

BOOK REVIEWS

AIR POLLUTION: FEDERAL LAW AND ANALYSIS. By David P. Currie. Wilmette, Illinois: Callahan and Company, 1981. Pp. xii, 602. \$75.00.

The federal law of air pollution control has grown enormously complex. Its most fundamental source, the Clean Air Act,¹ fills two hundred and twenty-eight pages in a recent commercial printing.² The legislative history of that statute is voluminous, as are the various sets of federal regulations which implement its mandates. More than two hundred judicial opinions have been handed down in the federal courts which construe various aspects of the Clean Air Act;³ and the Act has been the subject of a considerable body of secondary writing.⁴

IN AIR POLLUTION: FEDERAL LAW AND ANALYSIS, Professor David Currie attempts, with considerable success, to guide the practitioner, administrator and judge through this dense and often bewildering thicket of legal materials. His book provides a cogent, well-organized and carefully researched synthesis of the relevant law. Beyond his detailed summary, Professor Currie undertakes an independent exegesis of the Clean Air Act, its regulatory implementation by the United States Environmental Protection Agency ("EPA"), and its interpretation by the federal courts. This critique, while generally thoughtful and balanced, is at least in some respects open to question. It is likely to generate controversy at the same time as it resolves difficult questions of law and policy. Nonetheless, the work's breadth of coverage, clarity and careful statutory analysis merit high praise. This book should not be ignored in the current congressional reconsideration of the Clean Air Act.

Professor Currie's approach to air pollution control is summarized in the work's concluding chapter. He believes that "a vigorous program to regulate pollution by direct governmental action" (p.

1. 42 U.S.C. §§ 7401-7642 (Supp. I 1977 & Supp. II 1978).

2. D. CURRIE, AIR POLLUTION: FEDERAL LAW AND ANALYSIS (1981).

3. See the compilation in CURRIE, *supra* note 2, at Tables 11-22.

4. See, e.g., I F. GRAD, TREATISE ON ENVIRONMENTAL LAW 2-49 to 2-302 (1981); W. RODGERS, HANDBOOK ON ENVIRONMENTAL LAW 208-353 (1977). See also the several articles of his own the author cites in CURRIE, *supra* note 2, at iii, fn. 1-3.

10-1) is needed, that this program is most appropriately focused at the federal level, and that "[t]here should be a system of remedies adequate to make the program effective in preventing and deterring violations." (p. 10-2). Professor Currie approves, with good basis, the present thrust of the Clean Air Act and its regulations, which he regards as "something of a triumph" (p. 10-4) in reducing air pollution without unreasonable economic hardship. As Currie puts it: "the statute is extremely untidy, but it works." (p. 10-5).

Notwithstanding this approbation, Professor Currie makes numerous specific criticisms of the statutory scheme throughout his work. Many of the caveats stem from two premises: 1) the air pollution control effort should aim at achievement of "not absolute but optimal" (p. 10-1) protection of environmental and health values, *i.e.*, the expected benefits of any proposed requirement should justify the cost of complying with it; and 2) legislatures are best advised to limit their role to the resolution of "basic policy questions" of air pollution control, at the same time as they leave the setting of specific, detailed emission standards to "administrative specialists." (p. 10-1). These two assumptions, while difficult to dispute as abstract normative propositions, are frequently difficult to apply or of questionable merit in the establishment of specific air pollution policies.

This is especially true of Professor Currie's second premise. Though space does not permit a lengthy critique here, this reviewer tends to agree with those commentators who have expressed skepticism at the "neutrality" of government agencies in arriving at "expert" judgments regarding policy questions.⁵ Government agencies inevitably take many actions in a context of political pressure and controversy, especially in the environmental field. They sometimes advance their own conception of policy, and attempt to give it greater sanctity and authority, by embodying it in the seeming objectivity of an "expertise".⁶ Thus it is far from clear that agency decisions respecting many specific questions as to appropriate levels of emissions or pollution control technology would necessarily prove any more sound, objective or "scientific" than the resolution which Congress would reach respecting the same issues.

5. See, *e.g.*, T. LOWI, *THE END OF LIBERALISM* 72-93 (1969); J. SAX, *DEFENDING THE ENVIRONMENT: A STRATEGY FOR CITIZEN ACTION* 52-56, 60-62, 107 (1970); SIVE, *Some Thoughts of An Environmental Lawyer in the Wilderness of Administrative Law*, 70 COLUM. L. REV. 612 (1970).

6. L. JAFFE, *JUDICIAL CONTROL OF ADMINISTRATIVE ACTION* 580 (1965).

Regrettably, these concerns are not addressed in *AIR POLLUTION: FEDERAL LAW AND ANALYSIS*. Without extensive discussion, Professor Currie advocates congressional deference to the judgment of the EPA in the setting of various specific emission limitations, including those respecting light duty vehicles, which are presently established by Congress. (p. 2-10).

AIR POLLUTION: FEDERAL LAW AND ANALYSIS is divided into ten chapters, each of which considers in detail a specific topic regarding the federal scheme for regulation of air pollution. Each chapter is subdivided into sections of several pages each of which deal with particular aspects of the subject matter of the chapter. The coverage is comprehensive and the organization is logical.

After a brief introduction, in which he affirms the need for public regulation of air pollution, describes the history of federal legislation in the field and briefly reviews the current law, Professor Currie presents a detailed analysis of federal standards for mobile sources. Requirements for light- and heavy-duty vehicles, the waiver of light-duty standards, motorcycle and aircraft emission controls, enforcement of mobile source limitations, and regulation of fuels are all treated in detail. Of particular note are Currie's criticism of the Act's curious definition of the "useful life" of a light-duty vehicle as "five years or fifty thousand miles . . . whichever first occurs"⁷ (p. 2-70) and his suggestion that the EPA's authority to regulate aircraft use be explicitly conferred.⁸ (p. 2-108). These are the sort of "fine-tuning" changes in the Act's provisions which Congress would do well to adopt.

Currie's treatment of mobile source controls is weakened, however, by his failure to clarify the important interrelationship between performance warranties for vehicle emission controls and the Act's requirement that mandatory automobile inspection/maintenance ("I/M") programs be established in many non-attainment areas. As a practical matter, the vast majority of vehicle owners can become aware that the emission control devices on their automo-

7. Clean Air Act § 202(d)(1), 42 U.S.C. § 7521 (d)(1) (Supp. I 1977). As Professor Currie notes, this definition tends to artificially and unnecessarily limit the effectiveness of vehicle emission standards. As a result of this definition, such standards will be in effect for only half of the actual life of any newly manufactured car.

8. The author correctly observes that EPA regulation of aircraft use aimed at reducing emissions may not constitute "emission standards" under § 231 of the Act, 42 U.S.C. § 7571 (Supp. I 1977). He suggests, with considerable merit, that the statute be amended to eliminate this gap in the regulatory scheme.

biles are not functioning properly only if their cars fail to pass a vehicle inspection. Thus, without I/M programs, which Professor Currie criticizes (pp. 6-26 to 6-27), the vehicle emission performance warranties which he praises in his discussion of mobile source controls would have little real benefit for those they are designed to protect.

From mobile sources, Professor Currie moves to a comprehensive and generally perceptive treatment of direct federal regulation of stationary source pollution. New source performance standards, "designated facilities" (under section 111(d)⁹ of the Clean Air Act), regulation of hazardous pollutants, and emergency action provisions are all discussed in considerable depth, detail and sophistication. Among Professor Currie's helpful insights are his sound critique of the United States Supreme Court's questionable decision in the *Adamo Wrecking* case,¹⁰ (pp. 3-82 to 3-89) and his sensible observation that section 111 is defective in not allowing a standard to be set forbidding the construction of a source whose emissions would create an unreasonable health risk despite use of the best available technology. (p. 3-20). His trenchant criticism of the EPA's failure to implement aggressively section 111(d) of the statute (respecting designated existing facilities presently unregulated by the national ambient air quality standard-state implementation program provisions of the statute) is also well taken. (pp. 3-72 to 3-77). One hopes that it will not fall on deaf ears among the new leadership of the EPA.

Air quality standards and their implementation are the subject of Chapter 4 of *AIR POLLUTION: FEDERAL LAW AND ANALYSIS*. This is followed by detailed chapters on relief from implementation plans, pollution control requirements in non-attainment areas and the legal control of significant deterioration and visibility. The author's treatment of these subjects is, for the most part, thoughtful and fair.

Some aspects of the author's analysis of air quality standards, however, are open to question. Professor Currie's overemphasis of the possibility that compliance with primary (health-related) standards may in some circumstances "never be worth the cost," (p. 6-

9. 42 U.S.C. § 7411 (d) (Supp. I 1977 & Supp. II 1978).

10. *Adamo Wrecking Co. v. United States*, 434 U.S. 275 (1978). In *Adamo Wrecking* the Supreme Court narrowly construed the term "emission standard" in § 112 of the Clean Air Act, 42 U.S.C. § 7412 (Supp. I 1977 & Supp. II 1978), to mean a quantitative emission level as opposed to a rule prescribing work practices for the control of a hazardous pollutant.

27) and his suggestion that Congress restructure the variance provisions of the Clean Air Act to mitigate against any "undue economic hardship" engendered by air pollution control are troubling. As a general matter, it is difficult to disagree with the notion that pollution control regulation should be as cost-effective as possible and that every reasonable effort should be made to minimize any economic dislocation it might cause. Nonetheless, "hardship" or "dislocation" are notions which do not always admit of precise definition—by Congress *or* an agency—and economic "reasonableness" can sometimes provide an excuse for unnecessary delay and inaction in the attainment of important public health protections. It would be unfair to accuse Professor Currie of insensitivity to these concerns. His book intentionally strives for a balanced assessment of the federal law of air pollution control, and on many counts it succeeds. Still the work would have been improved if Professor Currie had devoted some portion of his 600-page volume to an accurate description of the deleterious effects of excessive air pollution on property, plant life and human health.¹¹ Such a summary would have underlined the real importance of attainment and maintenance of ambient air quality standards, and provided a fuller and clearer picture of the public policy implications of "trading off" concerns for health and the environment with traditional economic values.

The author's discussion of the enforcement provisions of the Clean Air Act makes a number of telling points. He recommends, with considerable merit, that section 113¹² of the statute be amended to expressly authorize the EPA to seek preventive relief before a violation takes place. (p. 8-3). Equally valid is his critical review of the EPA's noncompliance penalty policy (pp. 8-13 to 8-14) and his condemnation of the jaundiced notion that a pending state enforcement action constitutes a legal bar to any federal enforcement proceeding. (pp. 8-21 to 8-23).

Professor Currie misses the mark, however, with his suggestion that the authorization of administrative enforcement orders in section 113(a) of the Clean Air Act is an "illusory and time-wasting provision" (p. 8-10) which should be omitted from future versions of the statute. In this regard, the author seems unaware that to

11. For an excellent, non-technical discussion of these matters, *see* 1 F. GRAD, TREATISE ON ENVIRONMENTAL LAW, 2-8 to 2-17 (1981).

12. 42 U.S.C. § 7413 (Supp. I 1977).

repeal such a provision would limit the government's overall effectiveness in enforcing the statute.

In practice, some Clean Air Act violators have taken the position that they *will not* enter into consent decrees with the federal government. This position is explained on various grounds. Some companies take the view that a consent decree, filed in federal court along with a complaint, would be more likely to subject them to liability in pending or subsequent damage actions by third parties. Other violators feel their public reputation will be harmed by what they perceive as the "stigma" of being "sued by the government." When faced with this reluctance it seems reasonable that, in at least some cases, the government might be justified in issuing an administrative order to such violators, rather than insisting upon a consent decree containing identical requirements, or entering into protracted litigation. This is especially true in cases where all of the following factors are present: 1) the violations in question are relatively minor in terms of their impact upon public health or sensitive environmental values, 2) the government is convinced that the violator is likely to comply with the order, and 3) there are more pressing cases in which the government's scarce enforcement resources might be used to greater effect. The existence of an administrative order provision allows the government flexibility to balance and adjust its enforcement response to deal with a broad range of Clean Air Act violations and violators. It should remain in the law.

In his final chapter, Professor Currie focuses on judicial review under the Clean Air Act. Time limitations, standing, "non-statutory" review, citizen suits, court of appeals review of EPA adjudication and rulemaking, and the question of which court of appeals is the "appropriate circuit" in which to review certain actions are all considered. In many respects, this chapter is the strongest of the book.

Faced with a formidable analytic chore, Professor Currie reviews the leading statutory and case law on judicial review with great lucidity. One senses that the author is more at home in this area of the law than in dealing with economic concerns. His discussion frequently cuts to the heart of the ambiguities and conceptual weaknesses of these sections of the law, and his suggestions for reform are always provocative and usually sound.

Not all of Professor Currie's suggestions in this chapter are palatable. His opposition to vesting exclusive jurisdiction for review of nationally applicable standards in a single reviewing court is (pp. 9-

49 to 9-50) ill founded. His recommendation that the invalidity of a regulation be a permissible defense in an enforcement proceeding (pp. 9-44 to 9-48) would enormously complicate the already difficult task of enforcing state implementation plan requirements and EPA regulations. Currie also takes an unnecessarily restrictive view of the doctrine of standing; (pp. 9-61 to 9-65) his comments in that regard fail to take cognizance of the important and beneficial role which public interest groups have played in the development of the law in this field.¹³ These caveats aside, Professor Currie's discussion of judicial review under the Clean Air Act is generally astute and sensible. His analysis of the appropriate roles of the district and circuit courts in review of administrative actions pursuant to the Clean Air Act, for example, is especially valuable and clearly presented. In this and other respects, Currie's "Judicial Review" chapter will assist lawyer, judge and legislator alike in dissecting this murky aspect of the law.

Another useful feature of AIR POLLUTION: FEDERAL LAW AND ANALYSIS is its legible appendix which contains the full text of the Clean Air Act (as amended to June 1, 1981), with sections listed in both the United States Code and Statutes-at-Large numeration. This is a treat for the eyes of the weary lawyer—so used to the small print and italics which characterize many printings of the Act. Also of value are the tables and index. These indicate various sections of the Clean Air Act and judicial decisions which are discussed in the work, and helpfully categorize key terms and subjects.

On balance, this is a thoughtful and well-written book. It is extremely comprehensive, technical, and detailed in its coverage, and should provide a useful tool for novice and expert.¹⁴ The book does suffer from a lack of sustained consideration of some recent issues in the field (*e.g.*, acid rain regulation, indoor pollution, the Steel Industry Compliance Extension Act of 1981,¹⁵ etc.) and many of its conclusions will not please everyone. Nevertheless, AIR POLLU-

13. In the table of cases at the back of Professor Currie's book, 51 cases are cited in which citizen's groups are named parties. Many of these cases are of great importance. Environmental groups have also participated in a good deal of additional Clean Air Act litigation as intervenors or *amici curiae*.

14. Aside from National Commission on Air Quality, *To Breathe Clean Air* (Mar. 1981), Currie's book is the only full length work devoted to a comprehensive evaluation of the Clean Air Act.

15. Pub. L. No. 97-23, 95 Stat. 139.

TION: FEDERAL LAW AND ANALYSIS stands as an intelligent contribution to the current Clean Air Act debate.

*Joel A. Mintz**

* J.S.D. Candidate and Wien Fellow, Columbia Law School; J.D. 1974, N.Y.U. School of Law; from 1975-1981, Attorney and Chief Attorney, U.S. Environmental Protection Agency; Assistant Professor, Nova University Law Center.

CONTROLLING TECHNOLOGY: GENETIC ENGINEERING AND THE LAW.
By Yvonne M. Cripps. New York: Praeger Publishers. 1980. Pp. xii,
154.

There is always a sense of uncertainty, whether when man lifts his foot for the next step it is really going to come down pointing ahead.¹

In his quest for scientific knowledge and technological progress, man has always found it necessary to accept certain risks. A risk is acceptable when it is outweighed by the potential benefit of the risky activity. Certain areas of scientific endeavor practiced today carry extremely high risks but promise correspondingly high benefits to mankind in the future, and are therefore quite controversial. One of these is the proliferation of nuclear energy. Another is genetic engineering, in particular recombinant DNA technology. In *CONTROLLING TECHNOLOGY: GENETIC ENGINEERING AND THE LAW*, Yvonne M. Cripps, law lecturer at Victoria University of Wellington, New Zealand, asserts that the benefits of this latter new technology are too great to permit abandonment of the admittedly risky research going on. *CONTROLLING TECHNOLOGY* explores the possible means by which society can reduce the risks of genetic manipulation to an acceptable level. Cripps reviews and compares the approaches taken by various nations, and then proposes a comprehensive plan for governmental control of genetic engineering. Although this proposal is directed towards the author's native New Zealand, the ideas contained therein are useful to legislators, regulators, scientists and concerned citizens in any jurisdiction.

Although the book concentrates on legal and policy issues rather than scientific issues, some understanding of the technology involved is essential before those legal and policy issues can be examined properly. The book presents a brief overview of the history of genetics, beginning with Hippocrates and Aristotle. This is followed by a short description of modern recombinant DNA technology, which sets out the basic terminology involved (there is a concise glossary at the end of the volume).

As a threshold to the specific subject of the control of genetic engineering, Cripps poses a basic philosophical question: should science be controlled at all? Many scientists would answer this with an emphatic "no," as they feel that otherwise their impartial search for "the truth" would be hampered. One might suggest that to limit

1. J. BRONOWSKI, *THE ASCENT OF MAN*, 436 (1973).

control to *technology* would not impede the freedom of inquiry enjoyed by those who engage in researches of pure *science*, but unfortunately such a distinction between science and technology is not easily drawn today. The author suggests a compromise: a risk-benefit analysis should be used in deciding whether governmental control of a particular science or technology is necessary. Cripps argues that this decision should not be made unilaterally by scientists, who, she maintains, have "no special expertise in matters of ethics or morality." (p.12). The author is a fervent believer in public participation in decisionmaking as well as adequate dissemination of information to the public, and this theme is manifest throughout CONTROLLING TECHNOLOGY.

Having laid this philosophical foundation, the author turns to the next threshold question, should genetic engineering be controlled? Cripps concludes that it should, thereby establishing the basic premise of the book. On the benefit side of the risk-benefit equation, some of the breakthroughs already achieved by genetic engineering are the cheap production of certain hormones and other biochemicals, including insulin, and the invention of bacteria that can help clean up pollutants in the environment. The *potential* benefits of this technology are enormous: cancer cures, prevention of genetic defects, production of chemicals and biochemicals, and improved antipollution and agricultural techniques. The risks of genetic engineering are much harder to evaluate than the benefits; because the science is still so young, few accidents have actually occurred. One can imagine, though, a scenario where disabled bacteria might transfer their recombined DNA to normal bacteria which could escape the confines of the laboratory and multiply, causing widespread disease or ecological damage. It is clear that risks do exist, and that some control is needed, though an absolute ban would restrain scientific inquiry unnecessarily. What is needed is some means of maximizing benefit while minimizing risk. Cripps urges that a plan of control be devised and implemented at once, *before* a dramatic accident occurs.

Methods of control range from informal peer pressure and the threat of losing funding agency support, to non-mandatory guidelines which merely set voluntary standards, to actual legal control. Legal control might stem from the utilization of existing common law or statutes or from the promulgation of new regulations or from the drafting of a totally new statute. Much of CONTROLLING TECHNOLOGY is a discussion of what such a statute should contain. First,

however, Cripps describes and compares the actions taken by several different countries in attempting to control genetic engineering, focusing first on the United States.

The major mechanism of control of genetic engineering in the United States is the set of non-mandatory guidelines published by the National Institutes of Health ("NIH") in 1976. Cripps, in recounting the events leading up to the adoption of the guidelines, criticizes the 1975 Asilomar Conference (whose summary statement formed the basis for the NIH guidelines) for not including among its delegates a significant number of non-scientists. This is not to say, however, that all scientists are on the "same side" in this controversy. On the contrary, there are some scientists who see no need for control at all, while others assert that recombinant DNA experiments of certain types should be banned entirely. Another bone of contention is the method of containment to be emphasized: physical or biological. ("Physical containment" refers to preventing experimental organisms from escaping the lab. "Biological containment" refers to the use of weakened strains of the host organism that have reduced chances of survival outside the laboratory environment. Containment is made especially crucial by the fact that the host organism most often used in genetic engineering experiments, *Escherichia coli*, is a common inhabitant of the human bowel.)

Cripps points out that the guidelines represent a compromise between these groups. A dominant aspect of the guidelines is the set of four categories of physical containment laboratories, labeled P1 to P4, P4 labs providing the highest level of containment. The author notes that laboratories which are funded by NIH are effectively bound by the guidelines, but questions the effectiveness of voluntary guidelines lacking legal sanctions in controlling laboratories not so funded, especially the rising crop of entrepreneurial ventures in the genetic engineering field. This point is well-taken: the potential for profit in this new industry is enormous, and with so many new companies springing up and the science advancing so rapidly, it seems unlikely that the guidelines will be strictly adhered to if the effect of such adherence is to cause delay in obtaining results, especially when a breakthrough is imminent.

The degree of respect now accorded to the NIH guidelines is illustrated by a controversy arising from their promulgation. The controversy concerned the filing of an environmental impact statement ("EIS") in connection with those guidelines as required by the

National Environmental Policy Act of 1969 ("NEPA").² Any federal agency conducting "major federal actions significantly affecting the quality of the human environment" must file an EIS.³ Environmental groups, such as the Friends of the Earth, protested the failure of the NIH to file the EIS and invite public debate until *after* the guidelines had been issued. Although her discussion of the ensuing litigation is somewhat sketchy (pp. 29-30), the author does come up with an argument which is both sensible and relevant to environmental law in general—as well as to genetic engineering. In determining whether a federal action is "major" enough under NEPA to require the preparation of an EIS, the cost, amount of planning required, and time to complete the project are the factors normally considered.⁴ Cripps argues convincingly that a better test would relate to the potential impact on the environment, which, after all, is more closely tied to the policy behind requiring an EIS. (p.30). Recombinant DNA research portends a potentially large impact on the environment, yet the cost and time involved in planning is considerably less than, say, that involved in the problem of nuclear waste disposal.

The voluntary nature of the American system of control is in sharp contrast to the system of statutory regulations in place in Great Britain. (pp. 48-49). These regulations contain a four-level containment scheme similar to the NIH guidelines. The difference is that British researchers are *required by law* to inform the government of their proposed projects. Their duty to protect the health and safety of workers and the public is enforced by a national inspectorate. Great Britain is the only nation thus far to have instituted legislation on genetic engineering, though a number of other countries do control this research to some extent, as Cripps details in a brief comparative study. Most nations, like the United States, presently have non-mandatory guidelines for containment administered by supervisory committees. The composition of these committees varies greatly; the author favors those that reserve spaces for laymen as well as scientists, providing a more effective safeguard against biased decisions.

There has been some movement towards legislative control of recombinant DNA research in the United States. Existing statutes cannot effectively cover this research, but various genetic engineer-

2. 42 U.S.C. §§4321-4361 (1976).

3. *Id.* §4332(2)(C).

4. *Hanly v. Mitchell*, 460 F.2d 640, 644 (2d Cir. 1972).

ing bills have been introduced in Congress⁵ as well as in several state legislatures.⁶ Cripps suggests that regulation of the industry should really be at the federal level. This makes sense, but is somewhat inconsistent with her previous praise of local action in the case of the city of Cambridge, Massachusetts, which held hearings to establish city ordinances controlling genetic manipulation in 1976.⁷

Many scientists oppose legislation of any kind in this field because of its inhibiting effect on the freedom of scientific inquiry. (It is interesting that the NIH also initially opposed the transformation of guidelines into regulations, though for a slightly different reason: they felt that amendments could not be made quickly enough to keep pace with scientific developments.) Cripps differs with these scientists, declaring that "[t]he widest possible public interest must prevail" (p.44), and that political lobbying by short-sighted scientists should not overshadow that public interest. This statement is hard to disagree with, but one senses that it overestimates the power of the scientific lobby.

Cripps is set on the desirability of legal control as opposed to formal or informal nonlegal control. Legal sanctions do more than deter carelessness: they symbolize the importance society attaches to the subject matter. In outlining the existing New Zealand common law and statutes relevant to genetic engineering, Cripps concludes that "as in the United States," existing law provides an inadequate system of control, making the adoption of a new statute imperative. (p.70). The law of torts might afford some remedies, but problems of proving causation, among others, would make recovery uncertain even if a rule of strict liability were applied. Furthermore, the common law is even less effective in prevention than it is in compensation. In short, a new statute is in order.

The arguments of scientists who oppose legal control are not frivolous: it is obvious that regulation of research can slow down progress considerably. It is equally obvious that even the most well-meaning researchers will cut corners and even ignore voluntary

5. See H.R. 10,453, 95th Cong., 2d Sess., 124 CONG. REC. 159 (1978); S. 1217, 95th Cong., 1st Sess., 123 CONG. REC. 9998 (1977); S. 621, 95th Cong., 1st Sess., 123 CONG. REC. 3659 (1977).

6. See, e.g., New York Senate No. 4009, 200th Sess. (1977). An identical bill was introduced in the New York State Assembly on Mar. 14, 1977. New York Assembly No. 6740-C, 200th Sess. (1977). The bill was passed on July 6, 1977, but vetoed by Governor Carey on Aug. 5, 1977. 1977 New York Legislative Record and Index at S408, A661.

7. See Culliton, *Recombinant DNA: Cambridge City Council Votes Moratorium*, 193 SCIENCE 300 (1976).

standards in the race for new developments. This writer agrees with Cripps, therefore, that legal controls and sanctions are necessary. The amount of time "wasted" by scientists in dealing with administrative red tape is a small price to pay for the margin of safety that legal control will provide against risks which are quite considerable, albeit hypothetical. Furthermore, this legal control will be more effective, easier to apply and amend, and perhaps most important, attract wider attention if it is in the form of a new, self-contained statute. Unique problems require unique solutions.

The legislative proposals contained in *CONTROLLING TECHNOLOGY* are well-reasoned and thorough, covering all the problems outlined previously in the book. Nowhere, however, does Cripps set out a complete draft of this statute. In only a scant few areas does she suggest the actual language the act should contain. Since she enumerates several possible alternative solutions to many of the problems, and does not always purport to suggest that there is one "best" answer, one assumes that this omission was deliberate and not an oversight. Still, a draft would have been helpful to legislators and in giving force to the proposals, and even a skeletal outline would have tied the ideas together and made the presentation more concise and coherent.

The act would be comprehensive, covering all forms of genetic engineering experimentation, and applying to private companies as well as the government and academia. Cripps suggests that the statute use the term "any person," in American fashion, to afford a wide jurisdiction over potential offenders.

The first problem in drafting a statute is defining its scope. Specifically, a definition is needed of "genetic engineering" (a broader term than "recombinant DNA technology") or "novel genetic techniques," which the author prefers. (p.82). She suggests that a very broad definition of novel genetic techniques be devised, which could be limited by the insertion of various amendable exclusionary categories. This is an intelligent approach to ensure sufficient jurisdiction while preventing a flood of applicants whose experiments are not really hazardous. Is "novel genetic techniques" an appropriate term to use, however? One presumes that in the very near future these techniques will no longer be novel. In order to gain administrative efficiency, the act should ideally cover *all* microbiological hazards, even those not involving the unconventional gene-splicing techniques.

The heart of Cripps' proposal is a three-tiered structure of committees that would administer the act. At the top level would be the National Supervisory Commission, whose duty would be to advise the government on the promulgation of statutory regulations at least as restrictive as the existing guidelines. This body would also study the risks and benefits of genetic engineering research, work with environmental groups, hold public hearings, and report annually to the legislature. In sum, this commission would be charged with doing the groundwork for policy making rather than actually administering the statute. The composition of the commission would be diverse: its twelve members would include six scientists (three from government, one from private industry, and two genetic engineering specialists); one trade unionist; one industry representative; one "ethics specialist" or sociologist; one lawyer; and two laymen. In this way, all the concerned segments of society would be represented. One wonders, though, why medical doctors would not be included, as this is a health and safety issue. Also, since the commission would be appointed by cabinet officials, it is unclear how a nonpartisan mix would be assured.

By contrast, the next tier, the National Advisory Committee, would be completely comprised of scientists. This board would grant *licenses* to perform experiments presenting various levels of biohazard. A new license would be needed for each research project, for which a proposal would be submitted to the committee. The committee would be required to either grant or deny the license within six weeks. This is important in preventing a slowdown of scientific inquiry. It might even be feasible, at least in New Zealand, where very little novel genetic research was going on at the time *CONTROLLING TECHNOLOGY* went to press. Is it really reasonable, though, to expect that a six-member committee could perform this function adequately and with the requisite speed once the industry starts booming? Cripps does not provide for this possibility.

The lowest of the three tiers would be an Employer Safety Committee within each research institution, headed by a biological safety officer. This committee would pre-screen proposals to be submitted to the national committee, as well as run health monitoring and safety programs. The need for statutorily requiring such a committee is unclear. Self-screening of proposals would probably be done anyway, and the committee's presence would not necessarily reduce the number of applications submitted. Would it not be

adequate merely to require health checkups and perhaps standardized safety training?

In order to enforce the statute, a corps of inspectors is needed. Cripps reviews the various existing groups which could be used as an inspectorate, seeming to conclude that a body such as the New Zealand Health Department would be the best choice. (p.91). She states that a new independent inspectorate is undesirable, but does not explain this opinion. It is inconsistent with her previous conclusion that existing regulatory structures could not cover genetic engineering. As this new technology presents unique safety problems, any inspectors would have to be specially trained. Arguably then, a separate inspectorate should be created, though recruits could be obtained from other health inspecting bodies.

In the event of a hazardous situation, Cripps proposes that broad emergency powers be vested in an appropriate official. She suggests that the statute prescribe a liberal standing requirement for injunction suits, allowing "any person" to institute an action to enjoin a certain experiment or activity. To further encourage suits, she advocates the award of attorney's fees if the suit is deemed to serve a public purpose, and protection for the employee who takes action adverse to his employer. These provisions would promote private sector enforcement as a backup to the administrative system of control.

The question of procedures for appeal of administrative decisions is a difficult one, and the author fails to come to a clear conclusion in this area. The basic conflict is between the right to a "second chance" and the need for administrative efficiency. Clearly, there should be a right of appeal to a court of law on questions of law. It is not as clear whether there should be a right of appeal on scientific issues, and if so, which body should have jurisdiction.

Cripps maintains that public concern should provide an additional means of enforcement. Therefore, the public must have access to data concerning ongoing research. The problem is that this right conflicts with the proprietary right of a genetic engineering firm to preserve confidentiality in order to maintain a competitive advantage. Cripps proposes that there be some sanction against "unjustified disclosure" of confidential data. That is, a company might be compelled to release data, but it would be given some assurance that that data will remain secret unless it becomes evidence in some sort of proceeding.

The need for secrecy would be eliminated if the products of genetic engineering were patented; a patent protects the proprie-

tary rights of the inventor in his invention in return for the full disclosure of the knowledge inherent in that invention.⁸ Cripps argues convincingly that genetically engineered organisms should be patentable. She points out the favorable effects of patentability: incentives for further research and full public disclosure of the details of the invention. Patentability would promote scientific progress while fostering public awareness of the subject, an important consideration in the enforcement of safety regulations. Cripps spends a good deal of time criticizing the American courts for balking⁹ at allowing new living organisms created by recombinant DNA techniques to be patented. This criticism is well-founded, as these new organisms are inventions in the truest sense of the word, meeting all the normal requirements for patentability. Indeed, the issue has now been resolved by the United States Supreme Court in *Diamond v. Chakrabarty*,¹⁰ which was decided after CONTROLLING TECHNOLOGY went to press.

The possibility of a genetic accident presents the issues of liability to the injured party and whether the public should be compensated at all in the case of a mass accident. Analogizing to the possibility of a nuclear accident, Cripps concludes that a standard of strict liability coupled with a mandatory level of insurance should be statutorily prescribed. Since the goal here is compensatory, not punitive, there should be *complete* strict liability. In other words, liability would accrue whether or not the accident was accompanied by a violation. Requiring the sponsoring institute to carry approximately \$5 million worth of insurance is an intelligent solution to the problem of the source of funds for compensation. Cripps asserts that damages in excess of that amount should also be recoverable, but only at common law. She contends that insurance premiums will not be prohibitive since the chance of an accident actually occurring is small and since most research institutions are probably large

8. See 35 U.S.C. §§ 112, 154 (1976).

9. For example, the United States Supreme Court granted certiorari, vacated and remanded a decision of the United States Court of Customs and Patent Appeals, *In re Bergy*, 563 F.2d 1031 (1977), which held that microorganisms can be patented. *Parker v. Bergy*, 438 U.S. 902 (1978). The procedural history of the *Bergy* and *Chakrabarty* litigation is detailed in *Diamond v. Chakrabarty*, 447 U.S. 303, 306-307 (1980).

10. 447 U.S. 303 (1980). Ananda Chakrabarty of the General Electric Company developed a new strain of the bacterium *Pseudomonas* which digests crude oil, making it invaluable in oil spill control. Affirming the Court of Customs and Patent Appeals, the court held that such a live, human-made microorganism is patentable under the patent statute, 35 U.S.C. §101 (1976).

enough to handle them. This insurance expense would, however, make it difficult for a new genetic engineering business to get started.

The new statute would also define certain actions as criminal offenses in order to give the law deterrent force. These violations would result not only in formal penalties but also the stigma of criminal conviction. Acts which constitute offenses would include misrepresentation in obtaining a license, breach of license conditions, conducting research without a license, failure to comply with information requests, and the like. Since the goal here is deterrence, not compensation, Cripps argues that strict liability should not be imposed, although she does not indicate precisely what mens rea should be required. Penalties would include revocation of licenses as well as fines. (Cripps believes prison terms would be unnecessary, although she does leave the possibility open.) A new fine would be imposed each day the violation continued, and a larger fine would be imposed on corporations than on individuals. Cripps notes that an early bill introduced in the United States would have provided for a fine of \$10,000,¹¹ which, she argues, would have had little deterrent effect in a race for a multimillion dollar invention. Cripps proposes to deter lazy safety supervision by the imposition of vicarious criminal liability on each company director in the case of conviction of a project supervisor.

CONTROLLING TECHNOLOGY concludes with a chapter on the possibilities of international control of genetic engineering. This prospect is desirable in view of the fact that a large accident could conceivably affect people in many countries. But such controls would be difficult to achieve in practice. The existing international law framework is ill-equipped to deal with the problem at hand. Cripps believes it imperative that there be a world conference on genetic engineering for the purpose of standardizing regulations.

Cripps finds that the issues of liability and enforcement would probably be the thorniest problems for such a conference. One notable proposal to cope with these would entail the establishment of an international fund for compensating victims, contributions to which would be made in proportion to each nation's gross national product and the amount of research conducted. Unfortunately, there is presently little movement towards any international agreement. One hopes that the nations whose scientists are pursuing

11. S.621, 95th Cong., 1st Sess., §14 (a), 123 CONG. REC. 3659, 3660 (1977).

recombinant DNA research will take heed to Cripps and others who urge action *now*, before we are confronted with a tragic manifestation of these dangers.

With few exceptions, *CONTROLLING TECHNOLOGY* is well organized and logically constructed. An appendix containing a complete draft of the proposed statute, perhaps accompanied by the NIH guidelines, would have been a great convenience. It also would have been useful to have been provided at the outset with a more complete explanation of what constitutes a recombinant DNA experiment. A diagram or two would have been helpful in such a presentation. The author's footnotes are valuable and comprehensive if somewhat cumbersome to find at the end of each chapter. Although she avoids the moral issue of the genetic control of humans, Yvonne Cripps manages, in a brief volume, to present convincing arguments in a variety of legal genres: common law, comparative law, international law, administrative law and legislative drafting, as well as explore complex scientific, philosophical and ethical issues. Genetic engineering poses unique risks to man and his environment while promising immense benefits in the future. In *CONTROLLING TECHNOLOGY*, Yvonne Cripps has shown that it is not only desirable but possible to control these risks and still develop and exploit this technology.

Seth J. Atlas

