

# Constitutional Constraints on Regulation

Under the checks and balances of our system of government, the Constitution, as ultimately interpreted by the Supreme Court, requires certain procedural and substantive standards to be met by statutory or other regulation imposed upon an activity. These requirements depend on the nature of the activity involved. In the present case, it will be useful to consider first the regulation of basic research and then the regulation of technological applications, such as the production of pharmaceuticals by using genetic engineering methods.

## Research

With respect to research, the fundamental question is what limitations, if any, may be placed on the search for scientific knowledge. The primary applicable constitutional provision is the first amendment, which has been broadly interpreted by the Supreme Court to severely limit intrusion by the Government on all forms of expression.<sup>123</sup> Another constitutional safeguard, known as equal protection, is secondarily involved.

If the Supreme Court were to recognize a right of scientific inquiry, its boundaries would not exceed those for freedom of expression.<sup>4</sup> There is disagreement among commentators on this issue concerning the boundaries of the first amendments and certainly disagreement on the application of generally accepted principles to particular cases. Moreover, there have been no judicial decisions dealing with the precise issue at hand. However, it is possible to outline general principles derived from judicial decisions interpreting the first amendment, and indicate how they might be applied by the courts to attempts to regulate genetic research.

There are very few limitations on the written or spoken word. The prohibitions against obscenity or "fighting words"\* clearly would be inapplicable here.

<sup>4</sup>Harold P. Green, "The Soundaries of Scientific Freedom" *Regulation of Scientific Inquiry: Societal Concerns With Research*, Keith M. Huff (ed.) (Washington, D. C.: AAS, 1979), pp. 139-143.

<sup>5</sup>Thomas I. F. Emerson, "The Constitution and Regulation of Research," *Regulation of Scientific Inquiry: Societal Concerns With Research*, Keith M. Huff (ed.) (Washington, D. C.: AAS, 1979), pp. 129-137.

<sup>6</sup>John A. Robertson, "The Scientists' Right to Research: A Constitutional Analysis," *Southern California Law Review* 55:203, S. September 1978.

<sup>7</sup>Green, op. cit., p. 140.

<sup>8</sup>Emerson, op. cit., pp. 131-134.

\*"Fighting words" are those provoking violent reaction or imminent disorder.

For many years, the Supreme Court has conceptualized the right of free expression in terms of a marketplace of ideas—through the open and full discussion of all ideas and related information, the valuable, valid, or useful ones will be accepted by society, while the ridiculous or even dangerous ones will be so demonstrated and discarded. This is a consensual process; no person, group, or institution has sufficient wisdom to prejudge ideas and deny them admittance to that intellectual marketplace, even if they threaten fundamental cultural values, for such values, if worthwhile, will survive. Under this concept, scientists would certainly have virtually unrestrained freedom to think, speak, and write.

Difficulties arise with actions, such as experimentation, which may be essential to the implementation of freedom of expression. Recent Supreme Court cases have recognized a limited protected interest of the media to gather information as an essential adjunct to freedom of publication. By analogy, it may be argued that scientists would also be protected in their research, as a necessary adjunct to freedom of expression. On the other hand, the information gathering cases usually involve access to Government facilities, such as courtrooms or prisons. They are based on the principle that actions by the Government should be open to public scrutiny—a concept not directly applicable to the present issue. More importantly, the Court has long recognized that actions related to expression can be regulated and that regulation may increase with the degree of the action's impact on people or the environment. The Court would probably apply what has been called a structured balancing test;<sup>6</sup> i.e., regulation would be deemed valid only when the Government sustains the burden of proving: 1) that there are "compelling reasons" for the regulation; and 2) that the objective cannot be achieved by "less drastic means," i.e., by more narrowly drafted regulations having less impact on first amendment rights.

The second part of the test is fairly straightforward. Governmental restrictions must be kept to a minimum. E.g., where possible, they should be regulatory rather than prohibitory, temporary rather than permanent, involve the least burden, and so on.

The difficult part of this test lies in determining

<sup>9</sup>id. at p. 134.

what is a compelling reason. The protection of health or the environment is the most clearly acceptable reason for regulation. In addition, the protection of individual rights and personal dignity is generally considered an acceptable reason. E.g., the National Research Act<sup>7</sup> requires that all biomedical and behavioral research involving human subjects supported under the Public Health Service Act be reviewed by an Institutional Review Board in order to protect the rights and welfare of the subjects.

The above discussion relates to protection from physical risks due to the process of research. Could the Government regulate or forbid experimentation solely because the product (knowledge) threatens cultural values or other intangibles such as the genetic inheritance of mankind? Religious or philosophical objections to research, based solely on the rationale that there are some things mankind should not know, conflict with the basic principles of freedom of expression and would not be sufficient reason on constitutional grounds to justify regulation. Even if the rationale underlying this objection were expanded to include situations where knowledge threatens fundamental cultural values about the nature of man, control of research for such a reason probably would not be constitutionally permissible. The rationale would again conflict with the marketplace of ideas concept that is central to freedom of expression. However, what if the knowledge were to provide the means to alter the human species in such a way that the physical, psychological, and emotional essence of what it is to be human could be changed? No precedent exists to provide guidance in determining an answer. Were the situation to arise, the Supreme Court might fashion another limitation on the concept of free expression in the same way it developed the obscenity or “fighting words” doctrines.

The discussion thus far has had as its premise a direct regulatory approach to research. There is a more indirect approach, which would be constitutionally permissible and could accomplish much of what direct regulation might attempt, including prevention of the acquisition of some forms of knowledge. This is the use of the funding power. The lifeblood of modern science in the United States is the Federal grant system. Yet it is generally agreed that Government has no constitutional duty to fund scientific research.<sup>8</sup> This is a benefit voluntarily provided to which many kinds of conditions may be attached. The only constitutional limitation on such an approach would be the concept of equal protection—any restrictions must apply to all or must not be ap-

plied in a discriminatory way without compelling reasons.

Congress could therefore, mandate by law that certain kinds of research not be funded or be conducted in certain ways. An example is the National Research Act, discussed previously. However, this approach may have some serious practical limitations because of the difficulty of determining which molecular biological research might lead to the proscribed knowledge. Much discretion would have to be left to the funding agency, which is likely to be unsympathetic or even hostile to such an approach, if it views its primary mission as fostering research.

### *Applications and products*

Although fears have been expressed that current genetic technologies may lead to applications that would be detrimental, no one can reasonably conclude, at the present time, that this will actually occur. For this reason, the most constitutionally permissible approach in all probability will be to regulate the applications of the science. In such situations, whatever harms occur tend to be more tangible and the governmental interests, therefore, more clearly defined. Moreover, since fundamental constitutional rights are generally not involved, statutes and regulations are subjected to a lower level of scrutiny by the Federal courts.

The constitutional authority for Federal regulation of the applications of technologies such as genetic engineering lies in the commerce clause, article I, section 8 of the Constitution, which grants Congress the power “To Regulate Commerce with foreign Nations, and among the Several States.” In contrast to situations involving fundamental rights, the Supreme Court has interpreted this clause as giving Congress extremely broad authority to regulate any activity in any way connected with commerce. It has been virtually impossible for Congress not to find some connection acceptable to the courts between commerce and the goals of a particular piece of legislation.<sup>\*</sup> The standard of review of such legislation by the Federal courts is to determine if it bears a rational relationship to a valid legislative purpose. If so, the Court will uphold the legislation and will not second guess the legislators. This standard of review recognizes that a statute results from the balancing of competing interests and policies by the branch of Government created to function in that manner.

<sup>\*</sup>See *Wickard v. Filburn*, 317 U.S. 111 (1942) in which the Supreme Court upheld civil penalties for violation of acreage allotments established by the Agricultural Adjustment Act of 1938, covering the amount of wheat that individual farmers could plant, even if the wheat was intended for self-consumption. The rationale was that even though the individual farmer’s wheat had no measurable impact on interstate commerce, Congress could properly determine that all wheat of this category, if exempted from regulation, could undercut the purpose of the Act, which was to increase the price farmers received for their various crops.

<sup>7</sup>Public Law 93-348 (1974), 42 U.S.C. §2891-3

<sup>8</sup>Green, *op. cit.*, p. 141.