Government Regulation: Insuring Safety and Quality *

This paper provides a brief outline of the regulation of biotechnology across the board in the United States today. An important feature of this discussion is that its focus is not on laws and regulations for the issues of biotechnology, but rather on science.

It is no surprise to those who work in this legislative area that regulation is not driven by legislators, lawyers and regulators, but that it is driven by the *science* that underlies the regulation. The history of government regulation of the food supply is the history of science, *not* the history of the laws and regulations that have been involved.

This is illustrated by the following example from a statute enacted by the English Parliament in 1263. Parliament decreed, in order to protect the safety of the food supply, that nothing could be added to the then staple foods in England that was "not wholesome for man's body". The statutory standard today is remarkably similar, stating that nothing can be added to foods if it is a "poisonous or deleterious substance that may render the food injurious to health". And I challenge anyone to point out the difference between "not wholesome for man's body" which was the statutory standard 700 years ago, and "poisonous or deleterious substance which may render the food injurious to health", which is our statutory standard today and has been since the English statute of 1860. There is no difference.

If the 1263 law was the only law of the land today, the Food and Drug Administration (FDA) and United States Department of Agriculture (USDA) would be

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doing nothing differently. Thus the issue is clearly an issue of science, not of laws and regulation.

Government regulation of food and drugs, (which have always been related), has been of concern in our country for its entire 200 year history. Our earliest governmental federal statutes regulating any form of business were directed at the drug supply. From the Vaccine Act of 1813 on through the latter part of that century there was a plethora of laws and regulations enacted to prevent importation and exportation of adulterated food of any kind. These laws and regulations did not deal with regulation of domestic commerce of food and drugs because of a concern that these were matters for state and local governments only. In the last quarter of the 1800s in the United States we had a constitutional debate in Congress, in particular, over the role of the Federal Government which at that time was thought to be restricted to foreign commerce. Domestic commerce was considered a matter solely for state, local and county governments.

It was only the first decade of this century that Congress' and the Supreme Court's view changed. At that time, the laws that are seen today were put in place. Between 1900 and 1910, there was the Vaccine Act of 1902, the Food and Drugs Act of 1906, the Federal Meat Inspection Acts of 1906 and 1907, and the Insecticides Act of 1910. These laws effected what we still regard, with years and decades of enactment and revision, as our basic food protection laws. In the 1970s a plethora of amendments and revisions and new environmental statues were added. In addition to these regulatory laws, an overlay of broad statutory authority exists, vested in the United States Government, which regulates indirectly.

For example, the National Institutes of Health (NIH), the Department of Defense and other government agencies have broadly contracted grant authority, and that authority can be used to impose any form of restriction believed reasonable. That was the origin of the recombinant DNA guidelines created in the 1970s at NIH.

Many basic research scientists in the debate that occurred in the mid-1970s were shocked to discover that they could be regulated. The theory was promoted in conferences such as this from 1976 to 1978, by scientist upon scientist who took the lectern and said, "We demand the right to freedom of speech!", to which I always responded "Everybody in this country has the right to freedom of speech, but you do not have the right to free-

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dom of *action*, if freedom of action, including research, means potentially putting others at danger." Our courts have always been quick to point out the difference between speech and action. Any research scientist who wished to espouse recombinant DNA research was free to do so without restrictions. But once in action, the basic bench scientist stands in no different a position than the railroad or the pharmaceutical industry, or the food industry or anybody else. Scientists are as subject to regulation in our country as any other form of commercial enterprise. I cannot tell you how disappointed the research scientists were to hear that news.

Regulatory statutes can often be divided into two basic kinds of statutes—those that deal with products, like foods and drugs, and those that deal with processes, usually industrial processes, like clean air and clean water.

For the purposes of looking at how recombinant DNA and biotechnology can be regulated, it is presented as a progression from the laboratory to the consumer. This progression begins with basic chemicals. Is there any regulation of basic chemicals in our country? Absolutely; starting with the Toxic Substances Control Act, enacted in 1976 precisely to fill the gaps of all the other regulatory controls enacted over the years and to make sure that there was no lack of regulation. Before a new chemical of any kind may be put to any use in this country, it must survive a pre-market notification submitted to the Environmental Protection Agency (EPA), and it must not be vetoed for marketing. The Environmental Protection Agency has the identical authority over all new chemicals that the FDA had over all new drugs between 1938 and 1962. Not pre-market approval, but pre-market notification and veto—a slightly different form of regulation, but one which is effective nonetheless. And very stringently used by EPA these days. Therefore, basic chemicals are fully subject to regulation by the United States Government.

Next, an examination of plants and animals. Just plants as they sit there in the field, and animals as they walk around. Suppose we start tinkering with them, as we all know we are. Are they regulated? There are actually more regulations and more regulatory laws authorizing USDA in particular to regulate plants and animals as such than there are anything else in this entire system.

1 will name some of these. The Organic Act allows USDA to prevent plant pests; the Plant Pest Act, the Plant Quarantine Act, the Noxious

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Weed Act, the Federal Seed Act, Animal Quarantine laws, the meat and poultry, egg and food laws, the Endangered Species Act, and then the Department of the Interior has the authority to restrict the import and introduction of exotic plants or animals into the natural ecosystem. There are enough laws here. In fact, we have *more* than enough laws. It makes sense to take all of these crazy statutes and try to put them all together and make sense out of them. Something that Congress has never considered, and in its current state of affairs, probably will not get around to.

It is silly to think that entire new plant systems or animals could be injected into our environment without government control. Having at one point served on an Office of Technology Assessment (OTA) Committee looking precisely at the issue of whether there were regulatory gaps in this area, we could find none.

The introduction of plants and animals into consumer products—do we have authority there for the government to control the issue? We have the FDA, of course, and its control over food safety, that I will come back to in a moment; EPA continues to control pesticides; the Consumer Product Safety Commission was authorized in 1972 to control all consumer products not otherwise regulated by USDA or FDA; and we have USDA authority with continuous inspection over meat, poultry, and eggs. The odds of anything slipping through that system are very small indeed.

Let us go on to the workplace, where these products are produced. The Occupational Safety and Health Administration (OSHA) was created in 1970 precisely to deal with all workplace effects. In 1985, OSHA announced that its controls applied to all use of biotechnology in any workplace whatever including the research laboratories.

Let us look then at the environmental effects. Effects in the air, the water, the so-called, one of the great misnomers of all time—"deliberate release" problem. The Environmental Protection Agency has plenary authority under Clean Air Act, Clean Water Act, Resource Conservation and Recovery Act (RCRA), Superfund, the Marine Protection Act and a variety of statutes and regulations that we need not get into. The environment is as clouded with regulatory control as is the food and drug supply.

Transportation—is there any way that these rambunctious recombinant DNA molecules can be transported around the country under unsafe conditions? Well, the post office itself has already issued regulations saying

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you cannot mail them. The Center for Disease Control (CDC) has control over all etiologic agents of any kind; nobody can deal with them without CDC approval. The Department of Transportation deals with them under the Hazardous Materials Transport Act. So we have more than enough authority there.

Now you might say that pretty much covers everything. But additional regulatory controls in the United States make sure there are no cracks in this entire regulatory edifice. To make certain that everything else is controlled, Section 301 of the Public Health Service Act in effect authorizes the Public Health Service to do anything they need to do to protect the public health. Section 361, which I actually authored in the debates in 1976, is the single regulatory control mechanism for all of the new biotechnology. It states that the public health service, including FDA, may take any action of any kind whatever, intra-state or inter-state, in order to prevent (not control) the spread of communicable disease of any form. It is a holdover from 100 years ago, in the days when we were terribly concerned about the spread of infectious disease. That statute, one sentence long, could be used to control all aspects of biotechnology.

Thus we have a regulatory scheme in place in the United States today that is more than sufficient to control biotechnology. The real problem is enormous overlap of among these statutes. There is virtually nothing that cannot be controlled. I will get to two issues that have been raised about that. My judgement is there is no gap here, only the real problem of administrative overlap and therefore the need for administrative comity. I always pronounce that very carefully; we have enough administrative comedy. The problem is one of coordination, making certain that we do not kill an industry, kill a research, kill the greatest opportunity for humankind to improve public health that the world has ever seen.

There have been many people who have suggested that on top of all of this, we need new statutes and regulations to deal with biotechnology *per se*. I find that ludicrous. The attempt by the United States Senate in particular in 1978, to enact legislation designed to deal precisely with a broad new overarching control of biotechnology in my judgement would have nipped the scientific promise of biotechnology before it could have begun. That was successfully avoided by scientists uniting in their opposition; by discussions in particular with Senator Edward Kennedy, scientific progress and the need for flexibility; and by taking upon themselves in one of the

most extraordinary and wonderful events 1 have ever seen in the field of science, self-regulation through basically a voluntary regulatory system set up by the NIH in the form of the recombinant DNA guidelines; the development of the Recombinant Advisory Committee (RAC). If science had not acted responsibly, and had not done that, we would have seen the Senate enact legislation and we would not have the progress that we have seen to date.

The two issues mentioned as needing additional controls are: worker surveillance, (as though OSHA did not exist and did not have its authority), and "deliberate release", (to return to what I regarded as one of the great misnomers of all time). I keep pointing out the whole purpose of biotechnology is to release something into the environment, otherwise if you contained it, it would not very useful. Nonetheless, that has become one of the issues in terms of adequate regulation.

Our OTA committee reviewed the issues in detail and concluded that once again, we have more than enough laws. If we needed to energize some of our regulatory agencies to utilize those statutes, to take the opportunity to increase regulation in particular areas where it was needed, that was fine. But we did not need new laws and regulations.

Now let me turn very briefly to FDA and the regulation of food in particular. No new food ingredient—whether we call it a whole food or a food substance (we are not going to call it a food additive because that prejudges the issue), may be used in the food supply in the United States whether in meat or poultry or any other food unless it satisfies one of three criteria: 1) it must have been approved by USDA or FDA between 1938 and 1958, (i.e., a prior sanctioned substance); or 2) it must be "generally recognized as safe", a GRAS substance; or 3) it must be the subject of a food additive regulation. If it is not one of those three, it is illegal.

It is very simple. We have a wonderfully easy system, when you get right down to it. All you have to do is understand those three concepts. Now obviously there were no recombinant products prior to the Food Additives Amendment of 1958, and so one might easily conclude that ends at all. New biotechnology has to be regulated through a food additive regulation. Not true.

When one takes a plant and alters it, one can do that by natural breeding or selection or one can do it by recombinant DNA. When FDA issued its regulations well before biotechnology in the early 1970s, the agency anticipated the kinds of issues from breeding and selection and said that it is a

matter of judgement—a matter of science, not of laws and regulations—as to when a food ingredient is so changed that it is no longer subject to a prior sanction or a GRAS determination and requires a food additive regulation. Or when it changes just slightly, but not enough to worry about, it can remain subject to that prior sanction, or subject to an existing GRAS determination, or indeed subject to an existing food additive regulation, and does not need a new regulation.

Now FDA issued those regulations before Paul Berg did his work and the Recombinant Advisory Committee was formed. The regulations have not changed and they do not need to be changed. Some have argued that FDA should be more explicit; they should lay down heavy, rigid rules, telling everybody when things have changed so much that you need a new regulation and when they are sufficiently similar that you do not need a new regulation. I think that would be foolhardy. I think we would have rules and regulations that would tie us in knots rather than being helpful. Flexibility is a far greater attribute in government regulation than rigidity. It is, I hope, as meaningful to all of you as it has been to me, that the first FDA approval of a recombinant product came not in the form of a new, rigid, regulation, but in the form of a GRAS determination, thus sending a signal that FDA is prepared to remain flexible in its regulation in the future.