 'Rational and Irrational Polypharmacy.' *Psychiatr Serv*. 53:214.
- Kirk, S. & Kutchins, H. (1992). *The Selling of DSM: The Rhetoric of Science in Psychiatry*. New York: Aldine De Gruyter.
- Kirk, S. & Kutchins, H. (1994). 'The Myth of the Reliability of DSM'. *Journal of Mind and Behavior*. 15(1-2):71-86.
- Kirkevold, Ø. & Engedal K. (2004). 'Concealment of drugs in food and beverages in nursing homes: cross sectional study'. *British Medical Journal*, 330(20).
- Kirkley, A. *et al* (2008). 'A Randomized Trial of Arthroscopic Surgery for Osteoarthritis of the Knee.' *New England Journal of Medicine*. 359(11):1097–1107.
- Kirsch, I. *et al* (2002). 'The Emperor's New Drugs: An Analysis of Antidepressant Medication Data Submitted to the U.S. Food and Drug Administration.' *Prevention & Treatment.* 5 (23).
- Kirsch, I. *et al* (2008). 'Initial Severity and Antidepressant Benefits: A Meta-Analysis of Data Submitted to the Food and Drug Administration.' *PLoS Med.* 5(2): e45. doi:10.1371/journal. pmed.0050045 [online], available: http://medicine.plosjournals.org/perlserv/?request=getdocument&doi=10.1371%2Fjournal.pmed.0050045 [accessed: 3 March 2009].
- Klein, J. (2005). 'Five pitfalls in decisions about diagnosis and prescribing'. *British Medical Journal.* 330:781-783.
- Kluge, E-H. (1975). *The Practice of Death*. New Haven: Yale University Press.
- Kotchen, M. (2008). 'Review: Our Precarious Habitat.' *Journal of the American Medical Association*. 299:581-582.
- Kübler-Ross, E. (1975). *Death: The Final Stage of Growth*. New York: Simon & Schuster.
- Kuipers, E. (2007). 'Psychological Therapies for Schizophrenia: Family and Cognitive Interventions'. *Psychiatric Times*. XXIV(2).
- Kumar, C. *et al* (2006). 'Awareness and Attitudes about Disease Mongering among Medical and Pharmaceutical Students'. *PLoS Medicine*. 3(4), 0558.

- Kutchins, H. & Kirk, S. (1997). *Making Us Crazy: DSM The Psychiatric Bible And The Creation Of Mental Disorders*. London: Constable.
- La Fontaine, J. (1998). *Speak of the Devil*. Cambridge: Cambridge University Press.
- Laing, J. & Grubb, A. (2004). *Principles of Medical Law*. 2nd ed. Oxford: Oxford.
- Lancet (2004). 'Editorial: Depressing research.' *The Lancet*. 363 (9418):1335.
- Lancet (2009). 'Editorial: Force-feeding of prisoners—a shameful practice.' *The Lancet*. 374:1724.
- Lancet (2011). 'Editorial: Medical errors in the USA: human or systemic?'. *The Lancet*. 377:1289.
- Lancet Neurology (2009). 'Editorial: Antipsychotic drugs for dementia: a balancing act.' *The Lancet Neurology*. 8(2):125.
- Lanzoni, S. 'The enigma of subjectivity: Ludwig Binswanger's existential anthropology of mania'. *History of the Human Sciences*. 18(2): 23-41.
- Large, M. *et al.* (2008). 'The danger of dangerousness: why we must remove the dangerousness criterion from our mental health acts.' *J Med Ethics.* 34:877-881.
- Lazarou, J. (1998). 'Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies.' *Journal of the American Medical Association*, 279(15):1200-5.
- Leape, L. *et al* (1991). 'The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II', *New England Journal of Medicine*. 324:377-84.
- LeBel, J. (2011a). 'Editorial: Coercion Is Not Mental Health Care'. *Psychiatric Services*. 62(5).
- LeBel, J. (2011b). 'Letters: Coercion in Treatment: Researchers' Perspectives.' *Psychiatric Services.* 62(7).
- Lebensohn, Z. (1968). 'Mission to Moscow'. *American Journal of Psychiatry*. 125: 675-676.
- Lefley, H. (2006). 'Review: Daniel Isn't Talking: A Novel.' *Psychiatr Serv*. 57:1823.
- Lehtinen, V. (2006). 'Schizophrenia, neuroleptic medication and mortality.' *The British Journal of Psychiatry*. 188:122-127.
- Leiber, J. (1991). An Invitation to Cognitive Science. Mass: Blackwell.
- Lenzer, J. (2004). 'Bush plans to screen whole US population for mental illness'. *British Medical Journal.* 328:1458.
- Leucht, S. *et al* (2009). 'Second-generation *versus* first-generation antipsychotic drugs for schizophrenia: a meta-analysis.' *The Lancet*. 373(9657):31-41.
- Levy, M. & Alperstein, G. (1999). 'Correspondence: Patients with tuberculosis can be managed effectively in the community'. *British Medical Journal*. 319:455.
- Lewis, C. (1949). 'The Humanitarian Theory of Punishment.' *Twentieth Century*. March.
- Lewis, D. *et al* (2006). 'Editorial: Conflict of Interest'. *American Journal of Psychiatry* 163:571-573.
- Lexchin, J. & O'Donovan, O. (2010). 'Prohibiting or "managing" conflict of interest? A review of policies and procedures in three European drug regulation agencies'. *Social Science & Medicine*. 70:643-64.

- Lexchin, J. *et al* (2003) 'Pharmaceutical industry sponsorship and research outcome and quality: systematic review'. *British Medical Journal*. 326:1167-70.
- Lieberman, E. (2004). 'Pharmacracy or Phantom?' in Schaler (2004):225-241.
- Lieberman, J. (2006). 'Comparative Effectiveness of Antipsychotic Drugs: A Commentary on Cost Utility of the Latest Antipsychotic Drugs in Schizophrenia Study (CUtLASS 1) and Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE).' *Arch Gen Psychiatry*. 63:1069-1072.
- Lieberman, J. *et al* (2005). 'Effectiveness of Antipsychotic Drugs in Patients with Chronic Schizophrenia'. *New England Journal of Medicine*. 353:1209-1223.
- Lieberman, P. (2007). 'Knowing Without Reasons'. *Philosophy, Psychiatry, & Psychology*. 14 (1):23-24.
- Lindy, J. (2000). 'Review: The Therapeutic Alliance.' *Psychiatr Serv*. 51:1577-1578.
- Lipton, A. & Simon, F. (1985). 'Psychiatric diagnosis in a state hospital: Manhattan State revisited.' *Hospital and Community Psychiatry*. 36(4):368-373.
- Loring, M. & Powell, B. (1988). 'Gender, Race, and DSM-III: A Study of the Objectivity of Psychiatric Diagnostic Behavior.' *Journal of Health and Social Behavior*. 29(1):1-22.
- Luhrmann, T. (2000). *Of Two Minds: The Growing Disorder in American Psychiatry*. New York: Alfred A. Knopf.
- Luhrmann, T. (2010). 'Review: Metzl (2010): The Protest Psychosis: How Schizophrenia Became a Black Disease.' *Am J Psychiatry*. 167:479-480.
- Lundberg, G. (1998). 'Low-Tech Autopsies in the Era of High-Tech Medicine'. Journal of the American Medical Association. 280:1273–1274.
- Mack, J. (1994). *Abduction: Human Encounters With Aliens*. Southern Pines, NC: Scribner.
- Macklin, R. (1983). 'Personhood in the Bioethics Literature.' *Milbank Memorial Fund Quarterly, Health and Society.* 61(1):35-57.
- MacNeice, L. (1945). *Springboard: Poems 1941-1944*. New York: Random House.
- MacNeice, L. (2005). *Poems selected by Michael Longley*. London: Faber and Faber.
- Maden, A. (2001). 'Correspondence: Practical application of structured risk assessment.' *The British Journal of Psychiatry*. 178:479.
- Maden, A. (2003a). 'Editorial: Standardised risk assessment: why all the fuss?' *Psychiatric Bulletin*. 27:201-204.
- Maden, A. (2003b). 'Rethinking Risk Assessment. The MacArthur study of Mental Disorder and Violence.' *Psychiatric Bulletin*. 27:237-238.
- Maden, A. (2005). 'Editorial: Violence risk assessment: The question is not whether but how.' *Psychiatric Bulletin.* 29:121-122.
- Maher, D. (2003). 'Editorial: Treatment of tuberculosis Concordance is a key step'. *British Medical Journal*. 327:822-823.
- Mahon, D. (2006). *Selected Poems*. London: Penguin.
- Maitland, S. (2008). A Book Of Silence. London: Granta.
- Malcolm, N. (1981). 'Wittgenstein's Confessions'. *London Review of Books*. 3(21):16-18.
- Mangione-Smith, R. *et al* (1999). 'The Relationship Between Perceived Parental Expectations and Pediatrician Antimicrobial Prescribing Behavior'. *Pediatrics*. 103(4):711-718.

- Marder, S. (2007). 'Editorial: Lessons From Each Drug Trial.' *American Journal* of *Psychiatry*. 164:375-376.
- Margolin, J. *et al* (1995). 'Consequences of misdiagnosis and labeling in psychiatry'. *Harefuah*. 128(12):763-7.
- Markel, H. (2004). "'I Swear by Apollo" On Taking the Hippocratic Oath.' *New England Journal of Medicine*. 350:2026-9.
- Martens, P. & Holmberg, S. (2005). *Crime among persons born in Sweden and other countries: English summary*. Stockholm: National Council for Crime Prevention (Brå).
- Maslow, A. (1971). *The Farther Reaches of Human Nature*. New York: Arkana.
- Masson, J. (1993). Against Therapy. London: HarperCollins.
- Mathew, S. & Charney, D. (2009) 'Publication Bias and the Efficacy of Antidepressants.' *American Journal of Psychiatry*.166(2):140-145.
- Matson, J. & Wilkins, J. (2008). 'Comment: Antipsychotic drugs for aggression in intellectual disability.' *The Lancet*. 371(9606):9-10.
- Matthews, E. (2000). 'Autonomy and the psychiatric patient.' *J Appl Philos*. 17(1):59-70.
- May, P. *et al* (1976). 'Schizophrenia a follow-up study of results of treatment.' *Arch Gen Psychiatry*. 33:481-486.
- May, P. *et al* (1981). 'Schizophrenia: A Follow-up Study of the Results of Five Forms of Treatment.' *Arch Gen Psychiatry*. 38(7):776-784.
- McKay, D. (2000). 'Correspondence: Stigmatising pharmaceutical advertisements.' *The British Journal of Psychiatry*. 177:467-468.
- McLaren, N. (2011). 'A rejoinder to Pies (2010)'. *Psychiatric Times [online]*. 8 April.
- McManus, C. (2002). 'If you change a four-lane highway into a six-lane highway and back again, by how much do you increase its capacity?' *London Review of Books*. 24(20). [Online], available: http://www.lrb.co.uk/v24/n20/mcma01\_.html [accessed:18 August 2006].
- McMillan, J. (1999). 'Cognitive Psychology and Hermeneutics: Two Irreconcilable Approaches?' *Philosophy, Psychiatry, & Psychology*. 6(4):255-258.
- Meaney, A. & Cooney, C. (2003). 'An audit of psychotropic prescribing practice of general adult psychiatrists in elderly demented patients.' *Ir J Psych Med.* 20(2):59-64.
- Medix (2008). 'Market Research Report: Antipsychotics in Dementia Study.' [online], available: http://news.bbc.co.uk/2/shared/bsp/hi/pdfs/17\_06\_08\_fo4\_questions.pdf [accessed: 3 April 2009].
- Megone, C. (1998). 'Aristotle's Function Argument and the Concept of Mental Illness.' *Philosophy, Psychiatry, & Psychology*. 5(3):187-201.
- Melander, H. *et al* (2003). 'Evidence b(i)ased medicine -selective reporting from studies sponsored by pharmaceutical industry: review of studies in new applications. *British Medical Journal*. 326:1171-1173.
- Melander, H. *et al* (2008). 'A regulatory Apologia A review of placebocontrolled studies in regulatory submissions of new-generation antidepressants.' *Eur Neuropsychopharmacol.* 18: 623-627.
- Mele, A. (2004). 'Rational Irrationality'. *The Philosophers' Magazine*. 26:31-32.
- Melvin, B. (1986). 'Toward a diagnostic alliance between psychiatrist and psychologist.' *American Psychologist*. 41(1):52-59.

- Mental Health Foundation (2000). *Pull Yourself Together! A survey of the stigma and discrimination faced by people who experience mental distress.* London: The Mental Health Foundation.
- Mezer. R. & Rheingold, P. (1962). 'Mental Capacity And Incompetency: A Psycho-Legal Problem.' *Am J Psychiatry*. 118:827-831.
- MHC (2004). Annual Report including the Report of the Inspector of Mental Health Services. Dublin: Mental Health Commission.
- MHC (2005). Annual Report including the Report of the Inspector of Mental Health Services. Dublin: Mental Health Commission.
- MHC (2006). Annual Report including the Report of the Inspector of Mental Health Services. Dublin: Mental Health Commission.
- MHC (2007). Annual Report including the Report of the Inspector of Mental Health Services. Dublin: Mental Health Commission.
- MHC (2008a). *Report of the Inspector of Mental Health Services 2008: St. Luke's Hospital, Clonmel.* [online], available: http://www.mhcirl.ie/documents/34%20AC%20Rpts%202008%20Web/st\_1 ukes\_clonmel\_mhc\_2008.pdf [accessed: 4 April 2009].
- MHC (2008b). Report of the Inspector of Mental Health Services 2008:St. Michael's Unit, South Tipperary General Hospital. [online], available: http://www.mhcirl.ie/documents/34%20AC%20Rpts%202008%20Web/st\_ michaels\_s\_tipp\_mhc\_2008.pdf [accessed: 4 April 2009].
- MHC (2008c). Annual Report including the Report of the Inspector of Mental Health Services 2008. Dublin: MHC.
- MHC (2009). Report of the Committee of Inquiry to review care and treatment practices in St. Michael's Unit, South Tipperary General Hospital, Clonmel and St. Luke's Hospital, Clonmel, including the quality and planning of care and the use of restraint and seclusion. Dublin: Mental Health Commission.
- MHC (2009a). Annual Report including the Report of the Inspector of Mental Health Services 2009. Dublin: MHC.
- Migden, D. (2000). 'Correspondence: The Use of Physical Restraints in Medical Emergencies.' *New England Journal of Medicine*. 342(10):742-744.
- Miller, F. (2000). 'Placebo-controlled trials in psychiatric research: an ethical perspective.' *Biological Psychiatry*. 47(8):707-716.
- Mlodinow, L. (2009). *The Drunkard's Walk: How Randomness Rules Our Lives*. New York: Vintage.
- Monahan, J. et al (2001). Rethinking Risk Assessment: The MacArthur Study of Mental Disorder and Violence. New York: Oxford University Press.
- Moncrieff, J. & Double, D. (2003). 'Double blind random bluff.' *Ment Health Today*. Nov:24-6. PMID: 14689600.
- Moncrieff, J. & Kirsch, I. (2005). 'Efficacy of antidepressants in adults.' *British Medical Journal.* 331:155-157.
- Moncrieff, J. (2002). 'Editorial: The antidepressant debate.' *The British Journal of Psychiatry*. 180:193-194.
- Moncrieff, J. (2007). *The Myth Of The Chemical Cure: A Critique of Psychiatric Drug Treatment*. London: Palgrave Macmillan.
- Moncrieff, J. *et al* (2009). 'The subjective experience of taking antipsychotic medication: a content analysis of Internet data.' *Acta Psychiatr Scand*. 120(2):102-11.
- Mordini, E. (1994): *Italian Report 1994*. Rome: Istituto Psicoanalitico per le Ricerche Sociali.

- Mori (2003). 'Changing Social Values'. [Online], available: http://www.mori.com/mrr/2003/c030610.shtml [accessed 31 July 2006].
- Moritz, S. *et al* (2006). 'Incautious Reasoning as a Pathogenetic Factor for the Development of Psychotic Symptoms in Schizophrenia'. *Schizophrenia Bulletin.* 32(2):327-331.
- Morris H. (2004). 'Iatrogenic illness on a general medical service at a university hospital'. *Qual. Saf. Health Care*. 13:76-80.
- Mortimer, A. *et al* (2005). 'Primary care use of antipsychotic drugs: an audit and intervention study.' *Annals of General Psychiatry*. 4(18). [online], available: http://www.biomedcentral.com/content/pdf/1744-859x-4-18.pdf [accessed: 12 March 2009].
- Moser, L. & Bond, G. (2009). 'Letters: Reply to Roskes (2009)'. *Psychiatric Services*. 60(9).
- Mosley, J. *et al* (2002). 'A Controlled Trial of Arthroscopic Surgery for Osteoarthritis of the Knee.' *New England Journal of Medicine*. 347(2): 81-88.
- Moynihan, R. *et al* (2002). 'Selling sickness: the pharmaceutical industry and disease mongering'. *British Medical Journal*. 324:886–891.
- Mukherjee, R. *et al* (2002). 'The stigmatisation of psychiatric illness: the attitudes of medical students and doctors in a London teaching hospital.' *Psychiatric Bulletin.* 26:178-181.
- Mukherjee, S. *et al* (1983). 'Misdiagnosis of schizophrenia in bipolar patients: a multiethnic comparison.' *American Journal of Psychiatry*. 140:1571-1574.
- Mullen, P. (1984). 'Mental disorder and dangerousness'. *Aust NZ J Psychiatry*. 18(1):8-17.
- Mullen, P. (1990). 'Morbid jealousy and the delusion of infidelity' in Bluglass R. & Bowden. P. (eds.), *Principles and Practice of Forensic Psychiatry*. London: Churchill Livingstone; pp. 823-834.
- Mullen, P. (2001). Mental Health And Criminal Justice : a review of the relationship between mental disorders and offending behaviours and on the management of mentally abnormal offenders in the health and criminal justice services. A Report prepared for the Criminology Research Council of Australia. [online], available: http://www.criminologyresearchcouncil.gov.au/reports/mullen.html [accessed: 22 May 2009].
- Munro, A. (1999). *Delusional Disorder: Paranoia and Related Illnesses*. Cambridge: Cambridge University Press.
- Murdock, A. (1996). 'Irish psychiatric workers criticised'. *British Medical Journal*. 312:994-995.
- Muzinić, L. *et al* (2003). 'Forensic importance of jealousy'. *Collegium antropologicum*. 27(1):293-300.
- National Council on Disability (2000). From Privileges to Rights: People Labeled with Psychiatric Disabilities Speak for Themselves. Washington: National Council on Disability. [online], available: http://www.ncd.gov/publications/2000/Jan202000 [accessed: 1 June 2011].
- Neighbors, H. (1997). 'The (mis) diagnosis of mental disorder in African Americans'. African American Research Perspectives. 3:1-11.
- Neimark, G. (2009). 'Review: Kendler (2008): Philosophical Issues in Psychiatry.' *American Journal of Psychiatry*. 166:1301.

- Newton-Howes, G. & Mullen, R. (2011). 'Coercion in Psychiatric Care: Systematic Review of Correlates and Themes.' *Psychiatric Services*. 62:465-470.
- NICE (2004a). Depression: management of depression in primary and secondary care. Clinical practice guideline No 23. London: NICE. [online], available: www.nice.org.uk/page.aspx?o=235213 [accessed: 3 March 2009].
- NICE (2004b). *The costs of epilepsy misdiagnosis*. [online], available: http://www.nice.org.uk/download.aspx?o=109760 [accessed: 27 March 2007].
- Nickerson, R. (1998). 'Confirmation Bias: A Ubiquitous Phenomenon in Many Guises'. *Review of General Psychology*. 2(2):175-220.
- Nissani, M. & Hoefler-Nissani, D. (1992). 'Experimental studies of beliefdependence of observations and of resistance to conceptual change'. *Cognition and Instruction*. 9:97-111.
- Nissim-Sabat, M. (2007). 'Agency, Ontology, and Epistemic Justification: A Response to Freedman'. *Philosophy, Psychiatry, & Psychology*. 14 (1):13-17.
- Nordt, C. *et al* (2006). 'Attitudes of Mental Health Professionals Toward People With Schizophrenia and Major Depression.' *Schizophrenia Bulletin*. 32(4):709–714.
- NPSA (2001). *Introducing The National Patient Safety Agency*. [Online], available: http://www.npsa.nhs.uk/site/media/documents/240\_art.pdf [accessed: 27 March 2007].
- NPSA (2006a). Quarterly National Reporting and Learning System data summary: Summer 2006. [online], available: http://www.npsa.nhs.uk/site/media/documents/1847\_FINAL.APPENDIX.P SO\_QTRLY.pdf [accessed: 29 March 2007].
- NPSA (2006b). Patient Safety Observatory Report 2 July 2006. With safety in mind: mental health services and patient safety. [online], available: http://www.npsa.nhs.uk/site/media/documents/1846\_FINAL.PSO2\_MENT ALHEALTH.pdf [accessed: 29 March 2007].
- Nyberg, P. (2011). *Misjudging risk: causes of the systemic banking crisis in Ireland*. Dublin: Dept. of Finance.
- O'Neill, A-M. (2005). Irish Mental Health Law. Dublin: FirstLaw.
- Oaks, D.(2011). 'The Moral Imperative for Dialogue with Organizations of Survivors of Coerced Psychiatric Human Rights Violations.' in Kallert (2011), pp.185–211.
- Ödegård, S. (1998). 'From Punishment To Prevention? Medical Errors Reported in Sweden in 1989 and 1993.' *Safety Science Monitor*. [online], available: http://www.monash.edu.au/muarc/ipso/vol3/te1.pdf [accessed: 9 April 2007].
- Oireachtas Joint Committee on Health and Children, (2007). *The Adverse Side Effects of Pharmaceuticals*. Eighth Report. April. [Online], available: http://www.oireachtas.ie/documents/committees29thdail/committeereports2 007/side-effects.pdf [accessed: 5 May 2007].
- Oireachtas Sub-Committee on the Adverse Side Effects of Pharmaceuticals (2006), 10 Oct, [online], available: http://debates.oireachtas.ie/DDebate.aspx?F=HEP20061010.xml&Ex=All& Page=3 [accessed: 5 May 2007].
- Oireachtas Sub-Committee on the Adverse Side Effects of Pharmaceuticals (2006), 17 Oct, [online], available:

http://debates.oireachtas.ie/DDebate.aspx?F=HEP20061017.xml&Node=H3 &Page=3 [accessed: 16 December 2006 ].

- Olabi, B. (2009). 'Correspondence: Stigma and Schizophrenia.' *The Lancet*. 373:1335.
- Olabi, B. (2009). 'Correspondence: Stigma and Schizophrenia.' *The Lancet*. 373:1335.
- Oliver, D. (2008). "Acopia" and "social admission" are not diagnoses: why older people deserve better.' *Journal of the Royal Society of Medicine*. (101):168-174.
- Olofsson, G. (2007). The dark side of professions the role of professional autonomy in creating 'great professional disasters'. Paper given at the 8<sup>th</sup> Conference of the European Sociological Association in Glasgow. [online], available: http://dinsida.gu.se/infoglueCalendar/digitalAssets/1762541268\_BifogadFil

\_Olofsson%20professionspaper%20ESA%2026%20aug%202007.pdf [accessed: 26 May 2008].

- Owens, D. (2008). 'What CATIE Did: Some Thoughts on Implications Deep and Wide'. *Psychiatr Serv.* 59:530-533.
- Papineau, D. (2006). 'The Tyranny of Common Sense.' *The Philosophers Magazine*. [online], available: http://www.philosophersnet.com/magazine/article.php?id=1005 [accessed 25 July 2006].
- Parikh, S. (2009). 'Antidepressants are not all created equal.' *The Lancet*. 373(9665):700-701.
- Parker, G. *et al* (2003). 'Clinical trials of antidepressant medications are producing meaningless results.' *The British Journal of Psychiatry*. 183:102-104.
- Paul, C (2004). 'The relentless therapeutic imperative.' *British Medical Journal*. 329:1457.
- Paulose-Ram, R. *et al* (2007). 'Trends in psychotropic medication use among U.S. adults.' *Pharmacoepidemiol Drug Saf.* 16(5):560-70.
- Pedersen, S. (2005). 'Anti-Condescensionism Review of Bodily Matters: The Anti-Vaccination Movement in England, 1853-1907 by Nadja Durbach'. *London Review of Books*. 27(17) [online], available:http://www.lrb.co.uk/v27/n17/pede01\_.html [accessed: 21 August 2006].
- Perlis, R. *et al* (2005). 'Industry Sponsorship and Financial Conflict of Interest in the Reporting of Clinical Trials in Psychiatry.' *American Journal of Psychiatry*. 162:1957-1960.
- Persaud, R. (2005). 'Reviews: The Lobotomist: A Maverick Medical Genius and his Tragic Quest to Rid the World of Mental Illness.' *British Medical Journal*. 330:1275.
- Phillips, J. (2010). 'The Muddle that is DSM-V.' Association for the Advancement of Philosophy and Psychiatry, Bulletin. 17(1):10-12.
- Pichot, P. (1997). 'DSM-III and its reception: a European view.' *Am J Psychiatry*. 154:47-54.
- Pierre, J. (2009). "'What Do You Mean, I Don't Have Schizophrenia?'". *Psychiatric Times*. 26(2). [online], available: http://www.psychiatrictimes.com/schizophrenia/content/article/10168/1371 041 [accessed: 9 June 2010].

- Pies, R. (2004). 'Moving beyond the "Myth" of Mental Illness.' in Schaler (2004): 327-353.
- Pies, R. (2010). 'Psychiatry Remains a Science, Whether or Not You Like DSM5.' *Psychiatric Times [online]*. 25 February.
- Pies, R. (2010a). "'Prescribing Psychologists:" Practicing Medicine without a License?." *Psychiatric Times [online]*. 29 March.
- Pincus, H. *et al* (1998). 'Prescribing Trends in Psychotropic Medications.' *Journal of the American Medical Association*. 279(7):526-531.
- Pingitore, D. *et al* (2002) 'Comparison of Psychiatrists and Psychologists in Clinical Practice'. *Psychiatr Serv.* 53:977-983.
- Pinney, E. (1965). 'The Psychiatric Indications For Group Psychotherapy.' *Psychosomatics*. 6: 139-144.
- Pinta, E. (2006). 'Letter to the Editor: Limitations of Study on Violent Crime and Mental Illness.' *Am J Psychiatry*. 163:2193-a.
- Pinta, E. (2006). 'Letter to the Editor: Limitations of Study on Violent Crime and Mental Illness.' *Am J Psychiatry*. 163:2193-a.
- Pope, H. & Lipinski, J. (1978). 'Diagnosis in schizophrenia and manic-depressive illness: a reassessment of the specificity of 'schizophrenic' symptoms in the light of current research'. *Archives of General Psychiatry*. 35:811-828; [online], available: *Citation Classic*. 24. 13 June 1988: http://www.garfield.library.upenn.edu/classics1988/A1988N613300001.pdf [accessed: 8 October 2008].
- Porter, R. *et al* (2001). 'Treatment of severe depression-non-pharmacological aspects'. *Advances in Psychiatric Treatment*. 7:117-124.
- Potter, N. (2007). 'Uncertain Knowledge'. *Philosophy, Psychiatry, & Psychology*. 14(1):19-22.
- Priebe, S. *et al* (2009). 'Patients' views and readmissions 1 year after involuntary hospitalisation.' *British Journal of Psychiatry*. 194: 49-54.
- Priebe, S. *et al* (2010). 'Patients' views of involuntary hospital admission after 1 and 3 months: prospective study in 11 European countries'. *British Journal of Psychiatry*. 196, 179–185.
- Prins, H. (2000). 'Correspondence: Homicide is impossible to predict.' *Psychiatric Bulletin.* 24:152.
- Quitkin, F. *et al* (2000). 'Validity of Clinical Trials of Antidepressants.' *American Journal of Psychiatry.* 157:327-337.
- Quitkin, F. *et al* (2005). 'Correspondence: Re Efficacy of antidepressants in adults'. *British Medical Journal*. [online], available: http://www.bmj.com/cgi/eletters/331/7509/155#116205 [accessed: 27 February 2009].
- Radden, J. (2004). (ed.). *The Philosophy of Psychiatry: A Companion* (International Perspectives in Philosophy and Psychiatry). New York: OUP.
- Ravdin, I. (1957). 'Problems Of Surgical Residency Training.' *Journal of the American Medical Association*. 165:1373-1376.
- Rawls, J. (1973). A Theory Of Justice. Oxford: Oxford University Press.
- Ray, W. *et al* (2009). 'Atypical Antipsychotic Drugs and the Risk of Sudden Cardiac Death.' *New England Journal of Medicine*. 360:225-235.
- Read, J. & Bentall, R. (2010). 'The effectiveness of electroconvulsive therapy: A literature review'. *Epidemiologia e Psichiatria Sociale*. 19(4):333-347.

- Read, J. & Law, A. (1999). 'The relationship between causal beliefs and contact with users of mental health services to attitudes to the 'mentally ill''. *International Journal of Social Psychiatry*. 45:216-229.
- Read, R. (2003). 'Literature as Philosophy of Psychopathology: William Faulkner as Wittgensteinian'. *Philosophy, Psychiatry, & Psychology*. 10(2):115-124.
- Reeves, R. *et al* (2000). 'Unrecognized medical emergencies admitted to psychiatric units.' *Am J Emerg Med.* 18(4):390-3.
- Rego, M. (2007). 'Empiricism and the Craft Nature of Science.' Association for the Advancement of Philosophy and Psychiatry, Bulletin. 14(1):9-10.
- Reich, W. (1999). 'Psychiatric diagnosis as an ethical problem.' in Bloch (1999):193-224.
- Reznek, L. (1998). 'On the epistemology of mental illness.' *Hist Philos Life Sci.* 20(2):215-32.
- Ribeiro, B. (1994). *Coherence in Psychotic Discourse*. Oxford: OUP.
- Ribeiro, S. (2003). 'Tuberculosis compulsory treatment: advancement or retrogression?' *Jornal de Pneumologia*. 29.
- Rieder, R. (2001). 'Review: Luhrmann. Of Two Minds The growing disorder in American psychiatry.' *American Journal of Psychiatry*. 158(6):983-5.
- Rising, K. *et al* (2008). 'Reporting bias in drug trials submitted to the Food and Drug Administration: A review of publication and presentation'. *PLoS Med* 5(11):e217. doi:10.1371/ journal.pmed.0050217.
- Rissmiller, D. & Rissmiller, J. (2006). 'Evolution of the Antipsychiatry Movement Into Mental Health Consumerism'. *Psychiatr Serv.* 57:863-866.
- Ritchie, K. (1989). 'The Little Woman Meets Son of DSM-III'. *The Journal of Medicine and Philosophy.* 14:695-708.
- Robins L. & Barrett, J. (eds.) (1989). *The Validity of Psychiatric Diagnosis*. New York: Raven Press.
- Roche, G. (2000). An alternative conceptual structure for the resolution of 'endof-life' problems involving PVS patients. Unpublished MPhil thesis, University College, Cork. [Online], available: http://www.gerryroche.com/thesis/ [accessed: 21 August 2006].
- Rogers A. et al (1993). Experiencing Psychiatry: Users Views of Services. London: MIND.
- Rose, D. *et al* (2003). 'Patients' perspectives on electroconvulsive therapy: systematic review'. *British Medical Journal*. 326:1363.
- Rose, D. *et al* (2011). 'A Comparison of Participant Information Elicited by Service User and Non-Service User Researchers.' *Psychiatric Services*. 62:210-213.
- Rosenhan, D. (1973). 'On Being Sane in Insane Places'. Science. 179:250-8. Rosenheck, R. (2006). 'Outcomes, Costs, and Policy Caution: A Commentary on the Cost Utility of the Latest Antipsychotic Drugs in Schizophrenia Study (CUtLASS 1).' Arch Gen Psychiatry. 63:1074-1076. Rosenthal, M. (2005). 'Medical Errors and Medical Narcissism.' New England Journal of Medicine. 353:324. Roskes E. (2009). 'Letters: The Role of Coercion in Public Mental Health Practice'. Psychiatric Services. 60(9).
- Roskes E. (2011). 'Letters: Coercion in Treatment: Researchers' Perspectives.' *Psychiatric Services*. 62(7).
- Ross, R. (2008). 'Editorial: New Findings on Antipsychotic Use in Children and Adolescents With Schizophrenia Spectrum Disorders.' *American Journal of Psychiatry*. 165:1369-1372.

- Rost, K. *et al* (1994). 'The deliberate misdiagnosis of major depression in primary care.' *Arch Fam Med.* 3(4):333-7.
- Rotter, M. & Goodman, W. (1993). 'The relationship between insight and control in obsessive-compulsive disorder: implications for the insanity defense.' *Bull Am Acad Psychiatry Law.* 21(2):245-52.
- Royal College of Obstetricians and Gynaecologists (1996). A consideration of the law and ethics in relation to court-authorised obstetric intervention. No 1. London: Royal College of Obstetricians and Gynaecologists, 1994. (Supplement to No 1 published in December 1996.)
- Royal College Of Psychiatrists (2004). Evidence submitted to the Joint Committee on the Draft Mental Health Bill. [online], available: http://www.rcpsych.ac.uk/pdf/MHB\_draft04.pdf. [accessed: 21 August 2006].
- Royal Statistical Society (2001). News Release entitled '*Royal Statistical Society* concerned by issues raised in Sally Clark case' 23 October; online, available: http://www.sallyclark.org.uk/RSS.html [accessed: 7 August 2006].
- Rudnick, A. (1990). 'Towards a rationalization of biological psychiatry: a study in psychobiological epistemology.' *J Med Philos*. 15(1):75-96.
- Russell, B. (1952). 'Is There a God?' in Russell, B. (1997). Slater, J. & Köllner, P. (eds.). *The Collected Papers of Bertrand Russell, Volume 11: Last Philosophical Testament, 1943-68.* London: Routledge; pp. 543-48.
- Sachs, O. (1983). Awakenings. New York: Dutton.
- Sackeim, H. (2000) 'Editorial: Memory and ECT: From Polarization to Reconciliation.' *Journal of ECT*. 16(2): 87-96.
- Sackeim, H. *et al* (2007). 'The Cognitive Effects of Electroconvulsive Therapy in Community Settings.' *Neuropsychopharmacology*. 32: 244–254.
- Sackett D. *et al* (1996). 'Evidence based medicine: what it is and what it isn't'. *British Medical Journal*. 312:71-72.
- Sadler, J. (1996). 'Epistemic Value Commitments in the Debate over Categorical vs. Dimensional Personality Diagnosis.' *Philosophy, Psychiatry, & Psychology.* 3(2):203-222.
- Sadler, J. (2007). 'Tough Talk About a Tough Job.' Association for the Advancement of Philosophy and Psychiatry, Bulletin. 14 (1):10.
- Sartorius, N. (2002). 'Iatrogenic stigma of mental illness.' *British Medical Journal*. 324:1470–1.
- Sass, L. (1994). The Paradoxes of Delusion: Wittgenstein, Schreber and the Schizophrenic Mind. Ithaca: Cornell University Press.
- Savulescu, J. & Dickenson, D. (1998a). 'The Time Frame of Preferences, Dispositions, and the Validity of Advance Directives for the Mentally Ill.' *Philosophy, Psychiatry, & Psychology.* 5(3):225-246.
- Savulescu, J. & Dickenson, D. (1998b). 'Response to the Commentaries.' *Philosophy, Psychiatry, & Psychology*. 5(3):263-266.
- Savulescu, J. & Momeyer, R. (1997). 'Should informed consent be based on rational beliefs?' *Journal of Medical Ethics*. 23(5):282-288.
- Sawa, A. & Snyder, S. (2002). 'Schizophrenia: diverse approaches to a complex disease.' *Science*. 296:692–95.
- Schaler, J. (ed.) (2004). *Szasz Under Fire: The Psychiatric Abolitionist Faces His Critics*. Chicago: Open Court.

- Schneeweiss, S. & Avorn, J. (2009). 'Editorial: Antipsychotic Agents and Sudden Cardiac Death — How Should We Manage the Risk?' *New England Journal of Medicine*. 360:294-296.
- Schneeweiss, S. *et al* (2007). 'Risk of death associated with the use of conventional versus atypical antipsychotic drugs among elderly patients.' *Canadian Medical Association Journal*. 176 (5):627-632.
- Schorer, C. (1968). 'Mistakes in the Diagnosis of Schizophrenia'. *Am J Psychiatry*. 124:1057-1062.
- Schulze, B. (2009). 'Mental-health stigma: expanding the focus, joining forces.' *The Lancet*. 373:362-363.
- Schwartz, M. & Wiggins, O. (1999). 'The Crisis of Present-Day Psychiatry: The Loss of the Personal.' *Psychiatric Times*. XVI(8). [online], available: http://psychiatrictimes.com/p990860.html [accessed: 14 June 2007].
- Schweizer, A. *et al* (2003). 'Is psychoactive medication usage in care homes related to staffing levels?' *The International Journal of Pharmacy Practice*. 11: R42.
- Scull, A. (2005). *Madhouse: a Tragic Tale of Megalomania and Modern Medicine*. New Haven: Yale University Press.
- Scull, A. (2010). 'A psychiatric revolution.' *The Lancet*. 375(9722):1246-7.
- Seale, C. *et al* (2007). 'Antipsychotic medication, sedation and mental clouding: an observational study of psychiatric consultations.' Social Science & *Medicine*. 65(4):698-711.
- Seanad Éireann, 7 November 2002 [online], available: http://www.gov.ie/debates-02/s7Nov/Sect1.htm [accessed: 30 June 2007].
- Sedler, M. (1995). 'Understanding Delusions'. *The Psychiatric Clinics of North America*. 18(2):251-261.
- Shah, S. (1977). 'Dangerousness: Some definitional, conceptual, and public policy issues'. in Sales, B. (ed.) (1977). *Perspectives in Law and Psychology: Volume 1. The Criminal Justice system.* New York: Plenum Press; pp. 91-119.
- Sharfstein, S. (2005). *Presidential address to the American Psychiatric Association: 'Advocacy for Our Patients and Our Profession'* [online], available: http://md.nami.org/sharfstein.htm [accessed: 12 May 2007].
- Sharfstein, S. (2006). 'Psychosocial Treatment: We Owe It to Our Patients'. *Psychiatric News.* 41(5):3.
- Sharpley, S. *et al* (2001). 'Understanding the excess of psychosis among the African—Caribbean population in England: review of current hypotheses'. *The British Journal of Psychiatry*. 178:s60-s68.
- Shen, W. (1999). 'A History of Antipsychotic Drug Development.' *Comprehensive Psychiatry*. 40 (6):407-414.
- Shepherd, M. (1961). 'Morbid Jealousy: Some Clinical and Social Aspects of a Psychiatric Symptom'. *Journal of Mental Science*. 107:687-753.
- Shine, I. (2000). 'Correspondence: The Use of Physical Restraints in Medical Emergencies.' *New England Journal of Medicine*. 342(10):742-744.
- Ship, A. (2004). 'A 46-Year-Old Man With Anxiety and Nightmares After a Motor Vehicle Collision, 2 Years Later.' *Journal of the American Medical Association*. 292:2262.
- Shojania, K. *et al* (2003). 'Changes in Rates of Autopsy-Detected Diagnostic Errors Over Time: A Systematic Review.' *Journal of the American Medical Association*. 289(21):2849-2856.

- Shuchman, M. (2007). 'Approving the Vagus-Nerve Stimulator for Depression.' *New England Journal of Medicine*. 356(16):1604-1607.
- Siever, L. (2007). 'Review: Thornicroft: Shunned: Discrimination Against People with Mental Illness. *American Journal of Psychiatry*.164(80):1273.
- Sikich, L. *et al* (2008). 'Double-Blind Comparison of First- and Second-Generation Antipsychotics in Early-Onset Schizophrenia and Schizoaffective Disorder: Findings From the Treatment of Early-Onset Schizophrenia Spectrum Disorders (TEOSS) Study.' *American Journal of Psychiatry*. 165:1420-1431.
- Simon, R. (2004). 'The Legitimacy of the Defense of Insanity.' in Schaler (2004):199-201.
- Singh, S. *et al* (2007). 'Ethnicity and the Mental Health Act 1983'. *The British Journal of Psychiatry*. 191:99-105.
- Sirotich, F. (2008). 'Correlates of Crime and Violence among Persons with Mental Disorder: An Evidence-Based Review.' *Brief Treatment and Crisis Intervention.* 8(2):171-194.
- Sklar, D. (2000). 'Correspondence: The Use of Physical Restraints in Medical Emergencies.' *New England Journal of Medicine*. 342(10):742-744.
- Slater, L. (2005). *Opening Skinner's Box: Great Psychological Experiments of the Twentieth Century*. London: Bloomsbury Publishing PLC.
- Slaughter, J. *et al* (2001). 'Prevalence, clinical manifestations, etiology, and treatment of depression in Parkinson's disease.' *J Neuropsychiatry Clin Neurosci.* 13(2):187-196.
- Smith, D. (1978). ' "K is Mentally Ill": the Anatomy of a Factual Account.' *Sociology*. 12: 23-53.
- Smith, R. (2006). 'Lapses at the New England Journal of Medicine.' *Journal of the Royal Society of Medicine*. 99:380-382.
- Spitzer, M. (1990). 'On Defining Delusions'. *Comprehensive Psychiatry*. 32(5):377-397.
- Spitzer, R. & Fleiss. J. (1974). 'A Re-analysis of the Reliability of Psychiatric Diagnosis'. *British Journal of Psychiatry*. 125:341-347.
- Spitzer, R. (1975). 'On Pseudoscience in Science, Logic in Remission, and Psychiatric Diagnosis: A Critique of Rosenhan's "On Being Sane in Insane Places"'. *J Abnorm Psychol.* 84(5):442-52.
- Spitzer, R. (1976). 'More on pseudoscience in science and the case for psychiatric diagnosis. A critique of D.L. Rosenhan's "On Being Sane in Insane Places" and "The Contestual Nature of Psychiatric Diagnosis"'. *Arch Gen Psychiatry*. 33(4):459-70.
- Stalman, S. (2002). 'Letters: Prevention of Relapse in Schizophrenia.' *New England Journal of Medicine*. 346(18):1412.
- Stanford Encyclopedia of Philosophy, [online], available: http://plato.stanford.edu/contents.html [accessed 10 July 2006].
- Steadman, H. *et al* (1998). 'Violence by People Discharged From Acute Psychiatric Inpatient Facilities and by Others in the Same Neighborhoods.' *Archives of General Psychiatry*. 55(5):393-401.
- Steel, K. *et al* (1981). 'Iatrogenic illness on a general medical service at a university hospital'. *New England Journal of Medicine*. 304:638–42.
- Stevens, W. (1990). *The Collected Poems of Wallace Stevens*. New York: Knopf Vintage Edition.
- Stigma Shout (2008). Service user and carer experiences of stigma and *discrimination*. [online], available:

http://www.rethink.org/document.rm?id=6929 [accessed: 17 September 2009].

- Stone, J. et al (2005). 'Systematic review of misdiagnosis of conversion symptoms and "hysteria"'. British Medical Journal. 331:989. [online], available: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1273448
  - [accessed: 3 October 2008].
- Storr, A. (1997). 'Commentary on "Spiritual Experience and Psychopathology"'. *Philosophy, Psychiatry, & Psychology*. 4(1):83-85.
- Stortinget (1995) Dok.nr.8:70 (1995-1996). 'Forslag fra stortingsrepresentant Erling Folkvord om at Stortinget skal be Regjeringa om å oppnevne en granskingskommisjon til å granske Juklerød-saken, fra dens begynnelse i striden om nedleggelse av Holtane skole og fram til dens avslutning ved Gaustad sykehus' handlinger overfor Arnold Juklerød.' [Online], available: http://www.stortinget.no/dok8/1995/dok8-199596-070.html [accessed: 30 June 2007].
- Strawson, P. (1963). *Individuals*. New York: Anchor.
- Sullivan, H. Stack, (1956). *Clinical Studies in Psychiatry*. New York: Norton.
- Sullivan, H. Stack, (1964). [Commentaries by H. Perry]. *The Fusion of Psychiatry and Social Science*. New York: Norton.
- Summerfield D. (2001). 'Does psychiatry stigmatise?' *J Royal Soc Med*. 94:148-149.
- Summers, A. & Kehoe, R. (1996). 'Is psychiatric treatment evidence-based?' *The Lancet*. 347:409-410.
- Sutherland, S. (1992). *Irrationality*. London: Constable.
- Sutton, B. (2008). 'Taking Issue: Lessons to Be Learned From CATIE and CUtLASS.' *Psychiatr Serv*. 59:473.
- Swanson, J. *et al.* (2003). 'Effects of involuntary outpatient commitment on subjective quality of life in persons with severe mental illness.' *Behavioral Sciences & the Law.* 21(4):473-491.
- Swanson, J. (2008). 'Preventing the Unpredicted: Managing Violence Risk in Mental Health Care.' *Psychiatr Serv.* 59:191-193.
- Swartz, M. *et al* (2008). 'What CATIE Found: Results From the Schizophrenia Trial'. *Psychiatr Serv.* 59:500-506.
- Szasz, T. (1971). 'The sane slave: An historical note on the use of medical diagnosis as justificatory rhetoric.' *American Journal of Psychotherapy*. 25:228-239.
- Szasz, T. (2000). 'Second Commentary on "Aristotle's Function Argument.' *Philosophy, Psychiatry, & Psychology*. 7(1):3-16.
- Szasz, T. (2004a). 'Reply to Lieberman (2004): Pharmacracy or Phantom?' in Schaler (2004):242-251.
- Szasz, T. (2004b). 'Reply to Simon (2004): 'The Legitimacy of the Defense of insanity?' in Schaler (2004):202-223.
- Szasz, T. (2010). 'Psychiatry, Anti-Psychiatry, Critical Psychiatry: What Do These Terms Mean?' *Philosophy, Psychiatry, & Psychology*. 17(3):229-232.
- Szmukler, G. (2000). 'Homicide inquiries: What sense do they make?' *Psychiatric Bulletin*. 24:6-10.
- Szmukler, G. (2001a). 'Correspondence: Violence risk prediction in practice.' *The British Journal of Psychiatry*. 178:84-85.
- Szmukler, G. (2001b). 'Correspondence: The mathematics of risk assessment for serious violence.' *Psychiatric Bulletin*. 25:359.

- Szmukler, G. (2003). 'Risk assessment: 'numbers' and 'values'.' *Psychiatric Bulletin.* 27:205-207.
- Takei, N. *et al* (2005). 'Correspondence: Stigmatisation of people with schizophrenia in Japan.' *The British Journal of Psychiatry*. 187:589-590.
- Tanne, J. (2007). 'News: Number of bipolar disorder diagnoses leaps among US young people'. *British Medical Journal*. 335:535.
- Teichman, J. (1985). 'The Definition of Person'. *Philosophy*. 60:175-185.
- ter Meulen, R. (2005). 'The ethical basis of the precautionary principle in health care decision making.' *Toxicol Appl Pharmacol.* 207(2 Suppl):663-7.
- Thomas, C. *et al* (1993). 'Psychiatric morbidity and compulsory admission among UK-born Europeans, Afro-Caribbeans and Asians in central Manchester'. *The British Journal of Psychiatry*. 163:91-99.
- Thornicroft, G. (2006). *Shunned: Discrimination against People with Mental Illness*. Oxford: Oxford University Press.
- Thornicroft, G. *et al* (2009). 'Global pattern of experienced and anticipated discrimination against people with schizophrenia: a cross-sectional survey.' *The Lancet.* 373:408-15.
- Thornley, B. & Adams, C. (1998). 'Content and quality of 2000 controlled trials in schizophrenia over 50 years.' *British Medical Journal*. 317:1181-1184.
- Thornton, S. (2006). 'Karl Popper'. *The Stanford Encyclopedia of Philosophy*. [online], available: http://plato.stanford.edu/archives/win2006/entries/popper/ [accessed: 10 April 2008].
- Thornton, T. (1997). 'Reasons and Causes in Philosophy and Psychopathology.' *Philosophy, Psychiatry, & Psychology*. 4(4):307-317.
- Thornton, T. (2007b). Essential Philosophy of Psychiatry (International Perspectives in Philosophy and Psychiatry). Oxford: OUP.
- Thornton. T. (2007a). 'The Unexamined Life is not Worth Living: Philosophy as a Natural Component of Self-conscious Psychiatric Practice'. Association for the Advancement of Philosophy and Psychiatry, Bulletin. 14(1):10-13.
- *Time* (1974). 'An Instant Cure', *Time*, 1 April. [online], available: http://www.time.com/time/magazine/article/0,9171,904053,00.html [accessed: 1 August 2007].
- Tooley, M. (1972). 'Abortion and Infanticide'. *Philosophy & Public Affairs*. 2(1):37-65.
- Tranøy, J. & Blomberg, W. (2005). 'Lobotomy in Norwegian psychiatry'. *History* of *Psychiatry*. 16(1):107-110.
- Tranøy, J. (1996). 'Lobotomy in Scandinavian Psychiatry'. *The Journal of Mind and Behavior*. 17(1):1-20.
- Tresch, D. *et al* (1991). 'Clinical Characteristics of Patients in the Persistent Vegetative State.' *Archives of Internal Medicine*. 151:930-2.
- Trevino, J. (2008). 'Review: Rationality and Compulsion: Applying Action Theory to Psychiatry.' *Psychiatr Serv.* 59:583.
- Troller, J. *et al* (2008). 'Correspondence: Antipsychotics in individuals with intellectual disability'. *The Lancet*. 371(9623):1501.
- Tucker, G. (1998). 'Editorial: Putting DSM-IV in Perspective'. *American Journal* of *Psychiatry*. 155:159-161.
- Turing, A. (1950). 'Computing machinery and intelligence'. *Mind.* 59:433-460.
- Turk, J. *et al* (2008). 'Correspondence: Antipsychotics in individuals with intellectual disability'. *The Lancet*. 371(9623):1501.

- Turner, E. *et al* (2008). 'Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy'. *New England Journal of Medicine*. 358:252-60.
- Tversky, A. & Kahneman, D. (1983). 'Extensional versus Intuitive Reasoning: The Conjunction Fallacy in Probability Judgement'. *Psychological Review*. 90(4):293-315.
- Tyrer, P. & Kendall, T. (2009). 'Editorial: The spurious advance of antipsychotic drug therapy.' *The Lancet*. 373(9657):4-5.
- Tyrer, P. *et al* (2008). 'Risperidone, haloperidol, and placebo in the treatment of aggressive challenging behaviour in patients with intellectual disability: a randomised controlled trial.' *The Lancet*. 371(9606):57-63.
- Tyrer, P. *et al* (2008a). 'Correspondence: Antipsychotics in individuals with intellectual disability Authors' reply.' *The Lancet.* 371(9623):1502.
- United States Bureau of Justice Statistics Bulletin (2009). Prisoners in 2007. [online], available: http://www.ojp.usdoj.gov/bjs/pub/pdf/p07.pdf [accessed: 27 May 2009]
- University of Berkley, Department of Statistics, (2006). '*SticiGui: Statistics Tools* for Internet and Classroom Instruction: Chapter 16: Sampling.' [online], available: http://www.stat.berkeley.edu/~stark/SticiGui/Text/ch16.htm [accessed 5 July 2006].
- Valenstein, E. (1986). *Great and Desperate Cures*. New York: Basic Books.
- van Baars, A. *et al* (2010). 'Predictors of Perceived Benefit Among Patients Committed by Court Order in the Netherlands: One-Year Follow-Up.' *Psychiatric Services*. 61:1024-1027.
- Van Deemter, K. (2010). Not Exactly: In Praise of Vagueness. Oxford: OUP.
- Van Dorn, R. *et al* (2006). 'The relationship between mandated community treatment and perceived barriers to care in persons with severe mental illness.' *International Journal of Law and Psychiatry*. 29(6):495-506.
- van Os, J. & McKenna, P. (2003). *Does Schizophrenia Exist? Maudsley Discussion Paper 12*. London: Institute of Psychiatry.
- van Voren, R. (2002). 'Comparing Soviet and Chinese Political Psychiatry'. *J Am Acad Psychiatry Law.* 30:131–5.
- van Zelst, C. (2009). 'Correspondence: Stigma and Schizophrenia.' *Lancet*. 373:1336.
- Volokh, A. (1997). 'n Guilty Men'. *University of Pennsylvania Law Review*. 146:173. [online], available: http://www.law.ucla.edu/volokh/guilty.htm [accessed: 6 June 2009].
- Walsh, D. (1998). *Report of the Inspector of Mental Hospitals for the year ending* 31<sup>st</sup> December, 1998. Dublin: Government Publications.
- Walsh, D. (1999). *Report of the Inspector of Mental Hospitals for the year ending* 31<sup>st</sup> December, 1999. Dublin: Government Publications.
- Wang, P. *et al* (2005). 'Risk of Death in Elderly Users of Conventional *vs.* Atypical Antipsychotic Medications'. *New England Journal of Me*dicine. 353(22):2335-2341.
- Ward, E. (2006). 'Security and Asylum: the Case of Hannah Greally'. *Studies*. 95(377):65-76.
- Warren, M. (1973). On the Moral and Legal Status of Abortion. *Monist.* 57(1):43-61.
- Waterman, G. (2007). 'There Are No Philosophers in Medical Classrooms Either But There Definitely Should Be'. *Association for the Advancement of Philosophy and Psychiatry, Bulletin.* 14(1):13-15.

- Watler C. (1997). 'Correspondence: Lessons from Amy.' *Can Med Assoc J.* 157(1):13.
- Weiner, S. (2007). 'Reaction to Thomas Szasz.' Association for the Advancement of Philosophy and Psychiatry, Bulletin. 14(1):15.
- Welsh, S. & Deahl, M. (2002). 'Modern psychiatric ethics.' *The Lancet*. 359(9302):253-256.
- Whitaker, R. (2003). *Mad in America: Bad Science, Bad Medicine, and the enduring mistreatment of the mentally ill.* New York: Basic Books.
- Whitebook, J. (2005). 'Foucault's Struggle with Psychoanalysis.' in Gutting, G. (2005). pp312–347.
- Whittington, C. *et al* (2004). 'Selective serotonin reuptake inhibitors in childhood depression: systematic review of published versus unpublished data.' *Lancet*. 363: 1341–45.
- WHO (2006). *ICD-10, International Statistical Classification of Diseases and Related Health Problems.* 10th Revision. Version for 2006 [online]; available: http://www3.who.int/icd/currentversion/fr-icd.htm: [accessed 27 June 2006]
- Wieden, P. & Miller, A. (2001). 'Which Side Effects Really Matter? Screening for Common and Distressing Side Effects of Antipsychotic Medications.' *Journal of Psychiatric Practice*. 7(1):41-47.
- Wiggins, O. & Schwartz, M. (1999). 'The Crisis of Present-Day Psychiatry: The Loss of the Personal' Part 1.' *Psychiatric Times*. XVI (8) [online], available: http://www.psychiatrictimes.com/p990860.html [accessed 7 July 2006];

- Part 2 Psychiatric Times XVI (9)[online], available: http://www.psychiatrictimes.com/p990909.html [accessed 7 July 2006].

- Williams, M. (1999). *Wittgenstein, Mind and Meaning -Towards a Social Concept* of Mind. London: Routledge.
- Wilson, S. & Adshead, G. (2004). 'Criminal Responsibility'. in Radden (2004):296-311.
- Wilson, W. & Smith, K. (1995). 'The Doctors' Dilemma: Necessity and the Legality of Medical Interventions'. *Medical Law International*. 1:387-410.
- Wittgenstein L. (1969). *On Certainty*. [Anscombe, G & von Wright G. (eds.); Paul, D. & Anscombe, G. (trans.)]. New York: Harper.
- Wittgenstein, L. (1998). *Culture and Value*. [von Wright, G.(ed.); Pichler, A. (rev. ed.); Winch, P. (trans.)]. Massachusetts: Blackwell.
- Witztum, E. *et al* (1992). 'Labeling and stigma in psychiatric misdiagnosis.' *Isr J Psychiatry Relat Sci.* 29(2):77-88.
- Witztum, E. *et al* (1995a). 'Misdiagnosis and labeling in psychiatry and their consequences: Part II' *Harefuah*. 129(1-2):15-20.
- Witztum, E. *et al* (1995b). 'Stigma, labelling and psychiatric misdiagnosis: origins and outcomes.' *Med Law.* 14(7-8):659-69.
- Wong, Kim Eng. (2006). '*Delusional Disorder*'. [online], available: http://medicine.nus.edu.sg/pcm/book/23.pdf [accessed 6 July 2006].
- World Medical Association (2008). *World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects.* [online], available: http://www.wma.net/e/policy/pdf/17c.pdf [accessed: 16 March 2009]
- Yawar, A. (2009). 'The fool on the hill'. *The Lancet.* 373:621-622.

- Yolles, S., (1968). 'Impressions of the U.S. Mission on Mental Health: Conclusions and Recommendations'. *American Journal of Psychiatry*. 125:670-674.
- Youngner, S. (1998). 'Commentary on "Is Mr. Spock Mentally Competent?".' *Philosophy, Psychiatry, & Psychology.* 5(1):89-92.
- Ziguras, S. *et al* (2003). 'Ethnic Matching of Clients and Clinicians and Use of Mental Health Services by Ethnic Minority Clients'. *Psychiatr Serv.* 54:535-541.
- Zimmerman, M. (2003). 'What should the standard of care for psychiatric diagnostic evaluations be?' *J Nerv Ment Dis.* 191(5):281-6.
- Zimmerman, M. *et al* (2008). 'Is Bipolar Disorder Overdiagnosed?' *J Clin Psychiatry*. 69:935-940.

# Legal Cases

- Addington v Texas, 441 U.S. 418 (1979).
- Airedale N.H.S. Trust v Bland [1993] A.C. 789.
- Baxstrom v Herald (1966) 383 U.S. 107.
- Blehein v Minister for Health (2002). [Unreported. High Court, 7 Dec].
- Blehein v Minister for Health (2004). [High Court, 7 Dec]
- Blehein v Murphy and Others (1999). [High Court, 2 July]
- Blehein v St. John of God Hospital & anor (2002) IESC 43.
- Cross v Harris, 418 F.2d 1095 (1969).
- *Cudden v The Clinical Director of St. Brigid's Hospital* (2009). [Unreported, Supreme Court, 13 March].
- *DPP v B* (2011), Neutral citation (2011) IECC 1.
- *E.H. v St. Vincent's Hospital & ors* (2009). [Unreported, Supreme Court, 28 May]
- *Gooden v Waterford Regional Hospital* (2001). [Unreported, Supreme Court, 21 February]
- Gooden v St. Otteran's Hospital [2005] 3 IR 617.
- *HL v UK* (2005) 40 *E.H.R.R.* 32.
- In re Philip Clarke [1950] IR 235.
- In re T (Adult: Refusal of Treatment) [1992] 3 WLR 782.
- *In the Matter of a Ward of Court* [1995] 2 ILRM 401.
- Kansas v Hendricks, 117 S.Ct. 2072, 138 L.Ed.2d 501 (1997).
- North Western Health Board v HW and CW. (2000). [High Court, 27 October]
- Orton v St. John of God Hospital (2004). [High Court, 15 Dec]
- *Parhat, Huzaifa v Gates, Robert* (2006), U.S. Court of Appeals for the D.C. Circuit. 06-1397.
- *Re B (a minor)(wardship: medical treatment)* [1990] 3 All ER 927.
- Re MB (Caesarean Section) (1997) EWCA Civ 1361.
- *Re S* (*Adult: refusal of medical treatment*) [1992] 4 All ER 671.
- *RL v Director of St. Brendan's Hospital* (2008). [Unreported, Supreme Court, 15 February].
- *Ryan v AG* [1965] IR 294.
- Schloendorff v Society of New York Hospital 211 N.Y. 125; 105 N.E. 92 [1914].
- Starson v Swayze 201 D.L.R. 123 [Ontario Court of Appeal]; also Starson v. Swayze, 2003 SCC 32, [2003] 1 S.C.R. 722 [The Supreme Court of Canada] [online], available:

http://scc.lexum.umontreal.ca/en/2003/2003scc32/2003scc32.html [accessed: 22 December 2006].

- *T* (*a minor*) (wardship: medical treatment). The Times (1996), 25 October.
  - USA v Zacarias Moussaoui, Reply To Government's Position On Competency And Defendant's Self-Representation [online], available: http://notablecases.vaed.uscourts.gov/1:01-cr-00455/docs/65842/0.pdf#search=%22Moussaoui%20%20REPLY%20TO% 20GOVERNMENT%E2%80%99S%20POSITION%22 [accessed: 17 August 2006 ].
- USA v Zacarias Moussaoui (2002). U.S. District Court, Eastern District of Virginia High Profile Cases (Alexandria) CRIMINAL DOCKET FOR CASE #: 1:01-cr-00455-ALL [online], available: http://notablecases.vaed.uscourts.gov/1:01-cr-00455/DocketSheet1.html [accessed: 17 August 2006].
- *W. v L.* [1974] Q.B. 711.
- *Z. v Khattak & Anor.* [2008] IEHC 262.

# Statutes

#### Irish

- *Freedom of Information Act* (1997).
- *Health Act* (1947).
- *Mental Treatment Act* (1945).
- *Mental Treatment Act* (1953).
- *Mental Health Act* (2001).
- Non-Fatal Offences Against The Person Act (1997).

# <u>English</u>

- *Mental Health Act* (2007).
- Forced Marriage (Civil Protection) Act (2007).

# Lectures

- Blackburn, S. (2004). '*Trust me I'm a Scientist.*' Lecture given to a Cambridge Philosophy Society on 23 September.
- Fulford, B. (2001). Keynote lecture at a conference on '*Mental Illness and Accounts of the Mind*' held at University of Southampton, 3 March.

# Media

- BBC (2008). Transcript of 'File on 4' 'psychiatric drugs'. BBC. 17 June. [online], available: http://news.bbc.co.uk/2/shared/bsp/hi/pdfs/17\_06\_08\_fo4\_drugs.pdf [accessed: 3 April 2009].
- Browne, V. (2005b). 'Tonight with Vincent Browne'. *RTE Radio*. 10 May. A CD archive recording of the programme was made available to me by RTE.

- Channel 4 (2006). *Dispatches: Muslim Survey: Attitudes to Living in Britain,* [online], available: http://www.channel4.com/news/microsites/D/dispatches2006/muslim\_surve y/index.html# [accessed: 17 August 2006].
- Curtis, A. & Lambert, S. (2007). *The Trap: Whatever Happened to Our Dreams* of Freedom? Part 1: 'Fuck You Buddy'. BBC documentary first shown on 21 March.
- RTE (2003). *Prime Time Investigates: Bad Medicine*. 15 December. [Online], available: http://www.rte.ie/news/2003/1215/primetime.html [accessed: 30 March 2007].
- Shorter Oxford Dictionary, The New (1997). Compact Disk, version 1.0.03; Data Version: 02.10.96s. Oxford: Oxford University Press.
- Sandøy, H. (1997). For Your Own Good (Til Ditt Eget Beste). [DVD]. Oslo: Irisfilm AS.
- Sandøy, H. (2001). *Force Against Conviction (Makt og Mening)*. [DVD]. Oslo: Irisfilm AS; in conjunction with NRK [a Norwegian TV Network].