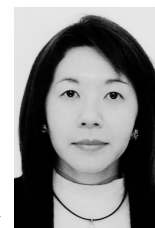


The Current Argument between Scientists and Government for Science and Technology Policy in U.S.



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1 Introduction

Science and technology are important keys if Japan is to be able to overcome the various problems it faces and open up new visions for the future. In other words, Japan must promote science and technology and appropriately surmount the issues it faces by actively developing the comprehensive policies shown in the Science and Technology Basic Plan along with concrete measures based on those policies. Not only in science and technology, but throughout society, Japan must stimulate the formation of a base for scientific, rational, and independent judgment on social issues. For example, it is necessary to understand the mechanisms by which disease and disasters occur and their influence spreads and to prepare countermeasures. Science and technology provide means to do so. At the same time, science and technology also have negative aspects, and we must remember to carry out appropriate measures in response to those aspects^[1]. “Regulatory science” is often used for scientific research regarding such risks.

In 1987, Dr. Uchiyama (Emeritus Director General of the National Institute of Health Sciences) advocated regulatory science mainly for pharmaceuticals and foods as “a science that works out methods to more accurately understand the origins and facts surrounding the substances and phenomena that surround us. It then predicts and evaluates effectiveness

(advantages) and safety (disadvantages) and contributes to national health through government administration”^[2].

In Europe and USA, the term was first used in a 1972 paper by the physicist Alvin Weinberg. He used it to refer to those problems that modern society can use science to address but that cannot be solved by science alone. In other words, he used it to refer to the science that handles issues such as the establishment of safety standards and other safety regulations. However, he mentioned only indicating the problem^[3]. Subsequently, in her 1987 paper entitled “Contested Boundaries in Policy-Relevant Science,” Sheila Jasanoff of the United States attempted to analyze the scientific bases of policies carried out by US regulatory agencies from a social constructionist perspective^{*1}. According to this article, regulatory agencies sometimes determine policy based on science in which cause and effect relationships are not necessarily clear. In other words, the paper made it clear that even statements that at first glance appear to be scientific are not always entirely so. Political and economic agendas may also be involved, and the boundaries between politics and science in regulatory science are always in motion^[4]. In particular, such regulatory science is widely used on issues that cannot be resolved by science alone, such as climate change and renewable energy, embryonic stem cell research, and education (e.g., evolution).

In this article, I will describe some recent cases where regulatory science is disputed by scientists and policymakers in the United States.

2 The regulatory system and the proposed draft peer review new standards by OMB in U.S.

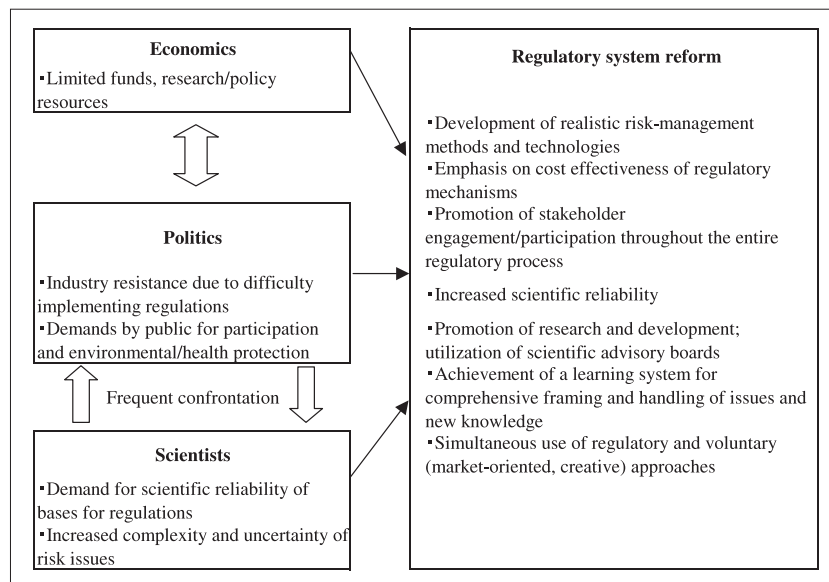
2-1 The regulatory system and organizations for in setting regulations

In general, regulatory systems are debated against the background shown in Figure 1^[5].

In 1993, the United States Congress enacted the Government Performance and Results Act of 1993 (GPRA). Under that law, for all programs they intend to carry out, all US Federal Government

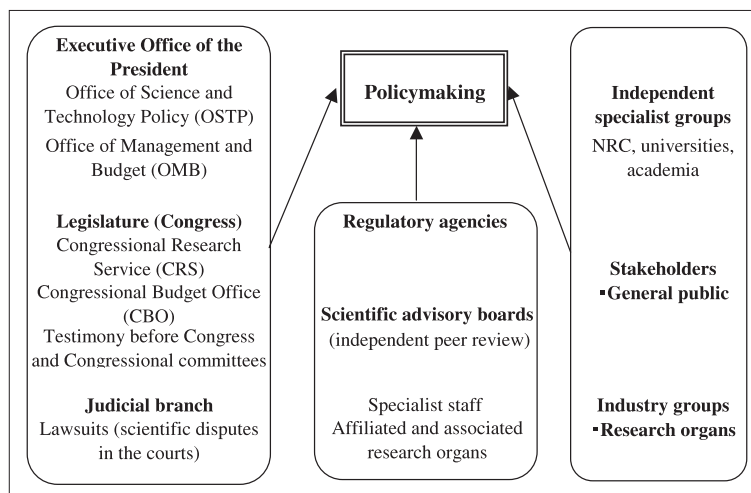
agencies are required to establish purposes, goals to be achieved, and indicator measurements, and to explain their results. In other words, the GPRA required that policies that should be implemented under the limited budget available be prioritized and their results be clarified. In the United States, enactment of the GPRA has meant the adoption of full-fledged administrative review within the Federal Government. In each agency, policymaking, work methods, and results are systematically evaluated^[6]. Organizations currently involved in US regulatory policy are shown in Figure 2.

Figure 1 : Overview of regulatory system



Created based on reference materials of the Second Meeting of the Subcommittee on Management of Genetically-Modified Organisms, Ministry of Economy, Trade and Industry, November 21, 2001.

Figure 2 : Organizations involved with regulatory policy in the US



Created based on reference materials of the Second Meeting of the Subcommittee on Management of Genetically-Modified Organisms, Ministry of Economy, Trade and Industry, November 21, 2001.

2-2 *The proposed draft peer review new standards by OMB*

In August 2003, the Office of Management and Budget (OMB) in White House released its proposed “draft peer review standards for regulatory science^[7].” The standards are intended to improve the quality, purposes, realism, and fairness of peer review when public funds are invested in research related to regulations carried out by the Federal Government. To be implemented by the OMB along with the Office of Science and Technology Policy (OSTP), the standards are positioned as new guidance for the distribution of important scientific knowledge. They would be applied to all scientific/technical research related to regulatory policy. For environmental and health warnings and all other research that will influence government regulations, the standards would introduce thorough peer review by neutral scientists in the same field. In particular, in the case of information significant to regulations, the proposed standards would require peer reviewers unconnected with the government agency having jurisdiction. In addition, specialists who receive funding from the government agency concerned and who have performed multiple peer reviews in recent years for that agency or one peer review on the same specific matter in recent years would not be eligible to be peer reviewers.

2-3 *Current status of “peer review” of research and development support in the United States*

Ordinarily, US government agencies (DARPA, NSF, DOE, NASA, etc.) utilize two selection methods, “peer review” and “program management,” in their R&D support programs. Peer review utilizes repeated evaluations of drafts by “peer reviewers” from the US and abroad. It is typically used in the support of basic research. Peer review could be called the basic principle for the selection of R&D programs in the United States. It is said that 30 percent of government research and development support programs utilize it^[8]. In the US, the making fair examination by numerous specialists such as outside peer reviewers, program managers are decided

acceptance of research, however the weakness is that review takes a great deal of time and money. Meanwhile, the role of program managers in R&D support is to utilize the results of examination by outside peer reviewers as data to be examined when deciding to accept or reject research based on its content, and to report the results as a recommendation to the top who will be making the decision.

3 Criticism of the OMB proposal

3-1 *Criticism of the OMB’s new peer review system by scientists*

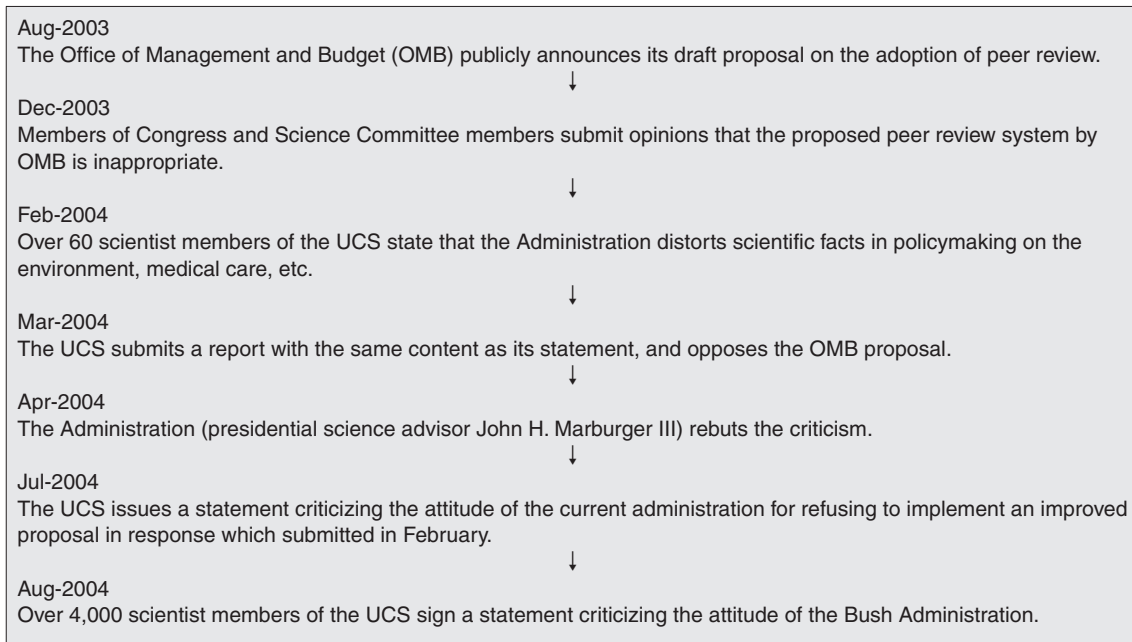
After publication of the OMB proposal, the Union of Concerned Scientists (UCS) received many objections and complaints from scientists, so it began a investigation of policymaking in scientific fields by the Bush Administration.

A history of the point of issues is shown in Figure 3.

In response to the OMB proposal, in February 2004, UCS published a 37-page report entitled “Scientific Integrity in Policymaking^[9]” that was signed by 60 scientists, including 20 Nobel laureates, a former Presidential Science Advisor, and former directors of the National Science Foundation and the National Institute of Standards and Technology. At the same time, the UCS published a statement declaring that the Bush Administration has distorted scientific fact for its own convenience in policymaking concerning the environment, health, biomedical research, and nuclear weapons^[10], and it opposed the OMB proposal as being biased towards the Administration and problematic in many ways. The report and the statement pointed to the following points as problematic.

- The Bush Administration has pushed some of the many government advisory panels towards dissolution and it appoints only scientists who have same opinion with advisory committees in Administration.
- In many Federal Government agencies, the current Administration appears to have suppressed or distorted inconvenient scientific knowledge, and it effects to

Figure 3 : History of the issues



particular impact on public health, public safety, and welfare.

- The Administration appears to have taken actions to control expert scientific advisory panels in order to avoid publication of reports that may contradict its policies.
- The OMB gives no examples of failure in formulating regulations or decision making based on scientific information.

In addition, the report asserts that the scope and scale of the manipulation and suppression of science are unprecedented. Furthermore, the scientists criticize the policies being advanced by the Administration under the name “Restoring the Integrity of Science^[11]” as likely having a negative effect on health and the environment^[12]. Moreover, they mention that the trends seen in recent policy shake the foundations of science, and the situation must be addressed quickly.

They also point out where the Administration interprets the term “peer review,” widely used among scientists, for its own convenience. Generally, scientific publications are peer reviewed by scientists in the same research field, and only papers that have passed through the review process are published. Through the review process, specialists in the research field examine the papers for novelty, and many papers are rejected for publication because of insufficient novelty or other reasons. Under

the OMB proposal, however, it is feared that the White House version of “peer review” will mean review only by review panels comprising reviewers who are friendly to the Administration and its corporate supporters. Because leading specialists in a field would only be able to engage in peer review only once every few years under the policy, it would be difficult to carry out proper peer review. In public comments^[13] on the proposal, scientists have stated that peer review itself would become meaningless.

3-2 Suggestions in the UCS statement regarding the OMB proposal

The UCS report concretely and explicitly notes examples of policies that are problematic to science, scientists, and social welfare. The report cites cases where scientists in the Environmental Protection Agency, Food and Drug Administration, Department of Health and Human Services, Department of Agriculture, Department of the Interior, and Department of Defense were subject to undue pressure on subjects such as climate change, mercury discharge amounts, public health issues related to reproduction, lead poisoning in fetuses and children, workplace safety, and nuclear weapons. The report states that new regulations and laws are needed to address the situation. It goes on to say that the President, Congress, scientists, and the public must do the following in order to restore

scientific integrity in policymaking in the Federal Government.

- The President should eliminate the danger of expert science advisory panels becoming unfair.
- Congress should hold hearings on the matters indicated in the report to halt this dangerous trend. Panels should be composed of non-stakeholders with a high degree of expertise. Anyone should be able to access the scientific information of the government, and an advisory organ like the Office of Technology Assessment should be established.
- Through academic societies and other groups, scientists must work to become more deeply involved in the issue. They must appeal directly to Members of Congress and use the media to make the point that misuse of science can lead to serious problems^[14].

3-3 *Opinions of other groups on the OMB proposal*

Members of Congress and the Science Committee in Federal Government also pointed out problems with the OMB proposal in December 2003. A written opinion^[15] was submitted stating that the adoption of the peer review system would be unrealistic and ill advised because it mandates peer review of matters that do not require it. For example, proposal peer review under the OMB would be required before Federal Reserve Board Chairman Alan Greenspan could set interest rates and before weather forecasts, including urgent hurricane warnings, could be issued.

According to the American Public Health Association, it could not understand why the OMB would offer such a proposal in the absence of evidence that the current system does not work or of a single example in which failure to peer review led to a flawed Federal Government regulation^[16]. In addition, Public Citizen^[17] points out that requiring peer review would delay the process of issuing warnings to the public on matters that endanger health, possibly causing unimaginably large problems. Public Citizen also

noted the problem of the OMB publication not giving even one example of a failure of regulation formulation or of decision making that was based on scientific data^[18].

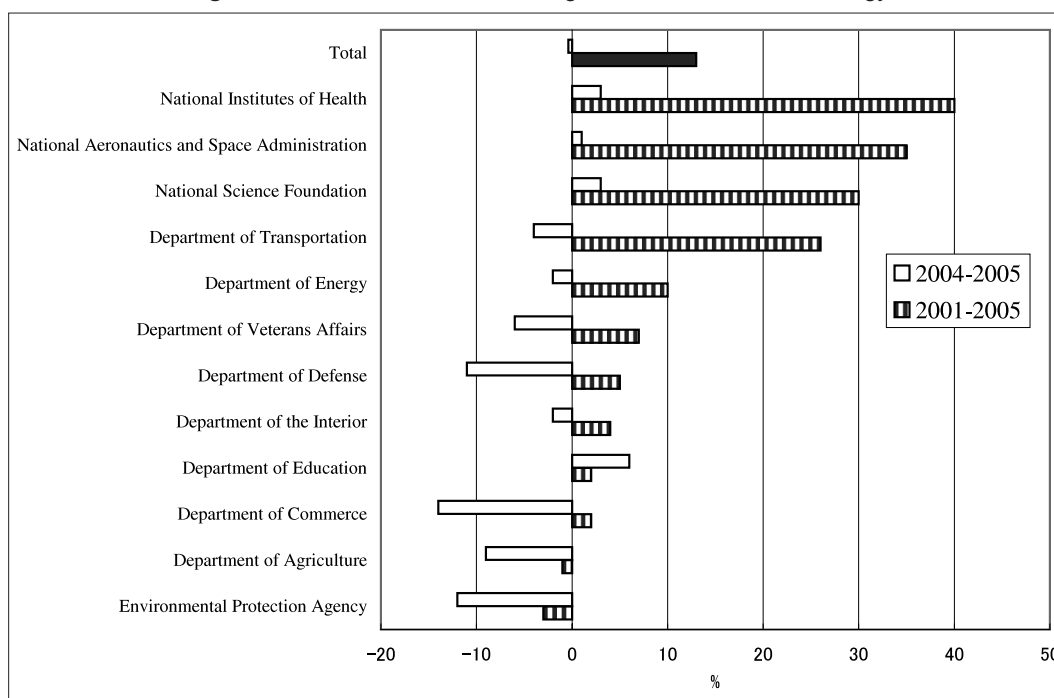
3-4 *Criticism of environmental policy*

Scientists and the protection of the environmental groups continue to point to Administration action on policies related to the environment in particular as problematic. Environmental issues are deeply connected to regulatory science, therefore scientists involved strongly oppose the OMB proposal.

Even though environmental issues extend across many fields, since the current Administration took office the budget and number of projects of the Environmental Protection Agency (EPA), which had fluctuated for several years, have declined relative to other agencies^[19]. The transitions of science and technology budget in government are shown in Figure 4^[20]. As can be understood from the chart, although the science and technology budget as a whole increased 30 percent from 2001 through 2005, the budget for the environment decreased.

In addition, a number of opinions are being offered on environmental policy, not just on problems with the peer review system mentioned above. For example, in August 2003, around the same time the OMB proposal was released, the Natural Resources Defense Council (NRDC) reported that the EPA is attempting to loosen Clean Air Act regulations, leading to an increase in the amount of pollutants emitted by older coal-fired power plants and oil refineries. The EPA's policy is that when, for example, a coal-fired power plant replaces boilers or other equipment, the plant would not have to install pollution control equipment to meet current standards if the cost of the pollution control equipment is less than 20 percent of the entire cost^[21]. Not only pollutants such as NO_x, SO_x, and soot emitted by coal-fired power plants aggravate asthma, chronic bronchitis, pneumonia, and so on, research showing a major causal relationship with cancer has also been published, so scientists point out that such loosening of regulations is a serious problem for the citizens.

Figure 4 : Federal Government budget for science and technology



4 The response to by the administration for the UCS statement

In reply to the UCS statement, Presidential Science Advisor John H. Marburger responded that the current Administration in fact strongly supports science^[22]. As evidence, he mentioned that the budget in NIH has been increasing as well as the National Science, so that the overall science and technology budget has increased compared with before as shown in Figure 4. The budget increases \$91 billion for fiscal 2005 (\$132 billion) compared with the 2001. This is the highest level in 37 years.

Other points made in the response include the following. A program on climate change has been in place since 2001. The emission of greenhouse gases especially CO₂ is a problem since the Industrial Revolution started and is a major issue in every country, as well as the US government is addressing solutions. With the purpose of reducing worldwide greenhouse gases, the Administration is spending about \$4 billion on understanding the mechanisms of greenhouse gases and their effects on human beings and for research and development in clean energy technologies. The President created the US Climate Change Science Program (CCSP) to

respond and receive comments and stakeholders including a two-stage independent review of the plan, set a standard for government-led research programs.

In addition, the OMB has for the first time hired toxicologists, environmental engineers, and public health scientists to review regulations and help agencies strengthen their scientific peer review process.

In this way, the Administration is using concrete examples to voice its objections to the UCS assertions. However, scientists are dissatisfied with other issues in addition to those noted by the UCS.

5 Recent trends

5-1 Issues with mercury regulations

In March 2004, an article reporting that the environmental policy in Bush Administration leans towards the energy industry appeared in the New York Times^[23]. In April, seven Members of Congress including Democratic Senator Hillary Clinton sent the EPA Administrator a request for an investigation regarding improprieties in guidelines on mercury emission regulations, a current matter of concern. There are approximately 1,100 coal-fired power plants in U.S. and the exhaust gas from burning coal includes mercury, which are estimated 48

tons/year. It's a 40 percent of annual mercury emissions. The mercury mixes with rain and falls to the ground, where it flows into rivers, lakes, and oceans, and accumulates in fish and shellfish. Recently there is concern that mercury may enter the body directly through respiration and have a particular impact on fetuses in the womb. The request for an investigation demanded clarification of the allegation that during the process of formulating regulations on mercury emissions, the Bush Administration deliberately removed wording from a National Academy of Sciences study in its proposal in order to minimize health concerns^[24]. In response to the letter, the EPA Administrator stated the following.

- The current Administration is the first to decide a schedule for reducing mercury emissions.
- The 90-percent reduction of mercury emissions is only a draft proposal.
- It is impossible to immediately install mercury removal equipment throughout the United States.

The Congressional Research Service also published reports^[25-27]. The Clear Skies Initiative*² and the mercury regulations proposed by EPA for power plants are also criticized as requiring lighter reductions of mercury emissions from the energy industry than it does from other industries^[28-29].

5-2 A new statement from the UCS

In July 2004, many more UCS member scientists, over 4,000, including 48 Nobel laureates, signed a statement criticizing the attitude towards scientific advice in the Bush Administration^[30]. The statement was issued to criticize the Administration for not adequately examining^[31] the report submitted in February 2004. The report added the following to the points previously made.

A project on the environmental impact of mines changed direction to a focus on rationalizing coal mining, leading to impacts on fish and wildlife. Furthermore, salmon are facing extinction, and this will have a major impact on wildlife that depends on them for food. Policy

countermeasures are urgently needed.

As seen in the case of the "Star Wars" initiative, there have been cases in the past of scientists individually or in groups objecting to particular Federal Government policies. However, for so many scientists^[32] to criticize a president's science policy as a whole is unprecedented. In November 2003, even Richard L. Garwin^[33], who received a National Medal of Science for his "valuable scientific advice on important questions of national security," signed the statement. In addition, some scientists with ties to the current Administration are among the signatories^[34].

Scientists point out that addressing issues such as reproductive medicine, pharmaceutical regulation, and the environment from a political rather than a scientific point of view will damage trust between the Administration and scientists. However, the opinion in Administration is that there are research fields such as embryonic stem cell research in which not only scientific views but also moral issues are important, so not everything can be handled uniformly by government.

6 Conclusion

Since 2001, research and development funding has increased in the Department of Defense, NASA, and the Department of Homeland Security in particular. It is noteworthy that they are all defense-related, and among many the agencies that is where the upward trend continues. On the other hand, the number of articles published in the United States in science and technology has been stagnant or declining for the past several years^[35], while they have doubled in Europe, China, Taiwan, South Korea, and Japan over the past 10 years, and the number of Nobel laureates from outside the United States is also increasing. Currently the US is restricting visas in comparison to the past, when it gathered numerous scientists from around the world.

Since the Republican administration took office, budgets for environmental fields have continued on a downwards trend compared with the previous administration. Recently, however, the Senate has reduced the cuts to the R&D budget in EPA^[36]. It seems that the action of the

scientists may have had some impact.

Those scientists organized themselves and put their pride as scientists ahead of party support and, in the form of the statements, objected to Administration policy. How the Administration will respond and how things will develop are the points worth watching now. We should always pay attention to the actions of scientists in science and technology fields in various foreign countries. The organization of scientists to point out problems to the government may happen in Japan in the future. It may be demanded or become necessary.

It is desirable that complex issues such as the environment or embryonic stem cell research be resolved through debate based on scientific judgment and rational premises, with risk considered even if some uncertainty must be permitted. And the most important thing is that scientists, government, and the citizens share information, exchange opinions, and attempt to understand one another.

Acknowledgements

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Note and Glossary

*1 A perspective that does not assume the existence of objective and absolute reality, but instead contends that reality is constructed by society.

*2 Clear Skies Initiative
A plan that sets caps for SO₂, NO_x and mercury emissions by power plants and sets a goal of 70 percent cutting from 2000 levels.

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