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Innovation in Regulatory Science: Metrics for Evaluation of Regulatory Science Claims Based on Best Available Regulatory Science

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Abstract

This paper describes the historical evolution of the Best Available Science concept leading to Best Available Regulatory Science (BARS) and Metrics for Evaluation of Regulatory Science Claims (MERSC). The paper identified five BARS Principles consisting of Open-mindedness, Skepticism, Scientific Rules, Ethical Rules, and Reproducibility. These Principles lead to three pillars. The pillar of Standardization consists of Proven Science (scientific laws and their applications); Evolving Science, consisting of Reproducible, Partially Reproducible, Association Based, Hypothesized Evolving Science; Borderline Science (Judgement and Speculation); and Fallacious Information. The pillar of Reliability includes Personal Opinions, Gray Literature, Peer-reviewed, and Consensus-processed Science. The final pillar describes areas Outside the Purview of Science, implying that societal objectives, ideology, or any other non-scientific issue are not science but policies. The separation of science from non-scientific issues and processes is a key element of regulatory science.

Keywords: best available regulatory science, level of maturity science, outside the purview of science, reliability of science

1. Introduction

One of the first issues that surfaced upon the formation of the regulatory science discipline was the evaluation of a scientific claim, notably claims related to policy decisions. There is reasonable evidence that the emergence of the term "regulatory science" occurred shortly after the formation of the Environmental Protection Agency (EPA) in 1970 [8, 11]. However, at that time the EPA was unwilling to accept that term claiming that there is nothing unusual about science used in developing or implementing regulation and arguing that "science is science" regardless of its application. Meanwhile, the Food and Drug Administration (FDA) has formally recognized regulatory science as a key element of its regulatory process [22]. Interestingly, a recent internet search for regulatory science identified more than 260,000 entries. The same search identified two schools of thoughts or visions in describing regulatory science.

The first and most widely spread vision is that regulatory science consists of the application of a scientific discipline to comply with relevant regulations. For example, Regulatory Pharmacology consists of compliance with pharmacology regulations and a regulatory pharmacologist needs to have competency in pharmacology discipline and learn the relevant regulations. The same applies to other scientific disciplines such as toxicology, microbiology, chemistry, physics, biology, medicine, and several engineering disciplines. This vision has caused major problems and significant discourse within the scientific community, and dissatisfaction within the regulated community on how the to manage a subject. The key questions that need to be addressed are:

1. Are scientists within the regulatory agencies who write regulations regulatory scientists?

2. Is there any role for the scientific community in regulatory science?

The second vision consists of recognizing that regulatory science is unique and qualifies as a new and emerging scientific discipline. The appearance of a regulatory science discipline was – if not entirely but predominantly – in response to the desire for a more appropriate process to meet scientific needs of those involved in regulatory and other policy processes. The

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formation of the Institute for Regulatory Science in the Spring of 1985 was a demonstration of addressing this need.

Responding to the second vision, several definitions for regulatory science were suggested. The FDA provided a definition that addressed its mission [22]. That definition can be generalized as follows:

Regulatory science is a scientific discipline consisting of the development and application of scientific methods, tools, approaches, and other relevant processes derived from various scientific disciplines used in regulatory and other policy processes including decisions.

A useful and simplified definition is:

Regulatory science consists of a scientific segment of the regulatory process.

Based on the above definitions, regulatory science community consists of 1) the staff of regulatory agencies, 2) scientists involved in compliance with regulations, and 3) regulatory scientists who are not members of regulatory or regulated community.

2. Evolution of the Best Available Science Concept

One of the key issues identified during the early history of regulatory science was how to assess the validity of scientific claims upon which regulatory decisions are based. In order to accommodate that need, the concept of Best Available Science (BAS) was developed and led to a number of publications, notably a key document describing Metrics for Evaluation of Scientific Claims (MESC) derived from BAS [7]. The BAS/MESC system was used in several publications, e.g.[10, 12]. The description of BAS can be categorized as follows:

1. BAS as legally defined or interpreted by the regulators
2. BAS based on the structure of relevant studies
3. BAS based on the judgment of the relevant community

2.1. Definition of BAS and Related Terms Based on Legal Mandates

Probably the earliest requirement to apply "best scientific information available" and similar terms is the Marine Mammal Protection Act of 1972 and later the Endangered Species Act (ESA) of 1977 [3]. The ESA requires that listing (or not listing) of a species must be based "solely on the basis of the best scientific and commercial data available." The Department of Interior interprets best available data to mean BAS as published in its implementation of the National Environmental Policy Act [19]. Similarly, regulations of National Marine Fisheries Service, an agency within the National Oceanographic and Atmospheric Administration state *"...regulations in force are based on best available science..."* [14]. Subsequent regulations, announcements and publications of these agencies and numerous other agencies and authors interpreted the terms such as "best scientific information available" or "best scientific and commercial data available." Note that neither agency provides a process on how to identify BAS. A report by the National Academies used BAS interchangeable with the terms included in the laws mentioned above [13]. In effect, the regulators are directed to use their judgment in identifying BAS or other relevant legal terms included in the law.

Several other laws, notably those dealing with the environment, use terms that imply the regulatory agency must use acceptable science and data. For example, § 103 of the Safe Drinking Water Act, under the heading "Use of science in decision-making", requires that the EPA Administrator shall use "the best available peer-reviewed science..." and "data collected by acceptable methods or best available methods..." [16]. In its regulations implementing various statutes, EPA repeatedly uses the term BAS. Although in the overwhelming majority of cases EPA does not describe what constitutes best available science, on at least one occasion EPA elaborates on the term in its definition of the charter of the Science Policy Council of the Office of Pesticide Programs (OPP): "To enhance the consistent use of best available science in our regulatory decisions by providing a central forum that assists OPP in identifying critical issues in pesticide safety, formulating solutions, and in transitioning new science, methodologies, and policies into our program" [20]. In its mission statement, EPA adopts as a purpose to ensure that *"...national efforts to reduce environmental risk are based on the best available scientific information."* In describing its strategic plan, EPA professes to use "The best available scientific approaches, data, and models to anticipate potential threats, evaluate risks, identify solutions, and develop standards that protect the environment and safeguard human health." Similarly, the US Forest Service's regulations require that "Science consistency evaluations...must ensure that plan amendments and revisions are consistent with the best available science" [4].

Congressional mandates on the application of technology are more descriptive. For example, the Clean Water Act requires the"best available technology" (BAT) in some applications [2], and mandates that the EPA Administrator consider specific factors in identifying BAT for application to specific water problems. Other provisions direct EPA to define through rulemaking the best practicable control technology currently available, best available demonstrated control technology, or best available technology economically achievable. The Clean Air Act requires the application of best available control technology (BACT) in some instances [1], and in others directs EPA to set emission limits to reflect the maximum achievable control technology (MACT). EPA rules defining what constitutes BACT and MACT for each industry are lengthy and routinely tested in court [21]. The number of documents that address issues related to BAT and similar terms is too large to be included in this paper and the reader is referred to the EPA's website at epa.gov.

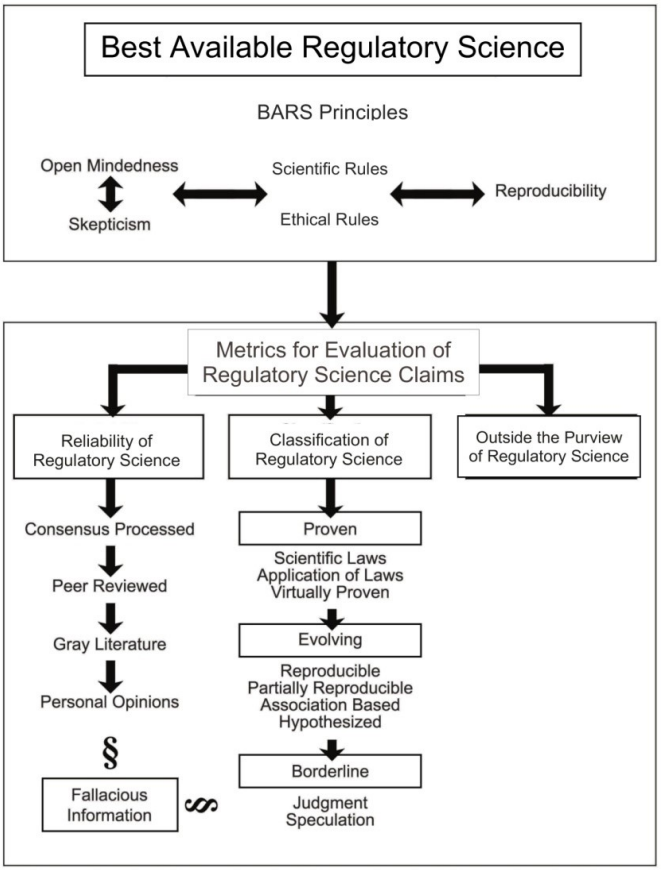

Figure 1: The structure of BARS/MERSC system.

2.2. Definition of BAS Based on the Structure of the Study

The review of literature on BAS resulted in a surprising finding. Several publications dealing with fisheries use BAS to describe how a study – including the publication of its results– is to be structured. A law passed by the state of Washington [17] and a paper published by Sullivan *et al.* [18] on behalf of the American Fisheries Association describe "best available science" for its implementation in fisheries.

2.3. BAS Based on Judgement

A careful reader will recognize that a large part of the information described above in the section addressing the definition of BAS in various laws is in fact based on the judgment of regulators. In a few cases, the legal mandate requires using science that has been peer reviewed. However, as described later in this paper, much of the science used in the regulatory process is evolving and thus it is not surprising that contradictory claims can be found in science that has been peer reviewed. Consequently, it should not be surprising that regulations based on the definition of BAS and related terms have been subjected to extensive challenges, including numerous court cases, as the judgment of a federal employee on what constitutes the "best" may not be the same as the judgment on the same subject by an affected or scientific community. Consequently, all government agencies in the U.S. that use the term "best available science" imply that they use information that is most suited to meet their needs.

3. Best Available Regulatory Science

The replacement of BAS with Best Available Regulatory Science (BARS) and MESC with Metrics for Evaluation of Regulatory Science Claims (MERSC) became necessary for two key reasons: The first important reason was the confusing and arbitrary manner on how several regulatory agencies, scholarly organizations, authors and others defined and applied BAS. The second reason was the decision of the FDA to formally recognize regulatory science as a key element of its regulatory process [22]. However, a large segment of the relevant scientific community interpreted regulatory science, as defined by the FDA, as if it solely and exclusively addresses regulatory science aspects of the FDA mission.

The development of the BAS/MESC and its application to regulatory science as described by the BARS/MERSC system were the result of extensive efforts to systematically evaluate

a number of issues addressing the needs of regulatory science. As shown in Figure 1, the result was a structure that included fundamental principles as well as three pillars, as follows:

3.1. Principles of BARS

The first step in addressing the needs of regulatory science was the recognition of identifying principles that would apply to all areas of the interdisciplinary and multidisciplinary nature of regulatory science. The initial BAS principles consisted of open-mindedness, skepticism, and reproducibility. Based on the experience with BAS and particularly its application to regulatory science, two principles were added. The updated five versions of the principles are:

Openmindedness Principle: This principle implies the willingness to consider new regulatory science claims. Every claim on a discovery; the development of a new drug; identification of a potential human health problem; or the description of an environmental risk requires the willingness to consider it.

Skepticism Principle: This principle implies that it is incumbent upon those who make a scientific claim to provide sufficient evidence supporting their claim.

Scientific Rules Principle: One of the important subjects in MERSC is compliance with the Scientific Rules Principle. As regulatory science includes the application of virtually all scientific disciplines that are used in the regulatory process, it is crucial that relevant methods, processes, and techniques are appropriately used. Furthermore, scientific laws apply not only to a specific discipline but to all scientific disciplines. For example, all scientific disciplines use specific computational methods and apply the rules of statistics in sampling, analysis, and reporting their results.

Ethical Rules Principle: The evolution of this principle required significant efforts. The impetus for the identification, development, and application of this principle was the recognition that one of the primary reasons for controversies associated with regulatory science is the assumption of regulators and regulatory scientists that the public is incapable of comprehending the unique structure of regulatory science. The Ethical Rules Principle consists of four parts:

1. Truthfulness: Truthfulness is universally accepted regardless of the ethnicity, religious belief, or cultural background. On occasion, individuals or organizations claim that it is in the interest of a good cause to be less than truthful by exaggerating the effect of exposure to an agent, overemphasizing the impact of an action, or hiding the existence of information that would support the opponents of a desirable decision. Those who do not comply with requirements of scientific truthfulness must recognize that it is unethical to be less than truthful regardless of the reason to do so.
2. Communicability: If a regulatory science issue is complex, it is the responsibility of regulatory scientists to explain the subject in a language that is understandable to the affected communities. As we will describe in this paper, there are several categories of affected communities and thus regulatory scientists should address not only the reliable and reproducible science but also other scientific issues described under Transparency.
3. Transparency: Science used in regulatory decisions is largely predictive in nature and inherently includes uncertainties. The Ethical Rules Principle requires that any assumptions, judgments, inclusion of default data, or any other issue that led to a conclusion must be provided to the scientific community in general, and the affected community in particular. Transparency may not be confused with the requirements of national security. On occasion, it may be necessary not to provide the scientific details of a subject to the public as it may create apprehension and cause damage to the society.
4. Scientific Ethics: In contrast to truthfulness and transparency, ethics depends, at least partially, on the ethical requirements derived from cultural, religious and other factors from various communities. Therefore, a large number of ethical rules have resulted from international agreements such as those developed by medical, chemical, and engineering organizations, e.g. ethicsweb at www.ethicsweb.eu

Reproducibility Principle: The ultimate proof of the validity of a scientific claim is to be reproducible by those who have the necessary competency and the needed equipment and facilities. This principle separates undisputed areas of science from those that include assumptions, interpretations, and in some cases, the inclusion of ideological and societal objectives in a scientific assertion.

3.2. Pillars of MERSC

As before, the original identification and description of MESC pillars had to be revised to make them applicable to MERSC. The three pillars of MERSC are:

1. Classification of regulatory science claims
2. Assessment of reliability of regulatory science claims
3. Areas outside the purview of science

3.2.1. Classification of Regulatory Science Claims

One of the primary reasons for the uniqueness of regulatory science is the need to consider the level of maturity of a regulatory science claim. Surely one would have more confidence in a claim that is based on a scientific law as compared to a judgment of a scientist or speculation of group, regardless of the groups reputation. It is well established that science evolves and that new discoveries, advancement of scientific knowledge, and numerous technologies result from the evolution of science.

Therefore, it is necessary to classify scientific claims in terms of their level of maturity and reproducibility.

Proven Science:

This group of regulatory science claims consist of scientific laws – sometimes called scientific principles – and their applications. The cornerstone of this group is compliance with the Reproducibility Principle, implying that any investigator who has the necessary skills and the proper equipment can reproduce it. Therefore, a scientific claim included in this group does not require assumptions or any other conditions for its validity. This group consists of scientific laws and the application of scientific laws provided they are entirely based on scientific laws and exclude assumptions.

Evolving Regulatory Science:

The overwhelming scientific advances in virtually all disciplines are Evolving Science. Virtually all regulatory science materials are included in this group.

Reproducible Evolving Regulatory Science: A reliable regulatory science claim that is not completely understood constitutes the core of this class based on two attributes:

1. It must comply with the Reproducibility Principle, implying it is clearly and unambiguously reproducible by those with appropriate skills and equipment.
2. It may not violate the Scientific Rules Principle.

Advancements in virtually all branches of science, including physics, chemistry, biology, and many other scientific disciplines, are based on the desire of investigators to develop knowledge into scientific law.

Partially Reproducible Evolving Regulatory Science: The key characteristic of this class is that the scientific foundation of a claim placed in this class is derived from Proven Science or Reproducible Evolving Science. Typically, it uses assumptions, extrapolations, default data, and other processes in deriving its results and conclusions. Consequently, a regulatory science claim in this class does not meet the Reproducibility Principle, as an investigator who is trying to reproduce it must not only have proper skills and the necessary equipment, but must also accept the asserted scientific foundation; assumptions; choice of mathematical processes; default data; and numerous other prerequisites. Regulatory science relies heavily upon this class. A heretofore unrecognized subject is the fraction of reliance upon Proven or Reproducible Evolving Science. Consequently, for the sake of simplicity, scientific claims in this class can be subdivided into mostly reproducible, somewhat reproducible, and slightly reproducible evolving regulatory science.

Association-Based Evolving Regulatory Science: This class is often called correlation or observation studies, and is not based on Proven Regulatory Science or Reproducible Evolving Regulatory Science. Most epidemiological studies fall in this class by attempting to correlate two otherwise identical groups except that one group is exposed to an agent, or condition. Although it has been well established that correlation does not imply causation, this class is extensively used in the regulatory process. One of the primary goals of this class is to eventually elevate it to Reproducible Evolving Regulatory Science. This class is also extensively used in so-called evidence-based medicine by providing one of the first steps in understanding the cause of a medical problem. A heretofore neglected and unrecognized area of this class consists of economic predictions. Often economists are asked to predict an event such as the growth rate of a segment or the entire gross national product. These predictions are based on previous events that do not necessarily imply their reproducibility in the future.

Hypothesized Regulatory Science: This class consists of an organized response to an observation, an idea, or any other initiating thought process. Experience shows that although many great scientific discoveries started with this class there is also a long list of claims that have proven to be either wrong or not worth pursuing.

Borderline Regulatory Science

As the title implies, this group does not qualify as science as described in the sections devoted to Proven or Evolving Regulatory Science. We have identified two classes in this group:

Judgment: On occasion, decisions must be made without having the needed prerequisites, including basic principles, the necessary data, and other scientific requirements. On occasion a scientist or a group of scientists is asked to guess or predict a regulatory science issue when virtually no scientific publications, data, or other materials exist. The outcome of such an effort is an educated guess.

Speculation: This class consists of claims that cannot meet standards described in any of the above classes. It is often based on the intuition of an individual who wants to stimulate a discussion or initiate a research project.

Fallacious Information

Historically, those who feel strongly about a subject have attempted to present information dressed as science to promote their societal goals. This class of information is often called “pseudo-science”, “junk science”, “voodoo science” or “politically-processed science”. As expected, this class cannot pass independent peer review, the key process for the determination of acceptability of a scientific claim. There are those who justify the dissemination of fallacious information on the basis that it is necessary to exaggerate a problem in order to move the population to accomplish a noble goal. What is being overlooked is that such an approach is unethical and has the potential of causing long-term damage.

3.2.2. Assessment of the Reliability of Regulatory Science Claims

One of the key issues in managing regulatory science is the reliability of scientific claims. How can a regulator, a judge, a member of a legislative body, a reporter, or anyone else judge the validity of a claim? The substantial increases in regulations dealing with energy, drugs, food, health, environment, and numerous other areas have caused a demand that the scientific foundation of regulations be evaluated to ensure that ideology, accommodation of special interests, or the arbitrary decision of the regulators do not influence the decision process. The desire for assessing the reliability of regulatory science claims is not limited to regulations. Legislative actions, judicial decisions, and countless policies dealing with subjects such as national security require an assessment of reliability of their scientific foundation. The reliability of scientific claims, in general, and regulatory science in particular, can be categorized as follows:

Personal Opinions:

The expression of views by individuals, regardless of their training, experience, and social agenda, are included in this group. In a free society, every individual has the right to express an opinion. This freedom of expression is also applicable to expressing views ranging from Proven Science to Fallacious Information.

Are the reputation and scientific standing of an individual the determining factors in accepting a claim? As we will see later, the acceptability of a personal opinion is impacted by the reputation of the claimant. This process, known as the Matthew Effect [6] influences how the media and the scientific community react to a scientific claim. Intuitively, one is inclined to accept a claim by an accomplished and renowned scientist. However, history is full of events when highly qualified scientists are proven to be wrong.

Personal opinions are seldom, if ever, acceptable as the foundation of reliable science. Society is entitled to convincing evidence that a scientific claim is valid. Unfortunately, the standard process of the public media is mostly reliance upon this category in its reporting of scientific issues.

Gray Literature:

This category consists of written information prepared by government agencies, advocacy groups and others that has not been subjected to an independent peer review. Often Gray Literature is an organized and written form of personal opinions. Experience shows that the scientific quality of this category is unknown and ranges from various classes of Evolving Science to Fallacious Information. This is the favorite category of many government agencies, advocacy groups, and individuals who want to promote an idea.

Peer-Reviewed Regulatory Science Claims:

The value of peer review and similar processes in assessing the validity of scientific assertions has been known for at least two centuries, and there is a voluminous literature describing the peer review process [9]. For the sake of simplicity, henceforth peer review in this paper will imply independent peer review. Typically, peer review is performed by a panel consisting of at least three members. Elements of peer review are:

Qualifications of Peer Reviewers: The qualifications of peer reviewers are evaluated based on their education, experience, recognition within their professions, and related elements.

Conflict of Interest: **Members of the panel must be independent,** that is, **have no conflict of interest. The guiding principle for conflict of interest in peer reviews is:** "Those who have a stake in the outcome of the review may not act as a reviewer or participant in the selection of the reviewers."

Peer Review Criteria: The primary objective of review criteria is to ensure the scientific validity of regulatory science claims. Typically, review criteria include:

1. Scientific Validity: Consistency with established scientific principles and relevant standards.
2. Structure of the Study: Typically, the description of the structure includes a description of the status of science, the methodology used in the investigation, the results, discussion of the results in the context of the status of science, and conclusions. Note that it is critical that conclusions are entirely derived from the results of the study.

Peer Review Oversight: Ideally, an oversight committee oversees the entire process and ensures that members of the panel are qualified and are independent.

Consensus-Processed Regulatory Science Claims:

This category consists of the result of a process used to resolve scientific disputes, particularly those in contested areas of science. This process is particularly useful in regulatory science, as in most cases scientific claims are at best Partially Reproducible Evolving Science and often include assumptions, judgments, default data, and related areas. The operational elements of consensus process are similar to those described for peer review.

3.3. Areas Outside the Purview of Science

There is overwhelming evidence that the inclusion of societal objectives in the scientific process would jeopardize the objectivity and consequently the acceptability of scientific claims. For example, many scientific studies have addressed racism (Wikipedia at en.wikipedia.org/*wiki*/*scientific_racism*). The primary objective of regulatory science is to provide policy makers with reliable information, including its level of maturity. The scientific foundation of a policy, including a regulation, should be identical if it is prepared in the U.S., Russia, China, Saudi Arabia, Israel, Iran, Brazil or any other country. The scientific process would include the description of the level

of reliability and the identification of the level of maturity of the science, both being reasonably objective. In contrast, the policies derived from science can be significantly different in the countries identified above.

Government Research Funding:

For several years, there has been a disagreement between members of the legislative bodies (House of Representative and Senate) and certain members of the scientific community, on the respective roles of the legislative branch of government and the National Science Foundation (NSF) in providing research support. A detailed description of the underlying arguments is beyond the scope of this paper. Briefly, there has been extensive criticism of certain grants [5] including the so-called Golden Goose Awards, created by the former Senator Proxmire (D-Wisconsin); by Senator Coburn (R-Oklahoma), who routinely issued a list of what he considered to be wasteful; and Representative Smith (R-Texas) who introduced legislation that would have placed certain limitations on NSF activities. In addition, there have been criticism of many government funding agencies, including the EPA, the U.S. Department of Agriculture, and the National Institutes of Health (NIH). The key and appropriate question would be: what is the respective role of policy makers, as represented by the Congress and implemented by the Executive branch of the government, versus the role of the scientific community? The BAS/MERSC provide the answer as follows:

> Under the U.S. system of government, the U.S. Congress appropriates funds for all government expenditures, including funds for scientific research. For obvious reasons, Congress needs and receives scientific advice. Traditionally, the Library of Congress has been the primary source of scientific support for members of the two houses of Congress. In addition, both houses of Congress convene hearings inviting scientists to provide advice not only to the members of the relevant committee but also to the Congress. Subsequently, Congress uses scientific advice from these sources to pass appropriations that fund various agencies, including the NSF. Specifically, the legislation may, and often does, include funding for specific area such as cancer research. The appropriation process is – according to the BARS/MERSC – Outside the Purview of Science.
>
> Once the appropriations are passed and signed into law, relevant agencies of the executive branch must implement the funding law. The implementation requires establishment of peer-review panels to prioritize the submitted proposals. The role of the funding agency, such as NSF, is to implement the result of the peer review.

To summarize, under US law, elected officials (the Congress) decide areas of research and development that are to be supported. The task of the scientific community is to assist the Congress in selecting activities and projects that are likely to succeed and identifying the best options . Once the funding decision is made by Congress, the role of the scientific community is to advise the implementing agency, such as NSF, in evaluating the scientific validity of submissions that seek funding.

The Desirability of Regulations:

In the U.S. and in several other countries, the desirability of certain regulations has been subject to considerable dispute. There are three groups on how to address the desirability of regulations:

1. The first group claims that the number of regulations must be kept at a minimum, since most regulations impede the free enterprise system and thereby the economic advancement of society. This group agrees that certain regulations are needed but argues that in the majority of cases there are too many regulations.

2. The second group argues that there is ample evidence suggesting that the government must ensure that industry and other segments of society abide by the rules of safety, health, environmental protection, and many other issues and requirements. This group argues that in the past many needed requirements have been neglected, and thus the only way to accomplish these goals is to force industry and other segments of society to comply with the needed requirements.

3. The third group follows the rules of BARS/MERSC. According to this process the desirability of regulations is Outside the Purview of Science. However, the acceptability of science used in the regulations must be based on the BARS/MERSC system. Briefly, those who initiate regulations must comply with the Scientific Rules and Ethical Rules Principles. Consequently, the affected communities must be provided with information on assumptions, judgements, inclusion of default data, and any other item that is not reproducible science typically used in scientific assessments as the foundation of regulations. In addition, they must justify their selection, identify potential alternatives for each of them, and the consequences of potential alternatives. Such an approach is likely to reduce the disagreements between the two first groups.

4. Implementation of BARS/MERSC

The description of the five principles and three pillars indicated several areas that are unique and would benefit from further elaboration.

1. Implementation of the Ethical Rules Principle requires significant attention to its elements.

2. The Level of Maturity of Science, as described in the pillar on Standardization of Regulatory Science Claims.

3. Inclusion of Areas Outside the Purview of Science in regulatory science claims.

4.1. Implementation of the Ethical Rules Principle

In contrast to Scientific Ethics, implementation of the other three elements of the Ethical Rules Principle requires a brief expansion:

The affected community can be categorized in three groups:

1. Individuals who are specialists in the relevant scientific discipline. This group includes members of various disciplines that are used in regulatory science.
2. Knowledgeable non-specialists consisting of individuals who have sufficient knowledge to understand a scientific issue and can communicate with individuals with insufficient understanding of the science. The overwhelming majority of policy makers, and members of various scientific disciplines are included in this group.
3. The third group consists of individuals who are neither specialists nor knowledgeable non-specialists.

Ideally regulatory science must be written in a language that is understandable to all three groups. However, the knowledgeable non-specialist (second group) is of particular interest as it includes many policy makers (e.g. members of the House of Representatives and Senators), a large segment of those who implement regulations, and interested members of the scientific community. In addition, key segments of the regulated community and various scientific disciplines are also likely to be knowledgeable non-specialists. Therefore, regulatory science must be written in a language that is understandable to this group. For example, many regulatory science documents include mathematical equations that are not readily understandable to this group. In the overwhelming majority of cases, the content of mathematical equations can be described in an understandable language for non-mathematicians.

4.2. Truthfulness

One element of the Ethical Rules Principle is Truthfulness. One of the most recognized proponents of truthfulness was Thomas Jefferson, who provided guidance to the government on how to get society involved in the decision process.

The Jeffersonian School relies upon a frequently quoted statement by Thomas Jefferson: *"If we think the people are not enlightened enough to exercise control with a wholesome discretion, the remedy is not to take it from them but to inform their discretion by education."*

The Anti-Jeffersonian School consists of those who consider no reason or need to involve the public in major decisions, particularly if the decision is too complex or is based on science beyond the ability of the public to comprehend. Thus, to proponents of this school, the public cannot comprehend its needs. This group believes that the release of relevant information would cause avoidable harm and would delay or negate the completion of a decision that, in the judgment of proponents of the decision, would be vital. Jonathan Gruber, a well-known and highly accomplished professor, claimed that the voters are too "stupid" to recognize the significance of a law [15]. Although he apologized for having made the statement, the claim remains in the public domain. The anti-Jeffersonian School includes the following groups:

- Many regulators who claim that regulatory science is too complex to be comprehended by a "lawyer" or a non-scientist. As described in this paper, in the overwhelming majority of cases regulatory science can be described in a manner that is understandable to a knowledgeable non-specialist, and, occasionally, to the general public. Regulators making this claim of complexity are more concerned that communicating the science would jeopardize their goal of enacting a regulation or any other policy decision.
- There are individuals, advocacy organizations, government agencies, and others who consider achieving a societal goal to be important enough to maintain secrecy and avoid informing the affected community on the scientific details of a societal decision.
- Another group considers the inclusion of the people, including the affected individuals and groups, to be unnecessary. According to the philosophical foundation of this group, most people are "too stupid" to understand the science and its application. Therefore, transparency is a wasted effort.

4.3. Transparency

As described in previous sections, regulatory decisions are often made based on insufficient scientific knowledge ranging from Partially Reproducible, Association-Based, Hypothesized Evolving or Borderline Science to Judgment and Speculation included in Borderline Science. Therefore, regulations include assumptions, judgments, inclusion of default data, and speculation. As described under regulatory science truthfulness, BARS/MERSC provides guidance on how to address the need for transparency implying that the regulators must provide to the affected community various key elements of their scientific decisions.

4.4. Addressing the Level of Maturity of Regulatory Science

One of the contested areas of regulatory science is assessment of causation of cancer as consequence of exposure to specific agents in general and ionizing radiation, in particular [10]. There are many studies addressing cancer occurrence in humans as a consequence of exposure to ionizing radiation, including those dealing with Hiroshima and Nagasaki; radium dial painters, and workers at facilities of the Atomic Energy Commission or the Department of Energy. Based on these studies, the U.S. National Academy of Sciences concluded that a linear, non-threshold model (LNT) should be used to assess the risk of exposure to ionizing radiation, implying that cancer may be caused by exposure to ionizing radiation linearly from levels that have been observed to zero. The French equivalent of the U.S National Academy of Sciences came to the opposite

conclusion, suggesting that there is a threshold for cancer causation. The French appear to have accepted the principles established by Paracelsus, the father of toxicology, that "the dose makes the poison." The French Academies explicitly relied upon numerous evidences contradicting the LNT model. For example, cancer in several cities around the world have radiation exposure caused by naturally-occurring radionuclides that have no more cancer in population that other cities with much less exposure. In addition, there is evidence called "hormesis" indicating that exposures to ionizing radiation cause low level positive health effects.

4.5. Areas Outside the Purview of Science and Regulatory Science

As described earlier, regulatory science is largely predictive in nature by using Evolving Science or Borderline Science to predict the beneficial effects of implementing a regulation and potential harms if the regulation is not implemented. As the above example of the LNT demonstrates, two highly distinguished scientific organizations come to contradicting conclusions. The reason is simple: In one case (U.S. National Academies) the judgment was based on the desire of the scientists to be conservative/protective. The same approach has been used to predict low-level exposure to other carcinogens and numerous other environmental pollutants.

The approach based on the implementation of BARS/MERSC would be to translate the scientific segments of the regulations for knowledgeable non-specialists. Decisions that would fall in Borderline Science (Judgment or Speculation) would be removed from science and would be addressed in policy decisions. The regulator would have to justify the decision based on the societal goals of the regulatory agency. The regulators may not claim that science or scientist "say so", as current is done.

5. Conclusion

The BARS/MERSC system provides a detailed process to assess a regulatory science claim. The global community is increasingly facing key decisions that are based on science or include scientific areas derived from various scientific disciplines. Society will be better served once the decision makers follow the BARS Principles and the three pillars derived from BARS. In particular, the regulators should follow the truthfulness and transparency elements of the Ethical Rules Principle; avoid including societal objectives in the science; and communicate the level of maturity of science used in the decision process.

6. Declaration of Conflicting Interest

The authors declare that there is no conflict of interest.

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8. Article Information

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