DRAFT LEGISLATION ON ASSISTED HUMAN REPRODUCTION

CMA BRIEF TO STANDING COMMITTEE ON HEALTH

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HENRY HADDAD, MD, FRCPC
PRESIDENT

ASSOCIATION MÉDICALE CANADIENNE
CANADIAN MEDICAL ASSOCIATION

Leadership for Physicians… Health for Canadians
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ASSOCIATION MÉDICALE CANADIENNE

CANADIAN MEDICAL ASSOCIATION

The Canadian Medical Association (CMA) is the national voice of Canadian physicians. Founded in 1867, CMA's mission is to provide leadership for physicians and to promote the highest standard of health and health care for Canadians.

On behalf of its members and the Canadian public, CMA performs a wide variety of functions, such as advocating health promotion and disease/accident prevention policies and strategies, advocating for access to quality health care, facilitating change within the medical profession, and providing leadership and guidance to physicians to help them influence, manage and adapt to changes in health care delivery.

The CMA is a voluntary professional organization representing the majority of Canada's physicians and comprising 12 provincial and territorial divisions and 43 affiliated medical organizations.

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EXECUTIVE SUMMARY

The Canadian Medical Association strongly supports the objectives of the proposed legislation on assisted human reproduction as laid out in the Preamble. However, we do not believe that criminalizing the medical and scientific activities named in the bill is an appropriate way to achieve those objectives. We consider that the objectives could be as well achieved by less drastic means than criminalization and, moreover, that criminalization would create major obstacles to legitimate medical and scientific progress in the treatment of infertility.

The CMA is not in principle opposed to the idea of prohibiting certain assisted human reproductive activities, although we have not at this time taken a position on whether any of the specific activities listed in section 3 of the draft legislation should be prohibited. Our issue is not with the prohibitions as such but rather with the means by which prohibitions, whatever they are, should be given effect. We propose that the determination of permissible activities, whether temporarily or long-term, should be made by a regulatory agency on the basis of up-to-date scientific information, public input and ethical review. Criminal legislation is very difficult to change and is therefore appropriate for activities whose status is unlikely to change over time, such as murder and theft, rather than medical and scientific activities that are constantly developing. The latter are better left to a representative regulatory body to determine if and when changes in health and safety considerations and public attitudes and values might justify allowing certain formerly prohibited activities to take place under specific conditions. Criminal penalties could apply where controlled activities are performed without authority of a license from the regulatory agency or in defiance of the licensing conditions established by the agency.

Because the draft legislation has little to say about an oversight and regulatory regime, we recommend that the bill not be introduced in Parliament until it incorporates specific provisions for a regulatory agency. Such an agency should:

- incorporate and utilize existing bodies and institutions as appropriate;
- acknowledge, respect and build upon the important role that various health providers and their professional colleges and associations play with respect to these matters; and,
- be sufficiently accountable to Canadians and involve Canadians as appropriate in ongoing policy decision-making and oversight regarding these matters.

The agency should be given appropriate responsibilities and accountability for coordinating the activities of organizations that are already working in the area of assisted reproduction and for carrying out functions that these organizations cannot perform.

CMA's interest in the topic

Assisted human reproduction (AHR) technologies and practices have increased our powers immensely with respect to matters about which Canadians care deeply. These technologies and practices pose new and complex issues in moral territory that remains largely uncharted. With these new powers come new responsibilities.

CMA members -- as physicians, researchers, and scientists -- are key stakeholders in issues involving AHR. As primary developers and providers of AHR technologies and practices, their contribution to the formation of reproductive and genetic policy is indispensable. Likewise, CMA members will play a vital role in the implementation of policy. How policy issues concerning AHR are decided and managed will shape their practice, whether in the laboratory or in the examining room.

To be sure, CMA recognizes that these are not just medical and professional issues but also issues of ethics, law, and public policy. We also recognize that many individuals and groups, in addition to the physicians and researchers who work with AHR, have an important stake in issues pertaining to their appropriate use. Patients who use reproductive services – in particular, women for the most part – may be deeply affected by AHR and have good reason to care about policy in this area. Indeed, so too do all Canadians. These issues, touching as they do on the fundamental realities of life, death and sexuality, challenge our traditional moral values. Indeed, they lead us to question our very identity, both as individuals and as a society.

The CMA represents the interests and the voice of organized medicine and advocates on behalf of the health and well being of all Canadians. Therefore, it clearly falls within the mandate of the CMA to respond to the government's proposals. The twin objectives of providing leadership for physicians and promoting the highest standard of health and health care for Canadians guided the CMA in its response to Bill C-47 in 1996-7, which work is carried forward in this brief.

Bill C-47 – CMA's response

On June 14, 1996 the Government of Canada introduced into the House of Commons Bill C-47, *An Act respecting human reproductive technologies and commercial transactions relating to human reproduction,* and simultaneously released a discussion document: *New Reproductive and Genetic Technologies: Setting Boundaries, Enhancing Health*. On September 30, 1996, CMA presented a brief to Health Canada in response to the discussion document: The brief included seven recommendations:

1. That, given the lack of substantive principled justification in the *Discussion Document*, the Government specify what criteria and principles will be used to decide whether a given NRGT [new reproductive or genetic technology] or related practice is deemed something to be prohibited, discouraged, merely tolerated, or positively encouraged in Canadian society.

2. That, in the case of NRGTs to be prohibited or otherwise discouraged, the Government specify what criteria and principles will be used to determine which instruments are most appropriate for the purpose of achieving the desired policy objective.
3. That, inasmuch as criminalization is an extreme regulatory option that poses a threat to the patient-physician relationship, the Government provide a clear test for deciding under what conditions a given NRGT should be criminalized.
4. That a clear ethical framework be developed to co-ordinate policy making in this area and applied with consistency and rigour to the issues at hand.
5. That all proposals advanced be subject to scrutiny with reference to both the principle of the least restrictive alternative and the principle of subsidiarity, which mandates that if a small community or body can accomplish a given objective, the responsibility should not be assumed by a larger body.
6. That, consistent with the principle of subsidiarity, a central regulatory agency be formed only if it has been demonstrated that the less restrictive and more local alternative of self-regulation in the context of national guidelines cannot accomplish the same ends.
7. That, in order to avoid spawning unnecessary layers of regulatory apparatus, the Government explore the viability of other regulatory options utilizing existing groups and associations, including the Royal College of Physicians and Surgeons, the College of Family Physicians of Canada, the Society of Obstetricians and Gynaecologists of Canada, the Canadian Fertility and Andrology Society and the Canadian Council on Health Services Accreditation, as well as the various provincial and territorial licensing authorities.

On November 7, 1996 CMA submitted a response to Bill C-47 with five recommendations:

1. The issues addressed in Bill C-47 should not be dealt with in a piecemeal manner, but rather should be addressed in the context of a comprehensive policy and regulatory structure, the development of which should precede legislation. Bill C-47 should therefore be withdrawn, and no further legislation should be brought forward until a comprehensive policy and regulatory structure has been developed.
2. The issues addressed in Bill C-47 should be addressed in the context of a clear ethical framework for evaluating new reproductive and genetic technologies.
3. The Government must clarify what test it is using for criminalization, and must apply this test in a fashion that is clear and open to public scrutiny.
4. Any test for criminalization must include a demonstration that no less restrictive alternative to criminalization will accomplish the policy objective.
5. The Government should address the concerns of Bill C-47 by building upon the strengths of the existing regulatory system.

When CMA appeared before the Sub-Committee on Bill C-47 on January 24, 1997, we argued that the bill should be withdrawn until a framework for regulating the NRGTs has been developed. Although the Sub-Committee did not accept this recommendation when it reported back to the House, the bill died on the order paper when an election was called in April 1997.

Developments between 1997 and 2001

Following the June 1997 federal election, Health Canada announced that it would develop a 'fused' approach to the NRGTs, which would combine prohibitions of certain activities and regulation of those activities that are not prohibited. In addition to meeting with Health Canada officials to discuss the details of this approach, CMA facilitated two meetings of medical and scientific stakeholder organizations to forge a consensus about the best way to regulate the NRGTs. Members of this group included the Association of Professors of Obstetrics and Gynaecology of Canada, Canadian College of Medical Geneticists, Canadian Council on Health Services Accreditation, Canadian Fertility and Andrology Society, College of Family Physicians of Canada, Federation of Medical Licensing Authorities of Canada, National Council on Ethics in Human Research, and Society of Obstetricians and Gynaecologists of Canada. Immediately following the second meeting, on March 11, 2000, the group met with officials from Health Canada to communicate the following results of their deliberations:

- To regulate NRGTs, the existing regulatory structures such as medical licensing authorities and accreditation bodies can and should be used as much as possible.
- A comprehensive regulatory scheme built on existing structures could be sufficient. There is no evidence that the prohibition of certain practices is necessary.
- If, however, there are to be any prohibitions, these must undergo a strict test for justification, and can only be introduced at the same time as a regulatory scheme.

In its June 2000 *Feedback Report: Discussions and Written Comments on Proposed Federal RGTs Legislation*, Health Canada noted the following concerns raised by CMA and others:

- The criminal law is too unwieldy an instrument for dealing with RGTs because it requires Parliamentary approval to be modified. Any federal instrument should be a more responsive one, i.e., capable of quickly adapting to scientific developments.
- Government should avoid "reinventing the wheel" in developing RGT regulations by making use of existing organizations for the tasks of education, standards development and accreditation.
- RGT legislation should not be framed in language that is too negative, i.e., as punitive, rather than constructively, i.e., as a means of ensuring RGT benefits to Canadians and their society.
- All regulations should be ready at the time legislation is introduced.

The *Feedback Report* did not mention the following concerns raised by CMA and others:

- The Government should specify what criteria and principles will be used to decide whether a given RGT or related practice is deemed something to be prohibited, discouraged, merely tolerated, or positively encouraged in Canadian society.
- The Government should provide a clear test for deciding under what conditions a given RGT should be criminalized.
- Any test for criminalization must include a demonstration that no less restrictive alternative to criminalization will accomplish the policy objective.

In addition to the discussions in which it has been directly involved, CMA has followed with interest the deliberations of Health Canada's Advisory Committee on the Interim Moratorium on Reproductive Technologies and its Working Group on Reproductive and Genetic Technologies. The extensive work of the latter group on potential regulatory frameworks for reproductive and genetic technologies does not seem to be reflected in the draft legislation.

On May 27-28, 2001, the CMA Board of Directors adopted a new policy on Assisted Reproduction that replaced all other CMA policy on this topic. It is attached as Appendix A.

The Draft Legislation

The *Proposals for legislation governing assisted human reproduction*, referred to the Standing Committee on May 3, 2001, are a definite improvement over Bill C-47. However, they still exhibit many shortcomings. The CMA is pleased that they do not represent the Government's definitive views on the subject and that the Standing Committee has been given the mandate to make changes to the bill before it is introduced in Parliament. In what follows we itemize first the strengths of the proposed legislation and then its weaknesses. We will conclude with specific recommendations for improving the bill.

Strengths

- The Preamble is a good statement of the principles that should govern the legislation; it begins with a clear statement about the benefits to individuals and to society of assisted human reproductive technologies (AHRTs).
- The Definitions section is much more complete and nuanced than in C-47 (CMA does not intend to comment on the accuracy of the definitions).
- The legislation has provisions for informed consent and privacy.
- The involvement of existing professional and regulatory organizations seems to be permitted in article 17.

Weaknesses

Prohibitions:

- There is no justification offered for prohibiting the activities listed in Sections 3 to 7.
- The prohibition of sex selection, "except for reasons related to the health of the resulting human being" (3(1) h), would seem to be unenforceable, given the absence of a definition of "health".
- The penalties (forfeiture under article 29, fines and imprisonment under articles 34 and 35, further punishments under article 37) are excessive.

Regulatory Agency and Ministerial Powers

- There is no mention of a regulatory agency. All controlled activities are under the authority of the Minister (Section 12). Other than the list of potential regulatory topics found in Section 40, there is no indication of what specific regulations will govern controlled activities or the granting of licenses to perform these activities.
- Section 15(3) appears to grant undue discretion to the Minister to withhold information from the applicant or licensee since it is a question of Ministerial "opinion" whether the identifying information in question is required to support an application.
- Section 16 falls under the heading of "danger arising from controlled activity" but it too gives undue discretion to the Minister. It speaks to the power of the Minister or the designated inspector to "take all reasonable measures" in the name of "harm to human dignity". The phrase "harm to human dignity" is subject to manifold interpretations but it is coupled with the power to "assume the management of those premises and that activity" (Section 16(2)).

Inspectors' Roles and Powers

- Section 23 states that the Minister may appoint any person as an inspector but does not offer any criteria or qualifications about who may be an inspector.
- Section 24 on the topic of "entry by inspectors" is too broad. Inspectors are granted the power to enter any place where they believe on "reasonable grounds that a controlled activity is performed or <u>that there is anything to which this Act applies"</u> (emphasis added). The preamble makes clear that this Act applies to no less than the recognition of the "importance of preserving and protecting human individuality and the integrity of the human genome". The inspector's powers should therefore be circumscribed to "where a controlled activity" is performed. Moreover, the inspector's powers once he or she has entered a place are unduly broad. Section 24(2)(d) could be interpreted to mean that an inspector has the power to order individuals working at a facility to produce their own blood and or other tissue samples for analysis. Finally, on the issue of inspectors and analysts, there is nothing in the draft legislation that appears to address their duty to keep confidential the information, samples, etc that might be obtained once they have entered the place of inspection.

Prohibitions and Ethical Principles

Accompanying the draft legislation were two explanatory documents: *Proposals for Legislation Governing Assisted Human Reproduction: An Overview* and *Guide to the Proposals for Legislation Governing Assisted Human Reproduction*. Unfortunately, neither of these documents provides any specification of criteria and principles used to decide whether a given AHR technology or practice is deemed something to be prohibited, discouraged, merely tolerated, or positively encouraged in Canadian society. Nor do they offer a clear test for deciding under what conditions a given AHR technology or practice should be criminalized. Finally, they do not demonstrate that less restrictive alternatives to criminalization cannot accomplish the policy objective. To elaborate:

The *Overview* document states (p. 4) that the prohibitions in the legislation are "based on ethical and/or health and safety concerns." As with other scientific and medical procedures, the health and safety concerns of AHRTs evolve rapidly as knowledge advances. Moreover, all such procedures involve risks, but that is not sufficient reason to ban them altogether. **These considerations argue against including prohibitions in the legislation on the grounds of health and safety.** As noted above, criminal legislation is very difficult to change and is therefore appropriate for activities whose status is unlikely to change over time, such as murder and theft, rather than medical and scientific activities that are constantly developing. The latter are better left to a representative regulatory body to determine if and when changes in health and safety considerations and public attitudes and values might justify allowing certain formerly prohibited activities to take place under specific conditions.

As for the ethical concerns that support the prohibitions in the legislation, the two background documents provide little guidance as to why these concerns have been dealt with in the way they have. The preamble mentions several important ethical principles, such as informed consent and protection of the vulnerable. However, the draft legislation is inconsistent regarding which one of these should be given priority when they conflict. For example, protection of children born as a result of assisted reproduction is given as a reason for banning human cloning and germ-line alteration but is not considered a reason for banning altruistic surrogacy, although that might not be in the best interests of the resulting children. Informed consent is considered sufficient to justify a number of activities, including altruistic surrogacy, but not others such as paid surrogacy. The dangers of commodifying human reproduction are sufficient to ban commercial surrogacy and various aspects of AHRTs but not the purchase and sale of gametes by sperm banks and private clinics because "these items are the basic components of their business operation" (*Guide*, p. 5) These distinctions may or may not be defensible ethically, but if they are, the Government has not done so. As a result, the legislation seems quite arbitrary.

Another ethical principle, human dignity, is cited in the *Overview* document to justify the prohibitions against transplanting reproductive material from animals into humans and using human reproductive material previously transplanted into an animal (p. 6).

There are two problems with this usage: first, 'human dignity' means many different things to different people and is therefore unsuitable for use as a criterion for deciding what should be permitted or prohibited in law; and second, the *Overview* document does not explain why the activities cited are violations of human dignity.

On other issues, the background documents trivialize the ethical concerns of those who would object to the prohibitions in the legislation. For example, with regard to germ line genetic alteration, the *Overview* states that this procedure would be desired "to select generic traits such as height and eye colour" (p. 5), but it does not mention the prospect of eliminating lethal genetic diseases.

Given this failure to justify the criminalization of certain AHRTs, CMA is strongly opposed to the criminal prohibition of specific activities in sections 3 to 7 of the draft legislation. As written, this bill would establish a dangerous precedent for criminalizing medical and scientific activities on vague and arbitrary grounds. Neither the bill nor the background documents offer any explicit justification or test for criminalization.

CMA Regulatory Proposals

The CMA recognizes that there may be good reasons for curtailing certain AHRT activities at present and perhaps indefinitely. However, further study and thought should be given to exploring how control might be effectively achieved under a comprehensive regulatory and licensing regime coupled with the federal criminal law power. For instance, even the Draft Legislation under Section 35 states that "a person who contravenes any of sections 8 to 11 [controlled activities]…or the terms and conditions of a licence is guilty of an offence". The CMA proposes that the activities currently under the "prohibited" category (Sections 3 to 7) could be moved to the "controlled" category. Thus, none of these activities could be performed unless they were under the authority of a license, and there would be no explicit prohibitions in the Act. Rather than having a blanket prohibition, the licensing body could spell out in the license the conditions for the occurrence of a specific ARHT.

One could imagine that a regulatory body might not issue any licenses in connection with the broad concept of "altering the genome of a cell of a human being or in vitro such that the alteration is capable of being transmitted to its descendants" as it is currently framed as a prohibited activity in Section 3(1)(b). However, by the same token, there could be limited instances in which this activity that might have otherwise fallen under the notion of "prohibited" is warranted because of the specific circumstances. Under the unwieldy strict prohibition model, there is no responsiveness to the evolving scientific and research environment. Moreover, in an effective regulatory regime, physicians and scientists would not be labouring under the apprehension of a blanket ban but could apply to the expert regulatory body for licensing approval.

The absence of a comprehensive regulatory framework, especially the nature, mandate, composition, and modus operandi of the regulatory body, is the major weakness in the draft legislation. This absence is inexplicable given the numerous references to regulations in the draft legislation and especially given the years of preparatory work carried on by Health Canada and its Working Group on Reproductive and Genetic Technologies. The Standing Committee has been asked for suggestions for the regulatory body and we hope that it will take advantage of Health Canada's extensive consultations on this matter.

In his testimony before the Standing Committee on May 10, 2001, Mr. Glenn Rivard, Justice Canada counsel, stated that "As drafted, all the decision-making responsibility resides with the minister, which is to say that the advice on that and the operations would be carried out within the Department of Health. If a recommendation were made for an independent agency and the government accepted that, you would have to draft additional provisions in the bill." CMA is not convinced that the Department of Health is best suited to regulate the AHRTs. An appendix to the *Overview* document accompanying the draft legislation describes how some other countries regulate these practices. The Human Fertilisation and Embryology Authority (HFEA) in Great Britain is one example of a relatively independent regulatory body that seems to be working well. Given the frequent interchanges between Health Canada and HFEA since 1997, the government should be able to provide the Standing Committee with concrete suggestions as to how a similar body could be established in Canada.

In conclusion, CMA strongly supports the advice of Dr. Patricia Baird to the Standing Committee in her testimony on June 5, 2001: "I think it's much more important to get a regulatory system established than delay and delay over particular specifics…. My strong preference would be to keep specific legislative prohibitions to a minimum necessary, and address the need for control in the conditions of license."

Recommendations

1. The draft legislation should not be introduced in Parliament until it incorporates specific provisions for a regulatory agency with appropriate responsibilities and accountability for coordinating the activities of organizations that are working in the area of assisted reproduction and for carrying out functions that other organizations cannot perform.

2. The regulatory agency should work in conjunction with or coordinate the following existing organizations and activities:

    - The development and monitoring of national standards for research related to human subjects including genetics and reproduction. It would work closely with the Canadian Institutes of Health Research, other federal and provincial research granting councils, the National Council on Ethics in Human Research and other such organizations.

- The development and monitoring of national standards for training and certifying physicians in those ARGTs deemed acceptable. As is the case for all post-graduate medical training in Canada, this is appropriately done through bodies such as the Royal College of Physicians and Surgeons of Canada and the College of Family Physicians of Canada.
- The licensing and monitoring of individual physicians. This task is the responsibility of the provincial and territorial medical licensing authorities which could regulate physician behaviour in respect to the ARGTs, just as they do for other areas of medical practice.
- The development of guidelines for medical procedures. This should be done by medical specialty societies such as the Society of Obstetricians and Gynaecologists of Canada (SOGC) and the Canadian Fertility and Andrology Society (CFAS).
- The accreditation of facilities where assisted reproduction is practised. There is already in Canada a well functioning accreditation system, run by the Canadian Council on Health Services Accreditation, which may be suitable for assisted reproduction facilities.

3. In order to maximize the effectiveness of these organizations, the regulatory agency, should, where appropriate, provide them with additional resources and delegated powers.

4. The regulatory agency should include significant membership of scientists and clinicians working in the area of assisted reproduction.

5. If criminal sanctions are to be invoked, they should apply not to specific medical and scientific acts in and of themselves but only in cases where activities are carried out without authority of a license or are done in defiance of the licensing conditions established by the national regulatory agency.

6. If, however, the legislation establishing the regulatory regime is to include prohibitions as well as regulation, the prohibition of specific medical and scientific acts must be justified on explicit scientific and/or ethical grounds.

7. In the name of accountability, the Standing Committee should provide the reasons for its conclusions, especially when it is faced with conflicting recommendations.

Appendix A

CMA POLICY ON ASSISTED REPRODUCTION (UPDATE 2001)

Introduction

Like all scientific and medical procedures, assisted human reproduction has the potential for both benefit and harm. It is in the interests of individual Canadians and Canadian society in general that these practices be regulated so as to maximize their benefits and minimize their harms. To help achieve this goal, the Canadian Medical Association (CMA) has developed this policy on regulating these practices.

Objectives

The objectives of any Canadian regulatory regime for assisted reproduction should include the following:

(a) to protect the health and safety of Canadians in the use of human reproductive materials for assisted reproduction, other medical procedures and medical research;

(b) to ensure the appropriate treatment of human reproductive materials outside the body in recognition of their potential to form human life; and

(c) to protect the dignity of all persons, in particular children and women, in relation to uses of human reproductive materials.

Principles

When a Canadian regulatory regime for assisted reproduction is developed, it should incorporate the following principles:

- For the regulation of assisted reproduction, existing organizations such as medical licensing authorities, accreditation bodies and specialist societies should be involved to the greatest extent possible.
- If the legislation establishing the regulatory regime is to include prohibitions as well as regulation, the prohibition of specific medical and scientific acts must be justified on explicit scientific and/or ethical grounds.
- If criminal sanctions are to be invoked, they should apply only in cases of deliberate contravention of the directives of the regulatory agency and not to specific medical and scientific acts.
- Whatever regulatory agency is created should include significant membership of scientists and clinicians working in the area of assisted reproduction.

Elements of a Regulatory Regime

The regulation of assisted reproduction in Canada should include the following elements:

- Legislation to create a national regulatory body with appropriate responsibilities and accountability for coordinating the activities of organizations that are working in the area of assisted reproduction and for carrying out functions that other organizations cannot perform.
- The development and monitoring of national standards for research related to human subjects including genetics and reproduction. The regulatory body would work closely with the Canadian Institutes of Health Research, other federal and provincial research granting councils, the National Council on Ethics in Human Research and other such organizations.
- The development and monitoring of national standards for training and certifying physicians in those reproductive technologies deemed acceptable. As is the case for all post-graduate medical training in Canada, this is appropriately done through bodies such as the Royal College of Physicians and Surgeons of Canada and the College of Family Physicians of Canada.
- The licensing and monitoring of individual physicians. This task is the responsibility of the provincial and territorial medical licensing authorities which could regulate physician behaviour in respect to the reproductive technologies, just as they do for other areas of medical practice.
- The development of guidelines for medical procedures. This should be done by medical specialty societies such as the Society of Obstetricians and Gynaecologists of Canada (SOGC) and the Canadian Fertility and Andrology Society (CFAS).
- The accreditation of facilities where assisted reproduction is practised. There is already in Canada a well functioning accreditation system, run by the Canadian Council on Health Services Accreditation, which may be suitable for assisted reproduction facilities.

Whatever regulatory body is established to deal with assisted reproduction should utilize, not duplicate, the work of these organizations. In order to maximize the effectiveness of these organizations, the regulatory body could provide them with additional resources and delegated powers.

Criminalization

The CMA is opposed to the criminalization of scientific and medical procedures. Criminalization represents an unjustified intrusion of government into the patient-physician relationship. Previous attempts to criminalize medical procedures (for example, abortion) were ultimately self-defeating. If the federal government wishes to use its criminal law power to regulate assisted reproduction, criminal sanctions should apply only in cases of deliberate contravention of the directives of the regulatory agency and not to specific medical and scientific acts.