



ETHICS, LAW AND REGULATORY AFFAIRS: COMPARISONS AND CONTRASTS

J. Michael Slocum, Esquire

Slocum & Boddie, P.C.

6225 Brandon Avenue, Suite 310

Springfield, Virginia 22150

(703) 451-9001; (703) 451-8557 (fax)

jmichaelsocum@slocumboddie.com

WHEN ETHICAL QUESTIONS ARISE

- When the exercise of preference somehow affects the welfare of others
 - ***Ethical questions arise***
- One of the problems for persons entering a profession, such as science, is that they may not recognize when choices about technical matters have moral implications

INTRODUCTION

Ethical Frameworks

- Utilitarian ethics
- Duty/deontological ethics
- Virtue ethics



RELATIONSHIP BETWEEN ETHICS AND LAW

- Law is a codification of societal ethics
- Is law the lowest common denominator of ethics or “the public’s agency for translating morality into explicit social guidelines and practices”

Beauchamp, T. L. and N. E. Bowie: 2004.
Ethical theory and business, 7th ed. (Prentice Hall, Upper
Saddle River, NJ) (continued)

RELATIONSHIP BETWEEN ETHICS AND LAW (2)

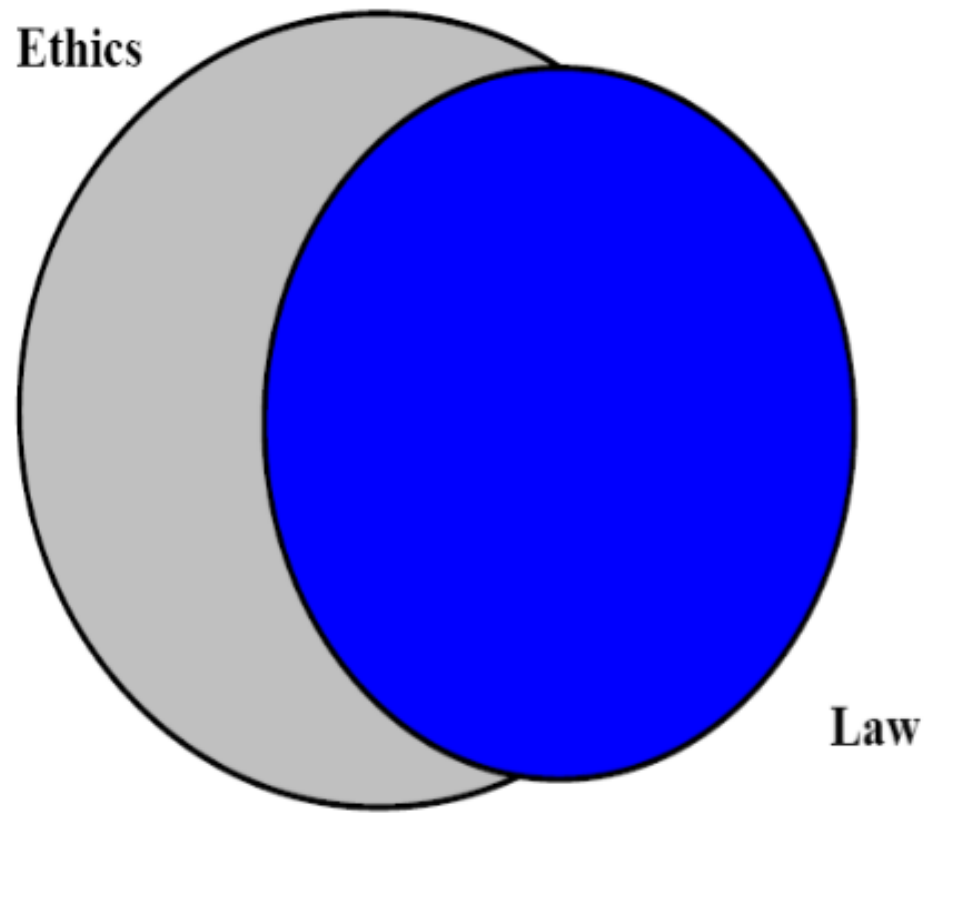
- An action may be:
 - Legal & moral • Legal & immoral
 - Illegal & moral • Illegal & immoral
- Does law drive ethics? Or are ethical concerns the source of law?

INTERSECTING DOMAINS_{No. 21-2004 ICCSR}

Research Paper Series - ISSN 1479-5124

Questioning the Domain of the Business Ethics Curriculum:

Where the Law Ends or Where it
Andrew Crane and Dirk Matten



LAW IS–

- Case law
- Statutory law
- “Natural” or religious law [dictated by some “authority”]

RELATIONSHIP OF ETHICS AND RELIGION

- Religious beliefs may be a major part of one's world view
- May determine method of moral reasoning
- May add other ***principles*** or alter their priority
- May define some of the “rules” of law and the “precepts” of ethical framework

The background of the slide features a light blue gradient with a faint, semi-transparent image of classical architectural columns on the left side. The columns are white and have ornate capitals. The entire slide is framed by a thin brown border.

RELATIONSHIP BETWEEN SCIENCE AND RELIGION

- Science is about what is
- Religion is about the meaning of what is

LAW VERSUS ETHICS

Practice		Policy
Individual	vs.	Society
Precedent	vs.	Potential
Individual concerns	vs.	“Community” concerns
Case by case	vs.	General principles
“Acceptable” results	vs.	Justice
Equity/Compassion	vs.	Justice
Advocate-based methods	vs.	Protector of society – “all knowing”

LAW VERSUS JUSTICE

- Non-maleficance
- Beneficence
- Autonomy
- Justice (treat like persons alike)
- Focus is on patient
- Focus is on society

THEORIES OF JUSTICE

- To each person an equal share
- To each person according to **need**
- To each person according to effort
- To each person according to contribution
- To each person according to merit
- To each person according to **free-market** exchanges

A HIERARCHY OF ETHICAL CONSIDERATIONS

- Lowest level ethical considerations—a statement of commonly held principles
- At the next level—internal ethical codes
 - Commonly applicable ethical code—usually brought about through the formation of a group or profession
- Finally—laws
 - Principles in the field that are shared with the larger society

PRINCIPLES OF PERSONAL ETHICS

A Framework For Universal

Principles of Ethics, **Larry Colero, Crossroads Programs Inc.**,
<http://www.ethics.ubc.ca/papers/invited/colero.html>

Principles of Personal Ethics include:

- Concern for the well-being of others
- Respect for the autonomy of others
- Trustworthiness and honesty
- Willing compliance with the law (with the exception of civil disobedience)

(continued)

PRINCIPLES OF PERSONAL ETHICS (2)

A Framework For

Universal Principles of Ethics, **Larry Colero, Crossroads Programs Inc.**,

<http://www.ethics.ubc.ca/papers/invited/colero.html>

- Basic justice; being fair
- Refusing to take unfair advantage
- Benevolence: doing good
- Preventing harm

PRINCIPLES OF PROFESSIONAL ETHICS

A Framework For Universal Principles of Ethics, **Larry Colero, Crossroads Programs Inc.**,

<http://www.ethics.ubc.ca/papers/invited/colero.html>

Professional Ethics, include:

- Impartiality; objectivity
- Openness; full disclosure
- Confidentiality
- Due diligence/duty of care
- Fidelity to professional responsibilities
- Avoiding potential or apparent conflict of interest

PRINCIPLES OF GLOBAL ETHICS

A Framework For Universal Principles of
Ethics, Larry Colero, Crossroads Programs Inc.,

<http://www.ethics.ubc.ca/papers/invited/colero.html>

Principles of Global Ethics include:

- Global justice (as reflected in international laws)
- Society before self/social responsibility
- Environmental stewardship
- Interdependence and responsibility for the 'whole'
- Reverence for place

ETHICS VERSUS ETHICS

- Ultimate ethical standard among the medical profession is the Hippocratic Oath. The oath states: 'I will follow that system of regimen which, according to my ability and judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous.'

(continued)

ETHICS VERSUS ETHICS (2)

- Standard demands that the physician use every means possible to cure the patient's ailment—but does this apply in a clinical trial, which is understood to be experimental, not treatment?

WHAT IS THE ROLE OF “REGULATORY AFFAIRS”

- Shaping and defining the Organization response to law and other forms of regulatory activity?
- Handling issues where the law could not, or had yet to, define right and wrong
- Developing the institutional response to certain laws, rules and rule-making processes? Current societal concerns?

ETHICAL ISSUES IN RESEARCH FACED BY REGULATORY AFFAIRS

- Informed consent issues
- Special subjects
- Balancing risk and benefit
- Issues related to lack of anticipated direct benefit to subjects
- “Societal” concerns
- “Environmental” concerns

ETHICS VERSUS LAW?

- Increasingly, physicians, researchers, policymakers and the public face numerous quandaries brought on by advances in biology and medicine advances ***the law is often ill-equipped to address***

Biomedical Ethics in U.S. Public Policy,
OTA-BP-BBS-105, June, 1993

- ***How much more true is this statement today?***

THE PROBLEM

- Focus on the legal issues leaves many wondering what is the point of all the disputation and discussion
- How to distinguish meaningless gobbledygook from carefully crafted moral argument—both seem like just a bunch of words

(continued)

THE PROBLEM (2)

- Rote solutions to one problem don't allow extension to new situations
- Ideals conflict or the law is not perfectly clear about what one ought to do

LAW PROVIDES

- The conventions and rules for appropriate research conduct
 - ***However, knowing the rules and conventions of science is not sufficient to ensure responsible research conduct***

WHY ETHICS AND NOT JUST THE LAW

- New ethical problems arise
 - Technology advances
 - Societal expectations change
 - Scientific disciplines evolve
- Ethical problems that were not anticipated by existing codes of conduct and are not explicitly stated in laws or rules

(continued)

WHY ETHICS AND NOT JUST THE LAW (2)

- But the law will hold scientists and institutions accountable for their decisions
- Professionals are expected responsibly and knowledgeably to arrive at morally defensible positions—even on novel and unprecedented issues



ETHICS IN REGULATORY AFFAIRS

- Ethical sensitivity, critical thinking skills and habits to effectively resolve the new situations likely to be encountered in professional life

FOUR BASIC PROCESSES

1. Interpretation of the situation—what actions are possible, who is affected by each course of action, how the parties (and the public) will regard the result (and the means to the end)
2. Judgment about which course of action is “morally right” (or ***fair*** or ***just*** or ***good***)

(continued)

FOUR BASIC PROCESSES (2)

1. Priority to moral values above other personal values such that a decision is made to do what is *right*
2. Perseverance, strength and skills to follow through, to overcome obstacles, fatigue and flagging will

SKILLS OF MORAL REFLECTION

Well-Reasoned Response to Ethical Challenges

- Issues and points of conflict
- Interested parties
- Consequences
- Obligations

STARTING POINT

- What values and norms undergird the practice of science
- By what standards professional practice should be judged
- How the profession's ideals translate into specific expectations, obligations and norms of practice
- Public values versus profession's values

ISSUES OR POINTS OF CONFLICT

- Ethical analysis must move beyond naming the issue (e.g., data ownership and access, plagiarism, etc.) to the nature of the moral conflict
 - What constitutes an ethical conflict?
 - A situation in which rights or obligations of parties conflict
- Choice between unfavorable or disagreeable alternatives

INTERESTED PARTIES

- Those directly involved
- Person(s) immediately affected
(such as that person's students,
employees or research subjects)
- People in the relevant institution
(the laboratory or university)
- Scientific community
- Society in general

CONSEQUENCES

- Not every remote consequence, but—
 - Those that have a good probability of occurring, and
 - Those that would have very serious consequences even if the probability of occurrence is not particularly high

CONSEQUENCES MAY BE MULTIFACETED

- CAUGHT:

- Lawsuit, loss of funding, loss of reputation

- NOT CAUGHT:

- Actor gets publication or grant more easily and quickly than if s/he had acted ethically. But what about “integrity?”

- The effects may appear to be minor in the short run, but often have a cumulative and debilitating effect

OBLIGATIONS

- Obligations toward the various interested parties
- Impact on another party's moral obligations
- Why the professional has a duty
- Moral justification in terms of values, principles, character or outcomes

ARE THERE UNIVERSAL ETHICAL STANDARDS IN RESEARCH

- Is a minimum standard of technical competence an ethical requirement?
- Bias versus differences of interpretation and judgment
- Negligent acts versus intentional acts and misrepresentations—is sloppy work ever unethical?
- Responsibility to participate in the monitoring of ethical behavior?

THE BASIS FOR “ETHICS”

- Ethics—principles of right and wrong—may be contracted, constructed, taught, propagandized and innately felt; furthermore, within each of these classifications, ethics may be as specifically or generally defined as the imagination allows
- Law cannot endure unless based on an ethical code

The Journal of Libertarian Studies, Vol. VI, No. 1 (Winter 1982)

(continued)

THE BASIS FOR “ETHICS” (2)

- Law is normative—what individuals should and should not do
- Ethics makes explicit that what we should be doing is *right* and what we should not be doing is *wrong*.

Efficiency vs. Ethics: Which Is the Proper Decision Criterion in Law Cases? by Roger A. Arnold, Department of Economics, University of Nevada at Las Vegas

The Journal of Libertarian Studies, Vol. VI, No. 1 (Winter 1982)

WHERE DO ETHICS COME FROM?

- Three alternate sources:
 - Traditional custom of the tribe or community
 - The arbitrary, *ad hoc* will of those who rule the State apparatus
 - By the use of “reason” –
 - “. . . what ought to be, irrespective of what is.”
John Edward Emerich Dalberg-Acton, *Essays on Freedom and Power* (Glencoe, Ill.: Free Press, 1948)

ETHICAL CHOICES AS RIGHT VERSUS RIGHT

- The *really* tough choices involve right versus right
 - Each side is firmly rooted in basic, core values
- Truth versus loyalty
- Individual versus community
- Short-term versus long-term
- Justice versus mercy

THEORIES FOR ETHICAL DECISION MAKING

- Ends-based
- Rule-based
- Care-based

CONSEQUENTIALISM– TELEOLOGICAL

- Utilitarianis–
 - ***Do whatever produces the greatest good for the greatest number***

RULE BASED– DEONTOLOGICAL

- “Act only on that maxim that it should become a universal law.” “Follow only the principle that you want everyone else to follow.”
- “If ***everyone in the world*** followed the rule of action I am following, would that create the greatest good or [in Kant's words] the greatest `worth of character'?”

(continued)

RULE BASED– DEONTOLOGICAL (2)

-
- How can we ***ever*** know the consequences of our actions?
Never mind outcomes: Stick to principles and let the chips fall where they may.

CARE-BASED THINKING— REVERSIBILITY

- ***Do to others what you would like them to do to you***
- Put yourself in another's shoes and imagine how it would feel if you were the recipient, rather than the perpetrator, of your actions