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# Conflicts of Interest in Medical Ethics

by

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Medicine is a learned profession that has its own intrinsic ethic. Under this intrinsic ethic, the end of medicine is ordered to a good that is health. Technique and conduct are not value-neutral but rather are ordered to this overarching good that is the nature-given end of health. Medicine is a profession precisely because it professes such a goal. Being a professional is more than being a technician. The public profession of medicine as a way of life is an affirmation of the moral nature of our activity. Medicine as a profession is a public declaration of a willingness to devote oneself to others and to serve a higher good. The physician is a moral being who professes and affirms the moral nature of his activity.

We have in recent years seen an attempt to convert our profession into a killing activity. Doctors as abortionists kill unborn children; doctors accept the responsibility to kill patients with or without their consent as in Holland, or to engage in the subterfuge of physician-assisted suicide, as in the state of Oregon in America. The doctor true to his calling will not violate the taboo against killing. He will not do it for love and he will not do it for money.

This is why medicine must be a profession and not merely a business. A physician who is guided primarily by the profit motive will have conceded that he is willing to sacrifice the best interests of his patient in the patient's pursuit of health.

Recently there has been an erosion of some of the safeguards that have accrued to the protection of the patient and the society.

Let us start with information published in medical journals. This information helps to shape diagnostic and therapeutic decisions. For a medical journal to be of value, it must publish authoritative, up-to-date

information that is free of commercial influence. This requires that the financial associations of authors are disclosed and that these associations do not influence published articles. This is the only way to avoid bias or the appearance of bias based on a conflict of interest. Beyond the authors themselves, this freedom from conflict of interest must extend into the process of peer review. If those who are assisting the editor in selecting articles suitable for publication are not also free from similar financial associations, the possibility of bias is reinforced.<sup>1</sup> Relationships between biomedical companies and research are growing rapidly. Beyond the direct support of research or therapeutic trials, authors may receive consulting fees, serve on advisory boards, own equity, receive patent royalties or receive honoraria for lectures or expert testimony.

Recently the *New England Journal of Medicine*<sup>2</sup> and, by inference<sup>3</sup> the *Journal of the American Medical Association*, have altered their policies so that authors of original articles as well as review articles and editorials will not have any "significant" financial interest in a company (or its competitors) that makes a product discussed in an article. The National Institutes of Health<sup>4</sup> and the Association of American Medical Colleges<sup>5</sup> have likewise relaxed their requirements regarding financial association and resultant possible bias. The attempt has been made to quantitate what degree of association could produce bias. The key provision is to set an upper limit on the annual sum received by an author in order to have a relationship considered "significant." Currently \$10,000 is the *de minimus* level. Beyond this, any holding in which the potential for profit is not limited, such as stock, stock options or patent holdings, would probably be disqualifying.

The justification for these changes in policy is said to be an inability to impanel an adequate number of authors and/or reviewers to carry out the functions of the journal because so many academicians and clinicians are involved in intertangling financial relationships with pharmaceutical companies.<sup>5,6</sup>

Inevitably the outcome of the policy will be an enhanced opportunity for the introduction of conflict of interest and a reduced confidence in the reliability of published data. This will extend not only to decision making by physicians and researchers but also to the general public. Almost every major media outlet in the United States has a science editor and staff that cover current medical literature, often counting on summaries and releases published for their edification by the journals themselves. Providing this service is a large source of income, for example, to the American Medical Association.

Let us take one example. An article in the *New England Journal* on RU-486 (Silvestre L. et al. *New Eng J Med* 322:645, 1990) concluded that RU-486 was "effective and safe." Those who thought the data to be

excessively sanguine and reassuring could be forewarned by the revelation in a prominent place that all six authors were employees of Roussel-Uclaf, which manufactured RU-486 and stood to make huge profits from sales. The knowledge that the so-called "scientific" article was in fact an ill-disguised promotional piece could result in a healthy cynicism on the part of readers. Not only was the unfounded enthusiasm promoted as factual by the manufacturer, but also by the entire publicity apparatus of the pro-abortion lobby and its media collaborationists.

### **Concerns Regarding Bias**

A delegation from the Catholic Medical Association met with the executive director and the editorial staff of the *JAMA* to express our concern that during the previous three years approximately fifteen pro-abortion articles were published and not one anti-abortion paper. Editorial bias was vehemently denied. Subsequently, however, we came into possession of an internal memorandum<sup>7</sup> leaked to us by an AMA employee informing the editorial staff of *JAMA* that, in fact, their policy was as demonstrated, that is, not to publish anti-abortion studies or statistical studies unfavorable to abortion.

If this ideological bias is now to be augmented by a potential for bias based on economic gain, the profession and the public will have been thoroughly compromised.

President Bush was recently called upon to make a Solomonic decision regarding stem cell research. While by no means a perfect decision, it did make the important distinction between embryonic stem cells (produced from embryos created for the purpose of being killed to harvest their stem cells) and stem cells produced from adult sources (umbilical cord blood, bone marrow, etc.). While forbidding federal funding of the creation of any new embryonic stem cell lines the president did concede, in his policy, the continuation of existing cell lines from embryos. These were the fruit of a poisoned tree and, since adult stem cells had outperformed embryonic stem cells both clinically and in the laboratory, it was difficult to comprehend the dogmatic insistence by the scientific community of the superiority of and need for embryonic cell lines.

It turned out that many of the existing embryonic cell lines that were allowed to be preserved were in fact owned by universities and other enterprises that had every intention of profiting from the propagation of and distribution of embryonic stem cells for research.

During the debate on cloning<sup>8</sup> in the U.S. Congress, it was revealed that three human cloning patents were pending in the U.S. patent office. The sponsor of the Human Cloning Prohibition Act, Senator Brownback,

pointed out that the notion that we have to kill one person in order to find a cure for another is a false tradeoff which disregards advances made in other non-embryonic stem cell sources. Even more frightening is the prospect of people in corporate America owning, trading, buying, and selling people (clones) as if they were property. This is an issue that must be included in the cloning debate. When Senator Brownback introduced a Human Unpatentability Amendment to outlaw patenting human clones, it was defeated.<sup>9</sup> This occurred on the same day that a team from the University of Minnesota reported on the versatility of adult stem cells and their ability to convert and morph into hundreds of specialized cells within the body.<sup>10</sup>

Jonathan Swift said, "Falsehood flies and the truth comes lingering after, so that when men come to be undeceived the jest is over and the tale has had its effect." The culture of death has for the last thirty years clearly controlled the press and the media now shows a sinister proclivity toward controlling the scientific literature and thereby the political process. Through the powerful incentive of the profit motive derives the clear conflict of interest between objective scientific investigation and advocate science in pursuit of monetary gain.

The ultimate perversion of the commercialism of medical research would be the sale of body parts for use in experimentation. The reality of a brisk business in fetal body parts has been exposed by numerous investigative pro-life agencies. This offshoot of the abortion industry has been demonstrated to advertise the availability of organs from aborted babies in scientific journals. These are not merely allegations but are truly undeniable since actual advertisements containing price lists for human tissues have been exposed. Such offerings as "fetal liver, second trimester fetal kidney, pancreatic islet tissue," each with an attached price list have been discovered, (having been placed by so-called laboratories doing business with abortionist sources).<sup>11</sup>

A movement is currently underway to approve the payment by potential recipients for donor organs. Currently the National Organ Transplant Act makes it illegal for "any person to knowingly acquire, receive or otherwise transfer any human organ for valuable consideration for use in human transplantation." The American Medical Association has called for a study of the possibility of paying donors for organs.<sup>12</sup> The background for this consideration of a radical policy change is, of course, the annual shortfall in the availability of donor organs. The United Network for Organ Sharing database indicates that there are now 75,000 patients waiting for an organ. Among those waiting for a heart or liver transplant one-third will die before an organ becomes available.

The primary source of donor organs will be the so-called Heart Beating Cadaver Donors. These are patients who have had an irreversible cessation of total brain function and are being maintained on ventilators in

intensive care units. These will constitute a pool of 10,000-12,000 potential donors per year. Despite extensive public awareness campaigns, the ratio of actual to potential donors has not increased sufficiently.<sup>13</sup> One response has been a greater reliance on living donors (kidneys), partial transplants (liver and lungs) and sources of dubious ethical propriety such as anencephalic infants and animals.<sup>14</sup>

Another potential source of transplantable organs is patients who have been declared dead by traditional cardiopulmonary rather than brain-based criteria. The success of transplants using organs from these sources has been limited by problems with warm ischemia. These non-Heart Beating Cadaver Donors fall generally into two categories: 1) Uncontrolled Cardio-Pulmonary Death (usually in emergency rooms) and 2) Controlled Timing and Place of Death. This second category follows a method commonly known as the Pittsburgh protocol.<sup>15</sup>

Under this protocol, families who have decided to forego life support are approached to donate organs. Warm ischemia time is minimized by taking the patient to the operating room, disconnecting life support there, and removing organs immediately or shortly after the pronouncement of death. Ethical issues surrounding the use of Non-Heart Beating Cadaver Donors have to do with the consent process, the question of irreversibility and early declaration of death. There are also intuitive problems related to the fact that the procedure seems staged or contrived in that the patient is declared dead after having been removed from the company of his near relatives and into an operating room.

Market forces have begun to erode the standard of uncompensated donation from living donors by the opportunity to obtain organs outside the United States. Americans are purchasing organs from strangers in China, Peru, and the Philippines and then returning to the U.S. for post-transplantation care.<sup>16</sup>

Another challenge to the altruistic principles underlying the Act is the increased frequency of kidney donations by patients unrelated to the recipients since a close genetic match is no longer as necessary. The possibility exists of illegal purchase and illegal profits beyond the control of transplantation centers.<sup>17</sup>

The movement to liberalize the rules to allow for a freer market in the purchase of organs raises the specter of a bidding war in which less deserving wealthy candidates for transplantation gain priority over poor candidates lacking the wherewithal to purchase organs. One economist has suggested that less affluent individuals could always take out loans to purchase organs as they now do to purchase automobiles or houses. What happens, however, if the borrower is incapable of repaying the loan? Can we have some mechanism for foreclosing on or repossessing a kidney?

The present system of providing ethical or humanitarian incentives for donation would protect the unbiased distribution of organs based on priority of need.<sup>18</sup>

Brokering criteria in the United States would be impossible to control. If the current prohibition against the sale of organs were rescinded, there would be no legal justification for preventing persons from bypassing the regulated system to compete in an unregulated market. The potential unfairness of such a market and the preferability of enhanced ethical incentives (public recognition, compensation of funeral expenses or tax credits) would be the better way to sustain broad societal interest.<sup>19</sup>

### **Bioterrorism**

Finally, a world of bioterrorism, a fundamental conflict of interest has arisen over the issue of whether biologists should publish work that could be misused. The National Academy of Sciences has set up a panel to study how to prevent the destructive applications of advanced biotechnology.<sup>20</sup> Recent studies on the 1918 pandemic influenza virus at the Armed Forces Institute of Pathology have suggested the potentials for reconstructing the 1918 virus and making it more resistant to the immune system.<sup>21</sup> Similar studies have been published to demonstrate how to engineer microorganisms to spread more readily, resist antibiotics and vaccines and thus be more effective as weapons for bioterrorism. There are serious questions as to whether such information should be made available in journals. A conflict of interest has arisen between bioweapons experts in the government and the American Society of Microbiology as to whether there should be special peer review. Needless to say, scientists are highly resistant to the notion that their work or any important data should be subject to censure for political reasons.

Though the conflicts of interest may not be as demonstrable in a socialized medical system as they are in a capitalist system, they are unavoidable in a privately based system either fee for service or managed care. The main protection against the intrusion of political and economic issues into medical care is a return to the Hippocratic system of medical ethics that remains viable in all cultures and all forms of reimbursement.

Finally, another opportunity for conflict of interest consists of so-called "advocate science." This consists in the propounding of so-called "scientific" claims or rejecting counterclaims based not on the quality of objective data involved but rather on a hidden political agenda or a desire for political correctness.

The principal occasion for the employment of advocate science is in research regarding the etiology and the treatment of homosexuality or same-sex attraction disorder. The media have promoted the idea that a

“gay gene” has already been discovered and certain professional organizations have not discouraged this assumption. If same sex attraction were genetically determined, then one could expect identical twins to be identical in their sexual attractions. Most studies, however, show that identical twins are discordant in their sexual attraction.<sup>22, 23, 24</sup>

There are, however, ongoing attempts to convince the public that same sex attraction is genetically based. Such attempts are politically motivated by the supposition that the public would be more likely to respond to changes in laws and religious teaching were they to believe that same sex attraction is genetically determined and unchangeable.

A similar controversy surrounds the issue as to whether the homosexual state is treatable and changeable. In the debate between essentialism and social constructionism, the believer in natural law would hold that human beings have an essential nature – either male or female – and that sinful inclinations such as the desire to engage in homosexual acts are constructed and can, therefore, be deconstructed. Some members of the American Psychiatric Association have gone so far as to allege that attempts to change homosexuals are not only unsuccessful but even unethical. There are a number of therapists however, who have written extensively that reparative therapy is successful with about 30% experiencing a freedom from same sex attraction and another 30% improvement.<sup>25, 26, 27, 28</sup> Dr. Robert Spitzer, the renowned Columbia University psychiatric researcher, who was largely responsible for the removal of homosexuality from the APA’s list of mental disorders, has now indicated that his most recent research indicates that sustained change can be achieved.<sup>29</sup>

Other examples of advocate science would include, first, the American Cancer Society’s refusal to admit a relationship between abortion and breast cancer,<sup>30</sup> despite overwhelming evidence and, second, the insistence of the National Institutes of Health on the effectiveness of the condom in preventing AIDS. When the question was posed at a large international meeting of AIDS experts as to how many would be willing to have sexual intercourse with an HIV positive person while wearing a condom, no one in the audience raised their hand.<sup>31</sup> The evidence strongly suggested that the officialdom of numerous professional organizations, such as AMA and American College of Obstetrics and Gynecology, has a hidden agenda of apologizing for abortion and upholding the homosexual rights lobby despite any evidence to the contrary and despite the conflicting opinion of many in their grass roots membership.

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