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Ethics of Clinical Research and the Cinema. *The* Other *Fugitive* (1993)

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Received 11 February 2006; accepted 12 March 2006

Summary

One of the arguments of the well-known action-thriller film *The Fugitive* allows us to comment diverse aspects relating to ethics and medical research. The principles theory, updated by the Belmont Report, applicable to both health care and biomedical research, is developed in this article.

Keywords: Clinical Research, Clinical Trial, Ethics, Bioethics, Medical Deontology.

Technical details:

Title: *The Fugitive*
Country: USA
Year: 1993
Director: Andrew Davis
Music: James Newton Howard
Screenwriter: Jeb Stuart and David Twohy on the characters by Roy Huggins and story by David Twohy
Cast: Harrison Ford, Tommy Lee Jones, Jeroen Krabbé, Joe Pantoliano, Julianne Moore, Sela Ward, Andreas Katsulas, Daniel Roebuck, L. Scott Caldwell, Tom Wood, Ron Dean, Joseph F. Kosala, Miguel Nino, John Drummond, Tony Fosco and David Darlow.
Color: Color
Runtime: 133 minutes
Genre: Action, Thriller
Production Companies: Warner Bros.
Summary: Dr. Richard Kimble is an eminent vascular surgeon in Chicago with an almost perfect life: a beautiful wife, prestigious professional career and a luxury house. But his life goes to pieces on the day that his wife is brutally murdered at the hands of a mysterious one-armed man. Dr. Kimble is accused of the crime and, although innocent, sentenced to death. On route to prison to serve his sentence, the bus he is on has a traffic accident because of a prisoner's rioting. Two prisoners manage to escape, one of them Kimble. The U.S. Marshal Samuel Gerard is in charge of the investigation and of capturing the fugitives. One is shot by Gerard, but Kimble remains free. During this escape-pursuit, he knows that to prove his innocence he must find his wife's real murderer. Pursued by Gerard, he starts his search for the "one-armed man" and this is how the part of the film that is interesting from a health perspective takes shape.
Awards and nominations: Oscar (1993) for the best supporting actor (Tommy Lee Jones). Nominated for the Oscar for the best film, best cinematography, best film editing, best music, best sound and best sound effects. Golden Globe (1993) for the best supporting actor (Tommy Lee Jones). Nominated for the Golden Globe (1993) for the best director (Andrew Davis) and best actor (Harrison Ford).

Based on a real event and on the famous TV serial to which it gave rise ["The Fugitive" (1963-1967)], it obtained good reviews and was a box-office success throughout the world. Characters full of vigour, memorable action sequences and effective direction. Tommy Lee Jones's success led him to act in a sequel with a similar plot, *U.S. Marshals* (1998), by Stuart Baird.

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Medical, research and ethical focus of the film

The Fugitive is clearly an action thriller. However, its plot and characters make it possible to carry out an ethical study of the medical profession in general and of clinical research in particular.

From this point of view, the film has four main characters of interest and comprises two plots. The main plot, on which most of the spectators will focus their attention, is the "pursuit of the fugitive", where, apart from the "one-armed man" (Andreas Katsulas) –the real murderer- (figure 1), the condemned fugitive, Richard Kimble (Harrison Ford) and the U.S. Marshal, Samuel Gerard (Tommy Lee Jones) intervene. But there is also a very striking secondary plot which focuses on different aspects of the clinical and research practice of Dr. Kimble, a vascular surgeon, and his colleague Dr. Nichols (Jeroen Krabbé), head of Morbid Anatomy.

Figure 1: "The one-armed man"

1. Summary of the film from the health perspective

Devlin MacGregor, a major pharmaceutical company according to its huge profits, and doctors at the Chicago Memorial Hospital are collaborating in the development of a drug (RDU-90 or Provasic) (Figure 2), which has properties that reduce arteriosclerotic build-up. This drug is in its clinical trial stage, and the main researchers are Charles Nichols and Alexander Lentz (David Darlow). During the course of the research, Richard Kimble observes important hepatic side effects of the drug; during an operation he comments that "this guy is bleeding from every needle puncture". Since the drug is pending approval by Food Drug Administration (FDA), the ambitious Nichols decides to eliminate all the negative results of the trial. Thus the liver samples and their respective pathological reports are changed for others from a healthy liver, curiously all from the same patient (Figure 3). But he also makes Dr. Lentz, who knows the truth, disappear in a deliberate car accident, and for indirect motives he even has Helen (Sela Ward), Richard Kimble's wife, killed. Nichols's hired killer is the "one-armed man" (Figure 4) and also involved in this sordid plot are directors of the pharmaceutical company sponsoring the research, on whose payroll is the film's notorious "one-armed man". The resolution of the plot unmasks Nichols and the "one-armed man" and reinstates Dr. Kimble, but does not report anything on the pharmaceutical company or any of its directors. What the film does make quite clear is that the firm offers details such as pleasure trips to the doctors who collaborate with it.

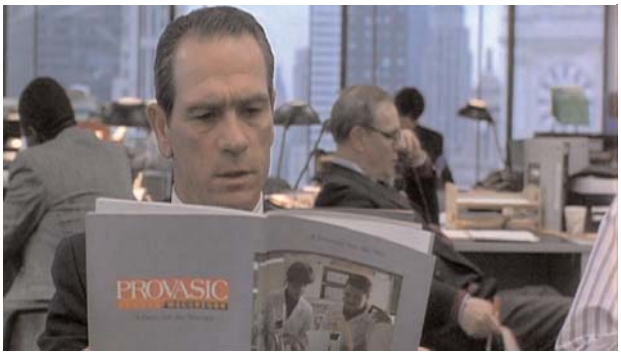

Figure 2: The *Provasic* dossier

2. **Profile of the main characters in the film**

Dr. Richard Kimble (Figure 5): the film presents an eminent vascular surgeon who is working in an important hospital in Chicago, and has numerous professional, scientific and human qualities. Nevertheless, circumstances make him be accused of murdering his wife. Kimble is not only extremely brave and intelligent, as can be seen in many episodes in the escape-pursuit, but also an excellent researcher –note how when looking for a certain artificial limb, he manages to find out where the "one-armed man"

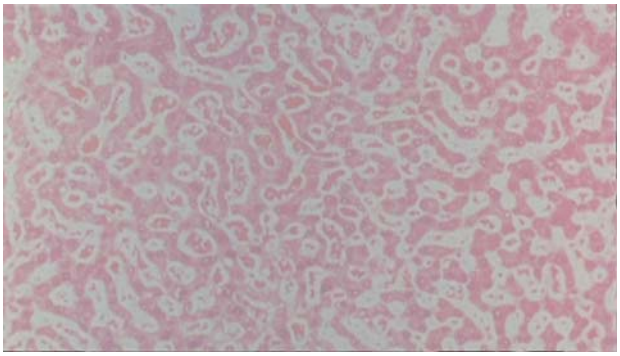

Figure 3: Samples of healthy livers

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Figure 4: The one-armed man's prosthesis

lives- but above all he is a "star" doctor, since he always puts the health of others before his own safety. Four scenes in the film reflect this: 1) when he goes to the operating theatre to help a colleague, in a problem that is not his speciality; 2) during the bus accident when he helps an injured policeman, risking his own life and freedom; 3) when, risking being recognised, he reports that the injured policeman who is arriving in the ambulance has an abdominal perforation at the gastric level; and 4) when he saves a child's life in his hospital, by changing the diagnosis and signing the authorization for an emergency operation, while disguised as a cleaner, and seeking clues about artificial arms (Figure 6). He also reveals his professional skills on his own person when he sews up the injury caused in the bus accident and administers himself anti-tetanus immunoglobulin. In short, his professional and ethical values are beyond reproach.

Figure 5: Doctor Richard Kimble

U.S. Marshal, Samuel Gerard (Figure 7), is the federal marshal in charge of pursuing Dr. Kimble, who finally admits his innocence. He is presented as a harsh, cold and apparently aggressive but humane man, as is revealed in the dialogue with Kimble at the end of the film. Gerard has many of the qualities of the good scientist: curiosity, ability to observe, creativity, vocation, a mission to serve; he is methodical, orderly, patient, imaginative, insistent, constant, optimistic, critical, etc. He is a highly analytic leader, who works in a team and is precise even in his language. His professional behaviour is always within the bounds of ethics.

Dr. Charles Nichols (Figure 8) is an eminent pathologist who works in the same hospital as Kimble; cynical "friend" and main researcher in the Provasic project. His boundless ambition leads him to participate, through the "one-armed man", in at least two murders, to falsify the results of the research and, above all, to incur in maleficence (harmful effects on the patients receiving a product). He is the amoral face in the film (the other fugitive): a leader of opinion, handsome, elegant, with studied poses, expensive tastes, ostentatious, without ethics, addicted to flattery and to the mass media, egocentric and in love with money.

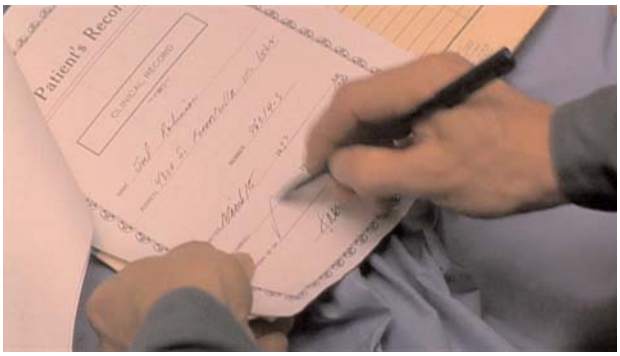

Figure 6: The sense of duty

Bioethics

In England (1721), an English surgeon, Charles Maitland, inoculated smallpox into six prisoners offering in exchange a promise of release[1]. During the Second World War, in Dachau (Germany), under the responsibility of Dr. Sigmund Rascher, the Nazis carried out many experiments between August 1942

Figure 7: Agent Samuel Gerard

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and May 1943; because of this, in the famous Nuremberg trials, 23 doctors were put on trial, accused of having carried out inhuman and cruel experiments with human beings; 17 were declared guilty and 7 sentenced to death[2]. These two examples, separated in time, reveal how the history of research with human beings is full of episodes that violate individual rights because of amoral and not at all ethical conduct on the part of certain "researchers".

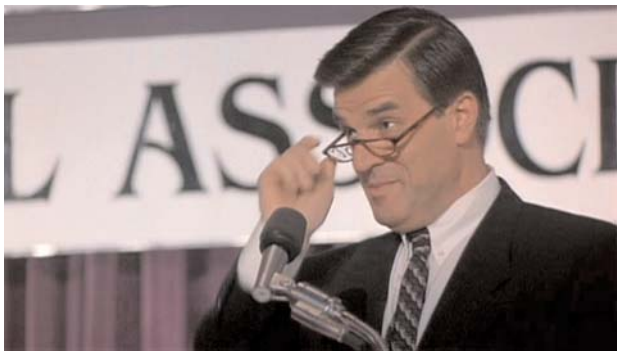

Figure 8: Doctor Charles Nichols

Moral and ethical?

Ethics is the systematic, critical and formal analysis of human behaviour in order to discern what is correct and what is incorrect, good or bad. Morals are a set of norms and beliefs that determine what people or nations consider correct or incorrect, good or bad in human action. In other words, ethics is the science of what is moral. Although etymologically morals and ethics mean the same and are interchangeable, morals were not invented by the philosophers, as is the case of ethics, but rather they form part of societies and individuals; thus, while there are Christian, Islamic or Socialist morals, the surnames of ethics are: Aristotelian, stoic, or Kantian.

Along this same line of ideas, bioethics came into being as the systematic study of human behaviour in the sphere of health sciences, and examined this behaviour in the light of moral values and principles. Bioethics is a much broader term than the many duties that doctors have to their patients (medical deontology). In any case, in today's society the terms "moral", "ethical" and "deontology" have practically taken a unitary meaning and are seen as action with a view to having an easy conscience.

The origin of all the doctors' rules of behaviour is social, and hence they are in continuous evolution, motivated by the social changes in which they are generated. In ancient society only a few principles were the foundation of the regulations in medical-surgical action: respect for life, for the person's safety, individual and collective health.

Since there are no legal duties in doctors' rules of behaviour, but rather the duties are moral at the discretion of one's own conscience, or of the conscience of the other doctors, throughout history an attempt has been made to encode these rules. There have been many efforts to encode medical ethics, this being explained by the increase in responsibilities with respect to the patient, his/her family and society.

The Hippocratic Oath (400 B.C.) was the first code of rules for medical conduct; the relationships of doctors with their teachers, with their pupils, with patients and with members of the profession (Figure 9). Since 1947, with the Nuremberg Code[3], which deals with experiments on humans in response to the abuse committed during the Second World War, declarations, principles and codes that seek to regulate and define the fundamentally deontological principles of doctors' social action have been more frequent. Over the last 50 years, the General Assembly of the World Medical Association has been shaping doctors' ethical behaviour, fitting it to our times and has adopted the Declaration of Geneva (1948)[4] and the International Code of London (1949)[5], which endorse and broaden the Hippocratic Oath.

Many declarations and letters could be cited, all sanctioned by the General Assemblies of the World Medical Association and signed by the countries members of the World Health Organization. Special mention should be made of the Declaration of Helsinki in 1964 which regulated the ethical rules for experiments with humans (clinical research) and which was revised in 1975 in Tokyo, in 1983 in Venice, in 1989 in Hong Kong, in 1996 in Somerset-West, South Africa, and in 2000 in Edinburgh[6]. Over twenty years ago, the Hospital Committee of the European Economic Community passed the Charter of the Hospital Patient, which includes all their rights, as well as the delimitations and functions of the hospital doctor[7]. The principles that inspired it come from the Universal Declaration of Human Rights, the European Social Charter, the UN International Covenant on Economic, Social and Cultural Rights and from the WHO resolutions passed in this sense.

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All these rules on social behaviour must be regulated by each country so that they can be applied throughout the nation and, within this, in the hospitals. Thus, mention must be made of the Spanish Deontological Code, drawn up by the General Council of the Official Associations of Doctors and updated in 1999 under the name of Code of Ethics and Medical Deontology, passed by the OMC (*Organización Médica Colegial* in Spain), which, in its final article indicates that it will be revised every two years[8]. Much subsequent legislation has appeared both for care and research aspects.

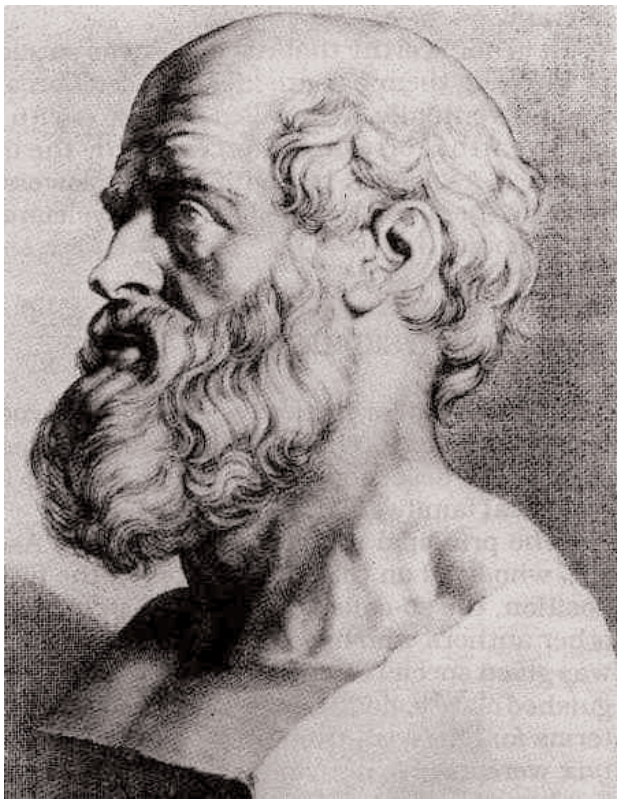

Figure 9: Hippocrates

Finally, it is important to remember that deontological codes (or compilations of professional ethical precepts) do not give the answer to all the ethical dilemmas currently posed. Thus, we must point out how history shows that scientific and social changes strengthen the ethical dimension of medical practice. Progress in medicine has done no more than reinforce this aspect in many fields, among which the following merit special mention: information for the patient, professional secret, organ transplants, abortion, problems in assisted reproduction, problems deriving from genetic manipulation, euthanasia, etc. and, of course, the matter we are dealing with – human clinical research (clinical trials).

Basic principles of modern medical bioethics

The Belmont report: *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* in 1978[6], among other aspects, completed the ethical principles on which many of the decisions taken in health care are based; these have consensus in western culture and are:

1) Beneficence: doing good to the patient (the basis of professional ethics)

2) Non-maleficence: avoiding harm to the patient (not subjecting the patient to unnecessary risks or tests. If these are necessary, benefits versus risks are evaluated)

3) Autonomy: participation of the patient in the decisions (passing from paternalism to co-decision. Important role of information, confidence and confidentiality)

4) Justice: distribution of resources among groups of patients (guaranteeing care for citizens in general, preventing the excessive, inadequate or ill-considered use of resources for some needs from exhausting the resources available for others).

Since these four basic principles can enter into conflict, they are divided into two levels:

1) Non-maleficence and justice, i.e. what is correct and what is incorrect and this corresponds with Law and

2) Autonomy and beneficence, i.e. what is good and what is bad, these two principles being the most specific of morality. Nevertheless, for some the number and hierarchy of principles is debatable.

This "principles" theory, updated by the Belmont report[9], can be applied to both health care and biomedical research.

Ethics in clinical research

The only requirements that research must fulfil are respect for the ethical norms and application of scientific method. Hence, the researcher's responsibility in experiments with humans is of huge importance.

There have been many important efforts to draw up guidelines for medical research (Table 1).

Any clinical trial, before it begins, must be approved (and then controlled) by a clinical trials committee. These committees usually include one or more people not working in health care and representatives of doctors, chemists and nursing staff. The aim is to protect the patient, the researcher and the

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Table 1: Most relevant legislation on clinical research

- Nüremberg Code (1947).

- International Declaration of Civil and Political Rights (UN, 1958).

- Declaration of Helsinki, 1964 (18th World Medical Association Assembly).

- Revisions of Tokyo (1975), Venice (1983) and Hong Kong (1989).

- Belmont Report (1979): Ethical Principles and Guidelines for the Protection of Human Subjects of Research.

- International guidelines for biomedical research involving human subjects. Council for International Organizations of Medical Sciences (CIOMS) and the World Health Organization (WHO) (1982).

-Convention for the protection of human rights and the dignity of the human being with regard to the application of biology and biomedicine. Council of Europe (1996).

- Spanish Royal Decree: RD 944/1978 (14 April) and Order of 3 August 1982. Regulation of clinical trials of pharmaceutical products and medicinal preparations on human subjects.

- Spanish Royal Decree: RD 561/1993 (16 April). Carrying out of clinical trials with medicines.

-European Community Directives on clinical trials: Directives 75/318/EEC modified by 83/579/EEC and Council recommendation 83/571/EEC.

institution where the study is being carried out: the patient from exploitation, the researcher form running unjustified risks and the institution from losing its reputation.

It is a good idea to end by recalling that although all the ethical rules are praiseworthy, we should not forget the one attributer to Ambrose Paré (16th century) "*above all, do unto others as you would have them do unto you*".

Acknowledgements

The Editors would like to thank the translation team of the Languages Service of the University of Salamanca for their collaboration in the English version of this Journal.

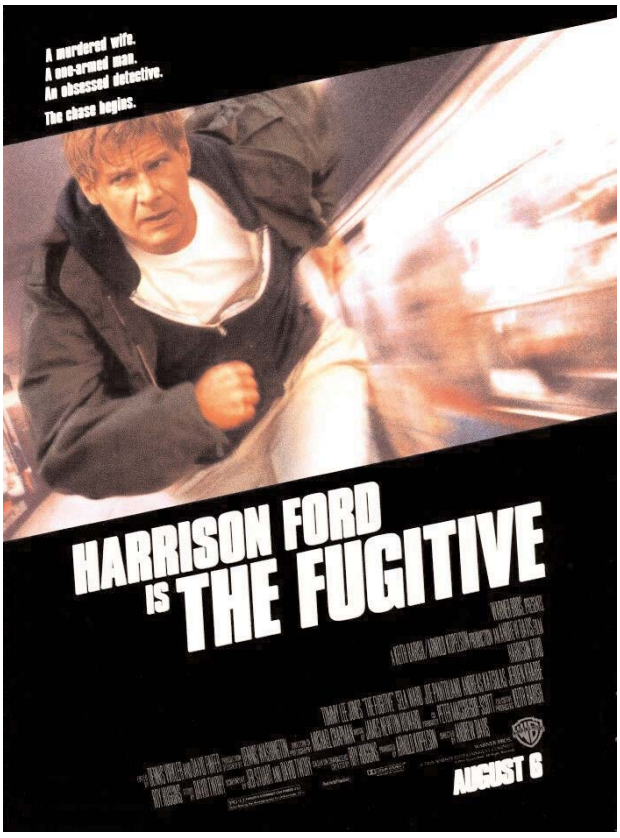
References

1.- Barquet N, Domingo P., Smallpox: The Triumph over the Most Terrible of the Ministers of Death . Ann Intern Med [serial on the Internet]. 1997, October [cited 2006 Jan 12]; 127: 635-642: [8 p.]. Available from: http://annals.highwire.org/cgi/content/full/127/8_Part_1/635

2.- Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10; Military Tribunal, Case 1, United States v. Karl Brandt et al., December 1946-August 1947. Washington, DC: Superintendent of Documents, U.S. Government Printing Office, 1950.

3.- Complete transcript of the Nuremberg Medical Trial: United States v. Karl Brandt et al. (Case 1). Washington, D.C.: National Archives, November 21, 1946–August 20, 1947. (Microfilm publication no. M887.)

4.- Declaration of Geneva. Adopted by the General Assembly of the World Medical Association at Geneva Switzerland, September 1948. [database on Internet]. [cited 2006 Jan 12]. [about 1 p.]. Available from:



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http://www.wma.net/e/policy/c8.htm
5.- World Medical Association. International code of medical ethics. World Medical Association Bulletin. 1949; 1: 109-111.
6.- World Medical Association [database on the Internet]. World Medical Association declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects [updated 2004 Oct 9; cited 2006 Feb 4]. [about 5 p.]. Available at: http://www.wma.net/e/policy/b3.htm
7.-HOPE [database on the Internet] Charter of the Hospital patient (Luxembourg, 9 May 1979) [cited 2006 Feb 4] [about 2 p.]. Available from: http://www.hope.be/07publi/publoth/Hospchart.htm
8.- Consejo General de Colegios Médicos. Código de Ética y Deontología Médica [homepage on the Internet] 1999. [cited 2006 Feb 4]. [about 25 p.]. Available from: http://www.cgcom.org/pdf/Codigo.pdf
9.- Belmont Report. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Bethesda, MD: Government Printing Office, [series on Internet]. 1978. April [cited 4 February 2006]. [about 7 p.]. Available at: http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm

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