



## Ruckelshaus Effect

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### *Abstract*

*The role of experts in society, from ancient philosophers to contemporary scientific advisors has been debated since antiquity. The founder of the EPA, William Ruckelshaus, argued that the role of scientists in society is to address only scientific issues. This paper provides the seven principles that are the foundation of Ruckelshaus Effect. It also describes direct and indirect consequences of Ruckelshaus Effect including the Evolution of Best Available Science (BAS) and Metrics for Evaluation of Scientific Claims (MESOC) derived from it that are based on five principles (open-mindedness, skepticism, universal scientific principles, transparency, and reproducibility) and include three pillars (reliability standardization of science in terms of its maturity, and areas outside the purview of science). This paper also addresses the relationship between the Ruckelshaus Effect, risk analysis (assessment, management and communication), and the evolution of regulatory science as a new scientific discipline.*

*Key words: Ruckelshaus Effect, Regulatory Science, risk analysis, policy, environment*

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### **Introduction**

The role of scientists in society has been debated since antiquity and continues to be discussed. In ancient times, philosophy was equated with science and in many civilizations philosophers were considered to be wise and their advice was often considered the ultimate source of wisdom. In recent times a modified version of the same argument has been used to seek advice from accomplished scientists. The argument is based on the assumption that experts who understand the science are not only qualified, but are fundamentally more qualified than others to draw conclusions from science, than those who do not have the necessary scientific competency to understand the science. On occasion, this argument is generalized claiming that an accomplished scientist is obviously capable of thinking logically, as demonstrated by the individual's accomplishment. Therefore, wouldn't it be logical to assume

that such an individual is more qualified than others to reach logical conclusion on any subject including societal decisions? Merton who coined the phrase "Matthew Effect" describes how scientists with recognized reputation are often given preference as compared to others regardless of the scientific value of their claim (1).

Experience shows that the above argument is not necessarily valid as demonstrated by the mixed record of accomplished scientists as administrators, societal decision-makers, and other areas that are outside the purview of science. Richard Rhodes (2) and Alice Kimball Smith and Charles Weiner (3) provide the history of the Manhattan Project indicating that there have been numerous accomplished scientists who have proven to be also effective administrators. J. Robert Oppenheimer is a prime example of a proven scientist and an effective administrator. He gained early fame for his work on the Born-Oppenheimer

Effect, and, during the development of the atomic bomb, he managed the laboratory that eventually became the Los Alamos National Laboratory. At least initially, he was an effective administrator who was responsible for the development of nuclear weapons. Another prime example is Glenn T. Seaborg, who received the Nobel Prize for the discovery of certain transuranic elements. Seaborg worked along with Oppenheimer on the Manhattan Project, and returned to Berkeley, where he expanded the fledgling university, and later served on the Atomic Energy Commission (AEC). Even after retiring from the AEC, he continued to help shape policy and advise later presidents.

Conversely there have also been accomplished scientists who proved to be poor administrators. Consider Einstein, who greatly influenced science in general and physics in particular. He is considered by the greatest scientist in the 20th century if not the greatest scientist in the history of science (4,5). As an administrator, however, he was strikingly unexceptional. He had little ability to administer and did not significantly influence the academic culture at Princeton University or the Institute for Advanced Studies. Because of his civic activism, and work on the creation of the Israeli state, he was offered presidency of Israel by David Ben Gurion, to which he replied, "I have neither the natural ability nor the experience to deal with human beings" (5).

### ***Formation of the Environmental Protection Agency***

During the late 1960s environmental issues became of significant public concern. One of primary reasons for the public concern was atmospheric nuclear weapons testing. While in the United States (US) some of these tests were conducted at the Nevada Test Site (NTS) others were performed elsewhere including certain areas of Pacific Ocean. The Soviet Union, United Kingdom, France and eventually China also developed and tested nuclear weapons. In addition, the discovery of careless disposal of chemical waste heightened the desire of the public to attend to environmental issues. Recognizing the public interest, the United States Congress passed several laws dealing with air, water, pesticides, drinking water, and others including the National Environmental Policy Act (NEPA) requiring that virtually all governmental action would have to include evaluation of environmental consequences (6). In 1970, President Richard Nixon, using his executive privilege, established the US Environ-

mental Protection Agency (EPA) by combining a dozen or so organizations from various federal departments and agencies. William Ruckelshaus was appointed as the first administrator of the EPA. At that time there was enthusiasm for the formation of the EPA in general and the appointment of Ruckelshaus in particular. Ruckelshaus faced significant problems in integrating these diverse agencies into a coherent organization. For example, most of these agencies had a research and development arm with their own culture and tradition. Similarly, there were other problems that continue to this date. For example, agencies that were brought in from the Public Health Service considered their primary mission to be the protection of human health. In contrast, agencies that came from other departments, notably the Department of Interior, were dedicated to the protection of the ecosystem. Ruckelshaus had to reconcile these seemingly irreconcilable differences. On more than one occasion he stated that one can try to meet both goals emphasizing that protection of human health does not need to conflict with protecting the ecosystem. Ruckelshaus also had to meet various legally mandated deadlines and perform other tasks. For reasons beyond the scope of this paper, Ruckelshaus left the EPA in 1973 and returned as administrator in 1983 succeeding Anne Gorsuch after she faced significant problems, particularly in dealing with Congress. Ruckelshaus left the EPA in February, 1985.

While Ruckelshaus was struggling to comply with several rather complex laws and meet numerous deadlines, the Food and Drug Administration, (FDA) an agency whose responsibilities occasionally overlapped with those of the EPA, was facing similar problems. Both the EPA and FDA had to make decisions based on science with variable quality, ranging from reasonably reliable peer-reviewed science to documents prepared by advocacy organizations or simply provided by an interested person. Often, the needed scientific information was non-existent or if it existed, included large uncertainties. At that time Ruckelshaus struggled with developing regulations that were based on a scientifically defensible foundation (7,8). Risk assessment was found to be a key if not the only process to address adverse effect of exposure to a pollutant. As expected, there was confusion on the definition of risk assessment, how a risk was to be managed, and many other highly contested subjects within both agencies and elsewhere. The National Research Council (NRC)- the research arm of the National Academy of Sciences, National Academy of Engineering, and the Institute of Medicine published a landmark report, known as the "red book",

on risk assessment and risk management (9). The red book provided guidance to the FDA and by implication, to other federal agencies on risk assessment, risk management and numerous other issues related to the interface between risk assessment and risk management often collectively referred to as analysis. According to the NRC, while risk assessment (one component of risk analysis) is a scientific process, and thus the domain of the scientific community, risk management (another component) is the domain of policy and by implication, not within the purview of science.

Recognizing that on occasion there is insufficient data, lack of understanding of a scientific process, and numerous other problems in performing risk assessment, the NRC report introduced a new concept known as “risk assessment policy”, in risk assessment. NRC defined risk assessment policy as “policy related to and subservient to the scientific content of the process...” (9). In order to avoid confusion between risk assessment policy (a scientific judgment) with societal objectives involved in risk management, the NRC emphasized that risk assessment should be contrasted “...with policy invoked to guide risk management decisions, which has political, societal, and economic determinants” (9). The fundamental reason for introducing risk assessment policy was that it reduced uncertainties in comparing alternative options for a specific regulatory decision sometimes called comparative risk assessment.

The red book became the foundation of a number of regulatory decisions and many other activities. In particular, the red book became the fundamental document governing the risk process and provided, indirectly, guidance on the respective roles of scientific community and societal decisions makers. In effect, risk assessment became one of the most important tools in regulatory decisions process.

In the US numerous laws require the formation of advisory committees based on the assumption that the scientific foundation of various policies is generally outside the skill set of the policymakers, and most times the electorate, and so scientists are enlisted to shed light upon the issues at play. In this paper we attempt to describe the role of scientists and the scientific community in societal decisions that include scientific components. In particular, we suggest that certain principles expressed by Ruckelshaus lend themselves to establish “Ruckelshaus Effect” as a mechanism to respond to the needs of policy makers and the general public.

## **Ruckelshaus Effect**

During his tenure at the EPA Ruckelshaus identified several elements that in this paper we define as Ruckelshaus Effect. The foundation of Ruckelshaus Effect was described in a speech given at the National Academy of Sciences (10) and in other publications (11,12). Accordingly, the Ruckelshaus Effect is based on several principles. Note that in the following the italics are entirely taken from the original documents:

**Fundamental Principle: The role of the scientific community is to address scientific issues.** As stated by Ruckelshaus the conclusions derived from science are outside the purview of science.

“...all scientists must make it clear when they are speaking as scientists—*ex cathedra*—and when they are recommending policy they believe should flow from scientific information.... What we need to hear more of from scientists is science.” On more than one occasion Ruckelshaus emphasized that citizen scientists are entitled to their opinion as is anyone else in the society, but they should not think that their opinion is somehow more worthy than the opinion of any other citizen because they are a scientist. That distinction makes it also clear whether they are speaking as a scientist or as a citizen.

**Principle 2: Scientific decisions must be free of non-scientific influences.** As emphasized by Ruckelshaus “Nothing will erode the public confidence faster than the suspicion that policy considerations have been allowed to influence the assessment of risk.”

**Principle 3: Governmental actions must be based on sound science.** Ruckelshaus stated: “...the standards we set, whether technology or health, must have a sound scientific basis.” Furthermore “...risk assessment...must be based on scientific evidence and scientific consensus *only*.”

**Principle 4: There should be a uniform process in the application of science in societal decisions.** Ruckelshaus elaborated in addressing this issue. “...we should make uniform the way in which we manage risk across the federal regulatory agencies. The public interest is not served by two federal agencies taking diametrically opposed positions on the given health risk...” Although Ruckelshaus referred to risk assessment the subject has general applicability.

**Principle 5: The obligation of the scientific community includes communicating science in a language that is understandable to the impacted community.** Again here Ruckelshaus provides explanation: "...scientists must be willing to take a larger role in explaining risks to the public—including uncertainties inherent in any risk assessment. Shouldering this burden is the responsibility of all scientists..."

**Principle 6: Regulatory decisions cover many non-scientific elements.** Ruckelshaus suggests that once scientific issues related to the adverse effect of an agent are addressed numerous other factors such as social and political factors must be considered: "We must then factor in its benefits, the cost of various methods available for its control, and the statutory framework for decisions." He further states: "No amount of data is a substitute for judgment."

**Principle 7: Successful societal decisions require public participation.** In numerous statements Ruckelshaus emphasized the need for public participation in societal decisions process. Quoting Thomas Jefferson he stated "If we think [the people] not enlightened enough to exercise their control with a wholesome discretion, the remedy is not to take it away them but to inform their discretion." He also stated "...we must seek new ways to involve the public in decision making process." He also suggested that those segments of the public that are impacted by a decisions "...need to be involved early on and they need to be informed if their participation is to be meaningful."

### ***Direct and indirect consequences of Ruckelshause Effect***

The need for a rational approach to manage regulations and other policy decisions existed before the Ruckelshaus Effect was formulated, and even after its formulation there continues to be a misunderstanding on the nature of science used in regulatory and other policy decisions and the role of individual scientists and the scientific community in the society once scientific issues have been addressed. Although Ruckelshaus expressed the ideas that eventually led to the establishment of Ruckelshaus Effect, there has been evidence supporting its underlying foundation and implementing its principles. The following are several issues that were directly or indirectly impacted significantly by Ruckelshaus Effect.

### ***Risk analysis***

As stated previously, risk assessment was one of the key reasons that Ruckelshaus Effect was formulated. Probably the first comprehensive risk assessment was the Wash 1400, a report known for its primary author and manager, Norman Rasmussen (13). Appendix VI of Rasmussen report contained extensive information on risk assessment of exposure to radionuclides and ionizing radiation. For some reason the authors of the red book were either unaware of Rasmussen Report or chose to disregard it as demonstrated by the fact it was not referenced in the red book.

Initially, there was confusion on the respective roles of risk assessment and risk management. At the EPA, the Cancer Assessment Group (CAG) often did both by not only trying to assess the science, but also recommend regulatory actions. Activities of CAG not only violated the fundamental principle of Ruckelshaus Effect but also its second principle by careless application of scientific information thus causing problems that haunted the EPA for many years. One of the key problems facing regulators was risk perception. In applying risk assessment to risk management, the regulators repeatedly observed that the affected communities had difficulties understanding the concept of risk. In effect, everyone wanted a risk of zero in the overwhelming majority of environmental regulations—an impossible goal to achieve. It was Ruckelshaus who initiated to process of risk communication, the third component of risk analysis.

Due to the significance of risk in many regulatory and other societal decisions, there have been a large number of reports by scholarly organizations, books and other documents. Whereas the NRC report (14) attempted to address uncertainties in risk assessment, the subsequent report (15) reviewed risk assessment for numerous chemical compounds. Note that in its report (14), the NRC Committee attempted to provide a guide on the terminology of various aspects of risk. The Committee indicated that EPA intended the study to deal with risk assessment rather than *risk analysis*, as written in the EPA's request. However, in order to avoid confusion, "...the Committee will use *risk assessment* to describe the process leading to risk characterization". The Committee used risk analysis as elements that improve the utility of risk assessment for decision making as well as the technical analysis that supports risk assessment.

The Drinking Water Act of 1996 also addressed issues relevant to the terminology of risk (16). Section 103 of the Act includes “Risk assessment, management and Communication” and defined each part, although “risk analysis” is not expressly used in that law (3). Using this logic, the American Association of Engineering Societies defined risk analysis as having three elements: risk assessment, risk management, and risk communication (17).

### **Scientific assessment**

Although numerous scholarly organizations have prepared and published scientific assessments, their number increased significantly as consequence of emergence of regulatory science. Despite the proliferation of scientific assessment documents, scientific assessment was legally defined as late as 2005 by the Office of Management and Budget (OMB) as “state-of-science reports, technology assessments, weight of evidence analyses, risk assessments, toxicological profiles of substances, integrated assessment models, hazard determinations, exposure assessments, or health ecological or safety assessments...” (18).

Scientific assessment consists of a critical evaluation of a topic. The outcome of a scientific assessment is a document that provides the reader with the status of science addressing a specific topic. The process requires that a consensus is reached on oft-contradictory information in the literature. The objective of scientific assessment is to respond to the scientific need of the sponsoring organization asking for help. Accordingly, scientific assessment consists of a critical evaluation of a subject, including the following:

- Assisting the sponsoring organization in resolving complex issues.
- Advising the organization of an appropriate course of action or pathway to reach the stated goal.
- Assisting the sponsoring agency in deciding alternative courses of action.
- Assessing existing scientific information on a specific topic and providing the sponsoring agency with the results of the assessment.

There are numerous organizations that perform scientific assessments. In the US, the NRC has traditionally provided scientific assessments for various government agencies addressing a wide range of problems. The NRC has

performed numerous scientific assessments covering a variety of topics. Examples of these topics include: issues related to endangered species (19); peer review of water resources (20); application of toxicogenomic techniques to predictive toxicology and risk assessment (21); and conflict of interest in medicine (22). In addition, various professional societies either alone or in cooperation with other professional societies perform this task.

### **Peer review**

One of the key issues identified in the initial development of regulatory science was the reliability of scientific information. The third principle of Ruckelshaus Effect requires that societal decisions “...must have a sound scientific basis” and “...must be based on scientific evidence and scientific consensus *only*”. Initially, many government agencies interpreted peer review as asking one or more individuals to review their activities. In many cases, these were a staff of contractors or consultants chosen by the sponsoring agency. Not surprisingly, the accusation of bias, hand-picking of supporters of the impending decision, and numerous other issues led to the development of a structured process. At the EPA a Science Advisory Board was established to review scientific documents produced by the EPA staff and EPA contractors. Recognizing the need for a more organized process, the OMB published a guide requiring that all agencies develop their peer review process so that regulatory science documents are peer reviewed using procedures that follow acceptable processes (18).

### **Best Available Science**

Probably the most comprehensive implementation of Ruckelshaus Effect is Best Available Science (BAS) and Metrics for Evaluation of Scientific Claims (MESC), derived from it. The evolution of the BAS concept can be traced back to late 1970s and later on stimulated by statements by William Ruckelshaus when the senior author of this paper, while working at the EPA, recognized the need for reliable scientific information in the regulatory process. These efforts eventually led to the development of the BAS/MESC system by Moghissi, et al. (18). A closer look at the BAS/MESC system indicates a strong consistency and no contradiction between BAS/MESC and Ruckelshaus Effect. The BAS/MESC is based upon four principles as follows:

1. The first principle requires *open-mindedness*. The scientific community, and hopefully everyone else, must be willing to be open-minded and consider new ideas even if they contradict existing scientific knowledge. Included in this principle is the requirement for reproducibility implying that a claim can be reproduced by those with relevant competency and access to appropriate equipment and facilities.
2. The *skepticism principle* is the counterpart to the open-mindedness principle and requires that the scientific community critically evaluate a new idea. We recognized the contradiction between the two latter principles (open-mindedness and skepticism) and hope that the BAS provides an approach to reconcile this contradiction.
3. The third principle, *universal scientific principles*, could have been just as well been called methods, approaches, processes, and other principles that are used by all scientific disciplines. For example, if a study in any field of science uses statistics, the study must use statistical methods that are well-known and well-established.
4. The fourth principle addresses the need for transparency. It is imperative that those who make a scientific claim identify the level of maturity of each segment of their claim including areas that meet the *reproducibility principle*; inclusion of assumptions, judgments, or default date; and consideration of societal and other areas outside the purview of science. Violation of *transparency principle* is one the primary reasons for disagreements of scientific foundation of policy decisions and numerous other areas of public interest.
5. Finally, the fifth principle deals with *reproducibility* of scientific claims. It requires that any investigator with appropriate competency, equipment and facilities should be able to reproduce a scientific claim.

The BAS/MESC relies upon three pillars as follows:

**Reliability of scientific claims:** One of the pillars of BAS/MESC consists of how the reliability of scientific information can be assessed. Briefly the BAS/MESC provides four categories for such an assessment. The first two categories (*personal opinion* and *gray literature*) are considered to be unreliable. Consistent with the third principle of the Ruckelshaus Effect, the BAS/MESC system con-

siders *independent peer review* to be the foundation of acceptability of science. Very early during the development of the BAS concept we recognized that there are —and there will always be—contradictory information, even in properly-performed peer-reviewed literature. Again here consistent with principle three of Ruckelshaus Effect, the BAS/MESC system envisions *consensus-processed science* to be the approach to resolve disputes in contested areas of science notably regulatory science. Furthermore, the BAS/MESC system also provides for processes to ensure the acceptability and integrity of both the peer review and the consensus process.

**Standardization of scientific information:** Another pillar of BAS/MESC deals with standardization of science in terms of its level of maturity. We have identified three classes of scientific information (in fact two classes and one class that claims to be science but it is not). *Proven science* consists of scientific information that is uncontested and constitutes scientific laws. The next class consists of *evolving science* and constitutes that area of science where the overwhelming majority of scientific advancements are made. It includes *reproducible evolving science*; *partially reproducible evolving science*; *correlation-based evolving science*; *hypothesized science*; *scientific judgment*; and *speculation*. The final group in this pillar of BAS/MESC is *fallacious information* sometimes called *junk science*. Originally, we called it the third group in this pillar but during the peer review of a document describing this group, the authors were advised that this group does not qualify as science.

**Outside the purview of science:** The final pillar in the taxonomy of BAS/MESC is consistent with not only the fundamental principle but also with several other principles notably principle two of Ruckelshaus Effect. As expressed by Ruckelshaus Effect, the BAS/MESC system does not imply that the scientific community or individual scientists have no role in areas that are outside the purview of science. Instead, it implies that the role of the scientific community or the individual scientist is similar to the roles of members of any other profession. A key responsibility of the scientific community as described by principle five of Ruckelshaus Effect and implied in the third pillar of BAS/MESC is the obligation of the scientific community and individual scientists to ensure that regulatory science is communicated to the public in general, and stakeholders in particular, in a language that is understandable to the intended audience.

## **Endorsement of Ruckelshaus Effect**

In August of 2009, the Bipartisan Policy Center echoed the Ruckelshaus Effect by stating that “The Administration needs...to ensure that when federal agencies are developing regulatory policies, they explicitly differentiate, to the extent possible, between that involve scientific judgment and questions that involve judgments about economics, ethics and other matters of policy” and “In general scientific advisory panels should not be asked to recommend specific regulatory policies.” (24). The BPC goes further and suggests that “...some disputes over “politicization” of science actually arise over differences about policy choices that science can inform, but not determine”. This endorsement was considered to be of sufficient importance that *Science* chose describe it in some detail (25).

## **Emergence of regulatory science**

Ruckelshaus Effect addresses problems facing regulatory agencies. One of the key problems that legislative, regulatory, judicial and other policy managers face is making decisions based on incomplete or uncertain scientific information. Eventually, it became necessary to address the needs of these decisions makers by providing a guide on how to manage the rather complex scientific issues in policy decisions, a process that eventually led to legitimating a new branch of science called regulatory science. A report by Moghissi, et al addresses the origin and the evolution of regulatory science (26). Initially, the primary objective of the newly established discipline was to support scientific needs of regulatory agencies notably EPA and FDA. Meanwhile numerous other agencies implicitly or explicitly rely upon regulatory science. For example, the US Nuclear Regulatory Commission relies heavily upon probabilistic risk assessment not only in the development of regulations but also in implementing them. Similarly, the Department of Interior relies upon regulatory science in dealing with endangered species and their protection, movement of groundwater in evaluating the quality and available quantity of groundwater, and the Department of Labor in assessing acceptable safety requirements at various industries. Recognizing that congressional actions often required input from regulatory agencies, regulatory science was also to support the needs of Congress. Finally, regulatory science was also to be applied in dealing with the courts. At that time, there were frequent court cases when an agency was sued for having taken an action, for not having taken an action, or for the content of a proposed regulation. The evolution of

regulatory science led to several new areas of science. In the following, key areas are addressed:

Regulatory science information including risk assessment can be logically placed in *partially reproducible evolving science*, *correlation-based evolving science*, and other classes with larger uncertainty. A reasonable question is how society can accept decisions that include assumptions, judgments, and include arbitrary chosen data if scientifically valid data are unavailable. If fact, a large number of decisions that the society accepts fall into these classes.

Let us use the example meteorology notably weather forecasting. Forecasts on rain, wind, snow and their severity are used to mobilize the necessary personnel and ensure availability of relevant equipment. How often the forecasts have been proven to be wrong? However, virtually every municipality has experienced both less than adequate preparation and over emphasis of preparatory activities based on weather predictions that prove to be wrong.

Decisions that are based on uncertain science must compare the consequences of the predicted effect including its uncertainties with potential impacts including economic costs of the countermeasures. Accordingly:

1. Risk assessment, or more accurately probabilistic risk assessment, is the vehicle that identifies the risk, the scientific tool for assessing potential adverse effects; and
2. Risk-benefit or cost benefit analysis is one of the primary decision tools available to decision makers to balance the predicted potential adverse effect with the societal costs.

## **Conclusions**

The wisdom of expressing fundamental principles dealing with the separation of science from the conclusions derived from science has proven to be a key to management of regulatory science, including risk analysis, and numerous other issues facing the society. It is highly likely that the implementation of Ruckelshaus Effect will significantly reduce disagreements on scientific foundation of societal decisions and will ultimately assist both the scientific community and the decisions makers. In particular it will also support the cause of environmental protection, the primary interest of William Ruckelshaus.

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The authors declare that they have no competing interests.

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