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A "One License–One Hearing" Policy

A landmark in the development of modern genetics was the "one gene–one enzyme" hypothesis. A "one license–one hearing" policy might provide a helpful impetus to the regulation of genetic engineering.

The development of a new biotechnology industry stands at a crossroad. The path traveled in developing new technologies has often been filled with recriminations between those who think we are going too slowly and those who think we are going too fast. Today, industrial advocates say that the new biotechnology industry is a fragile infant whose health is being impaired by the burden of bureaucratic red tape and unconscionable delays in litigation. Environmental groups say we are tampering with fundamental natural processes and that the hazards are too great to justify speed.

The vast majority of individuals on both sides are trying to do "the right thing." A good, safe destination is everyone's goal. However, different travelers use different premises and arguments on the most appropriate pathway. Science attracts adventurous souls who by nature are impatient with obstacles. Regulators are more cautious types, reasoning that change involves risk and that risk is more likely to lead to harm than to benefits.

An application for biotechnology experimentation can face interminable delays in multiple agencies in Washington, further delays in states and localities, and still be subject to lawsuits. Can scientists and environmentalists find a more direct and well-lighted path to safety and goodness? It seems possible that, with ingenuity and reasonableness, we can.

There are already a number of regulatory bodies in Washington with power to authorize genetic engineering applications and research. At the federal level each request for a license could be assigned to the agency most appropriate for that case, with notice given to all other regulatory bodies having overlapping interest or authority. The latter could appear as friends of the "court," posing questions to the primary regulatory agency and to the applicant; they might add words of wisdom, but they could not hold separate hearings.

After the federal regulatory decision is reached, similar processes would apply at the state and local levels but with a "one state–one hearing" limit also. Hearings should be widely publicized so that all interested parties could have a say. Protestors would be given ample time to present their cases, but unreasonable delays would not be allowed. No side should be allowed a rehearing under another regulatory jurisdiction. Court action or reconsideration should be reserved for serious substantive matters such as findings of erroneous or concealed data; suing parties should be liable for financial damages when legal delays are frivolous or ill-considered.

Some will argue that this is not the American way, that we are entitled to litigious and chaotic behavior patterns. Nonetheless, the public appears fed up with excessive lawsuits that are closing playgrounds, preventing parades, and bankrupting city governments. More rational procedures will require good will and superior imagination on all sides. The public is apprehensive regarding this new technology and determined to be vocal in the decision-making; impatient scientists and industry have to listen. In turn, biotechnologists can expect laypersons to make their arguments in a timely manner. Furthermore, responsible industrialists should be willing to blow the whistle on colleagues who push experiments or field trials too rapidly just as environmentalists should blow the whistle on colleagues who use excessive delaying tactics. By having one well-organized hearing for a federal license and one hearing for a state license, both accountability and deliberate speed can be accommodated.

We are entering the era of a global economy. No country can afford to have the senseless procedures and unproductive delays that are the hallmarks of the present system. Since biotechnology regulatory machinery is just being developed, rational procedures can more readily be instituted now rather than later when staff and jurisdictions have become entrenched. It has been said that society will always come to the right conclusion after it has exhausted every other possible alternative. In the present case, we cannot afford to grope to conclusions by legal trial and bureaucratic error. By opting for a path not taken heretofore, we can protect both the environment and an infant industry, and possibly find that a genetic analogy may lead to the survival of the fittest regulatory procedure.

—DANIEL E. KOSHLAND, JR.