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CASE COMMENT: R. V. MILLS – PRODUCTION OF HEALTH RECORDS IN CRIMINAL SEXUAL ABUSE CASES

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INTRODUCTION

On November 25, 1999, the Supreme Court of Canada released its long awaited reasons for judgment in *R. v. Mills*.[1] This case deals with the constitutionality of the legislative scheme governing compelled production in criminal sexual offence proceedings of private records in the hands of third parties. The Court's decision upholding the constitutionality of Bill C-46 (now sections 278.1 to 278.91 of the *Criminal Code*)[2] came down just days before the inaugural issue of the *Journal of Women's Health and Law* was released. In "Compelled Production from Third Parties of Health Records in Sexual Abuse Cases", which appeared in the Journal's first issue,[3] I dealt with the tests and procedures in criminal and civil proceedings governing defence applications for access to the health records of victims of alleged sexual abuse. There, I proposed a number of practical guidelines and tips for health care providers who treat victims of sexual abuse and whose records may, as a result, be targeted for production. Because of the uncertain state of the criminal law on production prior to the release of the Supreme Court of Canada's decision in *R. v. Mills*, I indicated that one of three possible approaches would be employed by a court hearing an application for production of health records: (i) the common law (or judge-made) test fashioned in 1995 by the majority of the Supreme Court of Canada in *R. v. O'Connor*,[4] (ii) the new legislative test found in the *Criminal Code*, which was developed by Parliament in the wake of *R. v. O'Connor* and subsequent public consultations and formally introduced in 1997, or (iii) a combination of these two tests based

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1 [1999] 3 S.C.R. 668.

2 *An Act to Amend the Criminal Code (production of records in sexual offence proceedings)*, S.C. 1997, c. 30.

3 E.K.P. Grace, "Compelled Production from Third Parties of Health Records in Sexual Abuse Cases: Legal Principles and Procedures and Guidelines for Health Care Providers" (1999) 1:1 J.W.H.L. 59.

4 [1995] 4 S.C.R. 411.

on findings by some courts that aspects of the legislative scheme were unconstitutional.[5]

By upholding the constitutionality of Parliament's approach to balancing the competing rights and societal interests implicated in compelled production of private records in criminal sexual assault cases, and interpreting some of the more contentious aspects of the legislative test, the Supreme Court of Canada in *R. v. Mills* has gone a considerable way to clarify the criminal law of production. In so doing, it has made noteworthy observations specific to health, and particularly therapeutic and counselling, records and the special, trust-like nature of the relationships which give rise to such records and are threatened by production orders. These observations should, with time, go some way in making sexual abuse victims' health records (as compared to other kinds of records) less prone to being ordered produced to courts and to the defence and, ultimately, less subject to being targeted by those accused of perpetrating sexual offences.

R. V. MILLS: THE DECISION[6]

At issue in *R. v. Mills* was whether some or all of sections 278.1 to 278.91 of the *Criminal Code* unjustifiably violated the Charter[7] rights of accused persons, and if so, whether, in their stead, some or all of the procedures established by the majority of the Supreme Court of Canada in *R. v. O'Connor*[8] should apply. A subsidiary but related question concerned the ongoing dialogue between courts and legislatures, when both bodies set out to make laws which conform to Charter standards, but do so in a way that produces divergent and even inconsistent results.

On the latter issue, members of the Court in *R. v. Mills*[9] were unanimous in confirming that it was open to Parliament to modify the common law approach to the criminal law of production developed in *R. v. O'Connor* by enacting legislation. The mere fact there are differences — even significant ones — between legislative and judge-made responses to the vexing problem of records production does not, the Court stressed, automatically render the legislative response constitutionally invalid.[10] In other words, the Charter allows for more than one valid approach in balancing competing Charter rights, and legislatures, not just

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5 Grace, "Compelled Production from Third Parties of Health Records", *supra*, note 3, at 63-68, 70-75.

6 Although a full nine-judge panel heard the appeal, Cory J. retired after hearing the appeal and did not participate in giving judgment. Chief Justice Lamer, in one of his last judgments before retiring, was alone in writing partially dissenting reasons. The Court's majority decision was penned by McLachlin J. (the new Chief Justice of Canada) and Iacobucci J., jointly, and hereafter, their reasons shall be referred to as those of "the Court".

7 *Canadian Charter of Rights and Freedoms*, Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (U.K.), 1982, c. 11.

8 *Supra*, note 4.

9 *Supra*, note 1.

10 *Ibid.*, *per* McLachlin and Iacobucci JJ., at 689-90, 710, 712; *per* Lamer C.J.C. at 682.

the courts, have a responsibility to protect and promote these rights. The Court observed that:[11]

> Courts do not hold a monopoly on the protection and promotion of rights and freedoms; Parliament also plays a role in this regard and is often able to act as a significant ally for vulnerable groups. This is especially important to recognize in the context of sexual violence. The history of the treatment of sexual assault complainants by our society and our legal system is an unfortunate one. Important change has occurred through legislation aimed at both recognizing the rights and interests of complainants in criminal proceedings, and debunking the stereotypes that have been so damaging to women and children, but the treatment of sexual assault complainants remains an ongoing problem. If constitutional democracy is meant to ensure that due regard is given to the voices of those vulnerable to being overlooked by the majority, then this court has an obligation to consider respectfully Parliament's attempt to respond to such voices.

However, the Court quite appropriately maintained that the solutions developed by politicians have to be consistent with the Charter and, where a legislative provision is open to different interpretations, courts are to presume that the interpretation which best accords with Charter standards is the one intended by Parliament.[12]

The facts in *R. v. Mills* involved an accused, Brian Mills, charged with committing sexual offences against the complainant, L.C., when she was 13 years old. At an earlier stage in the proceeding, Mills, in reliance on the *O'Connor* test for production, was granted access to portions of the complainant's therapeutic records in the possession of a counselling organization. Later, he sought production of records held by the complainant's psychiatrist and by the Child and Adolescent Services Association. However, by this time the criminal law of production had changed as a result of the enactment on May 12, 1997 of the Bill C-46 amendments to the *Criminal Code*. Without making an actual application for the records under the new legislative regime, the defence successfully challenged before the trial judge the constitutionality of the new *Criminal Code* provisions as a whole, on the basis they violated the accused's section 7 and 11(d) Charter rights to make full answer and defence and to a fair trial, and this violation could not be justified under section 1 of the Charter.[13]

A broad spectrum of interests besides those of the Crown and the accused were represented on the appeal before the Supreme Court of Canada. As a third party adversely affected by an interlocutory order of a superior court, the complainant whose records were at issue was the appellant. In addition, the federal and various provincial Attorneys General were granted leave to intervene as were a number of professional associations and advocacy groups, including the Canadian Mental Health Association, the Canadian Psychiatric Association, the Criminal Defence Lawyers' Association and the Women's Legal Education and Action Fund ("LEAF").

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[11] *Ibid.*, *per* McLachlin and Iacobucci JJ., at 712.

[12] *Ibid.*, at 689-90, 710-13.

[13] [1998] 4 W.W.R. 83 and 107 (Alta. Q.B.).

In considering the constitutionality of the new *Criminal Code* provisions, the Court focused on the five aspects of the legislative regime which the trial judge who had struck it down in its entirety found, and those seeking to uphold his ruling argued, represented unconstitutional departures from the common law *O'Connor* test. The Court's findings with respect to each aspect are summarized below.

THE BROAD SCOPE OF RECORDS COVERED

The broad definition of the records subject to the legislative scheme was argued to impose an undue burden on accused persons because it requires them to bring a production application for each different type of record covered.[14] The Court, however, made short shrift of this argument, stressing that the legislation contains a built-in limit on the kinds of records protected since it applies only to records "in which there is a *reasonable* expectation of privacy".[15] Further, it noted that the scope of the records covered is the starting, not the end, point of the analysis. When considering the constitutionality of the legislation, what is important is the fairness to all affected parties of the actual procedures established for gaining access to the records which are protected.[16]

The Court also rejected the argument that the legislation imposes an undue burden on judicial resources by requiring courts to hear production applications in respect of all manner of records. The balancing process mandated by the legislation should, it said, ensure records are not "needlessly or casually produced to the court for review" and, in any event, if the legislative scheme proves unworkable in practice, this is a matter to be remedied by Parliament, not the Court.[17]

THIRD PARTY RECORDS IN THE POSSESSION OF THE CROWN

Under the *Criminal Code* production regime, unless the person who is the subject of private records has expressly and knowingly waived the protections provided by the legislation, records which come into the possession or control of the Crown are treated in exactly the same manner as those in the hands of third parties. This was argued to be in direct violation of the Crown's common law obligation, set out by the Supreme Court of Canada in *R. v. Stinchcombe*,[18] to disclose to the defence all "relevant" (meaning, in the disclosure context, infor-

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[14] Pursuant to ss. 278.1 and 278.2(1) of the *Criminal Code*, the provisions apply to all records of complainants and witnesses in sexual offence proceedings containing "personal information for which there is a reasonable expectation of privacy", including "medical, psychiatric, therapeutic, counselling, education, employment, child welfare, adoption and social services records, personal journals and diaries and records containing personal information, the production or disclosure of which is protected by any other Act of Parliament or a provincial legislature".

[15] *R. v. Mills, supra*, note 1, *per* McLachlin and Iacobucci JJ., at 730, emphasis in the original.

[16] *Ibid.*, at 731.

[17] *Ibid.*

[18] [1991] 3 S.C.R. 326.

mation that "may be useful to the defence")[19] and non-privileged information in its possession. Further, because the Crown can obtain private records using its search and seizure powers, proponents of the view that the legislative scheme was unconstitutional argued the Crown had acquired an unfair advantage over accused persons who, in order to gain access to private records, must satisfy the requirements imposed by the *Criminal Code*, including the higher threshold in the production context of showing the records are "likely relevant" to an issue at trial or to the competence of a witness to testify.

It was on this issue only that former Chief Justice Lamer parted company with the rest of the Court. He held that, insofar as they apply to records in the Crown's hands, sections 278.3(3)(b) and 278.5(1)(b) of the *Criminal Code*, which require accused persons to establish the likely relevance of the record being sought, violate sections 7 and 11(d) of the Charter and these violations cannot be justified under section 1 of the Charter. By displacing the common law presumption that records in the Crown's possession are automatically relevant and by raising the relevancy threshold which must be satisfied by accused persons seeking such records, Lamer C.J.C. found the legislation gives the Crown a constitutionally unfair advantage over the defence.[20] Accordingly, he held that private records obtained by the Crown without a waiver by the person to whom the records relate should be subject to the common law principles established in *R. v. Stinchcombe*,[21] albeit modified to take into account the privacy rights implicated when the Crown obtains records without the affected person's consent. As a result, he found the onus should be on the Crown to resist disclosure of the records (not the accused to establish his or her entitlement to them) by demonstrating their irrelevancy or privileged nature.[22] If the Crown is unable to discharge this onus, the records (Lamer C.J.C. specifically mentioned therapeutic records) should, because of the privacy rights at stake, be disclosed to the trial judge for his or her review, and not directly to the accused as normally occurs on a successful *Stinchcombe* application. The judge would then follow the procedures set out in sections 278.6 to 278.91 of the *Criminal Code* to assess whether the records should be produced, in whole or in part and with or without conditions, to the accused.[23]

Unlike Lamer C.J.C., the majority of the Court had no difficulty with the fact records in the possession of the Crown, where no informed waiver has been given, are to receive the same treatment as those in the hands of third parties. It found that the waiver rule favoured by the majority of the Court in *R. v. O'Connor*[24] is now entrenched in the *Criminal Code*. Thus, under the legislative scheme, "[w]here a fully informed complainant [or witness] expressly waives the protection of the legislation, by declaration or by voluntarily providing her

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[19] See *R. v. O'Connor, supra,* note 4, *per* Lamer C.J.C. and Sopinka J., at 436, where the different meanings of relevance, depending on the context, is discussed.

[20] *R. v. Mills, supra*, note 1, *per* Lamer C.J.C., at 684.

[21] *Supra*, note 18.

[22] *R. v. Mills*, [1999] 3 S.C.R. 668 at 686.

[23] *Ibid.*

[24] *Supra*, note 4.

records to the Crown, the Bill C-46 procedure does not apply and the records are producible as at common law".[25] The rationale behind the waiver rule is that where the person with the privacy interest at stake is willing to relinquish her or his right to privacy and release a record in order to further the case against the accused, fairness dictates that the accused person have access to the record in preparing his or her defence.[26]

The majority of the Court also recognized that private records may (and do) fall into the hands of the Crown through a variety of means, without the knowledge, informed consent or assistance of the person to whom they relate.[27] In light of this reality, it is appropriate for Parliament to implement measures aimed at protecting privacy rights. It rejected the argument that the moment records come into the Crown's possession, by whatever means, any reasonable expectation of privacy in them is automatically lost, saying this wrongly treats privacy as an all or nothing right: "Privacy interests in modern society include the reasonable expectation that private information will remain confidential to the persons to whom and restricted to the purposes for which it was divulged".[28] Further, since no procedure for granting access to private records in the hands of the Crown obtained without an informed waiver was established in either *R. v. Stinchcombe*, the leading Crown disclosure case, or in *R. v. O'Connor*, it was open to Parliament to do so.[29]

Regarding the more fundamental objection raised, that the *Criminal Code* production regime unfairly favours the Crown, the majority in *R. v. Mills* found there is no principle of fundamental justice that says the Crown and the defence must enjoy exactly the same privileges and procedures.[30] To the extent accused persons face a greater procedural burden than the Crown in gaining access to private records, this is justified by the fact that, unlike the Crown which has a societal responsibility to protect the rights of others, an accused has no such responsibility and is motivated only by the need to defend him or herself against

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[25] *R. v. Mills, supra*, note 22, *per* McLachlin and Iacobucci JJ., at 733. By emphasizing that waiver in a technical sense would not be sufficient, the Court placed the onus on police authorities and Crown prosecutors to ensure that the protections available under the Criminal Code are explained fully to complainants and witnesses asked to consent to the release of their private records. The Court said, "[t]urning records over to the police or Crown, with knowledge of the law's protections and the consequences of waiving these protections, will constitute an express waiver pursuant to s. 278.2(2) [emphasis added]." The waiver may be expressed by words or conduct. *Ibid.*, at 739.

[26] *Ibid.*, at 733.

[27] For example, in *R. v. Nitsiza*, unreported, March 23, 2000, [2000] N.W.T.J. No. 15 (QL), Doc. No. CR 03823, Vertes J. (S.C.), the complainant was told by the investigating police officer she should turn over her personal diary to the Crown's office, which she did. It was unclear what, if any, information she was given about the protection of her privacy rights. However, she had told the victim witness assistance worker that her diary was "highly confidential" and these words were written on the front cover of her diary. The judge found there could be "no realistic argument that the complainant waived her right to confidentiality". *Ibid.*, at paras. 24, 27.

[28] *R. v. Mills, supra*, note 22, *per* McLachlin and Iacobucci JJ., at 735.

[29] *Ibid.*

[30] *Ibid.*, at 736.

criminal charges.[31] What must ultimately be asked when considering the constitutionality of the rules for production to the defence of private records obtained by the Crown is whether the procedures available to an accused for gaining access to the records are in accordance with the principles of fundamental justice, and not whether they are different from those which govern the Crown.

Lastly, the majority noted that the legislative scheme includes two mechanisms which serve to offset any unfairness which may flow from the Crown's possession of documents the accused has not seen. First, where the person with the privacy interest has waived the protections of the legislation, the Crown prosecutor is under a duty to disclose the record to the defence. Second, where no waiver has been given but a record is in the Crown's hands, the prosecutor must notify the accused of this, and while not disclosing the record's contents, provide sufficient information about the date and context of the record so the accused is equipped with a basis for arguing the relevancy of the record to his or her defence.[32]

In the final analysis, there should be little practical difference between the approaches favoured by the majority of the Court and Lamer C.J.C. This is because where the state has exercised its powers to seize the private health records of a complainant without consent (something one expects would be rare), such that they then form part of the state's "case-to-meet", the onus on the accused to establish the records' "likely relevance" would be easily discharged and the interests of justice requirement under the legislative scheme would almost certainly require disclosure, first, to the court for its review, and then to the defence to permit the accused to make full answer defence.

RESTRICTIONS ON THE GROUNDS AN ACCUSED MAY PUT FORWARD TO ESTABLISH LIKELY RELEVANCE

Section 278.3(4) of the *Criminal Code* lists a number of "assertions" which, on their own, are insufficient to establish a record's likely relevance to an issue at trial or to the competence of a witness to testify.[33] Those arguing for the unconstitutionality of the legislative scheme claimed this precluded an accused from relying at all on the factors listed when seeking to establish "likely relevance" and the court from considering these same factors when determining what is to

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[31] *Ibid.*, at 738.

[32] *Ibid.*, at 739. Relying on the Crown's obligation to provide information as to date and context, one judge suggested the Crown must, for the purpose of informing the accused and the court that the record may be "relevant" under the *Stinchcombe* disclosure test, and irrespective of how the record came into the Crown's possession, examine the record, as opposed to simply sealing it up and not looking at it. The obvious infringement to privacy that this examination represents appears not to have been considered. *R. v. Nitsiza, supra,* note 27, at paras. 28-32. In that case, Crown counsel had indicated there was one entry in the complainant's diary which made specific reference to the accused and met the *Stinchcombe* disclosure test. The judge ordered the entire diary produced to the court for inspection, but ultimately decided none of it should be produced to the accused.

[33] These assertions are set out fully and discussed in Grace, "Compelled Production from Third Parties of Health Records", *supra*, note 3, at 71.

be produced to the defence, with the result that an accused's right to make full answer and defence was unjustifiably infringed.

In rejecting this argument, the Court recognized the provision is geared to preventing speculative, unmeritorious and unsupported requests for production based on untenable myths and stereotypes which have "too often in the past hindered the search for truth and imposed harsh and irrelevant burdens on complainants in prosecutions of sexual offences".[34] However, out of concern that accused persons not be precluded from putting forward arguments which are necessary in order for them to make full answer and defence, the Court offered what it called a "constitutional reading" of the impugned provision. It found the provision merely prevents reliance on "bare assertions" of the listed matters "where there is no other evidence and they stand 'on their own'".[35] So long as an accused can point to "specific evidence or information", derived from sources such as the cross-examination of the complainant at a preliminary inquiry,[36] to support the assertions listed in section 278.3(4) and this evidence or information renders the records likely relevant to an issue at trial or to a witness' competence to testify, then he or she will still be able to rely on the assertions.[37] The Court stressed, in a refrain repeated at several points in its reasons, that it is the trial judge who is the ultimate arbiter of whether "likely relevance" under the two stages of the legislative test has been established.[38]

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[34] These myths and stereotypes include that a sexual abuse survivor's testimony is unreliable if she did not complain immediately after the incident (known as the "recent complaint" defence), or she had had previous sexual relations. The Court described the notion that a consultation with a psychiatrist, alone, demonstrates a witness' untrustworthiness as "a more recent, but equally invidious, example of such a myth". *R. v. Mills, supra*, note 22, *per* McLachlin and Iacobucci JJ., at 741.

[35] *Ibid.*, at 740.

[36] For a discussion of what may be elicited by cross-examining the complainant at a preliminary inquiry, see *R. v. Kasook*, unreported, May 19, 2000, Doc. No. CR 03860, [2000] N.W.T. J. No. 33, Vertes J. (S.C.), at paras. 11-13, 17-18, 26-40, 43.

[37] *R. v. Mills, supra, per* McLachlin and Iacobucci JJ., at 741-42. See *R. v. P.E.*, unreported, February 29, 2000, Doc. No. C 29185, [2000] O.J. No. 574 (QL), Weiler, Rosenberg and Feldman JJ.A. (C.A.), at paras. 13-17, where the Ontario Court of Appeal upheld the trial judge's refusal to order production of therapy records to the court on the basis that the defence had failed to establish the "evidentiary or informational foundation" necessary under s. 278.3(4) to overcome the "bare assertions" being advanced. The Ontario Court of Appeal further elaborated on what is required under s. 278.3(4) to establish likely relevance to the complainant's credibility in *R. v. W.B.*, unreported, June 13, 2000, Doc. No. C 22060, [2000] O.J. No. 2184 (QL) McMurtry C.J.O., Doherty and Rosenberg JJ.A. (C.A.), at paras. 75-77, where it said an accused "must be able to point to something in the record ... that suggests that the records contain information which is not already available to the defence [such that the complainant can be cross-examined about it at trial] or has potential impeachment value". It is not sufficient that a complainant say something to a therapist about a matter which *could* be the subject of cross-examination at trial. The Court of Appeal noted that the burden on the accused is not onerous. For example, it can be discharged by showing there are material differences between a complainant's police statement and her preliminary inquiry testimony, and the complainant in the interim spoke to the therapist about the very matters about which there is a discrepancy.

[38] *R. v. Mills*, *supra*, note 22, *per* McLachlin and Iacobucci JJ., at 741.

FIRST STAGE: PRODUCTION TO THE COURT REQUIRES BALANCING OF RIGHTS

With respect to the requirement in the *Criminal Code* that the rights of both the accused and the complainant (or witness) be considered at the first stage, where production to the court is being contemplated, the Court noted that Parliament benefited from a lengthy consultation process not available to the Supreme Court of Canada when it decided *R. v. O'Connor*[39] and from feedback on how the common law *O'Connor* test was working in practice. Because Parliament learned private records were, under the first stage of the *O'Connor* test, routinely being produced to the courts for inspection, resulting in recurring violations of complainants' and witnesses' privacy interests, it decided to supplement the "likely relevance" requirement with a "necessary in the interests of justice" standard and a non-exhaustive listing of factors to be taken into account by the presiding judge when considering the positive and negative effects of production to the court (and later, to the defence) on both the accused's right to make full answer and defence and the complainant's (or witness') right to privacy and equality.[40] In short, the *Criminal Code* production regime requires courts to consider, before examining the records, the rights and interests of all persons affected by the records' disclosure to the court, and not just those of the accused. This is a position consistent with that favoured by the minority of the Supreme Court of Canada in *R. v. O'Connor*.[41]

Those who argued the legislative scheme is unconstitutional claimed it is impossible for a judge to weigh rights in a vacuum without seeing the contents of a record, and insisted the only requirement at this first stage should be, as the majority of the Supreme Court of Canada in *R. v. O'Connor*[42] held, a record's "likely relevance" to an issue at trial or to the competence of a witness to testify. However, taking into consideration the full range of affected interests and rights, in addition to a record's "likely relevance", does not prevent an accused from ultimately seeing those documents, or portions thereof, necessary to make full answer and defence (which is a constitutional reading of section 278.5 of the *Criminal Code*). For this reason, the balancing at the first stage does not violate the principles of fundamental justice. In this connection, the Court noted that when a judge finds a record "likely relevant", but is uncertain whether production is necessary for the accused to make full answer and defence, the judge must err on the side of production to the court since this is what the interests of justice require.[43] The factors enumerated in section 278.5(2) are not determinative of any particular outcome, nor do they prevent a judge from considering other applicable principles of fundamental justice — rather, they are simply to

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[39] *Supra*, note 4.

[40] This approach is explained more fully in Grace, "Compelled Production from Third Parties of Health Records," *supra*, note 3, at 73. The relevant provisions of the *Criminal Code* are ss. 278.4 and 278.5.

[41] *R. v. Mills, supra*, note 22, *per* McLachlin and Iacobucci JJ., at 744-45.

[42] *Supra*, note 39.

[43] *R. v. Mills, ibid.*, at 748, 750-51.

be taken into account. The presiding judge is, the Court stressed, ultimately free to make whatever order he or she believes is "necessary in the interest of justice".[44]

The Court also found there is a sufficient evidentiary basis for a judge to undertake, at this first stage, an analysis of the interests of justice, notwithstanding that the contents of the records in question have not been reviewed. This basis can be derived from the Crown's disclosure of evidence, defence witnesses, the cross-examination of Crown witnesses at the preliminary inquiry and the trial, and/or expert evidence obtained by the defence.[45] The nature of a record can also provide an important informational foundation. For example, the Court noted that a complainant's expectation of privacy will generally be higher, and, therefore, worthy of greater protection when adoption or counselling records are at issue as opposed to school attendance records. Further, the record-taking practices involved in creating a particular kind of record, which may affect the record's reliability, can give a court the information it needs to take into account the factors listed in section 278.5(2) of the *Criminal Code*, without reviewing the record, and, in particular, to assess what the probative value of a record is.[46]

An example of a case, upheld on appeal, where the trial judge declined to order production to the court so it could review a counsellor's notes, notwithstanding his finding that the defence had demonstrated likely relevance, is *R. v. E.A.N.*[47] The counsellor had filed, in response to the defence's production application, an affidavit which was quoted at length by the British Columbia Court of Appeal in its decision. In addition to explaining the counselling techniques used (to rebut the suggestion of confabulation), the affidavit set out in clear terms why, from a legal perspective, it would be unsafe for a court to depend on the notes as a reliable, factual account of what was said in the counselling sessions. The trial judge was held to have appropriately exercised his discretion in concluding that, when all the factors in section 278.5(2) were taken into account, the negative effects of production far outweighed the positive effects.[48]

SECOND STAGE: PRODUCTION TO THE ACCUSED AND CONSIDERATION OF FACTORS REJECTED IN R. V. O'CONNOR

Those challenging the legislative scheme's constitutionality objected to the fact that factors specifically eschewed by the majority of the Supreme Court of Canada in *R. v. O'Connor*[49] — *i.e.*, the societal interest in encouraging the reporting

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[44] *Ibid.*, at 750.

[45] *Ibid.*, at 749.

[46] *Ibid.*, at 750. See also *R. v. Nitsiza, supra,* where a "spectrum" of privacy rights was recognized as existing, depending on the type of record involved. The counselling records and personal diary at issue in that case were viewed as being at the "higher end" of the spectrum. *Ibid.*, at paras. 19-20, 22.

[47] Unreported, February 10, 2000, [2000] B.C.J. No. 298 (QL), Saunders, Finch and Hall JJ.A. (C.A.).

[48] *Ibid.*, at paras. 14-16.

[49] *Supra*, note 39.

of sexual offences and in ensuring complainants of sexual offences obtain appropriate treatment, and the integrity of the trial process — had been selected by Parliament for inclusion among the factors to be considered by a judge when deciding whether and the extent to which production of private records to an accused person is justified.[50] The Court, again, found nothing objectionable with a requirement that judges take these additional factors into account, since there is nothing about them that precludes a constitutional outcome from being achieved. In short, judges are still empowered, the Court held, with a wide discretion to consider a variety of factors and make whatever order they believe is necessary in the interest of justice.[51]

WHAT DOES R. V. MILLS ADD IN RESPECT TO HEALTH RECORDS?

The Court in *R. v. Mills* conceded that society's interest in avoiding convictions of innocent persons necessarily means the rights of accused persons ultimately have to prevail where there is any reasonable doubt as to whether a record may be needed to make full answer and defence to criminal charges.[52] However, it went to great lengths to define the competing rights implicated in records productions applications — *i.e.*, rights to full answer and defence, privacy and equality — in a contextual and non-hierarchical manner. As the Court said, "[n]o single principle is absolute and capable of trumping the others; all must be defined in light of competing claims".[53] An accused person may, pursuant to section 7 of the Charter, only be deprived of his or her right to life, liberty and security of the person in accordance with the "principles of fundamental justice". While an accused's right to make full answer and defence is a core principle of fundamental justice, it must be defined in a manner which is inclusive of other principles of fundamental justice encompassed in sections 7 to 14 of the Charter, such as a complainant's right to privacy and to security of the person, as well as the equality rights enshrined in sections 15 and 28 of the Charter. In addition, the right to full answer and defence must not be allowed to distort the truth-seeking function of the trial process by allowing irrelevant evidence to interfere with the merits of a case. Similarly, it cannot trump other rights where non-disclosure of potentially relevant evidence does not prejudice the accused (because, for instance, the accused has other means of making a particular argument which do not infringe the complainant's right to privacy and equality, or do so in a less far-reaching manner than production of private records).[54]

The Court confirmed that an order for production of private records under the *Criminal Code* production regime constitutes a "seizure" within the meaning of

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[50] These factors, set out in ss. 278.5(2)(f), (g) and (h) of the *Criminal Code*, are described in Grace, "Compelled Production from Third Parties of Health Records", *supra*, note 3, at 73.

[51] *R. v. Mills, supra*, note 43, *per* McLachlin and Iacobucci JJ., at 752-54.

[52] *Ibid.*, at 726, 748, 750-51.

[53] *Ibid.*, at 713.

[54] *Ibid.*, at 719-20, 729, 737, 747.

section 8 of the Charter. As a result, the Charter right to privacy of the person who is the subject of the records is directly implicated by a defence production application.[55] Importantly, the Court recognized that protecting a patient's reasonable expectation of privacy in her or his therapeutic records serves to protect the trust and confidentiality which is at the heart of an effective therapeutic relationship. It also noted that preserving the privacy interest in therapy records protects the patient's mental integrity, a component of the right to security of the person under section 7 of the Charter. Thus, the very security of the person of the complainant or witness, and not just her or his right to privacy, may be infringed by a production order.[56] The Court also said the right to privacy will have particular force in the case of therapeutic and counselling records since these concern the complainant's or witness' "personal identity" and the maintenance of the records' confidentiality is "vital to protect a therapeutic relationship".[57]

When taking equality rights into account in defining, within the context of compelled production of private records, the meaning of the "principles of fundamental justice", the Court noted those whose lives are heavily documented, such as women with disabilities, aboriginal women and women who have been involved with child welfare agencies or who have been imprisoned, are particularly susceptible to having their privacy, security of the person and equality rights infringed by production orders. Courts must, therefore, demonstrate an "acute sensitivity to context" when determining the content of an accused's right to make full answer and defence in relation to a specific complainant's or witness' right to privacy.[58]

The particular context and purpose for which health and especially therapeutic and counselling records are prepared was also referred to by the Court to bring home the point that, contrary to what is often claimed by the defence, the "probative value" of such records may be limited. As the Court said, therapeutic and counselling records "can be highly subjective documents which attempt merely to record an individual's emotions and psychological state. Often such records have not been checked for accuracy by the subject of the records, nor have they been recorded verbatim".[59] These circumstances are important because defence counsel will frequently look to health records to provide a transcript-like record for impeaching the credibility of a patient with statements or views attributed to her or him in the records (*i.e.*, will seek to use the contents of the records as prior inconsistent statements). Thus, when judges take into account the factors listed in section 278.5(2) of the *Criminal Code* to determine whether production to the court and, ultimately, to the accused is in the interests of justice, they should bear in mind that the records may not be the reliable factual

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[55] *Ibid.*, at 720-22.

[56] *Ibid.*, at 723-24.

[57] *Ibid.*, at 722-23, 729.

[58] *Ibid.*, at 727-28.

[59] *Ibid.*, at 750. This was confirmed by the counsellor whose notes were targetted by the defence and who swore the affidavit referred to above and quoted by the British Columbia Court of Appeal in *R. v. E.A.N.*, *supra*, at para. 14.

accounts of historical events which defence counsel claim, or an appropriate basis for cross-examining witnesses.

PROPOSED GUIDELINES FOR HEALTH CARE PROVIDERS TREATING SEXUAL ABUSE VICTIMS

The proposed guidelines for health care providers relating to note-taking and record-keeping, responding to requests for notes and records and dealing with court proceedings, which are set out at the end of my article, "Compelled Production from Third Parties of Health Records",[60] remain unaltered in the wake of the Supreme Court of Canada's decision in *R. v. Mills*.[61] However, in light of *R. v. Mills*, it is now even more essential that, where a health care provider becomes involved on the patient's behalf in resisting court-ordered production of records, the following factors are emphasized:

(a) the confidential and trust-like nature of the relationship with the patient;
(b) the harm to the therapeutic relationship which will likely ensue if disclosure of records occurs;
(c) the harm to the patient's mental integrity, dignity and well-being which will likely occur if production is ordered;
(d) the therapeutic techniques used or processes followed and what these are aimed at achieving;[62] and
(e) the fact the records are not *verbatim* recordings of what transpires during sessions with the patient, and instead, reflect the author's subjective interpretations, impressions and selections from the sessions based on what the author believes is necessary for the medical or therapeutic treatment process (while, of course, complying with the relevant professional statutory record-keeping obligations).[63]

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[60] Grace, *supra*, note 3, at 83-91.

[61] *Supra*, note 43.

[62] In *R. v. E.A.N.*, *supra*, note 48, at para. 14, the counsellor who swore an affidavit in response to a production application explained:

> My approach to therapy is client-centered and non-directive; it is designed to strengthen the client's sense of self. This therapeutic process is not directed toward ascertaining historical 'truth' in the legal sense of seeking a comprehensive account of historical 'fact'. Rather, the 'truth' toward which my work is directed is the fullest understanding possible of my client's subject experience. My focus is on her internal world, not the external events of her life.

[63] In *R. v. E.A.N.*, *supra*, note 48, at para. 14, the counsellor's affidavit stated:

> In the course of the therapeutic process I take notes (the 'Notes'). I write the Notes after the session has ended, when the client is no longer present. I followed this practice in [the complainant's] case. The Notes are very general, do not include direct quotations, and are typically descriptive of feelings.
>
> The Notes were written to myself for the exclusive purpose of assisting me in the conduct of therapy. I did not show the Notes to [the complainant] (for example, to

CONCLUSION

In considering how competing rights should be balanced under the *Criminal Code* production regime, the Court demonstrated a heightened sensitivity to the compelling reasons why a sexual abuse victim may choose to resist disclosure of her or his therapeutic and counselling records, and to the very real damage that can be caused by their compelled production. It also showed an appreciation for how the nature and purpose of such records can make them ill-suited to the uses to which the defence often seeks to put them in court proceedings. As a result, it is reasonable to expect that criminal defence applications seeking production of health records of victims of alleged sexual abuse will, over time and as trial judges take the comments made by the Supreme Court of Canada to heart, become less frequent and "boilerplate" in nature. Early indications, based on my review of the case law since *R. v. Mills* was released, suggest that trial and appeal courts are now taking greater care in weighing all of the relevant factors when deciding whether to order production, and, by and large, appear to be ordering production less often than before.

However, it must be remembered that despite Parliament's effort to establish a clear, comprehensive and uniform legislative regime governing standards and procedures for production of private records, individual trial judges remain vested with a great deal of discretion. This discretion extends to deciding how to balance the competing rights of accused persons and complainants or witnesses and in determining whether to provide the defence with access to the records and, if so, to what extent and under what restrictive terms. As the Court in *R. v. Mills* repeatedly observed, and indeed took comfort from, individual judges have great latitude in determining a record's "likely relevance" and are free to make whatever order they ultimately deem necessary in the interests of justice.[64] This means that, at the ground level, experiences will continue to vary according to the particular presiding judge's subjective assessment of where the interests of justice in a particular case lie. As a result, change towards less frequent interference in therapeutic relationships caused by court applications for production of records can be expected to be slow and uneven. Nevertheless, *R. v. Mills* represents a significant step forward in recognizing the individual and social utility in preserving the confidential, trust-like relationships between health care providers and the sexual abuse victims they treat and counsel. Those resisting production of health records by asserting the privacy and equality rights of survivors of sexual abuse now have a more cogent basis from which to argue than ever before.

check for her view of their accuracy) because there would be no therapeutic purpose in my doing so. I believe the Notes would not be clear, and would sometimes be incomprehensible, to anyone other than me.

[64] Indeed, deference is already being shown by appeal courts when considering trial judges' exercise of their discretion under the *Criminal Code* production regime. See, for example, *R. v. E.A.N.*, *supra*, note 48, at para. 16.

ESTROGEN REPLACEMENT THERAPY IN POSTMENOPAUSAL WOMEN: EVIDENCE, PRACTICE AND COMMUNICATION

Muhammad M. Mamdani, Pharm.D., M.A., M.PH.
Karen Tu, M.D., M.Sc.*

An important and understandably sensitive decision for every woman following menopause is the use of estrogen replacement therapy ("ERT"). While some view menopause as a natural part of aging, others view it as a medical condition requiring treatment.[1] Physicians commonly prescribe ERT to postmenopausal women for a variety of reasons, including primary or secondary prevention of coronary heart disease ("CHD") and prevention or treatment of osteoporosis.[2] Parts of the medical community have generally favoured long-term use of postmenopausal ERT on the basis of its ostensible benefits on cardiovascular outcomes and osteoporosis.[3] Although ERT is clearly effective in the treatment of menopausal symptoms,[4] great uncertainty exists about its long-term use to prevent disease and prolong life in postmenopausal women.[5] Prior to initiating ther-

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1 P. Kaufert, P.P. Boggs, B. Ettinger, N.F. Woods and W.H. Utian, "Women and Menopause: Beliefs, Attitudes, and Behaviors: The North American Menopause Society 1997 Menopause Survey", Menopause, 1998;5:197-202; P. Toozs-Hobson and L. Cardozo, "Controversies in Management: Hormone Replacement Therapy for All? Universal Prescription is Desirable", BMJ, 1996;313:350-51.

2 S. Jacobs and T.C. Hillard, "Hormone Replacement Therapy in the Aged: A State of the Art Review", Drugs and Aging, 1996;8:193-213; E. Barrett-Connor, "Hormone Replacement Therapy", BMJ, 1998;317:47-61; L. Elinson, M.M. Cohen and T. Elmslie, "Hormone Replacement Therapy: A Survey of Ontario Physicians' Prescribing Practices", Can, Med, Assoc, J. 1999;161:695-98.

3 P. Toozs-Hobson and L. Cardozo, *supra*, note 1; J. Baron, G.B. Holzman and J. Schulkin, "Attitudes of Obstetricians and Gynecologists Toward Hormone Replacement Therapy", Med. Decis. Making, 1998;18:406-11.

4 P.E. Belchetz, "Hormonal Treatment of Postmenopausal Women", N. Engl. J. Med. 1994; 330:1062-71.

5 L.A. Brinton and C. Schairer, "Postmenopausal Hormone Replacement Therapy: Time for Reappraisal?", [Editorial] N. Engl. J. Med. 1997;336:1821-22.

apy, it is the responsibility of the physician to review extensively with each patient the risks and benefits associated with taking ERT and consider relevant issues that will affect the delivery of care. In particular, three areas of decision making warrant further consideration, namely issues pertaining to the existing evidence, patient compliance, and appropriate communication with the patient.

EXISTING EVIDENCE

The decision to initiate ERT is complicated by both objective and personal factors. Discussion of the major risks associated with ERT have largely centered around breast cancer and thromboembolism, whereas the major benefits, other than resolution of menopausal symptoms and atrophic vaginitis, have included cardiovascular and bone fracture endpoints.[6] Such discussion has been based on the best available evidence and is therefore typically deemed to be relatively objective in nature. Until recently, the best available evidence has primarily been limited to large observational studies reporting health outcomes over an extended period of time. However, such studies are often plagued by selection bias, which can potentially result in misleading findings. Indeed, several studies have found that estrogen users are typically more educated and healthier than non-users, implying that favourable findings may reflect better overall lifestyle status rather than a genuine effect of ERT.[7] If it follows that healthier lifestyles of ERT users translates to better health outcomes relative to non-users, negative health outcomes from observational studies may be unexpected and perhaps more difficult to dismiss. Regardless, potential study design limitations typically render findings from observational studies more speculative than conclusive.

Given such potential flaws inherent in its methodology, observational studies are often based on, and findings are usually supported by, other studies that suggest an association between exposure and outcome at the more traditional physiologic level. The risk of breast cancer associated with ERT has been supported by studies demonstrating estrogen-related compounds to stimulate normal human mammary epithelial cell proliferation.[8] Estrogen enhances the coagulability of blood by increasing circulating levels of factors II, VII, IX, and X and decreasing antithrombin III,[9] which supports the observation of increased risk of throm-

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6 S. Jacobs and T.C. Hillard, *supra*, note 2; E. Barrett-Connor, *supra*, note 2.

7 K. Matthews, K. Kuller, R. Wing, E. Meilahn and P. Plantingra, "Prior To Use of Estrogen Replacement Therapy, Are Users Healthier Than Nonusers?", Am. J. Epidemiol. 1996;143:971-78; K. Rödström, C. Bengtsson, L. Lissner and C. Björkelund, "Pre-existing Risk Factor Profiles in Users and Non-users of Hormone Replacement Therapy: Prospective Cohort Study in Gothenburg, Sweden", BMJ, 1999;319:890-93.

8 G.A. Colditz, "Hormones and Breast Cancer: Evidence and Implications for Consideration of Risks and Benefits of Hormone Replacement Therapy", J. Women's Health, 1999;8:347-57.

9 A. Goldfien, "The Gonadal Hormones and Inhibitors" in B.G. Katzung, ed., *Basic and Clinical Pharmacology*, 7th ed. (Stamford, CN: Appleton and Lange, 1998) at pp. 653-83.

bus formation and subsequent thromboembolism.[10] The beneficial cardiovascular effects are typically attributed to the favourable changes in lipid and lipoprotein metabolism induced by estrogen, including reduction in levels of low density lipoprotein cholesterol and increased levels of high density lipoprotein cholesterol,[11] although other mechanisms may be involved. A central feature of mechanisms around postmenopausal osteoporosis is the demineralization of trabecular bone secondary to estrogen deficiency.[12] Treatment of ERT has been shown to maintain, and often enhance, bone mineral density,[13] which is often assumed to result in a reduced risk of bone fracture. Such "physiologic rationalization" may lead to better acceptance of observed findings by linking surrogate measures that are more reliably assessed, and perhaps better accepted, to the endpoints measured in the observational study as supporting evidence. An assumption is often made that such relationships between exposure and surrogate measures are significant and clinically meaningful, thus supporting the observed findings, however these associations may in fact be minor and clinically inconsequential.

A greater level of confidence may be derived from experimental studies that are classified as double-blind randomized controlled trials ("DBRCTs").[14] The validity of findings from such studies rests on the premise that given randomization, both known and, perhaps more importantly, unknown confounding variables will be equally distributed between the groups being compared. Theoretically, the only difference between groups is the intervention of interest, *ceteris paribus*. The blinded nature of the study is assumed to minimize both reporting and recording biases.

However, even DBRCTs inherently possess substantial limitations. These types of studies are often expensive and labour intensive. As a result, DBRCTs are typically smaller in size and shorter in duration than most observational studies. Furthermore, the generalizability of DBRCT findings to actual practice is typically limited given the stringent inclusion and exclusion criteria that define the study population. Disagreement in findings between several DBRCTs addressing the same research question is not uncommon. Reasons for such differences include variability in patient populations, methods of intervention administration, methods of outcome measurement, and the play of chance.[15] Regardless, the

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[10] D. Grady, N.K. Wenger, D. Herrington, S. Khan and C. Furberg et al., "Postmenopausal Hormone Replacement Therapy Increases Risk for venous Thromboembolic Disease: The Heart and Estrogen/Progestin Replacement Study", Ann. Intern. Med., 2000;132:689-96.

[11] R.A. Lobo, "Clinical Review 27: Effects of Hormone Replacement on Lipids and Lipoproteins in Postmenopausal Women", J. Clin. Endocrinol. Metab., 1991;73:925-30.

[12] S. Jacobs and T.C. Hillard, *supra*, note 2.

[13] P. Eiken, N. Kolthoff and S.P. Nielsen, "Effect of 10 Years' Hormone Replacement Therapy on Bone Mineral Content in Postmenopausal Women", Bone, 1996;19(5 Suppl.):191S-193S; F. Al-Azzawi, D.M. Hart and R. Lindsay, "Long Term Effects of Oestrogen Replacement Therapy on Bone Mass as Measured by Dual Photon Absorptiometry", BMJ, 198;294:1261-62.

[14] G.H. Guyatt, D.L. Sackett and J.C. Sinclair et al., "User's Guide to the Medical Literature: A Method for Grading Health Care Recommendations", JAMA, 1995;274:1800-1804.

[15] G.H. Guyatt, D.L. Sackett, J.C. Sinclair et al., *ibid.*; A.D. Oxman and G.H. Guyatt, "A Consumer's Guide to Subgroup Analysis", Ann. Intern. Med. 1992;116:78-84.

DBRCT is generally viewed as providing the best available evidence among all other study designs.

With respect to postmenopausal ERT and long-term benefits, DBRCTs assessing clinical outcomes such as CHD events and fractures have been limited to a handful of studies. Only one large RCT examining the effects of a fixed ERT regimen as secondary prevention of CHD has been conducted,[16] albeit with extensive exclusion criteria. Contrary to numerous observational studies which led to our conventional beliefs of the cardioprotective ability of ERT, the Heart and Estrogen/Progestin Replacement Study ("HERS") demonstrated negligible effects on CHD events such as heart attack over an average follow-up period of four years in nearly 3,000 postmenopausal women. Subanalyses revealed a significant increased risk of such events during the first year of follow-up as well as a significant trend in declining risk over time. The initial detrimental effect was confirmed by an interim analysis of the Women's Health Initiative study,[17] a DBRCT involving over 27,000 postmenopausal women that is currently ongoing.

The availability of DBRCTs assessing fracture as a primary endpoint is extremely limited. Most DBRCTs evaluate the surrogate measure of bone mineral density and generally find significant improvements in such measures to be associated with ERT.[18] The findings are often extrapolated to infer sufficient clinical benefits to reduce fracture rates. The critical role of environmental factors such as the need to climb stairs and lifestyle factors such as poor cognition and coordination, which may significantly affect the chances of fracture independent of bone mineral density, are typically given little attention. Subanalyses examining the incidence of fractures in the HERS study revealed no benefits associated with ERT during the observation period, although it may be argued that the study had limited power to detect such an observation. One DBRCT of 75 postmenopausal women with one or more previous vertebral fractures due to established osteoporosis did, however, find significant benefits for fracture prevention associated with transdermal ERT over a one-year period,[19] implying potential benefit of transdermal ERT with respect to secondary prevention in the treatment of osteoporosis. There are no other DBRCTs confirming these findings nor have any DBRCTs examining the effect of different ERT regimens on the primary prevention of bone fracture as the primary endpoint been published as of yet.

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[16] S. Hulley, D. Grady, T. Bush, S.F. Hodgson, M.A. Kotowicz et al., "Randomized Trial of Estrogen Plus Progestin for Secondary Prevention of Coronary Heart Disease in Postmenopausal Women", JAMA, 1998;280:605-13.

[17] The Women's Health Initiative Study Group, "Design of the Women's Health Initiative Clinical Trial and Observational Study", Control. Clin. Trials, 1998;19:61-109.

[18] P. Eiken, N. Kolthoff and S.P. Nielsen, *supra*, note 13; F. Al-Azzawi, D.M. Hart and R. Lindsay, *supra*, note 13.

[19] E.G. Lufkin, H.W. Wahner, W.M. O'Fallon et al., "Treatment of Postmenopausal Osteoporosis with Transdermal Estrogen", Ann. Intern. Med., 1992;117:1-9.

PATIENT COMPLIANCE

A great deal of uncertainty surrounds the evidence that serves as the basis for the ultimate decision. In addition to the available evidence, practical considerations and available alternatives must be taken into account. Successful treatment involves not only selecting the optimal medical intervention, but also the appropriate use of the intervention once delivered. With respect to postmenopausal ERT, a critical issue that bridges evidence-based theory with practical application is patient compliance. Numerous factors affect patient compliance with postmenopausal ERT. Personal characteristics of both the physician and patient must be weighed. Physician characteristics can vary substantially with respect to practice style, knowledge base, subjective biases and communication skills. Patient traits also vary quite significantly with respect to clinical characteristics, personal beliefs about conventional medicine, desire for or capacity to understand relevant medical information, communication style and importance placed on personal health. The physician-patient interaction undoubtedly affects patient behaviour.

Most studies reveal that patient compliance with ERT is extremely poor. The two-year compliance rate typically ranges from 20-50 per cent.[20] Using data from provincial administrative healthcare databases, we examined the five-year prescription filling compliance rate for a cohort of female residents of Ontario over the age of 65 who initiated postmenopausal ERT in 1994. Drug utilization information was obtained from the Ontario Drug Benefits ("ODB") database. This database is a provincial administrative database maintained by the Ontario Ministry of Health. It contains drug utilization information including a scrambled unique healthcare number to ensure patient confidentiality, the date of prescription, and a drug identification number for elderly residents of Ontario aged 65 or greater. All elderly residents of the province of Ontario aged 65 or older receive medication through a government assistance programme. We defined new users of ERT as those who had no record of a prescription for oral or transdermal ERT within one year prior to the first prescription record in 1994. We defined prescription filling compliance as the continual filling of ERT with 365 days or less between subsequent prescriptions. The actual days of use could not be examined given limitations in the data available. For simplicity, we assumed 100 per cent compliance upon cohort entry. The results are presented in Figure 1, below, and reveal that of the 8,788 women we classified as new starters of postmenopausal ERT, only eight per cent were compliant for more than two years. Deaths would not account for our observations since only approximately one per cent of patients died during this period. It should be noted that the numbers estimate prescription filling compliance and not discontinuation, since it is possible that women may restart ERT following a period of discontinuation.

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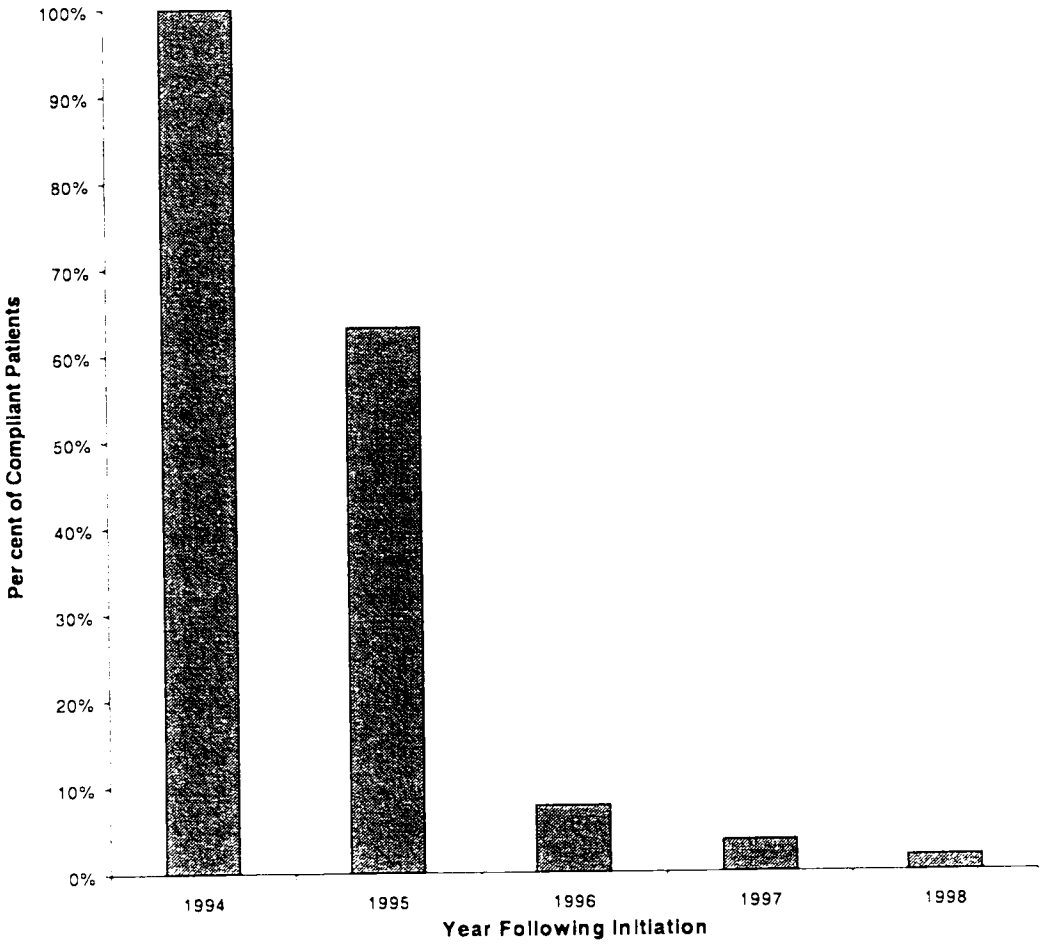
[20] B. Ettinger, D.K. Li and R. Klein, "Continuation of Postmenopausal Hormone Replacement Therapy: Comparison of Cyclic Versus Continuous Combined Schedules", Menopause, 1996;3:185-89; I. Den Tonkelaar and B.J. Oddens, "Determinants of Long-Term Hormone Replacement Therapy and Reasons for Early Discontinuation", Obstet. Gynecol. 2000;95:507-12.

Figure 1
Compliance with Postmenopausal ERT
Among Older Women Over Time
Commencing in 1994



The issue of compliance becomes especially important since potentially harmful effects may be incurred during the first year of postmenopausal ERT with respect to CHD events and that foreseeable benefits may require treatment over a much longer duration. Other studies have revealed that reasons for discontinuation are usually personal and include adverse effects, fear of cancer, dislike of taking tablets, not wanting continued menstrual bleeding and perceived lack of efficacy.[21] Alternatives for various indications also exist. For example, intake of

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[21] I. Den Tonkelaar and B.J. Oddens, *ibid.*; V.A. Ravnikar, "Compliance with Hormone Therapy", Am. J. Obstet. Gynecol., 1987;156:1332-34; S. Rozenberg, J. Vandromme, M. Kroll, A. Pastijn and F. Liebens, "Compliance to Hormone Replacement Therapy", Int. J. Fertil. Menopausal Stud., 1995;40 (Suppl. 1):23-32.

calcium with vitamin D[22] and weight-bearing exercise[23] for the prevention of osteoporosis has been shown to be particularly effective in increasing bone mineral density. These could be reasonable alternatives for women who are concerned about osteoporosis but are fearful of taking ERT.

APPROPRIATE COMMUNICATION WITH THE PATIENT

With such complexities and uncertainties not only within the available evidence but also in the actual practice setting, how does one counsel the patient? First, the science of medicine must be distinguished from its art. Medical science is subject to perpetual revision as its findings are always tentative and incomplete whereas the art of medicine involves drawing from the science to assimilate the best available information in arriving at an immediate decision that is socially acceptable.[24] Second, this necessarily implies that medical practice is engulfed and infiltrated by uncertainty of actual truth.[25] As a result, many recommendations in medicine are synthesized, be it correctly or incorrectly, from available evidence and do not represent actual truth but rather attempt to estimate it with a certain degree of uncertainty.

It should be pointed out that uncertainty of medical knowledge itself is not at issue, since uncertainty of knowledge will for a long time remain an essential characteristic of the art of medicine. The problem instead relates to the capacity to remain aware of, and the willingness to acknowledge, such uncertainty.[26]

Perhaps the more critical issue involves disclosure of uncertainty in the discussion of risks and benefits of ERT and the final recommendations to the patient. The lack of acknowledgment of uncertainty to patients is reinforced by the traditional authoritarian relationship that governs interactions between physicians and patients. It has been speculated that physicians' power and control are maintained by projecting a greater sense of certainty than is warranted, transferring a greater sense of confidence in the patient for the care received. Gorovitz and MacIntyre[27] point out, however, that

> [t]he first reaction of physicians to the invitation to dispense with the mask of infallibility is likely to be a humane alarm at the insecurity that a frank acceptance of medical fallibility might engender in the patient. But we wonder whether the

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[22] B. Dawson-Hughes, S.S. Harris, E.A. Krall and G.E. Dallal, "Effect of Calcium and Vitamin D Supplementation on Bone Density in Men and Women 65 Years of Age or Older", N. Engl. J. Med., 1997;337:670-76.

[23] E.M. Lau, J. Woo, P.C. Leung, R. Swaminathan and D. Leung, "The effects of Calcium Supplementation and Exercise on Bone Density in Elderly Chinese Women", Osteoporos. Int., 1992; 2:168-73.

[24] G.J. Annas, "Burden of Proof: Judging Science and Protecting Public Health In (and Out of) the Courtroom", Am. J. Public. Health, 1999;89:490-93.

[25] R. Fox, "Training for Uncertainty", in R. Merton, G. Reader, and P. Kendall, eds. *The Student-Physician* (Cambridge: Harvard University Press, 1957).

[26] J. Katz, "Why Doctors Don't Disclose Uncertainty", Hastings Cent. Rep. 1984;14:35-44.

[27] S. Gorovitz and A. MacIntyre, "Toward a Theory of Medical Fallibility", J. Med. Phil. 1976;51:1.

present situation, in which the expectations of patients are so very often disappointed during the medical treatment, is not a greater source of insecurity.

Given failure to acknowledge uncertainty, patients are often led to expect too much from physicians' interventions and may later foster a sense of mistrust, posing a significant threat to the patient-physician relationship. Legal standards and recent movements in medical practice require more open communication between patient and physician.[28] Indeed, a shift in professional practices toward greater acknowledgement of uncertainty may not satisfy all patients since blind faith in physicians is therapeutic for some. However, acknowledging uncertainty in the benefits and risks associated with postmenopausal ERT fosters an honest relationship between physician and patient and places greater responsibility on the patient, leading to a more active involvement throughout the treatment process. For the vast majority, such a relationship is welcomed.

CONCLUSION

The challenge for physicians is to be well informed and serve as the primary source of unbiased information upon which the patient's decision is made. Patient decision aids may provide an efficient and effective means of presenting relevant information in a manner acceptable to the patient.[29] The patient must feel satisfied that they have sufficient information and are aware of the uncertainties of current medical knowledge to make an informed decision with consideration given to their personal preferences and characteristics.[30] This may require more intensive and time-consuming involvement on the part of the physician, however such an investment is a major part of the art of healing.

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[28] See *Reibl v. Hughes*, [1980] 2 S.C.R. 880 and T. Richards, "Patients' Priorities: Need to Be Assessed Properly and Taken Into Account", BMJ, 1999;318:277.

[29] A.M. O'Connor, P. Tugwell, G.A. Wells, T. Elmslie, E. Jolly et al., "Randomized Trial of a Portable, Self-administered Decision Aid for Postmenopausal Women Considering Long-term Preventive Hormone Therapy", Med. Decis. Making, 1998;18:295-303.

[30] M.T. Connelly, N. Ferrari, N. Hagen, and T.S. Inui, "Patient-identified Needs for Hormone Replacement Therapy Counseling: A Qualitative Study", Ann. Intern. Med., 1999;131:265-68. This article has been peer-reviewed.

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present situation, in which the expectations of patients are so very often disappointed during the medical treatment, is not a greater source of insecurity.

Given failure to acknowledge uncertainty, patients are often led to expect too much from physicians' interventions and may later foster a sense of mistrust, posing a significant threat to the patient-physician relationship. Legal standards and recent movements in medical practice require more open communication between patient and physician.[28] Indeed, a shift in professional practices toward greater acknowledgement of uncertainty may not satisfy all patients since blind faith in physicians is therapeutic for some. However, acknowledging uncertainty in the benefits and risks associated with postmenopausal ERT fosters an honest relationship between physician and patient and places greater responsibility on the patient, leading to a more active involvement throughout the treatment process. For the vast majority, such a relationship is welcomed.

CONCLUSION

The challenge for physicians is to be well informed and serve as the primary source of unbiased information upon which the patient's decision is made. Patient decision aids may provide an efficient and effective means of presenting relevant information in a manner acceptable to the patient.[29] The patient must feel satisfied that they have sufficient information and are aware of the uncertainties of current medical knowledge to make an informed decision with consideration given to their personal preferences and characteristics.[30] This may require more intensive and time-consuming involvement on the part of the physician, however such an investment is a major part of the art of healing.

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[28] See *Reibl v. Hughes*, [1980] 2 S.C.R. 880 and T. Richards, "Patients' Priorities: Need to Be Assessed Properly and Taken Into Account", BMJ, 1999;318:277.

[29] A.M. O'Connor, P. Tugwell, G.A. Wells, T. Elmslie, E. Jolly et al., "Randomized Trial of a Portable, Self-administered Decision Aid for Postmenopausal Women Considering Long-term Preventive Hormone Therapy", Med. Decis. Making, 1998;18:295-303.

[30] M.T. Connelly, N. Ferrari, N. Hagen, and T.S. Inui, "Patient-identified Needs for Hormone Replacement Therapy Counseling: A Qualitative Study", Ann. Intern. Med., 1999;131:265-68.

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