

Establishing an Operation Model for Biotechnology Regulation

Chun-Ying Wu, M.D., M.P.H., LL.B

Harvard Law School

Address for Correspondence:

Chun-Ying Wu, M.D., M.P.H., LL.B.,

PhD candidate of National Taiwan University

LL.M. candidate 2003 of Harvard Law School.

375A Harvard Street, 23A

Cambridge, MA 02138

E-mail: dr_taiwan@hotmail.com

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ABSTRACT

In contrast to the rapid pace of biotechnology advancement, biotechnology regulations are trapped in the dilemma between the utility of biotechnology and the protection of human dignity. When human beings are not only the subjects, but also the objects of policy debates, the ideologies behind these arguments become more difficult to settle. Traditional legal arguments seem not quite helpful in providing resolutions. Sometimes, they increase the chaos of communication between the proponents and the opponents.

This article is trying to establish a more objective model for biotechnology policymaking. This model is developed to provide a method to enable the biotechnology policymakers to take abstractive ideas about the relationships between utility and socio-ethical concerns and put them in a form they can visualize and communicate. Graphs are used to demonstrate arguments and ideas underlying what happen in the real world. The different opinion groups will be easier to communicate with each other and find the most controversial points to solve the disputes.

The basic assumptions, operations, applications and also the limitations of this model have been introduced. This model is helpful in comparing different biotechnologies, comparing different groups' opinions, choosing optimal regulation policy, and also explaining the effect of federal funding for biotechnologies. This model is only a prototype; further development into a more sophisticated or even quantitative model is desirable in the future.

INTRODUCTION:

As early as 1976, scientists had suggested that “objective, scientific techniques – instead of the present anecdotal approach – can be used to design and justify a national biomedical research policy.”³ In the past three decades, the biomedical science has developed with a magnificent speed; however, the traditional policy argument methods are still used in the biotechnology policymaking process.

From euthanasia, abortion, assisted reproductive technology, to recombinant DNA technology, stem cell research and human cloning, the rapid progress of biomedical sciences has led to ethical, legal and social concerns worldwide. The newly developed biotechnologies have shown their capacity to modify, manipulate, or even create organisms, including human beings. Creating a livestock with human genes to produce specific human proteins is no longer astonishing.⁵ To harvest histocompatible organs or tissues from genetic modified creatures for transplantation will become possible in the near future.⁸ The rapid development of biotechnology provides more effective and fascinating therapy for hundreds of thousands of patients; however, the possible threat to human dignity and social values also leads to uneasiness and anxiety. These Kantian concerns advocate a stricter regulation or even total prohibition whenever powerful biotechnologies emerge.¹¹ However, a more conservative regulation probably prohibits the development of these promising biotechnologies and decreases their utility.

Many articles have discussed the conflicts between utilitarian and socio-ethical concerns in the regulation policy about biotechnologies, but the traditional policy argument methods are relatively subjective and sometimes just a translation of ideology.⁷ Actually, the “social values – rights, morality, utility – to which policy argument appeals are the very stuff of the universalization projects of ideological

intelligentsias.”⁷ These policy arguments do not solve the dilemmas in the biotechnology regulation. On the contrary, they increase the chaos of communication between the proponents and the opponents of the biotechnologies.

This article is trying to establish a more objective model for biotechnology policymaking. This model is developed to provide a method to enable the biotechnology policymakers to take abstractive ideas about the relationships between utility and socio-ethical concerns and put them in a form they can visualize and remember. Graphs are used to demonstrate arguments and ideas underlying what happen in the real world. The proponents and opponents will be easier to communicate and find the most controversial points to solve the disputes.

THE DILEMMAS IN BIOTECHNOLOGY POLICY ARGUMENTS

Dilemma among policy argument is a common phenomenon, but it is more complicated and more difficult to figure out in biotechnology policy. In contrast to other policy arguments, human beings are not only the subjects of the policy, but also the policy objects.⁹ Human right and internalized social norms decide the policy, but also determined by the policy. This circular situation makes the choice between the priority of human right and the priority of utility becomes much more difficult.

If we choose the utility-priority normative approach, we have no standpoint to prohibit or limit the development of biotechnology because of its valuable utility. Under this concept, every person has freedom and autonomy to pursue their benefits through exploitation of new biotechnologies.⁹ Organ market should be justified because they are efficient to allocate the resources. Genetic modified organisms should be highly appreciated because of their significant economic benefits. Somatic

cell nuclear transfer (SCNT) technology should be encouraged because it provides promising regenerative therapy.

In the non-utilitarian side, I choose the concept of deontology to represent this perspective.¹ With this Kantian concern, human rights should be respected independent of utilitarian consideration.¹⁰ No human being should be treated as a measure. If a scientific research probably results in any injury to human subjects, it cannot be justified unless the research is for the benefits of that person and the benefits outweigh the risks.⁴ According to this philosophy, many biotechnologies are totally unacceptable. Organ market is not ethical because no part of the body can be treated as a good. Germ line manipulation and human cloning are not morally acceptable because no embryos should be used as a measure.

Our social values do not accept the extreme utilitarian ideas about the application of biotechnologies. On the other hand, it is also impractical to impose the extreme deontology philosophy on the development of biotechnologies. To get a balance between these two ends, an operation model has been developed to regulate biotechnology.

ESTABLISHING AN OPERATION MODEL FOR BIOTECHNOLOGY REGULATION:

This model is developed to provide a method to enable the biotechnology policymakers to take abstractive ideas about the relationships between utility and socio-ethical concerns and put them in a form they can visualize and remember. This prototype model is trying to use graphs to represent the conceptual relationships between utility and socio-ethical concerns to find an optimal regulation policy.

Biotechnology policymakers can use these to demonstrate their arguments and ideas underlying what happen in the real world. The proponents and opponents will be easier to communicate and find the most controversial points to solve the disputes.

A) Basic assumptions:

This model is established on three assumptions. The first assumption is that increased utility justifies a looser regulation. Utility is defined as the total welfare of the society. If a biotechnology can achieve a higher level of preference and interest for the society, the utility is higher. Without the consideration of socio-ethical concerns, we suggest that a good regulatory policy should be more liberal to a more useful biotechnology and more conservative to a less useful biotechnology. Based on the utilitarianism viewpoint, it is an efficient way to impose fewer restrictions on the more useful biotechnologies to pursue the highest total social benefits.

The second assumption is that increased socio-ethical concerns will ask for a stricter regulation. The socio-ethical concerns are considered in many ways, including the possible threats to human dignity, social relationship, parenthood, environment, ecosystem, etc. The change of socio-ethical concerns is associated, but independent from the change of utility of biotechnologies. No matter how useful a biotechnology it is, once the socio-ethical concerns are elevated, the society tends to restrain the use of that technology until the concerns are relieved.

With the advancement of biotechnology, utility is frequently increased, but it is not always the case. Many biotechnologies increase the utility, but some biotechnologies might decrease the welfare of the society. The socio-ethical concerns are related, but independent with the advancement of biotechnology. The newly developed biotechnologies might increase socio-ethical concerns because of uncertainties. In contrast, many biotechnology advancements lessen the tension by

proving improved safety or efficacy. As we have mentioned above, the change of utility or socio-ethical concerns by biotechnology advancement will influence the attitudes of regulation. And it is the third assumption that the optimal regulatory policy is the balance point when the utility and socio-ethical concerns meet together. The balance point is supposed to be the intermediate most acceptable for both utilitarian and socio-ethical concerns.

B) Compositions of the model:

In this operation model, the X-axis is the utility of biotechnologies. Utility is defined as the total welfare of the society. The calculation of utility is morally neutral. And the utility of the society might not be compatible with the individual's interest or preference. If a biotechnology can achieve a higher level of preference and interest for the society, the utility is higher and it will move toward right-hand side in the X-axis (Figure 1).

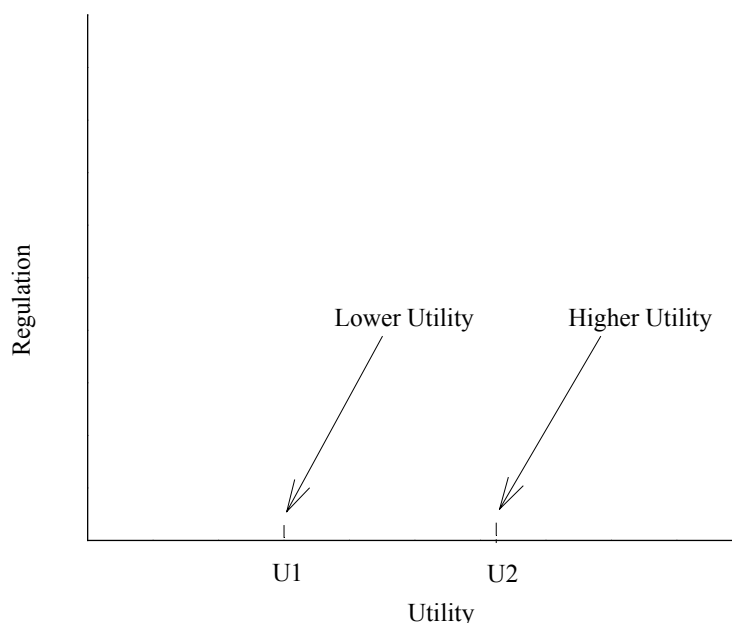


Figure 1. The utility is higher when it moves toward right-hand side along X axis

The Y-axis is the regulatory policy. It ranges from the complete laissez-faire

without any regulation (lower end) to absolute prohibition (upper end). This regulatory policy is calculated based on the amount of prohibition imposed on biotechnology; it does not matter whether the biotechnology will benefit or endanger our society. When we move toward the upper end of the Y-axis, we will impose more regulations on biotechnology (Figure 2).

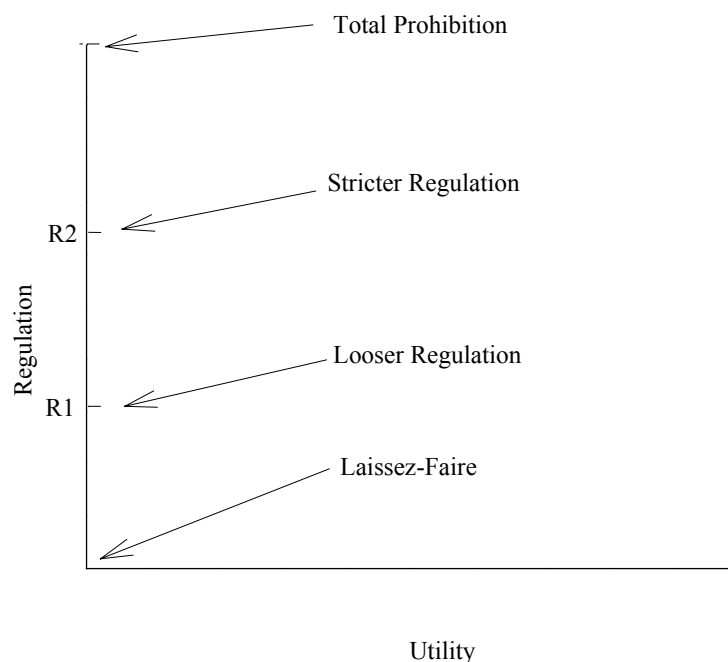


Figure 2. The regulation is stricter when it moves toward upside along Y axis

The C line stands for socio-ethical concerns. According to our first assumption, increased utility justifies a looser regulation. When the socio-ethical concerns are not changed, there exists a negative interaction between utility and regulation. Therefore, we can plot the C line that all points on the C line stand for the same socio-ethical concerns (Figure 3).

The coordinates on X-axis and Y-axis of every point on the C line represent the optimal regulation (Y coordinate) for that level of utility (X coordinate) in the certain socio-ethical concerns (C line). For example, the optimal regulation is R1 for the biotechnology with U1 utility. When the utility is improved by biotechnology

advancement and the utility level moves from U_1 to U_2 , the optimal regulation should be reduced from R_1 to R_2 (Figure 4).

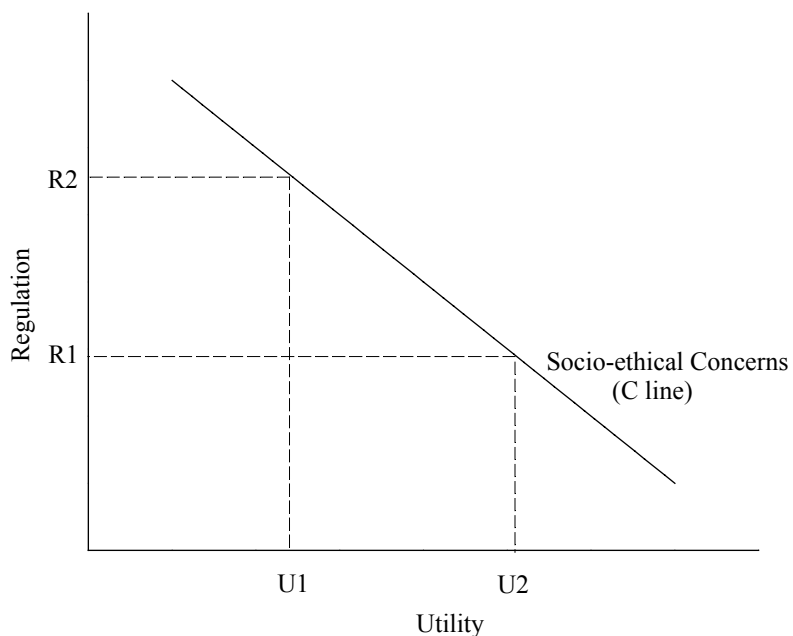


Figure 3. With same socio-ethical concerns, there exists a negative interaction between utility and regulation

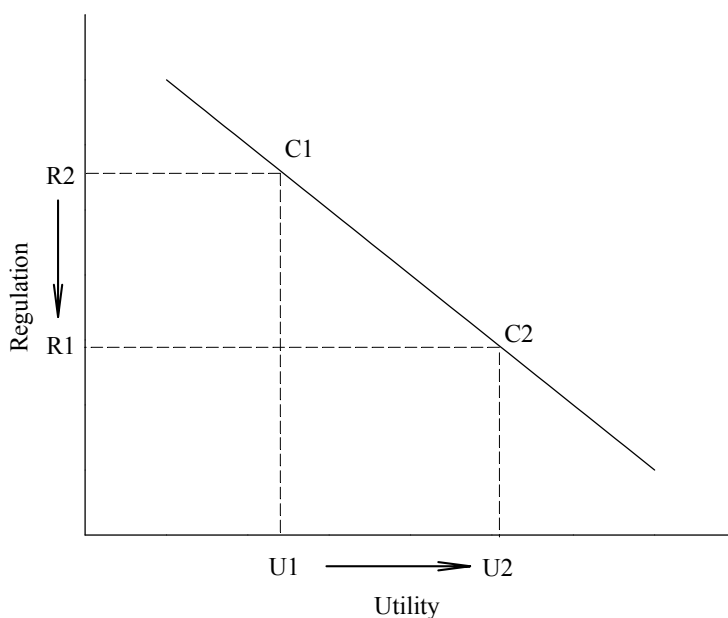


Figure 4. With the same socio-ethical concerns, a looser regulation is justified if utility improved by biotechnology

The C line is not static; it can move toward right-hand side or left-hand side. According to our second assumption, increased socio-ethical concerns will ask for a stricter regulation. With the same utility level, the C line will move toward right-hand side when the socio-ethical concerns are elevated and the C line will move toward left-hand side when the socio-ethical concerns decrease. In Figure 5, the elevated socio-ethical concerns shift the C line from C1 to C2. If the utility does not change, the optimal regulation will shift from R1 to R2. It is compatible with our second assumption that increased socio-ethical concerns will ask for a stricter regulation.

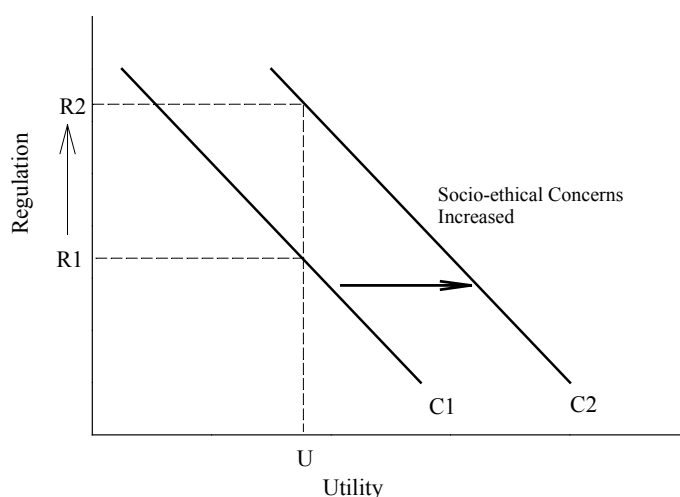


Figure 5. The elevated socio-ethical concerns will increase optimal regulation, if utility does not change

C) Basic operations of model:

1) Regulatory policy influences biotechnology advancement:

As we have discussed before, change of utility and socio-ethical concerns will shift the regulatory policy. On the other hand, regulatory policy changes will influence the utility. A more liberal regulation will encourage the biotechnology industry to

develop and apply the technologies in more aspects and the utility has more chance to increase. In contrast, a more conservative regulation will deter the progress of biomedical science and limit the application of biotechnologies. In Figure 6, I suppose that socio-ethical concerns are fixed in a certain society. When we shift the regulatory policy from an optimal regulation point (R1) to a more liberal attitude (R2), we will create a “utility gap” between U1 and U2. Utility gap is the amount between current utility status and permitted utility status. A reduced regulation will encourage the biotechnology industry to fill up the biotechnology gap. In contrast, a stricter regulation (moving from R1 to R3) will deter the biotechnology utility (moving from U1 to U3) (Figure 7). The interval between U1 and U3 is called “utility waste.” Utility waste is the amount that current biotechnology has the ability to do, but not permitted to do. A stricter regulation will increase a larger biotechnology waste.

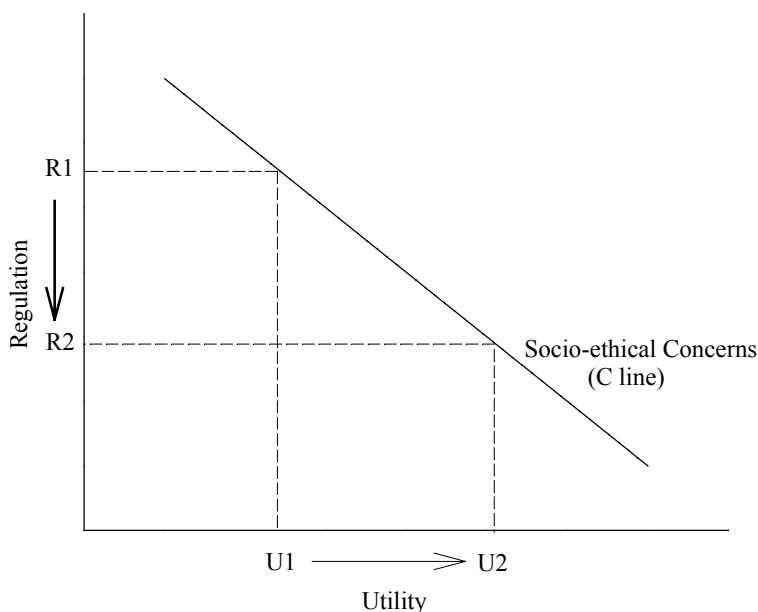


Figure 6. When the government shifts from the original regulation (R1) to a more liberal regulation (R2), a "utility gap" between U1 and U2 will be created.

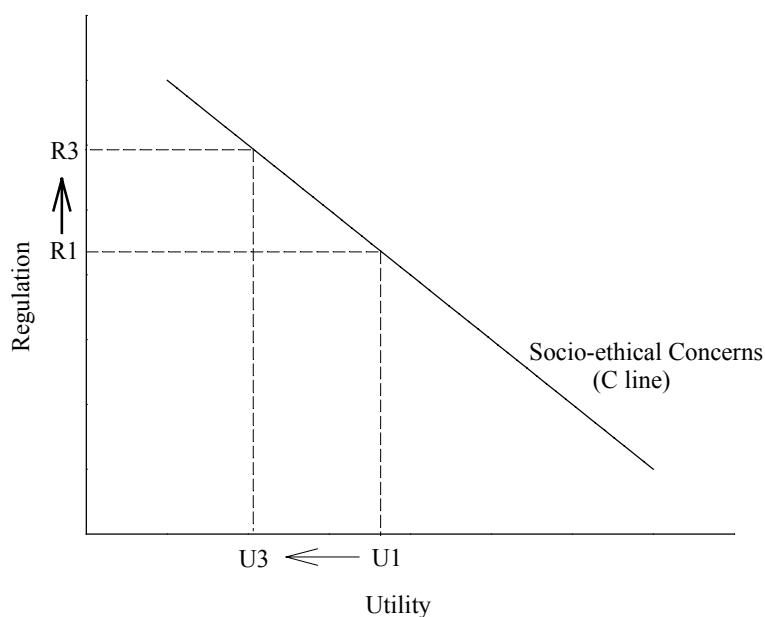


Figure 7. When the government shifts from the original regulation (R1) to a stricter regulation (R3), a "utility waste" between U1 and U3 will be created.

2) The elasticity of regulation:

Up until now, we have observed that when the regulatory policy changes it will cause a shift in the utility of biotechnologies. A movement along the socio-ethical concerns curve represents this. Here we will consider another application of this model: the concept of elasticity of regulation. This concept will help explain why the utility shift responses to regulation changes vary for different biotechnologies.

Biotechnology policymakers realize the inverse relationship between regulation and biotechnology utility. They are aware that, on average, the utility of biotechnology will increase if they choose a looser regulation and vice versa. The interesting issue is whether the regulatory policy changes lead to different effects in different biotechnologies? The measure of the responsiveness of utility shift to the regulatory policy change is called the "regulatory elasticity of utility." Regulatory elasticity of utility (REU) is defined as the ratio of the change in utility to the change of regulation, i.e.

3) Socio-ethical concerns change independently:

In the real world, socio-ethical concerns always change, sometimes much faster than the change of utility. The socio-ethical concerns change can happen independently without the advancement of biotechnology. Some episodic events can lead to dramatic change of socio-ethical concerns. In 1998, Chicago physicist Richard Seed announced that he was going to open a human cloning clinic for infertility couples.⁶ In the end of 2002, the Clonaid Company announced that it has successfully cloned the first human baby, Eva.² Although these announcements lack scientific evidence to support their ability to do human cloning, they became headline news and attracted worldwide attention. The socio-ethical concerns elevated suddenly and significantly in a short period. In response to these elevated socio-ethical concerns, the House passed the bills to prohibit SCNT technology absolutely. This phenomenon can be demonstrated in Figure 9.

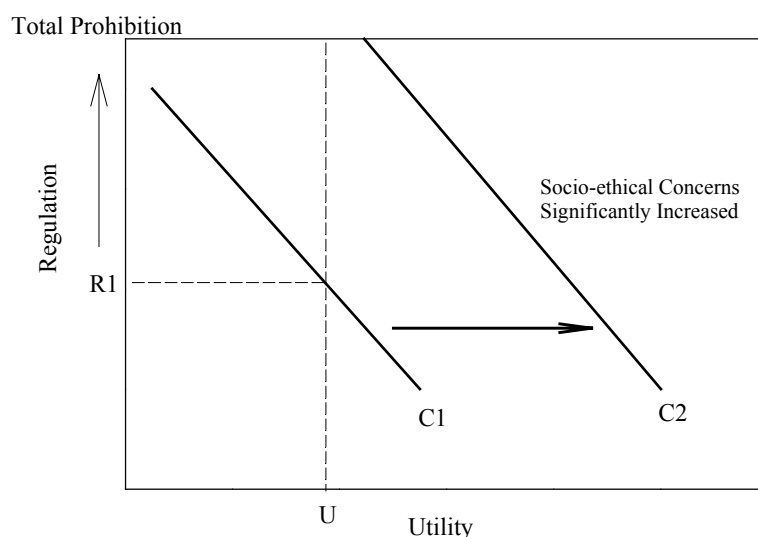


Figure 9. The significantly elevated socio-ethical concerns shift the regulation to total prohibition

In contrast to the suddenly elevated socio-ethical concerns by episodic event, the

society sometimes become used to the existing biotechnologies and accept them gradually. In this situation, socio-ethical concerns will decrease gradually and a more liberal regulation is desirable.

4) The regulation fluctuation index (RFI):

REU is used to describe the relative response of utility to the change of regulation. However, different biotechnologies have different speed of development. A rapid progress biotechnology certainly will lead to a much faster change of utility as well as socio-ethical concerns in the society. In such a case, we can expect more requirements for regulation change. If a newly developed biotechnology dramatically increases the socio-ethical concerns at the initial stage, the society definitely will ask to increase regulation. With its rapid progress, this biotechnology shortly proves its high utility. Then it becomes much more acceptable for the society to regulate this biotechnology with a more liberal attitude. The fluctuation for regulation requirement from the initial stage to the later phase in a certain time is called “regulation fluctuation index (RFI).”

$$RFI = (\text{fluctuation for regulation requirement}) / \text{time}$$

In Figure 10, the regulation requirement is shifted from R1 to R2 because of the significantly elevated socio-ethical concerns in the initial stage of certain kind of biotechnology development. The biotechnology proves its utility later and the regulation is justified to a looser regulation (R3).

A biotechnology with a higher fluctuation for regulation requirement means that the attitudes for regulation will change dramatically in a short time. In such a case, a rigid regulation, such as statutes or jurisdiction, is not a good choice to regulate this

biotechnology. A soft regulation regime is more practical.

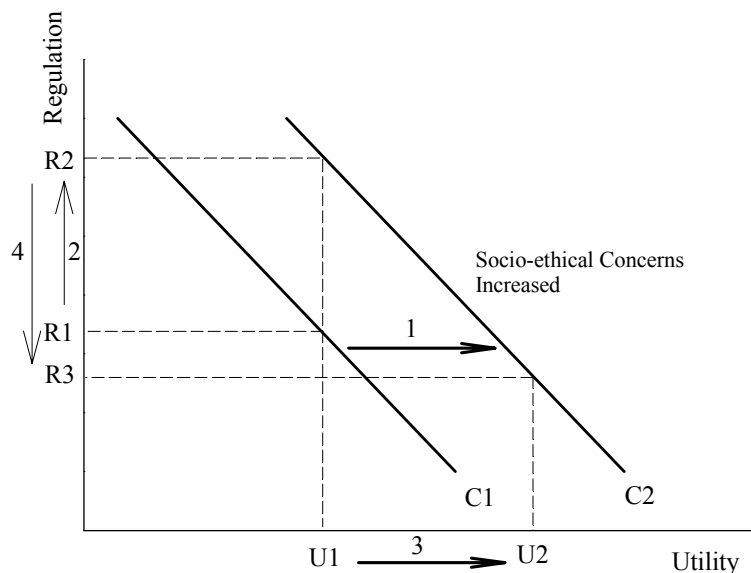


Figure 10. The regulation requirement is fluctuated with the elevated socio-ethical concerns and utility

D) Apply the model in real cases:

After introducing the basic operations of this model, we would like to apply this model in real cases to test how this model works in the actual situations. We illustrate this model by using researches involving human embryos as examples.

1) Comparing different biotechnologies

For convenience, we divide the researches involving human embryos into three classifications: infertility research, stem cell research and reproductive cloning research. We apply the model to compare these three kinds of researches. To plot the graphs, we must make some priority arrangement about the utility and socio-ethical concerns of these researches. This priority arrangement is a temporal judgment here. We will have more discussion about the priority arrangement in later section. We

suppose the reproductive cloning research leads to highest socio-ethical concerns, followed by stem cell research, then infertility study. The utility is highest in infertility research, followed by stem cell research, then reproductive cloning research.

If we agree temporally with the current judgment, we can plot the C lines for these three kinds of research and find the optimal regulations respectively (Figure 11). We can observe that reproductive cloning research is justified for the strictest regulation because of its lowest utility and highest socio-ethical concerns. In contrast, the infertility research is most acceptable with its highest utility and lowest socio-ethical concerns.

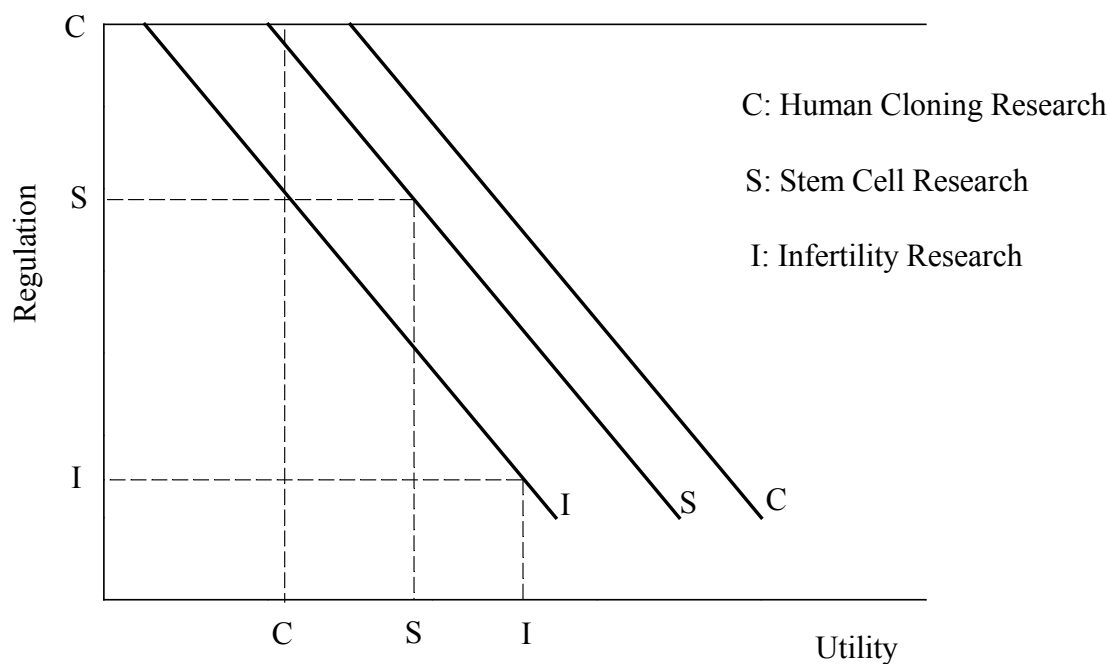


Figure 11: The different levels of socio-ethical concerns and utility decide the regulation

2) Comparing different groups' opinions

As we have mentioned in the above section, the arrangement of priority might

not be agreed among different populations. For instance, the religious group might argue that the socio-ethical concerns for stem cell research are as high as the reproductive cloning research because both of them use human embryos only for research, not for the benefit of embryos themselves (Figure 12). And the scientists doing the stem cell researches might advocate that the utility of stem cell research should be much higher than the infertility study because stem cell research is very promising in curing a wide range of diseases (Figure 13).

Using these graphs, we can compare the different opinions about the researches involving human embryos with a more objective and straightforward way. This model provides the proponents and opponents to communicate more efficiently.

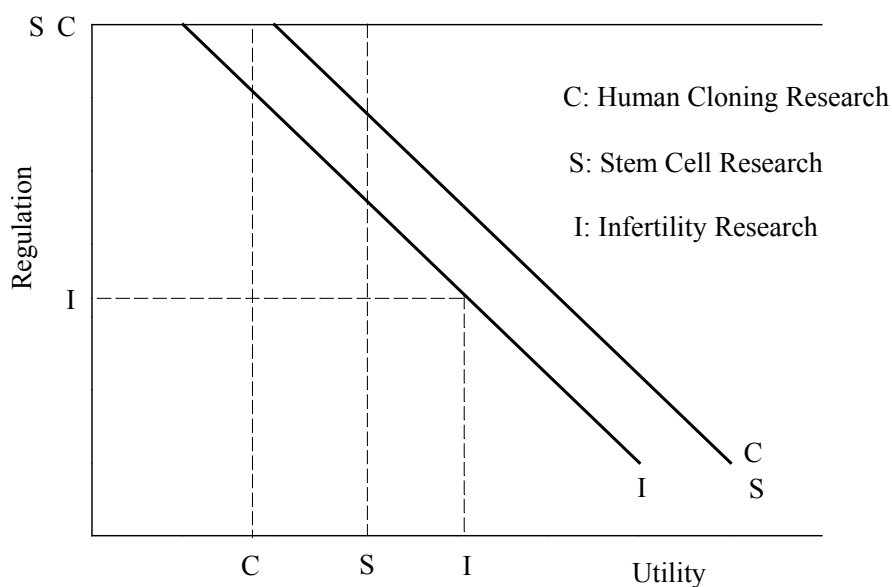


Figure 12: The Comparison by Religious Groups

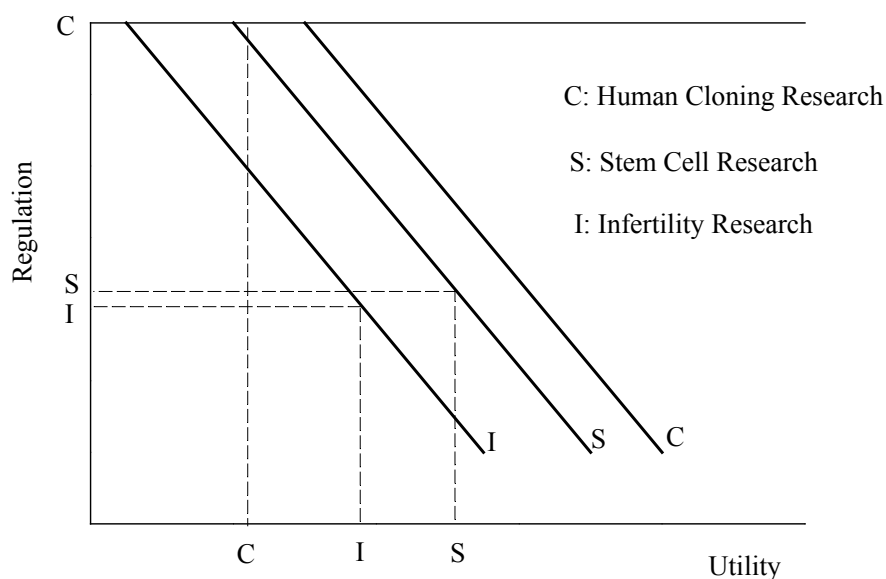


Figure 13: The Comparison by Scientists

3) Choosing the optimal regulation:

This model is developed not only to give a more clear description of the conflicts between utility and socio-ethical concerns, but also to provide a means to find the optimal regulation regimes. Let's take the human embryos research for example again. Among the three types of human embryos research, stem cell research has the highest regulation fluctuation index (RFI) because it dramatically increases the socio-ethical concerns at the initial stage and it is the most promising technology to prove its utility in the later phase. As we have discussed in the RFI section, a soft regulation regime will be more suitable for stem cell research. It is unwise to prohibit the stem cell research at this moment because it will inhibit the chance for stem cell technology to prove its utility.

4) The effect of federal funding:

This model is also useful in providing another interesting explanation about the

effects of federal funding. Traditionally, the federal government is more likely to provide funding for basic biomedical research than the applied biomedical research because the applied biomedical research is much easier to find niches to recruit private firms to invest the research. In contrast, the basic biomedical research is less attractive for the private investors because it costs a lot of money and probably does not lead to any reward. However, many basic biomedical researches have been proved to be very important in the future. Government funding plays an essential role in providing the financial support for these basic biomedical researches.

When federal government agrees to provide funding for a certain kind of biotechnologies, it means that federal government has believed that this biotechnology is not against the consensus of the public. And a higher regulatory requirement is also justified for the institutes that receive the federal funding.

In Figure 14, we suppose that federal funding elevates the regulation from R1 to R2. This regulation change has different effects for different biotechnologies.

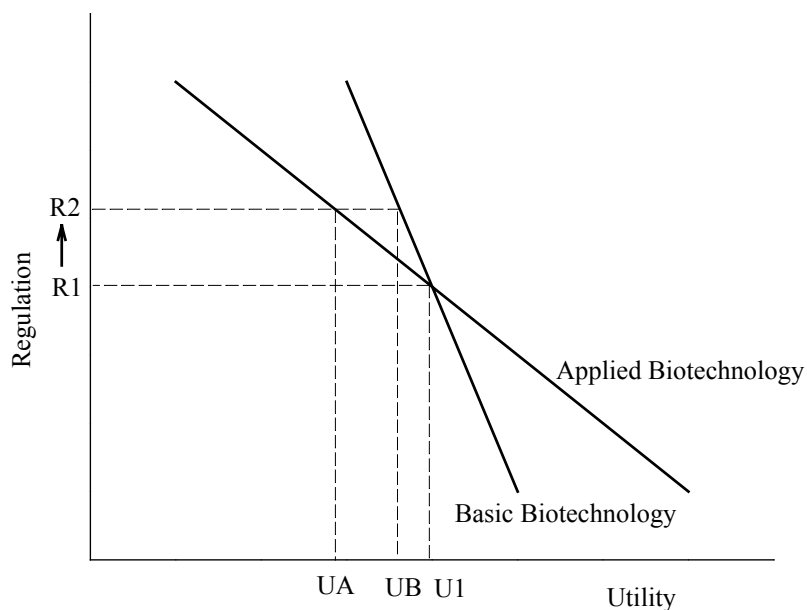


Figure 14. Federal funding has different effects for applied and basic biotechnologies

The biotechnologies with higher regulation elasticity of utility (REU) will suffer from more utility waste than the lower REU biotechnologies. As we have discussed in the section of REU, applied biomedical science has a higher REU and the utility waste will be higher after receiving government funding because of the stricter regulation. In contrast, the basic biomedical science will have limited utility waste after receiving government funding. Therefore, government funding is more important for basic biomedical science because it provides essential financial support and leads to limited utility waste. In contrast, government funding is less welcome for applied biomedical science.

E) Limitations of this model:

There are several limitations in applying this model. First, this model is only a prototype, more concrete data from systemic collection to verify the accuracy is necessary. Further development into a more sophisticated model is desirable in the future. Some might challenge the practicability of this model because it is impossible to get consensus for the highly debated biotechnologies. Actually, this model is not designed to solve the disputes directly; it is developed to provide a more convenient way for the proponents and opponents to communicate and find the most controversial points to solve the disputes.

Second, this model is developed to be an operation model. However, we only perform conceptual analyses here. It is an ideal to develop this model into a quantitative model to provide the policymaker more definite conclusions. Actually, we can easily and quickly understand the different opinions among different groups by conducting public opinion polls. And it will be more convenient for the policymakers to find the most controversial points to fill the gap.

Third, some might argue how can we define the time frames for utility and socio-ethical concerns? Should we use the short-term, medium-term, or long-term time frames to calculate? Different biotechnologies have different process pace, how long should we wait for the biotechnology to prove its utility or change the socio-ethical concerns? This argument is actually difficult to answer. However, this model can be easily used to demonstrate the possible changes of utility as well as socio-ethical concerns in the short-term, medium-term, and long-term time frames. Compared with traditional legal argument methods, this model provides a relatively concise and clear viewpoint.

CONCLUSION

When the biomedical science develops with a faster and faster speed, the fierce debates on the utility and socio-ethical concerns of biomedical science will never end. When these issues gradually become everyday headline news, we wish this new model could provide another alternative method for policymakers to communicate with each other in an efficient and concise way. This model is only a prototype; further development into a more sophisticated or even quantitative model is desirable in the future.

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