



THE "KETHICAL" DILEMMA

NOVEMBER 2009

POINTS TO CONSIDER

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It's no surprise that firms in the life sciences often face ethical issues that go beyond the typical business ethics topics found in other industries. The public's trust in bioscience firms today often becomes tainted when their leaders fail to execute ethical decision-making. While the public's visibility of bioscience firms' ethical decision-making (or lack thereof) often arises from high-profile events directly impacting patient lives, this may not accurately reflect the types of ethical decisions a bioscience firm faces day-in and day-out. In 2006, a survey was conducted with the 100 largest US biotech and pharmaceutical firms to better understand their ethical issues.

When asked about the *most common* ethical issue, the responses were as follows:

Rank	Ethical Concern
1	Employee behavior
2	Conduct of clinical trials
3	Sales practices
3	How to market products
5	Corporate governance
6	Regulatory strategy
7	Who to partner with
8	What research to conduct
8	What products to develop
10	Accounting practices
11	Company mission
12	Where to do business
13	Product pricing

Here are some points to consider:

- How can we help shape the KGI curriculum to help us address and manage these ethical issues?
- As we enter industry and begin to encounter these issues, how can we help foster ethical decision making among our peers?
- Do you believe that the occurrence rankings of these issues accurately represent the public's view of overall ethical importance?

Source: Finegold D *et al.*, Ethical decision making in bioscience firms, *Nature Biotechnology* 2006; 24; pp 285-290



Image: <http://www.wma.net>

Sources:
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Are the Ethics Ethical?

Sarah Arlien

There are a number of business and logistical reasons to outsource your clinical trials to a country outside the United States, particularly to a developing nation. Common arguments are less time, less money, better science, what's not to love? The Declaration of Helsinki (DoH), a set of ethical principles issued by the World Medical Association states:
"Medical research involving a disadvantaged ... community is only justified if the research is responsive to the health needs and priorities of this population or com-

munity and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research." (WMA, 2008)

The difficulty with this principle is in the requirement for both parts to be met. Companies are unlikely to do a trial if they have no evidence to suggest that it will be efficacious in the population and thus will generally meet the first part of the principle. There are a number of debates over the meanings of the second part of the princi-

ple. One way of interpreting this would be that if the trial drug is approved, the people who participated should have access to that new treatment. However, the company may not plan to market the drug in the country or may want to sell it at a price beyond the means of the people who participated in the study. Is it ethical to not do a study that could help trial participants because the trial results will not benefit the population beyond the trial itself? Cast your vote online at [Are the Ethics Ethical?](#)

Animal Testing: An Ethical Compromise?

Neelima Kumar

Before conducting clinical trials in humans, the FDA requires every pharmaceutical and biotechnology company to complete pre-clinical tests in two animal species to confirm the safety and efficacy of a drug (1). This requirement, however, is not solely restricted to the life sciences industry, and is widely seen even in the cosmetics industry.

Animal testing and experimentation has always been one of the “gray areas” of bioethics debates. On one hand, we have animal rights extremists who allege that all forms of life should be protected, as the word bioethics stems from the Greek words ‘bios’ (meaning life) and ‘ethos’ (meaning character), and literally meaning the ‘ethics of life’ (2). For them,

valuing human life over animal life is a paradox in itself since the “Woese classification” places humans within the animal kingdom (3). This brings us to the moot point in question - Is it *ethical* to disregard the worth of an animal’s life in the quest to enhance the quality of our own lives?

To deal with this tangled situation, regulatory agencies like the FDA limit animal experimentation to minimize the suffering caused by testing (4). Cosmetics and personal care companies such as Revlon and Procter & Gamble are moving towards on-plant and tissue culture testing as a means of reducing the suffering caused to animals (5, 6).

While the use of animals for testing personal care prod-

ucts and cosmetics has been met with considerable opposition worldwide, their use in the testing of potentially lifesaving treatments and drugs provokes mixed responses. While the ideal scenario would involve feasible alternatives to animal testing, there are no suitable substitutes currently available. The proponents of drug testing in animals also argue that direct testing on humans is not a viable option, given the enormous ethical and economic hurdles involved.

Do drug companies need to strike a fine balance while deciding between the value of an animal’s life and the degree to which humans shall benefit from a new drug? There seems to be no right answer to this debate and in the mean-



<http://kyoder1112.files.wordpress.com/2009/05/animal-testing-cage-jpg>

time one can only hope that alternative means of testing are discovered that will obviate the need for animal experimentation.

While some critics point out that animal activists are being excessively righteous in their demand for animal rights, it is worthwhile to recall the words of famed French philosopher René Descartes, “I think, therefore I am” (7). We as inhabitants of a common planet are morally obligated to respect all life on earth!

Dual-Use Dilemma: Ethics in Research

Marc Pollack

When a new discovery in the scientific field yields highly beneficial information, the community at large sees it as a great step forward. For example, if a laboratory manages to reconstruct the genome of a deadly virus like the Spanish Flu virus, the possibility of finding a vaccine to the disease is seen as huge benefit. However, a reproduction of the Spanish Flu could lead to another pandemic if it were placed in the wrong hands, one that could spread far more rapidly than its predecessor. Nonetheless, this kind of

research can have highly beneficial aspects to them, though many others that pursue important information instead uncover troubling facts (8).

In New York, a “live” polio virus was constructed using the RNA map of the virus and stitched together pieces of the corresponding genes, which was then able to infect and kill mice (8, 9). Since all the materials they used to create this were obtained by mail order, this is very disturbing information (8).

This is the dual-use dilemma, where a beneficial scientific discovery is used as a weapon and frankly, the response to the problems it presents has been pretty subdued. Some publications, like *Science*, have decided to screen out publications that they would deem more damaging than beneficial. The National Science Advisory Board for Biosecurity (NSABB) was created in 2004 to deal with this issue, but all it really does is rely on the scientific community to weed out situations in which

ensorship is necessary, leading to a strictly voluntary censorship.

There have been calls for certain papers to not include at least the materials and methods pages, but the counter argument that these are necessary for replication and verification of the experiment still takes precedence (8). The question becomes how to increase security while limiting the least amount of academic freedom and scientific progress (9).

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"Outsourced" Clinical Trials: An Ethics Minefield

Chandana Thorat

One third of Phase III trials for US based companies are conducted outside the United States, typically in developing countries (1). These sites are preferred due to the genetically diverse population, large numbers of patients, and a drastically reduced cost of conducting clinical research. Additionally, lax laws and regulatory policies in foreign countries make these places ideal for conducting trials.

The global outsourcing of clinical trials raises many ethical issues. Participants' rights may be compromised due to a wide disparity in education, economic and social standing, and health care systems (1). In 2005, five women from Cameroon became infected with HIV after participating in a trial for anti-HIV drug Tenofovir by

Gilead Sciences. NGOs claimed that because only English information was given to mostly French speaking volunteers, the participants were not adequately informed about the trial's risks (2).

During trials for the drug Nevarapine (Boehringer Ingelheim) in Uganda, 2003, officials did not obtain patients' consent for changes in experiments and administered doses that were not previously reviewed or approved. Lax policies allow improper record keeping, delays, and underreporting of potentially fatal conditions to persist. Thus, it is no surprise that 14 deaths in the Uganda trial were never reported (2). Another recent study explains that from 2006-2008, 49 babies died in clinical trials in All India Institute of Medical Sciences

(AIIMS), India despite approval from the AIIMS ethics committee and the federal Health Ministry (3).

Issues concerning outsourcing of trials need to be addressed. Would these same trials be allowed in wealthier, more developed countries, and would the same ethically problematic results occur? (1). Also we know why off-shore trials are attractive for drug companies, yet what are benefits for these off-shore trial participants? Should big pharma be responsible for this seemingly irresponsible and apathetic behavior? Dialogue between the academia, industry and regulatory agencies around the world will help develop long term solutions for these problems (1).



<http://www.ngpharma.com/article/Building-Relationships-Around-the-Globe/>

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Corporate Ethics in Pharmaceutical Companies

Sri Ramya Maddilate

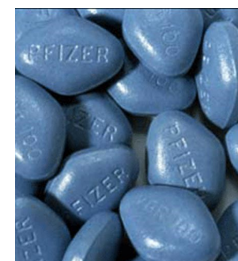
Recently, Merck created a phony peer reviewed medical journal article with Elsevier publications. Merck paid an undisclosed amount to Elsevier to publish plagiarized data that supported the efficacy of Merck's drug Vioxx. Vioxx has resulted in serious health complications among patients who used it (1). If the company viewed patient safety as its primary concern, it would not have taken such an extreme measure to prove the drug's efficacy.

Companies like Pfizer, Monsanto, etc. are involved in many ethical controversies. Monsanto's code of conduct

clearly states that it must comply with applicable laws, rules and regulations of federal, state, provincial and local governments, and other appropriate private and public regulatory agencies. Pfizer - the world's largest pharmaceutical company -has a code of conduct which is famously known as "the blue book," which cites patient safety as their number one priority. Pfizer must work diligently to understand their products' safety and tolerability in order to provide high quality information on risk and benefits to both patients and medical professionals around the world (3).

In the "Kano" controversy, Pfizer deviated from its code of conduct, resulting in detrimental effects for patients. Pfizer tested the experimental antibiotic Trovan in Kano, Nigeria, during an outbreak of meningitis that affected thousands in 1996. Among 200 children who were tested, Pfizer says 11 died of meningitis, but Kano officials say about 50 died whilst others developed mental and physical deformities from Trovan antibiotic (4).

In retrospect, it is evident that these life science companies are violating corporate bioethics. But how unethical can a company become to an-



nex profits? How many companies are strictly following their corporate ethical code of conduct? It is the job of each and every employee, researcher, and bioethicist to ensure that these companies strictly comply with their corporate code of conduct. As future industry people, we must ensure that companies implement stringent ethical decision making and focus more on patient benefits rather than corporate profits. This should definitely be on top of our "things to learn at KGI" list.

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Wordsearch

Rachelle Fryd



ANSWERS from Last Edition's Crossword Puzzle

DOWN: 1. Golden Rule, 2. View, 4. Kindness, 5. Statute, 7. Judgement [sic], 8. Violin, 9. Violations, 13. Honesty

ACROSS: 3. Keck, 6. Yao, 10. Justice, 11. Conscience, 12. Law, 14. Conduct, 15. Unity, 16. Claremont, 17. Ethics

1. ...reconstruct the genome of a deadly virus like the _____ flu...
2. In New York, a "live" polio virus was constructed using the _____ map of the virus...
3. The _____ dilemma: ethics in research.
4. National Science Advisory Board
5. A set of ethical principles issued by the World Medical Association
6. International Council for Harmonization
7. The global outsourcing of _____ has raised many ethical issues
8. _____ claimed that the participants were not adequately informed about the risks and only English information was given to mostly French speaking volunteers.
9. The _____ gives strict guidelines to every pharmaceutical and biotechnology company....
10. ...their use in the testing of potentially _____ treatments and drugs has had mixed responses.
11. French philosopher that says, "I think, therefore I am."
12. What do _____ mean for you?
13. I do know that each of us needs to _____ some of these ethics...
14. _____ ethics in pharmaceutical companies
15. _____ says 11 of them died of meningitis.
16. It's no surprise that firms in the _____ often face ethical issues that go beyond the typical business ethics topics found in other industries
17. Number one ethical concern.

Note from the Editor

Be sure to participate in the "Are the Ethics Ethical" survey—results will be announced in the next issue. Would you like to write for us? Do you have comments, corrections, questions, or concerns? Email mpesce11@kgi.edu.

- Michelle Pesce, editor, MBS '11

What Do Ethics Mean to You?

Ian Foti-Landis

What do ethics mean for you? For me, ethics are internalized, non-coercive guidelines to maintain order and protect the rights of the members within a group. There are many different organizations which we are members of: family, school, jobs, cities, and they all have different ethical systems to work within.

Right now I'm a student at Keck Graduate Institute and the accepted ethical code of conduct here is the KGI honor code. In KGI the ethics apply more to the proper citation of work, submitting your own work and only taking credit for what you have completed on your own. I understand the gist, but the only problem is the details. What are the details? I'm not really sure myself, the nuances are a bit vague, but I can tell you the overarching idea is "don't cheat." Simple,

as long as your definition of "cheating" matches mine. Is helping a teammate on a homework assignment a violation of the honor code? If I ask for clarification of an important concept on a take-home exam which helps me understand a question I normally wouldn't, but doesn't provide me with an answer—is this a violation? And what about just discussing an article for class with someone and using their idea as a launching point for a paper? Does the honor code provide me with the necessary rules and nuances of ethics which will help me navigate the ethical paths of a career, or does it simply walk me gently by the hand through ethical dilemmas, never allowing me make the tough decisions myself? I don't know.

I do know that each of us needs to internalize some of these ethics which

are stressed in school. That's the whole point right? To make sure that we learn certain lessons and can apply them in the workplace. We are in school where learning the ethical paths and options available is also something to learn and apply. I can't help but feel though that it's been stressed to me enough at this point the importance of ethics and acting ethically, especially within the academic or industry sphere. Once the initial requirements of what we should and should not do are outlined, it's really up to each of us to determine the best way to work within these requirements and to bridge the different ethical environments we live in. I think this idea should be the main focus of the honor code, and that it's our task to decide if it achieves that.