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Law Center Report

Research Report Announcement

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ABANDONMENT UNDER § 102(c) AND FORFEITURE*

PAUL T. MEIKLEJOHN**

A person shall be entitled to a patent unless . . . he has abandoned the invention . . . .[1]

The statutory defense of abandonment of an invention and the judicially-created doctrine of forfeiture of the right to a patent were construed recently in *Moore v. United States*.[2] Briefly, the trial judge concluded that more than a 13-year delay between Moore's actual reduction to practice of his invention and the filing of his patent application did not constitute an abandonment of the invention nor did it amount to a forfeiture of his patent rights. The court found that the defendant had not carried its burden of proving that Moore engaged

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[1] 35 U.S.C. § 102(c).

[2] 194 U.S.P.Q. 423 (Ct.Cl. 1977).

Moore v. United States

David Pelton Moore, a patent attorney,[4] sued the United States Government in the Court of Claims for infringing the claims of one of his patents.[5] To appreciate the legal issues involved in this case, some background information is necessary.

The patent in suit involved solid explosive compositions and solid propellant compositions.[6] The trial judge found that Mr. Moore conceived the idea of using rubber as a binder in an explosive composition as early as 1939.[7] The government stipulated that he actually reduced his explosive to practice not later than January 1942.[8]

Moore attempted to interest the Navy in his composition (which he called "Moorite") just after the outbreak of World War II, but the Navy required a disclosure of the formula as a prerequisite to testing. Moore did not supply the Navy with the requested information.

In 1948, Moore and Moldex Rubber & Plastics entered into a contract to develop Moore's patent whereby he was to receive a percentage of the returns. Moore and Moldex attempted to interest the Navy in Moorite as a propellant. That same year, twenty pounds of propellant were given to the Navy, without charge, for testing. The composition was tested at Picatinny Arsenal with Army and Navy personnel participating in the tests. The tests did not result in any orders or sales.

The court found that Moore never lost interest in his invention. On the contrary, he attempted, albeit unsuccessfully, to interest several corporations in producing his rubber explosives and propellants during the period from 1950 to 1955. In 1955, Moore interested John L. Lewis and the United Mine Workers in producing Moorite. As a result, Moore filed his first patent application on July 27, 1955. This application was placed under a secrecy order "which prohibited Moore

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[4] Mr. Moore received an LL.B. degree from Columbian College Law School (now the National Law Center of the George Washington University) in 1897 and a Master's Degree in Patent Law in 1899. He was registered to practice before the U.S.P.T.O. on March 2, 1899 and is currently a member in good standing.

[5] Mr. Moore is the sole or joint patentee on more than seventy United States patents ranging in subject matter from "Milk Jar Closure or Cap" (U.S. Patent No. 761,005, which issued on May 24, 1904) to "Spring Needle Knitting Machines" (U.S. Patent No. 3,407,630, which issued on October 29, 1968).

[6] Reissue Patent No. 26,108, entitled "Solid Explosive Composition and Method of Preparation Employing Vulcanized Rubber and a Solid Inorganic Oxidizing Salt", reissued on November 1, 1966.

[7] 194 U.S.P.Q. at 425.

[8] *Id.*

nical developments."[13] He noted further that "the patent incentive need not be resorted to if inventors are willing to make a full, voluntary public disclosure of their inventions."[14] The trial judge then found that 35 U.S.C. § 102

> delineates the types of situations in which an inventor loses his right to a patent. Included among these, for example, are 35 U.S.C. § 102(b) which provides that an inventor shall be entitled to a patent unless he has previously described the invention in a printed publication, and 35 U.S.C. § 102(c) which provides that an inventor shall be entitled to a patent unless 'he has abandoned the invention.'[15]

The judge concluded that the constitutional goal of encouraging disclosure

> should be pursued regardless of when the invention was reduced to practice, and in the absence of any action proscribed by statute, or of instances where it can be shown that the public would have derived the benefit of the invention by the acts of another in due course. In the absence of such a showing, which includes the case presently before the court, a patent is in order because the public will be benefited by the invention's disclosure.[16]

The court distinguished many of the early abandonment/forfeiture cases, reasoning that they concerned "actions which are now proscribed by 35 U.S.C. § 102."[17] Furthermore, in every previous case in which abandonment and/or forfeiture were grounds for invalidity, "the public would have benefited by the public disclosure of the invention in due course even without the granting of the patent."[18] The trial judge concluded that the public would not so benefit absent Moore's patent application and therefore held that the abandonment/forfeiture defenses failed.

A. Burden of Proof. The burden of proving abandonment or forfeiture was on the Government by a showing of clear and convincing evidence.[19] The Government's proof of "mere delay" between the re-

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[13] 194 U.S.P.Q. at 426.

[14] *Id.* at 427.

[15] *Id.*

[16] *Id.*

[17] *Id.*

[18] *Id.* The public would have benefited in these cases because either the inventor's own activities were sufficient to put the invention in the public domain or the activities of others were such that the invention eventually would have been disclosed.

[19] Petersen v. Fee Int'l, 381 F.Supp. 1071, 182 U.S.P.Q. 264 (W.D. Okla. 1974); Panaview Door & Window Co. v. Van Ness, 135 F.Supp. 253, 107 U.S.P.Q. 31 (S.D.Cal. 1955).

> monopoly. *Besides, as we have seen, even that privilege has its limits, for he may conceal it so long that he will lose his right to a patent even though he does not use it at all. With that question we have not however any concern here.* [Emphasis in original.][24]

The trial judge in *Moore* found that the "cases cited by Judge Hand as support for the proposition that mere delay may work a forfeiture do not, upon close analysis, support such a conclusion."[25] These cases were *Woodbridge v. United States*[26] and *Macbeth-Evans Glass Co. v. General Electric Co.*[27]

In *Woodbridge,* the patent applicant had violated a special statutory provision which allowed him to place his application (which was ready for issuance as a patent) in the secret archives of the Patent Office for up to one year "for the sole purpose of providing time for the inventor to file a working model of the invention."[28] Nine and a half years later Woodbridge wanted to let the patent issue, but in such an amended form that the application would cover similar inventions patented by others during the nine and a half year interval. The facts in *Moore* were distinguished from those in *Woodbridge* in that

> (1) Moore did not have his allowed patent application held in a secret archive in a manner contradictory to a statutory provision; (2) although others were working in the same general field, defendant has not by the necessary clear and convincing evidence shown that others invented and patented the very same invention covered by the Moore patent in suit; and (3) it appears that but for Moore's filing for a patent, his invention would not have been brought to the attention of the public.[29]

Macbeth-Evans involved facts — secret use for profit for over nine years — which today would constitute a 35 U.S.C. § 102(b) bar to patentability. These facts were not present in *Moore.*

The trial judge next distinguished a recent case in which mere delay was found to be the basis for a forfeiture holding. In *Levinson v. Nordskog Co.,*[30] the district court held that "a person who, after conceiving and perfecting an invention, keeps it secret for five years until he thinks it will receive a more favorable market"[31] forfeits his right to a patent on that invention. The trial judge noted that, al-

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[24] *Id.* at 520, 68 U.S.P.Q. at 58-9.

[25] 194 U.S.P.Q. at 429.

[26] 263 U.S. 50 (1923).

[27] 246 F. 695 (6th Cir. 1917), *cert. denied,* 246 U.S. 659 (1918).

[28] Moore v. United States, *supra* note 2, at 429.

[29] *Id.* at 430.

[30] 301 F.Supp. 589, 163 U.S.P.Q. 52 (C.D.Cal. 1969).

[31] *Id.* at 590, 163 U.S.P.Q. at 53.

> Young forfeited nothing and would get a patent. All he *forfeited,* as I tried to point in *Brokaw v. Vogel, supra,* last paragraph of the opinion, was the right to rely on his prior actual reduction to practice in a priority dispute. Considering what Robinson said, quoted above, another, and perhaps better, way to have stated it would have been that Young was estopped by his conduct to rely on his reduction to practice in a priority dispute. [Emphasis in original.][38]

D. Forfeiture By Delaying the Issuance of a Patent. The Government relied on three cases — *Ex parte Hull,*[39] *Vitamin Technologists v. Wisconsin Alumni Research Foundation,*[40] and *Wirebounds Patents Co. v. Saranac Automatic Mach. Corp.*[41] — to support its contention that Moore forfeited his right to a patent by filing a series of CIP applications.

In *Hull,* claims were allowed in the application filed initially but, instead of allowing the patent to issue, the applicant filed a CIP application which added refinements to the original invention. When these claims were found to be allowable, he carried all of them into a second CIP application, adding further refinements. Six CIP applications were eventually filed. Hull admitted that he filed them in order to "prevent others from seeing his invention and improving on it."[42] Although the Board of Appeals held that Hull's actions did not bar his right to a patent, they questioned whether a court would enforce such a patent and warned Hull that if he filed another CIP application without allowing the present one to issue, there could be "a rejection based on conduct that is contrary to the purpose of the Constitution and patent laws."[43]

In *Vitamin Technologists,* the Ninth Circuit Court of Appeals concluded that the inventor was using CIP applications to hide the invention. The court dealt with an unconscionable scheme involving manipulation of the patent laws to deny the benefits of the invention (Vitamin D irradiation for rickets) to the margarine industry and the poorer segments of the public. The court found that during a period of extensive commercial use in the natural dairy products industry, an application was filed which contained claims which were allowed. However, by filing a continuing application, the inventor purposely delayed the issuance of allowed claims which were of the same scope as those which eventuated in the patent.

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[38] *Id.* at 1286, 180 U.S.P.Q. at 395-6. [Rich, J. concurring.]

[39] 191 U.S.P.Q. 157 (Bd.App. 1975).

[40] 146 F.2d 941, 63 U.S.P.Q. 262 (9th Cir. 1944).

[41] 65 F.2d 904, 18 U.S.P.Q. 171 (6th Cir. 1933).

[42] Moore v. United States, *supra* note 2, at 435.

[43] *Id.*

i.e., mere delay, without more,[47] will result in neither abandonment nor forfeiture. The implications of the court's opinion will be treated separately below with respect to the abandonment and forfeiture defenses; the forfeiture defense will be treated separately with respect to pre-filing and post-filing activities.

A. Abandonment. Proof of abandonment requires that one *intend* to abandon.[48] This intention may be either express or implied.[49] Factual situations in which abandonment is express are somewhat exceptional. In such situations, clear and convincing evidence would have to be produced[50] that the inventor either orally or in writing stated, in effect, "I hereby abandon this invention." Such factual situations are quite rare as evidenced by the paucity of cases in which a court has held that there was an express abandonment.

An intention to abandon the invention may also be implied. The quantum of evidence needed to imply such an intention depends upon the standard applied by a particular court. The court in *Marvin Glass*[51] required that the implication be the necessary one, while the court in *Moore* required that the intention to abandon be merely "the only *reasonable* explanation of [the inventor's] 'inaction'."[52]

Under the stricter "necessary implication" test, the inventor must not have engaged in any activities which would be inconsistent with the intention to abandon. For example, in *Levinson*,[53] the inventor left the device shut up in his basement laboratory (and later in his

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[47] For a discussion of the issue of whether "mere delay, without more" is redundant, *see* Peeler v. Miller, 535 F.2d 647, 190 U.S.P.Q. 117 (C.C.P.A. 1976), where Judge Rich stated, "The addition of 'without more' to 'mere' seems to be a redundancy of the kind to which lawyers are peculiarly prone." 535 F.2d at 654, 190 U.S.P.Q. at 123n.10. Judge Miller, concurring, replied,

> The error of the superflous comment in footnote 10 of the majority opinion is demonstrated by the statement of the obvious in the opinion itself: 'Surely, the word mere does not imply a total absence of a limit on the duration of the delay.' The language in Young v. Dworkin was taken from Gallagher v. Smith, 41 C.C.P.A. 734, 743, 206 F.2d 939, 946, 99 U.S.P.Q. 132, 138 (1953).

535 F.2d at 655, 190 U.S.P.Q. at 124n.1.

[48] Marvin Glass & Assoc. v. Sears, Roebuck & Co., 318 F.Supp. 1089, 1102, 167 U.S.P.Q. 33, 44 (S.D.Tex. 1970).

[49] *Id.*

[50] Petersen v. Fee Int'l, *supra* note 19: Panaview Door & Window Co. v. Van Ness, *supra* note 19.

[51] Marvin Glass & Assoc. v. Sears, Roebuck & Co., *supra* note 48.

[52] Moore v. United States, *supra* note 2, at 428.

[53] Levinson v. Nordskog Co., *supra* note 30.

took place at the time A decided his invention was worthless and destroyed the tangible embodiments of it.

It should be noted that A's patent could be rejected in an *ex parte* context or found invalid in infringement litigation under both 35 U.S.C. §§ 102(c) and 102(g). The § 102(g) defense would apply if there were a prior invention of another "who had not abandoned, suppressed, or concealed."[58] The difference between the § 102(c) and § 102(g) defenses is that under § 102(g), Inventor A has a chance to prove that Inventor B also "abandoned, suppressed, or concealed"; thus B cannot rely on his reduction to practice which precedes A's filing date. Inventor A might prevail over Inventor B even though both "abandoned, suppressed, or concealed" if either A had renewed his interest in the invention while B never did, or if A had renewed his interest in the invention at a point in time prior to when B renewed his interest.[59]

A factual situation in which a § 102(c) defense might apply, but a § 102(g) defense would not, is as follows: An inventor demonstrates his intent to abandon his invention by making a notebook entry which might read "not worthwhile", and then destroying the physical embodiments of the invention. Later the inventor realizes the value of his invention and applies for a patent. No "invention by another" is involved so § 102(g) is inapplicable. However, under these facts a court may find an implication to be necessary that the inventor abandoned his invention. If so, he would be absolutely barred under § 102(c). However, the inventor may be successful in arguing that his renewed interest in this invention, as evidenced by his patent application, represents the "recapture" or rediscovery of his invention.[60]

A question which may be raised is whether filing a patent application would ever be sufficient to rebut an inference that the inventor abandoned his invention. In this connection, it should be remembered

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[58] 35 U.S.C. § 102(g). These issues may arise in the context of an *ex parte* rejection by a Patent Examiner, *In re* Bass, 474 F.2d 1276, 177 U.S.P.Q. 178 (C.C.P.A. 1973); or as a validity defense in infringement litigation, Sutter Products Co. v. Pettibone Mulliken Corp., 428 F.2d 639, 166 U.S.P.Q. 100 (7th Cir. 1970); and Grinnell Corp. v. Virginia Electric & Power Co., 277 F.Supp. 507, 156 U.S.P.Q. 443 (E.D.Va. 1967).

[59] *See* Steierman v. Connelly, 192 U.S.P.Q. 433 (Bd. Pat. Int. 1975), where the board indicated that an inventor who had once abandoned, suppressed or concealed his invention could renew his interest in the same for priority purposes.

[60] Some have suggested that, by analogy to personal property, it may be possible for an inventor to recapture or rediscover an abandoned invention. *See* 1 PATENT PREPARATION AND PROSECUTION PRACTICE, Chap. 4 at 4-11 (Kayton ed. 1976). Certainly it is in the public interest not to bar the inventor who rediscovered his invention if the public would benefit from the disclosure.

> gain an understanding of the meaning of 'suppressed' and 'concealed,' which concepts have been codified in § 102(g). *Case law 'doctrines' are no more; the question is now simply one of statutory construction.*
>
> I may say that this approach to the law is one which has just occurred to me in the study of this case and I present it in the hope of making the law simpler and clearer in the future by the exclusion from opinions of *unnecessary legal theories like forfeiture.* [Emphasis added.][63]

In *Moore,* a delay of more than thirteen years between reduction to practice and filing a patent application was not sufficient, in itself, to constitute forfeiture of the right to a patent. The question, then, is what is left of the forfeiture doctrine after *Moore.* To answer this question, it is necessary to distinguish forfeiture from abandonment. As noted above, abandonment generally involves some act or acts which indicate that an inventor no longer believes in his invention coupled with the absence of indicia inconsistent with an intent to abandon.[64]

The trial judge concluded that Moore did not forfeit his invention because (1) the Government failed to prove by clear and convincing evidence that his invention was in the public domain, through acts which are proscribed by § 102,[65] and (2) the Government failed to prove by clear and convincing evidence that the public would eventually receive the benefits of Moore's invention because others working independently had made substantially the same invention.[66] If the invention were in the public domain because of acts which are proscribed by § 102, there would be no need for a forfeiture defense. The statute is determinative.

To the extent any non-statutory defense like forfeiture exists, however, it may be successfully rebutted even after years of delay between reduction to practice and filing, by showing that (1) others working independently were not making substantially the same invention during the time when the first inventor delayed, or (2) even if others were making substantially the same invention, the public would not eventually receive the benefits of the invention through the diligent acts of these other inventors. The forfeiture defense would be stronger if it could be proven that the first inventor was spurred into filing by the activities of the subsequent inventor, but

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[63] 489 F.2d at 1286, 180 U.S.P.Q. at 395-96 [Rich, J. concurring].

[64] One could forfeit his invention, however, while constantly retaining his interest in it. In many of the cases in which forfeiture was concluded, the inventor was "too interested" in his invention — *i.e.,* his interest was such that it amounted to a statutory bar under 35 U.S.C. § 102(b).

[65] *See* note 29, *supra.*

[66] *See* text accompanying note 16, *supra.*

on the inventor's tendency to be greedy, should not punish him if he lawfully attempts to delay the issuance of his patent, regardless of his reason for doing so.[73]

The Commissioner has been given, by statute, the power to "establish regulations".[74] Such a regulation may be needed to deal with some of the problems discussed in this section. In the absence of such a regulation, courts should not interfere as long as the applicant does not violate any statute.

Conclusions

Although the statutory defense of abandonment and the judicially-created doctrine of forfeiture are often mistakenly applied to activities which are already proscribed by other parts of § 102, they rarely are truly in issue in real life situations. Mere delay, even for more than thirteen years, is not enough to constitute abandonment or forfeiture. Abandonment requires proof by clear and convincing evidence of an intent, either express or implicit, to abandon the invention. An intent is not to be inferred if acts inconsistent with such an intent are shown. Forfeiture, if ever a viable defense, requires proof by clear and convincing evidence that while the first inventor delayed filing his patent application, others working independently made substantially the same invention and the public would no longer benefit from the issuance of the first inventor's patent. Finally, if forfeiture may result from the deliberate delaying of the issuance of a patent, the mere filing of one or more continuing applications will not amount to a forfeiture. To support a conclusion of forfeiture because of a delay in the issuance of a patent, a court at least would have to find that the applicant either abused USPTO practices or intended to delay issuance for the sole purpose of keeping the invention from the public.

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[73] *Cf.* Overland Motors Co. v. Packard Car Co., 274 U.S. 417 (1927); and Woodbury Patent Planing-Mach. Co. v. Keith, 101 U.S. 479 (1879). It should be noted that every paper filed by an attorney or agent representing an applicant or party to a proceeding in the Patent and Trademark Office must be signed by that attorney or agent, except for papers which are required to be signed by the applicant or party in person. That signature constitutes a certificate that, *inter alia*, the paper "is not interposed for delay." 37 C.F.R. § 1.346. Thus, an attorney or agent could not *lawfully* attempt to delay the issuance of a patent.

[74] 35 U.S.C. § 6, in pertinent part, reads as follows: "(a) The Commissioner . . . may . . . establish regulations, not inconsistent with law, for the conduct of proceedings in the Patent and Trademark Office."

Identifying and Regulating Environmental Carcinogens: Living with Uncertainty*

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The identification and regulation of environmental carcinogens presents major public policy problems. The growing list of identified carcinogens is not the only issue. Consistent relationships between the current knowledge of environmental carcinogens and their regulation are difficult to attain because of changing laboratory standards for determining carcinogenicity, the hypothetical nature of extrapolating laboratory data to potential human risk, and the numerous federal agencies responsible for regulating carcinogens.

The federal system for regulating carcinogens needs revision because of rapid advances in cancer-testing techniques and the add-on approach that has been characteristic of regulatory legislation in this area. However, for reform to have meaning, the underlying problems must be understood, a precondition that is largely absent and further

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*The viewpoints expressed in this paper are those of the authors and not necessarily of the organizations with which the authors are affiliated.

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aberrations in mammalian cell lines, to the determination of mutation rates in bacterial or cell cultures or in fruit flies.[1] Little is known about the predictive value of the relationship among these tests.

The Ames test, the most widely known short-term test, uses mutants of the bacterium *Salmonella typhimurium*. It presumes that cancers and mutations stem from cellular DNA alternations, and that the demonstration of a chemical's mutagenicity shows it is potentially carcinogenic. The mutants used in the Ames test do not have the ability to synthesize the amino acid histidine. In a histidine-free culture, growth does not occur. When a mutagenic substance is added, mutations occur, including those which repair the histidine production defect. Bacteria able to grow in the absence of histidine are counted. Strong mutagens result in larger numbers of bacteria being able to grow in the absence of the amino acid.

This is relatively a shotgun approach wherein site specific DNA effects are related to carcinogensis. Ninety percent of known carcinogens tested are mutagenic in the Ames test[2] and, conversely, Ames claims that almost every mutagen that has been given an adequate cancer test has been found to be a carcinogen.[3]

The utility of short-term tests is in the screening of large numbers of chemicals. Animal experiments are expensive and time consuming. Accepted protocols for rat experiments now require expenditures of $100,000 to $200,000 per test and three years to perform. Short-term tests can be done for a few hundred dollars and be completed in weeks to months.

Animal experiments provide stronger evidence that a chemical is carcinogenic in humans. Of the known human carcinogens, nearly all are carcinogens in animal tests.[4] Because no clear distinctions exist between chemicals which are carcinogenic in laboratory animals and chemicals which are carcinogenic in humans, most scientists regard all chemicals which have been shown to be carcinogenic in animals to

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[1] Congress of the United States, Office of Technology Assessment, *Cancer Testing Technology and Saccharin*, Washington, D.C.; U.S. Government Printing Office, 1977.

[2] McCann & Ames, *Detection of Carcinogens as Mutagens in the Salmonella/microsome test: Assay of 300 Chemicals, Discussion*, 73 Proc. Nat'l Acad. Sci. 950 (1976).

[3] Ames, McCann & Sawyer, *Mutagens and Carcinogens*, 194 SCIENCE 132 (1976).

[4] National Academy of Sciences, *Pest Control: An Assessment of Present and Alternative Technologies*, Vol. 1: *Contemporary Pest Control Practices and Prospects: The Report of the Executive Committee*, Washington, D.C.: National Academy of Sciences, 1975).

non-exposed population. Moreover, chemicals to which humans are actually exposed may be at such a low dose that the impact may not be detected by epidemiologic tools.

If a chemical has been shown to be carcinogenic in animals (what might be termed the "qualitative" proof of carcinogenicity in humans), a quantitative estimate is made on its effect in humans. Because high doses are used in animals, a mathematical model is constructed for the dose-response relationship. Since extrapolation to the low dose levels is the issue, the choice of the mathematical model may be crucial. Usually, the results of the most sensitive animal experiments are used to extrapolate to the potential carcinogenic effect in humans[8] because the safest assumption is that humans are the most sensitive animal species.

Rodent experiments in which groups of 50 rodents are tested at different dose levels would not detect an incidence of less than 1 to 50 and if doses comparable to human exposure were used, the results of these experiments would almost always be negative for low-potency carcinogens. Hence, the results of high dose levels in animal experiments are used to calculate the expected response at lower dose levels. Epidemiologic studies can confirm or contradict the animal test evidence for cancinogens that produce a strong response in animal tests and which can be expected to produce a large increase over the prevailing rate of cancer in humans. For weak carcinogens, the expected increase as predicted by the animal test data might still be less than that which could be detected by epidemiologic studies. Although the epidemiologic studies in these cases show no effect, they would not contradict the results of positive animal experiments.

Problems Interpreting Experimental Evidence

Many uncertainties complicate the relationships between short-term tests, animal experiments, and human epidemiologic studies. The reliance that should be placed upon them as proof of cancer causation in humans is also unclear. These uncertainties can be separated into three concerns:

- Are the experimental conditions acceptable?
- Are the conclusions reached from each experimental result valid?
- How are the results of different experiments to be reconciled when some are positive and some negative?

The experimental condition sought is the isolation of one variable so

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[8] Ames, *supra* note 3.

involuntary feeding but the route of administration may also affect cancer causation.[15] Therefore, while there may be little problem in concluding that a chemical causes cancer in test animals, if the route of administration is not identical to that of humans, the connection between animal test results and human experience remains questionable.

The definition of "tumor" is crucial for three reasons. First, benign tumors do not necessarily mean that a chemical does not cause cancer. Benign tumors are not without risk and may be an early state of malignant tumor genesis.[16] Indeed, chemicals which induce benign tumors often induce malignant ones. Second, tumors and their different manifestations (benign, pre-cancerous hyperplasia, invasive malignancy, etc.) are ultimately determined by individual pathologists using essentially morphological criteria (they look at gross and microscopic preparations and make expert judgments), thus, differences in interpretation always remain.

Finally, rapid advances in cancer testing technology almost guarantee that animal experiments undertaken according to current guidelines will not conform exactly to guidelines existing at the end of the experimental period. Thus, even with recommended guidelines for experimental protocols, subjective, albeit expert, judgments are unavoidable.

The method of interpreting the results of technically acceptable experiments is the second area of uncertainty. Statistically significant increases in cancer formation in exposed, versus control groups of animals show that the chemical tested is carcinogenic. However, there is some controversy as to whether this statistical test must be met before carcinogenesis is proven. Many researchers accept findings of tumors in unexpected sites or of unusual type as proof of carcinogenesis even though their rates may not be statistically significant. Benign versus malignant tumor formation raises similar issues and becomes especially troublesome when statistical significance depends on the inclusion or exclusion of benign tumors.

The third area of uncertainty appears when attempting to *reconcile positive with negative test results*. Positive test results almost always carry more weight than negative test results when comparing tests of the same general classification, *i.e.*, short-term tests, animal tests, or human epidemiologic studies. For example, cyclamates were taken off

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[15] *Id.*

[16] *Id.*

The organization of the Clearinghouse is described in its charter:[20]

> There shall be four standing Subgroups of the Committee. Each shall have not more than fifteen members, all of whom shall be members of the parent Committee. The Subgroups shall be: (1) the Subgroup on Chemical Selection to review, to nominate, and to rank chemicals that require carcinogenicity testing, (2) the Subgroup on Experimental Design to advise on appropriate experimental designs for routine tests and to develop protocols for studies intended to improve the state-of-the-art, (3) the Subgroup on Data Evaluation and Risk Assessment to assess the carcinogenicity of chemicals based on the adequacy of bioassay studies and data and to estimate the human risk posed by chemicals adjudged to be carcinogens, and (4) the Executive Subgroup to coordinate and to direct the activities of the Committee and to advise on matters not within the charge of one of the other Subgroups.

The Subgroup on Chemical Selection advises the head of the carcinogenesis program about which chemicals should be tested by the NCI in animal experiments. This advice ranges from "the appropriateness of testing specific chemicals in the near-term to a systematic approach for identifying representatives of large, environmentally important chemical classes for evaluation in the long-term."[21]

In practice many of the advisory activities of the Sub-group begin with nominations of chemicals by the Chemical Selection Working Group. This latter group is composed of federal employees of various agencies. Federal Health, the Subgroup, advises the Associate Director for Carcinogenesis whether a nominated chemical should or should not be tested. The final decision rests with the Associate Director.

In addition to receiving nominations from the Chemical Selection Working Group, the Subgroup itself may nominate chemicals suggested from other sources, including its own members. The Subgroup members recognize that the chemical-by-chemical approach is slow and that it does not assure that more important chemicals will be considered at an early time. Currently, the Subgroup is considering two methods for establishing priorities. The first of these is grouping chemicals on the basis of human exposure levels. For example, chemicals could be grouped into those encountered in the workplace, in food, in the air, in water, etc., generally reflecting existing Federal regulatory authority. From each of these groups, the chemicals that are most frequently encountered or that are most suspect could be

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[20] National Cancer Institute, Amended charter, Clearinghouse on Environmental Carcinogens, (typescript) May 5, 1977.

[21] National Cancer Institute, Objectives of the Clearinghouse on Environmental Carcinogens, (draft) August 31, 1977.

The chemical dichlorvos was fed at two dose levels for 80 weeks to rats and mice in separate experiments. The animals were then sacrificed at the end of two years. A number of lesions found in test animals were absent in controls. In treated mice, 2 squamous-cell carcinomas, 1 squamous-cell papilloma, and areas of focal hyperplasia were found in esophageal epithelium. None of these conditions was found in control animals, but it was pointed out that such conditions occur spontaneously. No tumors were found in rats, but non-neoplastic, proliferative lesions were seen in the upper gastrointestional tract in 2 rats and an epithelial hyperplasia of the esophagus was observed in another. A number of treated rats developed fibrous tumor-like nodules of the skin, but these were not considered significant. The staff concluded that there was insufficient evidence to support the carcinogenicity of dichlorvos under the conditions of the tests. The primary reviewer was critical of the small number of control animals. He noted other pathologies (not mentioned in the staff presentation) which he said he had been produced in two other comparable studies, and stated that dichlorvos was a mutagen in microbial systems.

Following the discussion, the Subgroup voted to accept the report with two dissents. The primary reviewer argued that if inadequate control data made it impossible to decide that the chemical was a carcinogen, the same deficiency made it impossible to decide that it was not. The other dissenter stated that the rarity of epithelial tumors of the esophagus convinced him that they were treatment-related. Another discussion followed, and it was decided to recommend dichlorvos to the Subgroup on Chemical Selection for possible retest. The motion to refer was passed unanimously.

In this case a report cited by the primary reviewer as inadequate was accepted by the Subgroup. The conclusion was that the chemical was not carcinogenic. Having accepted the report as negative, with a conclusion based on admittedly inadequate data, the Subgroup then voted to consider the chemical for retest.

Federal Regulation of Environmental Carcinogens

Regulation in the United States is usually organized according to where or how people are exposed to danger, rather than according to the type of substance encountered. Thus, a single carcinogen may be regulated by a maze of sometimes conflicting and often inconsistent and uncoordinated statues and programs depending, for example, on whether it is found in the workplace, in foods, drugs, or cosmetics, in the air or water, or in "consumer products."

This regulatory inconsistency is heightened by the fact that it is

Toxic Substances Control Act of 1976 (TSCA),[33] which is sometimes thought of as an attempt to introduce rational and comprehensive regulation of toxic substances (including carcinogens). However, TSCA does not mandate a comprehensive and coordinated regulatory program for carcinogens and other toxic substances. It is more accurately described as a program to "fill in the cracks" in regulatory coverage, since substances covered by other acts are still to be regulated by those acts whenever possible.

These statutes and selected relevant characteristics of their regulatory coverage are summarized in Table I. Also, the Department of Agriculture (not shown on the Table) administers legislation, such as the Federal Meat Inspection Act,[34] which can be (but rarely has been) used to regulate carcinogenic substances.

Specific versus general risk. As mentioned above, only two of the relevant statutes contain specific procedures for regulating carcinogenicity as opposed to toxicity in general. Although most of the regulatory provisions of the Food, Drug, and Cosmetic Act apply to general risks, three sections of that Act contain directives for regulating the specific risk of cancer. Substances that are ingested as food additives, color additives, and residues of animal drugs in food products are subject to very specific and explicit action if they are shown to be carcinogenic. Unlike carcinogenic substances in other areas, no allowable exposure levels may be set. Once carcinogenicity has been demonstrated to the FDA's satisfaction, there is no regulatory discretion. No risk-benefit analyses may be considered; the substance must be totally banned from foods.

The wording of the three sections dealing with the specific risk of carcinogenicity is similar. The most well-known is the "Delaney Clause," applicable to food additives, under which the proposed ban on saccharin was issued: "[N]o additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animals."[35]

The Toxic Substances Control Act (TSCA) indicates that chemical substances suspected of presenting an unreasonable risk of carcinogenesis, mutagenesis, or teratogenesis, should be given priority regulatory attention by the EPA.[36] Action is to be taken against such sub-

[33] *See supra* note 24.

[34] Federal Meat Inspection Act, 19 U.S.C. § 1306 (1967) (*as amended* 1970).

[35] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 34B(c) (3) (A). This is § 409(c) (3) (A) of the separately bound Public Law.

[36] *See supra* note 24, at § 4(f).

ARCINOGENIC SUBSTANCES

(e) Benefit-Risk Analysis or Consideration of Factors Other Than Safety	(f) Discretion in Regulating	(g) Relationship to Other Federal Statutes
Risks dominate; no such analysis permitted if color or food additives or residues from animal drugs are carcinogenic; if a naturally-occurring substance in food is carcinogenic, technological feasibility of removing it may be weighed against the health risk.	Carcinogenic food and color additives, and foods with carcinogenic residues of animal drugs,* must be banned; otherwise discretion is not prohibited	The Act takes precedence in areas of foods and related substances; for residues from pesticides there is an interagency memorandum of agreement between FDA and EPA.
Explicitly required; the benefits and the risks (safety) of a drug must be considered in regulating.	Yes, FDA may permit carcinogenic drugs or substances in drugs to be marketed if the benefits outweigh the risks	Takes precedence in the area of foods
No benefits to health are presumed; risks predominate in analysis; those "cosmetics" claiming positive health benefits are treated as drugs.	Banning takes place based on the discretion allowed by the adulteration sections of the Act; public health is only criterion	Takes precedence in the area of cosmetics
Explicitly required by the Act.	All regulatory actions are at the discretion of EPA	See Column "b"
Permitted	All regulatory actions are at the discretion of the Commission	At the discretion of the EPA, these Acts take precedence over the Toxic Substances Control Act
Explicitly required by the Act	All regulatory actions are at the discretion of the Commission	Not applicable to substances covered by Food and Drug Act; close relationship to Hazardous Substances Act
Not explicitly mentioned; has been interpreted as allowing it, and the Commission uses such analyses	Banning is at the discretion of the Commission; certain labeling requirements are non-discretionary	Not applicable to substances covered by Food and Drug Act
Permitted by the Act; required by the implementing regulations	Yes	Takes action when other Federal agencies have not, for workplace hazards

stances, who stated that the EPA *must* require premarket testing.[43] The statutory language itself is not definitive, but seems to back the discretionary view in its use of such phrases as "the Administrator *may* require . . ." (emphasis added). Whether pre-market testing is discretionary or mandatory, the EPA does have authority to prohibit manufacturing, processing, and marketing before and after the substance is allowed on the market.[44]

In theory, the standards of safety and of benefits from use, which the EPA utilizes in making regulatory decisions, do not differ between new and established substances. In practice, it may be more difficult to develop information on new substances, since so much of it will be based on projections of possible effects. Conversely, taking action on established substances is more difficult despite better information, because it is usually harder to remove a substance from the market than it is to prevent its entry.

The Food, Drug and Cosmetic Act (FDCA) does make some distinctions between new and established substances. If substances were in use before passage of the FDCA and if they pass a lenient screening test, even though added to food, they are not considered to be "food additives" and are therefore not subject to the sections of the FDCA relevant to food additives, unless significant questions about their safety are raised by the Food and Drug Administration (FDA).[45] On the other hand, new food additives must be given pre-market clearance by the FDA.[46] Standards are the same for new and established food additives. The FDA's refusal of a petition to market a new food additive, its removal of an established food additive from the market, and its reclassification of a substance added to food as a formal "food additive," thereby requiring it to meet food additive safety standards, are all made on the basis of the approach used to interpret evidence on safety. There is a difference, however, in which party has the legal responsibility to demonstrate the safety or danger to health of a food additive. For new food additives, the sponsor of the petition (usually a manufacturer) must show its safety.[47] But once a substance is in use, it is up to the FDA to make a case for its potential dangers.[48] This burden of going forward with the evidence is also true for color addi-

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[43] D. Davis, Environmental Protection Agency; Personal Communication, 1977.

[44] *See supra* note 33, at § 6.

[45] *See supra* note 35, at § 321(s).

[46] *Id.* at § 348(a).

[47] *Id.* at § 348(b).

[48] E. Allera, Food and Drug Administration; Personal Communication, 1977.

risks. The NCI guidelines are used by most of the agencies either implicitly or as a starting point. However, the agencies prefer to judge the quality of evidence on a case-by-case basis, and few agencies have developed standard criteria to be used for these judgments. The Occupational Safety and Health Administration has, however, abandoned the case-by-case method in favor of classifying carcinogens in terms of the types of test results providing the evidence of carcinogenicity.[53] It feels this may eliminate some of the problems related to judging the strength of results and to interpreting what the results may mean to human health. It should also somewhat streamline the regulatory process.

EPA's Cancer Assessment Group is responsible for assessing risks. This group makes its own judgments about the reliability of the evidence and the weight to be assigned to those tests considered most reliable. The National Institute of Occupational Safety and Health (NIOSH), a scientific agency within the United States Department of Health, Education and Welfare, was created to provide scientific support and resources for the OSHA's programs, and for related programs throughout the government. NIOSH often performs the assessments of risks for OSHA. It bases its judgments on NCI advice to a degree, but prefers to be flexible and to make its own judgments.[54] NIOSH is also involved in the benefits side of the analysis when it estimates the technical feasability (including the cost) of eliminating or reducing exposure to a carcinogen in the workplace. As will be discussed below, the cost of removing something is, in effect, an economic benefit of keeping it.

The second underlying problem, that of interpreting the significance of test results in terms of the possible human health impact, has caused agencies much consternation. When a risk-benefit analysis is performed, it is not enough to identify a threat to health; the threat must be quantified in order to balance it against the benefits. All the agencies assume that animal results are applicable to humans. The agencies differ in their methods of extrapolation. The authors were not able to develop statements detailing how they differ because the individual agencies vary their methods, often on a case-by-case basis. A common method, however, is the use of a straight-

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[53] Occupational Safety and Health Administration, Department of Labor, Regulation of Certain Toxic Materials: Identification, Classification, and Regulation of Toxic Materials Posing a Potential Occupational Cancer Risk to Workers; Draft Regulation, 42 Fed. Reg. 192 (January 21, 1977).

[54] R. Boggs, National Institute of Occupational Safety and Health, Department of Health, Education, and Welfare, Personal Communication, 1977.

versus *y*, but rather on a subjective social judgment about the *idea* of lives versus dollars.

Living With Uncertainty

Regulation of environmental carcinogens is now approached in one of two ways: (1) Substances under the Delaney Clause *must* be banned once a scientific conclusion is reached that a carcinogenic effect has been shown; or (2) Other substances *may* be banned or placed under restricted production and use once a carcinogenic effect has been shown *and* the benefits of their use have been taken into account. This has led to inconsistent interpretations of the relevance of test results to human risk. The former approach allows no regulatory discretion once carcinogenesis is shown. Under the Delaney Clause induction of cancer by means other than voluntary consumption, including involuntary feeding, would not be accepted as conclusive. Thus, the saccharin ban was proposed only after repeated experiments in which animals ingesting the artificial sweetener developed cancer.[56]

The contrast between the Delaney Clause and other federal regulatory authorities does not reflect a fundamental difference in outlook between carcinogens that are ingested and carcinogens to which one is exposed in other ways. Such differences in regulatory discretion have the effect of forcing the scientific community to use inconsistent standards for determining carcinogenicity. Public access to substances under the Delaney Clause depends wholly on the scientific determination of carcinogens, whereas public access to substances not under the Delaney Clause depends on several factors only one of which is the scientific evidence of carcinogenesis. Faced with these circumstances, the scientific community can be expected to demand more rigorous proof under the Delaney Clause than under other regulatory authorities.

It is harder to understand why the scientific community has not developed criteria by which the relative merits of individual experiments can be judged and through which more consistent conclusions can be reached. Some of the issues in test standardization and interpretation are not readily amenable to agreement, such as the inevitable criticisms that individual experiments have not ruled out certain extraneous factors, the problems associated with benign versus malignant tumors, and the numerous pathological changes that are related but not equivalent to tumor formation. But so many of the

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[56] *See supra* note 1.

developed for the integrity of individual tests in similar fashion to OSHA's attempt to classify carcinogens on the basis of the kinds of test results. For example, final conclusions from animal tests might be limited to findings that are statistically valid. Findings of tumors that are not statistically significant or which are questionably related to carcinogenesis should not be ignored, but they also should not be given the same weight as statistically validated tumors, which is presently done by some test reviewers. In other words, some review structure should be developed for judging the validity of individual tests.

Human epidemiologic studies can be misleading. When the surveyed population consists of easily identifiable exposed groups such as workers in chemical plants, the data are quite reliable. But suspected substances to which large populations are exposed make it exceedingly difficult to isolate the effect of the substance under scrutiny from all other possible causes of the type of cancer under observation.

These epidemiologic studies usually provide probabilities on the statistical significance of their findings; *i.e.*, the degree of statistical confidence that the effect shown or not shown was not due to chance and would be replicated in similar studies. These studies usually are not explicit in stating how much of a difference from the prevailing rate of the type of cancer under observation they would be able to detect. This is particularly important for suspected carcinogens that are relatively weak. In such situations, animal tests might show a definite though low-potency effect. The failure of human epidemiologic studies to detect a carcinogenic effect may not contradict the animal data at all. Extrapolations from the animal data might result in predicted human cancer rates that were below the rates that the epidemiologic studies were capable of detecting, and it could be equally argued that the epidemiologic studies do not contradict, and might even support, the animal findings.

For regulatory purposes, animal tests and human epidemiologic studies are inadequate tools. Animal tests take too long; epidemiologic studies come after the fact. Short-term tests may offer the most promise. But the field is still in the early stages of development and, despite the conviction of some scientists that they are capable of predicting carcinogenicity, a more accurate statement would be that they are currently testing the hypothesis that short-term tests can predict carcinogenicity. Furthermore, short-term tests yield little information on the potential *quantifiable* effect in humans, a significant shortcoming for regulatory purposes.

Aflatoxin Contamination in Milk

MARY LOUISE DUFAULT*

Aflatoxin B_1 is one of the most potent chemical carcinogens known.[1] Recently it has been found in milk supplies in the United States. Aflatoxin B_1 is a by-product of a common mold growth found on grains and other feed supplies.[2] It is now well established that carcinogenic aflatoxin metabolites, ingested from feed by dairy cattle, are secreted in cows' milk. A real concern exists over permitting even low levels of aflatoxin in cows' feed because of the possible risk to human consumers.[3]

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[1] Present knowledge of the aflatoxins dates from 1960 when more than 100,000 turkey poults died in England after eating peanut meal imported from Africa and South America. From the poisonous feed were isolated *Aspergillus flavus* and a toxin produced by this organism that was named aflatoxin *(Aspergillus flavus* toxin — A-fla-toxin). J. JAY, MODERN FOOD MICROBIOLOGY at 401 (2d ed. 1977) [hereinafter JAY].

[2] *See generally* Hesseltine, *Natural Occurrence of Mycotoxins in Cereals,* 53 MYCOPATHOLOGIA ET MYCOLOGIA APPLICATA 141, 148 (1974); Maggon, *Biosynthesis of Aflatoxins,* 41 BACTERIOLOGICAL REVS. 822 (1977); Rodricks, *The Occurrence and Control of Mycotoxins and Mycotoxicoses,* 2 (1) F.A.O. FOOD AND NUTRITION 9 (1976); and C. EMMONS, MEDICAL MYCOLOGY 52 (3rd ed. 1977).

[3] Carcinogenicity can vary greatly with only minor changes in structure. However, when one hydroxy group is added between furane rings of B_1 to form M_1, toxicity is not altered. This directly contradicts information in Aflatoxin Contamination of Milk, 42 Fed.Reg. 61630 (Dec. 6, 1977), which states, "M_1 though less potent than B_1 . . ." *See* Hesseltine, *supra* note 2, at 148.

Possible Solutions – Technological Innovations

Cereal grains, the basis of cattle feed, are the most important food source contaminated with aflatoxins.[7] Aflatoxins are produced on cereals both in the field and in storage. The most important factors controlling aflatoxin formation in the field and in storage are relative humidity, moisture and temperature.[8] One practical solution to acute or sub-chronic toxicoses is to avoid moldy food or feed. Avoidance means either prevention by the use of good harvest and storage techniques and hybrid grains resistant to aflatoxin, fungicides and pesticides, or removal by examination of food or feed and removal of moldy lots. Current technology is directed to storage. Little is known about how to avoid contamination during the growth of grain, and little progress has been made in developing resistant strains of grains.[9]

Avoidance by Prevention and Removal. Research has indicated that prevention would be the most effective and profitable way to avoid aflatoxin contamination in the long run. Prevention would necessitate improvements in harvest and storage practices. Aflatoxin mold is most likely to develop immediately following harvest while the crop is still at high moisture content. Prevention would include drying the crop quickly to safe moisture levels before storage. For some crops mold growth appears most rapidly when outer layers are damaged or broken. Insect or rodent damage increases incidence. Preventative measures to diminish risk of aflatoxin contamination should therefore include rapid post-harvest drying procedures, which may need to be done artificially, protection against rodents and insect damage, and storage at low moisture content.[10] The risk of using fungicides

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[7] Other foodstuffs found to contain aflatoxins are peanuts, cottonseed, soybeans, peas, beans, cornpeas, cassava and sweet potatoes. The grains include corn, rice, wheat, millet, sorghum, sesame and barley. Wogan, *Aflatoxin Risks and Control Measures,* 27 FED. PROC. 932, 935 (1968).

[8] Temperatures ranging from 24-30°C. produce optimal aflatoxin yields: 11-45°C. is the usual range supporting growth. Products with moisture levels above 16% are capable of supporting growth. Light was found to inhibit formation. *See* JAY, *supra* note 1, at 402. *See also* Hesseltine, *supra* note 2, at 141-53; and Maggon, *supra* note 2, at 829.

[9] *See* Rodricks, *supra* note 2, at 12 & 13. Some think that plant breeding is not the solution but that pesticides are. A 1977 study is cited showing that *Aspergillus flavus* was found only in insect damaged corn. Hollis, *The Realism of Integrated Pest Management as a Concept and in Practice – with Social Overtones,* 1977 ANN. MEETING OF ENTOMOLOGICAL SOC'Y OF AMERICA SYMP. 1.

[10] Rodricks, *supra* note 2, at 12; and Wogan, *supra* note 7, at 935-6.

teurized or stored milk have given conflicting results. Stoloff reported complete aflatoxin recovery from pasteurized and stored raw milk. Freezing for 120 days resulted in approximately a 45% loss. Previous studies had showed losses of up to 87% after freezing for 120 days, but the 45% figure would appear to be the more reliable.[14] While a 45% reduction by freezing is certainly significant, freezing milk supplies for four months is manifestly an economic impracticability. Milk inactivation studies would, of course, not be necessary if aflatoxin could be eliminated from dairy cattle feed.

Implications for Technological Innovation. The health risk associated with low dietary intake of aflatoxins is not known with certainty. That there is some risk seems likely. Aflatoxins have been shown to produce extreme cases of cancer in some experimental animals. In specific, stable human population groups there seems to be an association between aflatoxin consumption and the incidence of human liver cancer.[15] Both factors have convinced most public health scientists that exposure to aflatoxins should be reduced to the lowest levels technologically feasible.[16]

Primate studies, which give the most accurate animal correlation of risks to humans, have demonstrated that the difference between "no apparent effect" and liver damage levels from the organospecific aflatoxin is smaller than anticipated by researchers. Epidemiological studies are lacking, but several deaths of children have been linked to aflatoxin-contaminated rice and cassava.[17] For reasons not yet fully known, in all species studied, young animals and male animals have been found to be more susceptible to acute and subacute toxicity than have adult animals or female animals, respectively.[18] Children under

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[14] Stoloff, *Stability of Aflatoxin M in Milk,* 58 (12) J. DAIRY SCI. 1789 (1975). Three plausible explanations were offered giving credence to the 45% figure rather than a figure almost double that.

[15] Rodricks, *supra* note 2, at 12.

[16] *Id.* at 12.

[17] Campbell & Stoloff, *supra* note 12, at 1010-16. There are contributory nutritional factors as well, such as protein malnutrition, which make it difficult to say with absolute certainty that aflatoxin intake alone caused death. Contaminated cassava at the rate of 1.7 mg/kg of child's weight for a short time may have caused death of one child. Wogan, *supra* note 7, at 932. For most animal species, the LD_{50} value is in the range of 0.5-10 mg/kg body weight. Lethal dietary aflatoxin levels in the duckling were 0.3 ppm and in the rat they were 3-4 ppm. While acute lethality data of this sort are useful as an index of species susceptibility, they do not give information on effects of prolonged consumption. Since modern research on this problem has only been underway since 1960, more information will doubtless come in.

[18] Wogan, *supra* note 7, at 932-4.

The United States needs a policy to deal with the problem of how much aflatoxin, if any, can safety be ingested. Incentives for improved techniques must be provided which will not wipe out the dairy industry or small farmers. Aflatoxin B_1 is not just a carcinogen; it is one of the most potent carcinogens known. Aflatoxin at high levels presents risks to the health of livestock thereby precipitating an economic problem. Contamination by aflatoxin M_1 at even less than acute levels may well present the problem of cancer development for humans, particularly for the young.

Epidemiological studies are badly needed to complement studies in experimental animals. More technological development is necessary for the prevention of aflatoxin, utilizing natural methods where effective, with backup of pesticides and fungicides where necessary. Differences in varietal susceptibility need close examination. Suitable drying and storage techniques need to be developed. Detoxification methods need greater attention. Sampling and analysis procedures need refinement. Much more research on an effective aflatoxin elimination or inactivation method of milk processing is crucial. Even the United States in the past few years has experienced the effects of having specific foods in short supply. This country is not wealthy enough to lose milk and grain through aflatoxin contamination or unsophisticated enough technologically to justify not coming up with a knowledgeable answer.

Implications for Public or Regulatory Law

The implications for public or regulatory law are clear. Congress through appropriate agencies must decide how the aflatoxin problem is to be handled from a legal perspective. Elimination or inactivation of aflatoxin in milk is proving complex and, at present, are goals which have not been achieved. The next question then is what is to be done with contaminated milk. The Food and Drug Administration (FDA) is authorized by statute to regulate this type of problem. Possible solutions range from outright restriction on sales of contaminated milk to establishing tolerance levels below which aflatoxin contaminated milk may be sold. Incongruous as it might seem, what is done turns on the label applied to aflatoxin, *not* on the scientific data base available.

FDA Classifications – Tolerance Levels. FDA classifications for various substances in foods are not necessarily mutually exclusive; there can be overlap or the possibility of uncertainty as to the category under which a food is best defined. For example, Section 409 of the

bad news. It is good that at least some low level has been set above which aflatoxin-contaminated milk cannot be sold. However, there is still some question as to the safety of such milk even at 0.5 ppb particularly for the very young. By setting what is called an "action level," the FDA has temporarily legalized the sale of milk contaminated with aflatoxin up to 0.5 ppb and it is not known if this is reasonably devoid of hazard. Not classifying aflatoxin as a "food additive" has made it possible to sell contaminated milk legally with the FDA's approval. The rationale seems questionable at best in light of the potent carcinogenic capabilities of aflatoxin.

At first glance it would seem that since aflatoxin is a "poisonous ingredient" in milk it should be governed by Section 408. However, it is also a "naturally occurring toxin" under Section 402(1)(a) as it is not put into milk as an additive in the sense that, for example, color is added to margarine. Section 408 covers poisonous or deleterious substances *added* to food. It might also be expected that Section 408 would prohibit *poisonous* foods per se. Such, however, is not the case. Under Section 408 the FDA may exercise its discretion for the "protection of the public health" and set tolerance levels for poisonous ingredients which "cannot be avoided by good manufacturing practice."[33] Only when those limits are exceeded would Section 402(a)(2)(A) apply, which designates a food as adulterated and therefore unsafe.[34]

Section 402 does apply to "naturally occurring poisons." Like Section 408, it gives the FDA discretion in determining whether a food such as aflatoxin contaminated milk is or is not adulterated. Section 402(a)(1) states that "in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health."[35] A lower standard therefore applies for naturally-occurring poisons than for *added* poisonous, unsanitary or deleterious substances. No statutory authorization exists at present to set official standards for natural poisonous and deleterious substances comparable to the authority to set standards for some food additives and pesticide chemicals.[36]

It should be noted that the effect of some poisons on the body varies

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[33] Sec. 408; 21 U.S.C. § 346.

[34] Sec. 402 (a) (2) (A); 21 U.S.C. § 346 (a) (1) (A).

[35] Sec. 402 (a) (2); 21 U.S.C. § 346 (a) (2).

[36] Note, *Health Regulations of Naturally Hazardous Foods: The FDA Ban on Swordfish,* 85 HARV. L. REV. 1025, 1034 (1971-72) [hereinafter *The FDA Ban on Swordfish*].

tomatically prohibited from sale at any measurable amount, no matter how minute. Aflatoxin is clearly not "added" as that term is generally used. However, Section 201(a) defines "food additive" to mean "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food."[43] Clearly, aflatoxin found in milk could come within this definition.

The term "food additive" does not usually include "pesticide chemicals" on raw agricultural commodities, which are covered by Section 408(a). Subsection (a), "[T]olerance for pesticide chemicals in or on raw agricultural commodities," states that any pesticide chemical not generally recognized as safe shall be considered unsafe unless a tolerance in or on the raw agricultural commodity has been prescribed or it has been exempted from the requirement for a tolerance, all at the discretion of the FDA. If tolerances or exemptions have been made, the food is not considered adulterated within Section 402 (1) (a). If there is no residue, registration of the pestidice is also granted.[44]

Case Law. The definitions discussed above were interpreted in 1974 by the Court of Appeals for the Seventh Circuit in *Ewig Bros., supra,* a case concerned with fish contaminated with DDT. The court held that *before* the contaminated fish are processed DDT is a "pesticide chemical" on a raw product, while *after* processing the presence of DDT causes the fish to be adulterated as a matter of law without any proof that it is actually unfit as food.[45] If DDT in processed fish is considered a food additive, then certainly aflatoxin in processed milk must be considered a food additive.

Precedent or legal basis for the acceptability of aflatoxin in milk can also be drawn from *United States v. An Article of Food Consisting of Cartons of Swordfish,*[46] wherein mercury in swordfish was held to be a pollutant and therefore an "added substance" within the meaning of Section 402 (a) (1) notwithstanding the claimant's argument that mercury could not be an "added substance." The claimant contended that mercury, found in fish for centuries, is not naturally pro-

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[43] Sec. 201 (s); 21 U.S.C. § 321 (s).

[44] Sec. 408a (1); 21 U.S.C. § 346a (1).

[45] *See* United States v. Ewig Bros., *supra* note 6, at 722.

[46] *See* note 38, *supra.*

Case law suggests that aflatoxin in milk could be considered a food additive under Section 409. The sole criterion for identifying a food additive is whether a substance which may become a component of, or affect the characteristics of, any food is generally recognized among qualified experts as having been shown to be safe.[50] The now famous Delaney Amendment, Section 409(c)(3)(A), specifically provides that "no additive shall be deemed to be safe if it is found to induce cancer when intested by [hu]man or animal."[51] The additives need not be intentional. The definition includes incidental additives as well; accidental ones are excluded.

The FDA has no discretion but must prohibit the contaminated food if a carcinogen is present as a food additive at any amount. The purpose of the 1958 Delaney leigslation, as explained in 1972 in *Continental Chemiste Corp. v. Ruckelshaus*, was to prohibit the use of food additives which had not been adequately tested to establish their safety.[52] Prior to such testing, new additives are to be banned by a statutory concept of per se adulteration.

Burden of Proof. The purpose of Congress in approving the Food Additives provisions of 1958 for Sections 402 and 409 was to prevent injury to the public health by sale and transportation in interstate commerce of misbranded and adulterated foods. The burden of proof was shifted. Prior to 1958 the Government had to prove a substance was harmful. Now the burden is on the processor to prove a substance is safe. Satisfaction of the criterion of safety requires proof of a reasonable certainty that no harm will result from the additive, but it does not require proof beyond any possible doubt.[53]

The Delaney Amendment to the Food Additives Amendment of 1958 indicates the magnitude of Congressional concern about hazards created by carcinogenic chemicals.[54] Since its passage, the Delaney Amendment has met with the scathing criticism that it was the result of technical naivete and scientific advocacy rather than scientific objectivity.[55] The major criticism has to do with the Amendment's

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[50] United States v. 41 Cases, 420 F.2d 1126 (5th Cir. 1970).

[51] *See* note 27, *supra.*

[52] Continental Chemiste Corp. v. Ruckelshaus, 461 F.2d 331 (1972).

[53] Myers, *Construction and Application of Food Additive Provisions of FDCA* (21 U.S.C.S. § 321(s), 321(u), 342(a) (2) (c), and 348), 21 AM. L. REP. FED. 314, 321-7 (1974).

[54] *Id.* at 345.

[55] Blank, *The Delaney Clause: Technical Naivete and Scientific Advocacy in the Formulation of Public Health Policies,* 62 CAL. L. REV. 1084, 1120 (1974); Hall, *Safe at the Plate,* 12 NUTRITION TODAY 6 (1977).

less than expected.[58] The same plan would seem to have potential value for aflatoxin-contaminated grain as it would increase the incentive to eliminate the hazard at its source. A plan should be developed at the state level, too, which would include all milk, not just that involved in interstate commerce.

Conclusions

In the United States, formal policy procedure, not informal rulemaking, is needed to deal with the aflatoxin problem realistically. The FDA in particular, of all the federal agencies, has seen the value of the former with the opportunity for the presentation of opposing viewpoints, cross examination, etc. Informal standards are effective only to the extent that suits are won in court. A private litigant's chance of prevailing over a government agency like the FDA over a technical standard, however informal, is especially slim.[59] Grave problems of inference would be present relating cause with effect, and legal cause with actual cause. An individual's chances of recovery against a milk company would be remote.

In some parts of the world the threat of cancer is remote when compared with the immediate reality of hunger, but in the United States we can afford to be concerned with even a slight risk of cancer.[60] Ultimate cost may actually be less if costs are internalized by the industry than if aflatoxin-contaminated milk carries a high social overhead. On a global scale, no fully satisfactory risk-benefit equation has been established for aflatoxin or for any toxicant which is to some extent unavoidable in food (where the only benefits are economic and the conservation of food supplies).[61] Evaluation of risk takes on a new dimension where food is the only fundamental life support system for which there is no choice. Where the ultimate hazard is starvation, not risk-benefit, risk v. risk would have to apply.[62]

It would seem that, in light of the best available information, there is no safe level of aflatoxin consumption. Steps should be taken quickly to insure better avoidance of aflatoxin formation for the good of consumers and the economics of the dairy industry. Unless there is some greater risk in not so doing, aflatoxin should be considered a

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[58] Fistere, *supra* note 48, at 692 (in reference to 21 U.S.C. § 303(c)).

[59] LOWRANCE, *supra* note 42, at 9.

[60] Rodricks, *supra* note 2, at 14.

[61] *The FDA Ban on Swordfish, supra* note 36, at 1035-8.

[62] Hollis, *supra* note 9, at 11.

An Assessment of the Use of Cost-Benefit Analysis in Regulatory Agency Decision Making*

Michael S. Baram**

CONSIDERABLE dissatisfaction has been expressed with the process and results of regulatory agency decision making. Recommendations have been made that the Federal agencies employ rational, "balancing" approaches such as cost-benefit analysis in conducting their standard-setting and adjudicatory functions.

This paper examines some current uses of cost-benefit analysis by several agencies in their decision-making processes, and identifies and discusses apparent limitations.

Statutory and Judicial Requirements

Statutes enacted by the U.S. Congress provide the frameworks for regulatory decision making by the Federal agencies and prescribe, usually in general terms, several criteria and considerations to be employed by the agencies in carrying out their discretionary and mandatory functions. Such statutes commonly impose on an agency the requirement *simultaneously* to consider technical and economic feasibility charac-

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simple technique for decision making, and has been extensively used by the Corps of Engineers, the Bureau of Reclamation, and other departments and agencies in the design of water-resource programs, dams, and flood-control and other projects. Engineers and economists are therefore experienced in the application of the technique to developmental purposes. Congress has promoted its use in water-resource programs through the creation and activation of the Water Resources Council.[4] Further, the courts have not objected to the use of the technique per se as a method of reaching balanced decisions in such developmental programs, have generally been unwilling to substitute their judgment for that of the agency on developmental matters which involved the application of the technique, and have usually stated that alleged deficiencies in such uses of cost-benefit is a matter for Congressional review in annual authorization and appropriation hearings held by several Congressional committees on the sequential elements of these long-term developmental programs.[5]

Quite recently, use of cost-benefit has been undertaken by *regulatory* agencies as well, in their decision making to set standards, issue licenses, and reach siting and other regulatory and nondevelopmental decisions. These agencies include, for example, the Environmental Protection Agency and the Nuclear Regulatory Commission.

Several committees of the National Academy of Sciences, the Academy itself, and other advisory and professional associations have recommended further use of the technique by these and other regulatory agencies as the most feasible method for bringing about rational decision making. Social scientists and economists have worked on further development of the technique to enable its users to accommodate qualitative or not readily quantifiable considerations.

Chief among the several regulatory agencies to adopt the technique, provide in their regulations for its use, and employ it as a matter of course in their decision making is the Nuclear Regulatory Commission (NRC). NRC now employs cost-benefit in setting radiation standards "as low as practicable," and in its licensing of nuclear facility construction

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[4] The Water Resources Planning Act, 43 U.S.C. 1962, created the Council. *See generally,* U.S. Water Resources Council, *Summary and Analyses of Public Response to Proposed Principles and Standards for Planning Water and Related Land Resources and Draft Environmental Statement,* July 1972.

[5] *See,* for example, EDF v. Corps of Engineers, 325 F. Supp. 728 (1971); Conservation Council of North Carolina v. Froehle, 340 F. Supp. 222 (1972); and discussion in Hillhouse, *Federal law of water resources development* in FEDERAL ENVIRONMENTAL Law (E. Dolgin & T. Guilbert eds. 1974) at 872-873.

TABLE 1
ECONOMIC BENEFIT/COST ANALYSIS IN ENVIRONMENTAL IMPACT STATEMENTS *

	Prepared	Included
Agriculture		
Forest Service	Generally	Yes
Soil Conservation Service	Yes	Summarized
Commerce	Yes	Yes
Defense	Sometimes	Yes
Air Force	Yes	No
Army	Sometimes	Sometimes
Navy	Yes	Summarized
Corps of Engineers	Yes	Yes
Health, Education, and Welfare	No	No
Food and Drug Administration	Yes	Yes
Housing and Urban Development	No	No
Interior		
Bureau of Indian Affairs	Yes	No
Bureau of Land Management	Often	No
Bureau of Outdoor Recreation	Occasionally	No
Bureau of Reclamation	Yes	No
Fish and Wildlife Service	No	No
National Park Service	No	No
Geological Survey	No	No
Justice		
Law Enforcement Assistance Administration	Yes	Yes
Labor	No	No
State	No	No
Transportation	Not usually	When prepared
Federal Aviation Administration	Not usually	When prepared
Federal Highway Administration	Not usually	When prepared
Treasury	Not usually	
Energy Research and Development Administration	Yes	Yes
Environmental Protection Agency	No	No
Federal Energy Administration	No	No
Federal Power Commission**	Yes	Yes
General Services Administration†	Yes	No
Nuclear Regulatory Commission	Yes	Yes

*Source: Council on Environmental Quality, *Environmental Impact Statements: An Analysis of Six Years Experience by Seventy Federal Agencies*, Washington, D.C., 1976.

**FPC prepares comparative economic-analysis and cost-effectiveness studies on proposed actions but does not conduct classic benefit-cost studies.

†GSA does a cost evaluation, but an "economic benefit/cost" analysis is not always included or attached to the EIS.

use of weighting factors in cost-benefit analysis. How shall we set and determine the adequacy of such factors, in light of conflicting values and varying attitudes about the distributional patterns, and citizen willingness to accept certain probabilities of risks?

e. *Post-hoc Considerations and Enforcement.* After using cost-benefit to establish regulatory actions, it can be assumed that unintentional and intentional violations of the prescribed regulations will occur. The Nuclear Regulatory Commission has learned that despite its application of radiation standards (developed by use of cost-benefit) to utilities, violations occur, such as excessive accidental releases of radioactive effluents. How to enforce or otherwise act on the basis of such violations when, despite the unforeseen increased costs, the economic viability of the regulated party and the needs of dependent consumers are at stake: plant shutdown, the imposition of new safeguards (retrofitting), or waiver of requirements? In other words, is the cost-benefit basis for designing and regulating power plants, in this case, enforceable once the plants have been built and are in operation?[11]

f. *Structural-political Considerations.* In light of the foregoing issues, what structural-political considerations should be addressed? Again, to consider the experience of the Nuclear Regulatory Commission, the cost-benefit analysis used to approve the construction and operation of a new facility is premised on a specific population dose of radiation and its valuation.[12] Yet the Commission lacks the authority to control population density and migration in regions off-site from the plant, and the States are reluctant and/or incapable of maintaining the population subject to exposure at the density levels used in the calculations for initial approval of the facility. Will such structural-political developments proceed concurrently with the use of cost-benefit to assure its efficacy and enforceability over time? Further, in light of the valuation and distributional issues noted earlier, what political developments will be necessary and achievable to enable meaningful participation or representation of various constituencies including the unborn?

g. *Technology-forcing Considerations.* If the emitted substance to be controlled to some degree by cost-benefit regulation is always going to be harmful to some, such as is the case for radiation and for toxic chemicals with linear dose-response relationships, the objective of regulation is to force the development and application of new tech-

[11] *See* discussion in Chap. 4 of NAS-BEIR report, *supra* note 6.

[12] *See supra* note 6.

> portation (DOT) to consider both the costs and benefits.... However, in considering the National Traffic and Motor Vehicle Safety Act, (P.L. 89-563, 1966) which empowered DOT to set motor vehicle safety standards aimed at reducing deaths and injuries, Congress rejected draft language requiring such studies for safety standards. (Hearings Before Committee on Interstate and Foreign Commerce, U.S.H. Rep., 89th Congress, 2d Session, on HR 13228, "Part 2, Traffic Safety", p. 1203).

Similar Congressional rejection of cost-benefit for setting standards and for other features of regulatory decision making, in favor of the determination of health parameters and other ambient effect-oriented approaches, is found in the legislative history and enactments on Clean Air and on Water Pollution Control. The Federal courts, in reviewing regulatory agency decisions on pollutants with considerable health implications, have also demanded that health factors be given a high priority in the thinking and nature of such decisions, indicating that cost-benefit alone would be inappropriate.[14]

j. *Accountability.* To what extent will the use of cost-benefit analysis promote the accountability of government decision makers to the courts, the affected interests, and the public at large? Will the jargon and arcane nature of the methodology retard lay understanding of agency decision processes? The cost-benefit approach of the Nuclear Regulatory Commission is complex and not easily comprehensible. The courts and other accountability mechanisms must be evaluated in terms of their ability to cope with the advent of regulation based on cost-benefit. For example, the following balancing analyses are all now potentially applicable to the NRC process of approving an application by a utility for a license to operate a nuclear power facility:

(a) Use of cost-benefit by the NRC in promulgating agency standards and other rules of general applicability to power plant performance.

(b) Use of cost-benefit by the NRC in promulgating limitations for a specific power plant for design approval.

(c) Use of balancing analyses in determining whether or not the separate construction and operating licenses should be issued for a specific plant.

For the first two steps, use of cost-benefit is mandated by the NRC's *Appendix I* and other regulations.[15] Alternately, the use of a "balanc-

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[14] *See,* for example, EDF v. Ruckelshaus 439 F.2d 584 (D.C. Cir. 1971).

[15] *See supra* note 6.

This inventory of issues attending the use of cost-benefit analysis in regulatory decision making indicates that research and public discussion on the subject at this time is a responsible and necessary course of action, if future decision making is to be both rational and humane.

Special Considerations in the Regulation of Environmental Carcinogens

a. *Regulatory Patchwork.* Responsibility for the regulation of environmental carcinogens is scattered throughout many U.S. government agencies today. So, as a toxic metal such as cadmium, or an herbicide, or any other carcinogenic chemical wends its way through the environment and food chain to its human receptors, it passes through the jurisdiction of many agencies. But despite the many watchdogs, the same carcinogen may elude certain critical controls because of serious regulatory omissions or gaps in legislated authority enacted by Congress.

The Federal agencies with primary regulatory responsibilities for the control of environmental carcinogens are the Environmental Protection Agency, the Nuclear Regulatory Commission, the Food and Drug Administration, and the Occupational Safety and Health Administration. However, other agencies, ranging from the U.S. Army Corps of Engineers to the Department of Transportation, also play roles in the regulation of carcinogens. Each of these agencies has statutory authority to regulate the use and emission of *some* of the substances, from *some* of the sources, in *some* of the pathways, for the purposes of protecting *some* of the population under *some* circumstances.

Each agency has its own objectives, analytical approaches, databases, and control criteria, but often no agency has adequate authority or motivation to control at certain critical points. Substances such as polychlorinated biphenyls (PCBs), implicated in cancer of the liver, have therefore eluded coherent systematic control. To some extent, this gap may be the result of the agencies' failure to coordinate or implement their functions properly. However, the primary problem seems to be inadequate Congressional legislation, which has established agency functions in this inefficient and uncoordinated manner.

This regulatory patchwork results mainly from uncertainty as to what constitutes cancer, the diversity of suspect substances and their pathways to their victims, the many possible but difficult-to-test synergistic factors, and the varied susceptibility of the affected population.

general point where costs or risks are equivalent to benefits. Some agencies add margins of safety or weighting factors to their analysis, either by choice or to satisfy statutory requirements.

The problems of such "balancing" approaches have been discussed earlier in this paper, and include:

- What value should be placed on human life, illness, or suffering?
- Who should decide on such values?
- How should such values be determined?
- How are cases judged where benefits accrue to some but risks accrue to others? How does one judge the distributional and equity issues?
- How should we value the lives of the unborn?
- How reliable and objective are the designated costs of new control equipment, which are largely based on information from the industry to be regulated?
- How accurate is the agency's assessment of benefits to society from the activity in question?

These are significant problems for the balancing process, and at the least, new techniques are badly needed to elicit public attitudes and apply ethical safeguards to protect minorities and the unborn. For example, when the Corps of Engineers proposes to use a chemical herbicide to clear duckweed from navigational channels, and the EPA approves the action (and thus approves the subsequent contamination of the water, environment, and food chain), some relatively arbitrary judgments have been made by the two agencies as to the probability of human illness or death to be sanctioned, possibly resulting from the originally beneficially intended use of the herbicide.

c. *The Costs Add Up.* Today's fragmented use of "balancing" by individual regulators has a pernicious, cumulative effect over many agencies' decisions. Each decision by each separate agency inevitably rationalizes an additional contribution of carcinogens and risks to the human environment. So each decision effectively increases the total amount of environmental cancer. Such regulatory decisions occur daily. These "justifiably" allowable risks could conceivably accumulate to the point where an entire present or future population could be at substantial risk. Although each regulatory body is concerned only with its own incremental contribution to future cases of environmental cancer, each incremental contribution adds to the number of people whose lives will be affected.

capabilities, which must somehow provide the "felicific calculus" to integrate rationality and humanism in decision making.

The regulatory context in which cost-benefit is now being used is a relatively intangible one for most citizens. It is remote in spatial and emotional terms, more complicated and less amenable to citizen understanding and participation, than the developmental context which is usually set at the local level and which usually involves issues which can be appropriately resolved by a balancing of local interests — which are more readily identifiable and measurable.

The questions about uses of cost-benefit in the regulatory context raised in this paper are significant in that they relate to societal capacity to protect human health and welfare for this and the succeeding generations which will bear the risks of contemporary decisions on radioactivity and other harmful substances.

Serious consideration should be given to the adoption of alternatives to cost-benefit for such regulatory decision making, in light of the questions which have been raised. It is unlikely and unacceptable that alternatives be chosen which do not balance various factors in some systemic and structured process. Therefore, the choice of an alternative is limited, and *cost-effectiveness* analysis becomes an obvious candidate.

Cost-effectiveness analysis requires the articulation of objectives, the weighing of the alternative means to achieve the various articulated objectives, and the selection of the least cost approach. For regulation of nuclear energy sources of radioactivity, use of the cost-effectiveness approach would mean the establishment of societal health objectives and risk parameters (e.g., carcinogenic risks) by Congressional or other institutional processes that are acceptable as being socially representative.

The task of making such decisions on health objectives would certainly be a difficult one, but once accomplished, the results could serve to insure that regulatory decision making on energy and other activities involving harmful externalities is accountable to articulated societal objectives for environmental health. This process would also force consideration of our role in providing stewardship for future generations. Consideration of alternatives to cost-benefit for regulatory decision making, such as cost-effectiveness analysis, is perhaps the most critical need of the times from the standpoint of human health and survival.

Group Exemptions (1978 Draft) for Licensing Restrictions in the EEC (A Forensic View)

GABRIEL P. KATONA*

Parturient montes, nascetur ridiculus mus.
(The mighty mountains in labor give birth
to a mere mouse.) *Horace, Ars Poetica*

The latest draft Regulation for providing a group or block exemption for licensing restrictions has surfaced from the EEC Commission. This latest draft, which differs only slightly from a number of earlier drafts, shows the rather inflexible attitudes of its drafters. Numerous comments have been published about the earlier versions, but it was thought better to wait until now to see if the strong criticism leveled at the Commission from various quarters would result in salutary changes showing up in the later drafts. Regretfully, this is so only to a very small extent.

In all fairness, in criticizing the Commission draft, one must also look at the practices prevailing in the Common Market countries before the Commission started to regulate in this surprisingly drastic, unusual fashion.

We in the United States have lived under, and have become used to, various antitrust laws which have existed since the last part of the nineteenth century. On the other hand, except for some limited type

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should be prohibited. The Rome Treaty, on the other hand, in Article 85(3) contains a system of exemptions for innocuous restrictions which may nevertheless appear to have an anti-competitive effect under Article 85(1). Thus it became a *fait accompli* in the EEC that the point of departure is "all is wrong" except that which is permitted.

Under these circumstances, a properly conceived project for indicating kinds of licensing restrictions which would generally appear to be "clean," should merely aim at compiling a list of licensing restrictions which would have *no detrimental effect.* Instead, the Commission, in Article 1 of the draft, chose to concentrate on clearing those restrictions the use of which, as the EEC points out in its introduction, would have, in its opinion, a *salutary* effect. The Commission was looking at such factors as whether a restriction improves the production of goods; whether it promotes technical progress by increasing the number of production facilities; the quantity of goods produced in the Common Market; whether they make it possible for entities other than the patentee to manufacture goods using the latest technology and to develop such technology further by making patent holders more willing to grant licenses and by making it easier for other enterprises to decide to run the risks involved in investing capital. This is the wrong approach. Licensing restrictions should not be judged on the basis of whether they bring about a desirable result but rather whether there is any reason for prohibiting them. The only proper time one might look at possible desirable results occurs when desirable and undesirable results have to be balanced against each other in order to determine whether a restriction should be cleared or not.

The premise of the Commission's regulation effort is not only wrong but it is also poor politics. This accounts for the extremely poor reception of the proposed Regulations not only by private industry but also by governments of member states. In the proposed Regulations, the Commission went far beyond the mere compilation of licensing restrictions which they would view as not being objectionable. The wrong premise of the Commission can be illustrated by the following statement from the preamble of the draft regulation:

> The Regulation must specify what obligations in restraint of competition may be contained in a patent licensing agreement. It may be left to the contracting parties to decide which of these obligations they specifically include in the patent licensing agreements to best achieve the desired advantages.
>
> The Regulation must also determine the restrictions or clauses which may not be included in patent licensing agreements to which it applies.

methods of lawmaking. On the other hand, the Commission might wish to promulgate informal guidelines which explain its philosophy about impermissible practices instead of an *ex cathedra* expose of the same.

The author sees no need for qualifying a list of unobjectionable restrictions as the Commission intends to do in Articles II and III of the proposed Regulation. While it is generally true that it is possible to include a restriction in a license agreement the presence of which would have the effect of creating an undesirable result, there still would be no need to tar any unobjectionable restrictions also present in the same agreement as being suddenly unacceptable. The objection should rather focus on condemning that part of the agreement which brought about an undesirable result even when coupled with a per se unobjectionable restriction. Therefore, any compilation of unobjectionable restrictions by way of a block exemption could stand on its own without mentioning any other restrictions which in the view of the Commission would be questionable or objectionable.

Another problem with the draft Regulation is its unduly broad prohibitive approach. The Commission should address itself to problems of restriction of trade between the member states. While these problems might be at the heart of the Commission's objective, this central topic has taken a back seat to the much broader prohibitive tenor of the latest draft. In so doing, the Commission has also placed itself into unnecessary conflict with a number of national laws such as know-how provisions, exclusivity, etc., in the case of field of use restrictions.

The poor approach taken by the Commission throughout this Regulation is further illustrated in the introductory portion where the Commission tries to explain its thinking. For example, it states that "the Commission considers that control over the marketing of a licensed product within the Common Market is not a matter that relates to the existence of the patent," and "obligations on the part of the licensor are not matters which relate to the existence of the patent." These statements further illustrate the broad brush interpretation of the prohibitions of Article 85(1) by the regulators of the Common Market who tend to create broad prohibitions. All one can do then is to create exceptions to the prohibitions. This may be the reason why countries such as the United Kingdom, which have legal systems which find it difficult to accept this kind of "lawmaking," are so vehemently opposed to these proposed Regulations. Fortunately for those of us in the United States, our system does not provide for the promulgation by the Antitrust Division of such regulations without

ous use of United States antitrust decisions as the basis for one or another position taken by Commission officials. On the occasion of such past pronouncements, various of the so-called "cartel cases" decided in the 1940s and 1950s by the United States Supreme Court, were referred to as purportedly illustrating condemnation of certain patent licensing practices. In making such references, Commission officials entirely ignored the fact that very few of these "cartel cases" have any precedent value in judging individual licensing restrictions by themselves because all of these cases involved one or more clearly pernicious practices in addition to one or more licensing restrictions which would, by themselves, be quite legal even today.

The fundamental error of the Commission is that it decided that exclusive licenses fall under Article 85(1) and can be exempted only under Article 85(3). The author believes this attitude of the Commission is entirely unreasonable.

Patents assure a form of legal exclusivity to their owners. For that reason alone, any legal decision concerning exclusive arrangements which does not involve patents immediately loses any value as a precedent.

Now that it has been established that the Commission's views lack any ideological underpinnings for generally condemning exclusive licensing arrangements (on which, incidentally, the EEC court has never spoken but only the Commission in such cases as the *Davidson Rubber*[7] case and the *Raymond/Nagoya*[8] cases) a more reasoned examination of the alleged anti-competitive effects of exclusive patent licenses will be undertaken.

It is a legal axiom that the owner of a right can delegate that right to another. The right to exclude others, which is inherent in the patent right, can be sold or licensed to others. So long as there is a right in the patent owner not to license his patent and to continue to exclude others from the use or practice of the patented invention, the effect remains the same if he exclusively licenses that right to another person. The result then is that it is still one person who has the right to exclude others from practice in the patented invention. Consequently, the exclusive license under a patent right would leave the economy in the same shape as if the patentee had not licensed his rights at all. Therefore, nothing pernicious is perceivable in an exclusive patent license as long as the net result of that act on the economy did not result in any change. This is exactly why exclusive patent

[7] Davidson Rubber Co., O.J. EUR. COMM. (No. L 143) 31 (1972).

[8] Raymond/Nagoya Rubber Co., O.J. EUR. COMM. (No. L 143) 39 (1972).

ity is that it would have the effect of preventing the licensor himself from manufacturing and using the patented invention which he, if it had been generated by him, would be best qualified to exploit. So what?! Why is the Commission concerned with having the best qualified exploiter do the exploitation? In any event, exclusive licenses normally have minimum performance conditions which make the license cancelable if the conditions are not met. Therefore, if the exclusive licensee is not the best qualified exploiter of the invention then this will become known and the exclusive license can be terminated.

It is clear that the Commission has failed to provide a cogent reason for its suspicious attitude towards exclusive manufacturing licenses. It has not analyzed its reasons and it has in no way demonstrated that exclusive patent licenses would lead to an economically undesirable result. It is interesting to note that, after all that tempest in the introductory comments, it does grant unqualified block exemptions for manufacturing and use exclusivity albeit only for qualified block exemptions for exclusive licenses to sell.

The Commission engages in another faulty assumption in treating exclusive patent licenses to sell in the same way it treats export prohibitions. In its misguided thinking, the Commission tends to lose sight entirely of the fact that patents can in no way be asserted against exports from, but only against imports into, a country if a patentee has a patent in the country to which the import is being sent. The Commission appears to confuse exclusive licenses to sell a patented product with exclusive sourcing agreements, as evidenced by its reliance on *Standard Oil.*[11]

The analysis applied to exclusive licenses in general would also apply to an exclusive license to sell a patented product. The only pernicious result that could flow from exclusive licenses to sell patented products would be the possibility that under some circumstances the free movement of goods within the EEC would be hindered. The internationalization of the doctrine of exhaustion of the patent monopoly within the EEC, as last and most clearly enunciated in the *Centrafarm*[12] case, would take care of that problem. Therefore, no basis is seen for drawing an artificial distinction in the case of exclusive licenses for sales of patented products especially in such an arbitrary fashion as done in the second part of Article I. The fresh winds

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[11] Standard Oil Co. of California v. United States, *supra* note 3.

[12] Centrafarm B.V. v. Sterling Drug, Inc., [1974] C.J. Comm. E. Rec. 15/74.

Law Center Report

We are pleased to report the publication of the first monograph in the P.T.C. Law, Science and Technology Monograph Series: *The Presumption of Validity: A Study of its Effect on Case Law Since 1952,* by David A. Lowin. (Information on the purchase of this monograph appears at page 313 of this issue.)

This monograph is the result of P.T.C. sponsored research, analyzing over 1,100 cases in the United States District Courts and Courts of Appeals. The cases selected were restricted to those headnoted with specific court reference to the presumption of validity, a limitation which assured that the presumption was at least considered.

The following information was accumulated from each of the cases studied: the court, the judge, the year, the number and types of patents involved, the number and types of patents held valid and invalid, and the reasons for holdings of invalidity. This voluminous information is presented in easily readable tabular form for each court and judge involved, including overall summaries of their records. The monograph also includes several interesting graphic displays of the study results.

One industrial legal advisor to the P.T.C. who critiqued the report commented that the study would be of important help to practitioners in gaining insight into the attitudes of the individual courts throughout the land.

We shall be reporting the publication of other recently completed research programs (IDEA, Volume 20, No. 1, p. 119) in the next issues.

Robert H. Rines
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of the *Sylvania*[13] decision have not yet wafted as far as the Commission.

The concluding part of Article I, despite its convoluted language, reveals that it qualifies the block exemptions granted in Sections II and III in that the exclusive sales license exemption of Section II and the export prohibition exemption of Section III are limited only to cases where either the licensor or the licensee is a relatively small company, the period of the restriction is limited in a manner specified by the Regulation, and the licensee is involved in the manufacture as well. Another provision allows unrelated entities to be sold throughout the EEC. This last provision would appear to make the entire limited dispensation of Sections II and III completely meaningless.

In summary, Article I exempts a number of insignificant licensing restrictions. By the same token, one might include in the block exemption a large number of other similarly innocuous restrictions, such as an obligation by the licensor to maintain patents or to notify the licensee before abandoning any; accounting requirements; audit clauses; etc. Thus, the only significant exemption clarified by Article I is the exclusivity of manufacturing and use restrictions and the limited variety of exclusive sales and export prohibition restrictions. All of the other items of the block exemption are obviously acceptable.

Article II contains restrictions on the licensee which the Commission apparently views as being of questionable validity. If these restrictions had been entirely acceptable, the Commission would have included them in the block exemption provisions of Article I. Thus, the uncertainty is compounded by the Commission's creation of a gray area. This is entirely undesirable.

Article IX of the draft Regulation is the real sleeper because it casts a shadow over the entire block exemption exercise. In this Article, the Commission reserves the right to withdraw the benefit of the block exemption of Article I with respect to an agreement if, upon an examination undertaken on its own initiative or upon the initiative of another, it finds that the net result of an agreement would not qualify it for exemption. Article IX sets forth a number of illustrative conditions which could trigger a personalized examination of an agreement.

In view of the foregoing and in view of the adverse comments of the various experts from both private and government sources, the author expects the controversy to continue for some time.

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[13] Continental T.V., Inc. v. GTE Sylvania, Inc., 433 U.S. 36 (1977).

licenses have not been condemned in any responsible circles, with the exception of the Commission's mistaken intrusion into this field. It is conceivable that in one extremely rare situation, where it could be established that the acquirer of an exclusive license already has a dominant position in the relevant market in the EEC, the acquisition of the exclusive license would deepen that dominance so that a case for "monopolization" akin to a violation of Section 1 of the Sherman Act[9] (or the reverse of the situation which existed in the *Burroughs/Geha* and *Burroughs/Delplanque*[10] cases), could be established. Even in that situation, it is not the granting but the acquisition of the exclusive license which might bear examination.

In the introduction to the most recent preliminary Draft of the proposed block exemptions, the Commission distinguishes between exclusive patent licenses for manufacturing and using in contrast to exclusive patent licenses for sales of patented goods, with the latter being acceptable only under certain narrow circumstances. This recognition of the separate character and licensability of the three main attributes (manufacture, sale, and use) of patent rights is by now the only surviving feature of the largely defunct Christmas Message of 1962 which would now be officially overruled by the draft Regulation. Furthermore, in the introduction, the Commission uses its own arguments to support its grudging reluctance to place exclusive manufacturing and use licenses on the "white" list of Article I. The Commission makes it very clear that it does not approve of such exclusivity because the patentee waives his right to determine at any time the number of licensees to whom he would grant a license. The Commission objects to the possibility that a patentee, having granted an exclusive license, is no longer in the position of being able to change his mind later to grant licenses to others as well. Whereas, if he had not granted any licenses, or if he had granted only a nonexclusive license, he could decide at any later time to grant further nonexclusive licenses. The Commission does not indicate why this result would be undesirable and the author can see no reason why the Commission would take this attitude. In the absence of an explanation, the aforementioned consequence of granting exclusive manufacturing or use licenses becomes merely an unqualified truism without harmful effect.

The other truism explaining the Commission's dislike for exclusiv-

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[9] 15 U.S.C. §§ 1-7.

[10] Burroughs/Geha Werke and Burroughs Delplanque, O.J. EUR. COMM. (No. L 13) 50, 53 (1972).

first engaging in the Constitutional lawmaking process of obtaining authority from our elected representatives.

These pronouncements from the Commission must be viewed in the context of the purpose of the Regulations. In the almost acceptable Article I, the Commission sets forth those licensing restrictions which, each viewed by itself, would not raise an eyebrow within the Commission. Therefore, one might say that the itemized list of the first part of Article I constitutes a list of exceptions to the policing obligations of the Commission. This does not detract from the fact that the theoretical underpinnings of the document are based on entirely incorrect premises.

The EEC Commission's position on exclusive licenses presents neither solace nor sense. It is the first organization in developed countries by which exclusive patent licenses have been attacked. The Commission's attitude stems primarily from a misunderstanding about the nature of patents and of license agreements involving features of exclusivity.

In a speech to a largely United States audience, a senior official[2] of the Commission stated that United States law is an important source for the Commission's antitrust philosophy. He cited *Standard Oil Co. of California v. United States*[3] as the paragon case for the ideological underpinnings of the Commission's position on exclusive patent licenses. There is one hitch: the *Standard Oil* decision dealt neither with patents nor with licensing. That case was concerned with exclusive dealing arrangements in which a buyer was compelled not to use, or to deal in, the goods of the seller's competitors, *i.e.*, a violation of Section 3 of the Clayton Act.[4]

It is interesting to note that the Commission attempted to carry its mistaken reading of the *Standard Oil* case a step further by applying the "quantitative substantiality" test (by trying to quantify the substantial lessening of competition) into their earlier rulings (such as in *Kabelmetall/Luchaire*[5] and *AOIP/Beyrard*[6]) on the perceived legality of certain exclusive patent license agreements. This kind of superficial misreading of United States law would also account for the previ-

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[2] J. Verges, *A Review of EEC Competition Policy and Regulations vis-a-vis Licensing Technology*, 19 (3) IDEA 195, 201 (1978).

[3] Standard Oil Co. of California v. United States, 337 U.S. 293 (1949).

[4] 15 U.S.C. §§ 12-27.

[5] Kabel-und Metallwerke Gutehoffnungshutte/Ets. Luchaire, O.J. EUR. COMM. (No. L 222) 34 (1975).

[6] Association des Ouvriers en Instruments de Precision/Beyard, O.J. EUR. COMM. (No. L 6) 8 (1976).

The premise should have been to provide a list of "clean" restrictions to reduce any uncertainty in the industry and also to reduce the administrative burden of the Commission in policing agreements. Instead, we must contend with a most complex, interwoven document which, in Article I, sets out a rather meager list of such "clean" or "white" restrictions; in Article II sets out a set of "gray" restrictions, the presence of which in an agreement would not vitiate the "cleanliness" of any of the "white" restrictions from Article I that are in an agreement; and, in Article III sets out a number of "black" restrictions, the presence of which in an agreement would make "dirty" any restrictions from Article I which are in agreement. Thus, by inference, the Commission went further than it should have in establishing a list of "gray" restrictions by inferring that the legality of the restrictions in Article II might be questionable; and an additional list of "black" restrictions in Article III which they infer to be per se violations of Article 85 (1) of the Rome Treaty. Whether this kind of lawmaking is the proper role of the Commission, or whether it should be left to the European parliamentarians and the courts is an issue that will not be addressed here. However, the author believes this kind of approach was a grave mistake and the Commission should have foreseen the difficulties that would occur as a result of its promulgation of the "gray" and "black" lists in addition to Article I.

The basic error hails from Regulation 19 of 1965, which foresaw the inclusion of a prohibited list in any future block exemptions. This basically wrong approach was compounded by the inclusion of the "gray" list of Article II. The block exemptions require an entirely new approach instead of a superannuated Regulation from 1965. That Regulation is about as ready to be killed off as is the Christmas message from 1962.[1]

A further problem is created by the fact that the English language version of the proposed regulations is almost incomprehensible. The lack of clarity is exemplified in the following passage: "Patent licensing agreements of the category defined in Articles 1 and 3 of this Regulation impose no restrictions which are not indispensable to the attainment of these objectives. In the context of this Regulation such restrictions are excluded by Article 3."

The proper approach would have been, and still could be, the compilation of a set of restrictions which the Commission views as unobjectionable. The Commission should not issue any Regulations about what it considers impermissible. That should be left to the usual

[1] 139 J.O. EUR. COMM. 2918 (1962).

cartel laws, no such contraints existed in Europe. This accounts for the rapacious licensing tendencies and restrictions demanded by European licensors, particularly those in France, Germany and Switzerland. It was the survival quite late into the twentieth century of such European rapacity which has led quite a number of non-European countries, mostly South American countries, to introduce quite stringent restrictions to protect domestic licensees. We have heard again and again from South American regulators that their restrictions were aimed primarily not at American but at European licensor practices.

Before the establishment of the EEC, European licensing partners were generally puzzled by the United States antitrust laws. Initially, they had to be persuaded to refrain from the insistence on certain clauses, especially if they were in the position of licensor, when they negotiated with a licensing partner from the United States. As their experience with United States licensees increased, they have gradually become used to that "strange phonomenon," the United States antitrust laws. However, in their licensing activities in other countries, they continue to use clauses which are not acceptable to United States partners.

It was in this licensing atmosphere that the Rome Treaty, with its regulatory bureaucracy, was established. The extreme licensing restriction practices have brought about more extreme kinds of regulatory tendencies by the Commission. Therefore, what we in the United States may perceive as an excess of zeal in the regulatory proposals of the Commission, is really only a return to the more extreme licensing practices of European licensors.

United States antitrust laws have been developing gradually in the courts and through legislation since the end of the last century. Europe, on the other hand, was thrown suddenly into the sea of antitrust regulation and had to learn to swim right away. Even with the gradual development of antitrust laws in the United States, antitrust enforcers in the United States continue to manifest a bias against the legally sanctioned restrictions inherent in patents. It is small wonder then that the European antitrust enforcers who did not have the tempering effect of time are manifesting an even greater anti-patent bias. One might have been less surprised to see such a document issue from a group of developing countries than from the EEC.

The correct premise is that a businessperson should be free to do anything he desires unless it is prohibited by law. Under normal circumstances, regulation should not be directed towards permitting certain licensing restrictions, but towards deciding whether any

One may differ with this conclusion. The results of such incremental decisions may not be additive; there may be safe thresholds of exposure within which no harm occurs; the analysis possibly assumes an erroneous linear relationship between dose and response; perhaps only the same, particularly susceptible human receptors will be at risk, although their risk will be increasing. Nevertheless, some sort of cumulative effect can be expected. Over time it will be substantial.

Taken to its logical extreme, our present fragmented uses of "balancing" in regulation present an even more absurd scenario:

Each agency justifies its own small contribution to environmental cancer on the ground that it constitutes only a minute fraction of all cancer. (Some agencies, such as the Nuclear Regulatory Commission, have already adopted this logic.) But all agency regulations together will create an environment in which the number of cancer cases has increased. So, the Catch 22: as the number of victims of environmentally induced cancer grows ever larger, the significance of each agency's contribution actually diminishes.

Therefore, an agency could conceivably justify an even greater contribution to environmental cancer in the future, and set even less effective controls on the toxic substances it is required to regulate. This scenario, though not yet realized, can be anticipated, given the fragmentation of regulatory authority and the use of balancing in the many small decisions made by the regulators.[17]

Conclusions and Recommendations

The implications of using cost-benefit in regulation deserve analysis far beyond the scope of this review, primarily because of our increasing reliance on the technique to justify decisions which put the health and safety of present and future generations at risk. Assuming that this reliance will continue, we must rigorously review the capabilities of Congress, the administrative agencies, and courts for insuring that uses of the technique are socially appropriate on legal and ethical grounds. We must reinforce the features of administrative practice and judicial review that promote the accountability of those employing the technique, and develop measures for evaluating uses of the technique on specific regulatory matters. The central issue is our capacity for social control of science and technology. We are learning that our problems lie not with stereotypes of agencies and industries, nor with "bad" technologies, but with our analytical and regulatory

[17] For discussion of the issues raised in this section, *see* M. Baram, *Regulation of Environmental Carcinogens*, 78 TECH. REV. (No. 8) at 40-42 (1976) and Chap. 4 of NAS-Beir report, *supra* note 6.

Environmental carcinogens fall into several classes, traceable to specific sources. The major classes of environmental carcinogens include the trace metals (beryllium, cadmium, etc.), synthetic and organic chemicals (DDT, PCBs, etc.), combustion products (aromatic hydrocarbons), other chemical products (nitrites, asbestos, etc.), and ionizing radiation from medical, industrial, and energy activities.

Each presumed carcinogen has its own environmental and commercial pathway from source to human receptor. Common pathways include air, water, soil, the food chain, drug use, and the direct application of medical and other services. Some human receptors are "voluntarily" exposed as consumers and workers, some are "bystanders" who have not voluntarily subjected themselves to exposure, and some fall into both categories. The human receptors vary in their susceptibility to cancer; the most susceptible include the very young, the pregnant, and those who smoke cigarettes. The unborn are also extremely vulnerable to these substances and create a relatively new and difficult class of receptors for the agencies to try to protect.

The specific contribution to human cancer of each substance and each source, each pathway and causal relationship, the intervention of exogenous and synergistic factors, and the adequacy of laboratory and animal data and their extrapolation to humans are among the myriad issues besetting government regulatory agencies. As a result, the Federal agencies must grapple with the serious problems of legal proof in their attempts to set standards. The same uncertainties confront the Federal courts when they review agency rule-making on standards and other agency decisions.

b. *The Analytical Pattern.* At the heart of the regulatory confusion in dealing with environmental cancer is the analytical method used by the separate regulatory authorities. Many agencies employ a "balancing process," in which the costs of establishing and maintaining any levels of emission and human exposure to a carcinogen are balanced against the economic or social benefits accrued by the production and use of the substance. In some cases, agencies use a highly formalized cost-benefit analysis. In other cases, the weighing of the benefits and risks to society which would be incurred from the various levels of emissions and exposure is more informal. In either case, the net risk or cost and the net benefit is estimated, valued, and quantified before the agency determines which of several possible levels of emission and exposure it should allow, in light of available control techniques.

This balancing approach leads each agency to impose a limitation or level of control on the source of an environmental carcinogen at the

ing analysis" is mandated by NEPA for all three steps when such steps constitute "major actions" of environmental significance.

For the dual licensing procedures of the third step, the NEPA mandate for "balancing analyses" is clear; and a Federal court has recently cautioned that the NEPA requirement applicable to the issuance of an operating license may not be short circuited — that a facility which meets NRC regulations does not concurrently and automatically qualify for licensing without the required weighing of risks and benefits under NEPA. Nevertheless, for the specific case before it, the court concluded that:

> Apart from the requirements of NEPA or similar ones already implicit under AEA [Atomic Energy Act], it would be pointless, and a waste of agency resources, to require the AEC [Atomic Energy Commission] to reapply efforts that have already gone into its basic health and safety regulations, in individual licensing proceeding, in the absence of some evidence that a particular facility presents risks outside the parameters of the original rule making. And in evaluating the sufficiency of agency determinations in particular cases it would be stultifying formalism to disregard the whole record and test AEC compliance by only the evidence received at so-called "health and safety" hearings; or NEPA compliance only on the basis of so-called "environmental" hearings.[16]

This judicial decision promotes administrative efficiency by eschewing duplication of balancing analyses, and seems to make good sense. But it is clear that such efficiency is justified only when the risks and benefits appropriate for the facility-licensing balancing task under NEPA have been adequately considered in the prior balancing undertaken by the agency under its own regulations (e.g., NRC *Appendix I).* Determination of these justifying circumstances is a complex task which rests ultimately with the courts. The extent to which the courts can handle this difficult task responsibly will therefore depend on judicial willingness to examine the substantive features of agency decision processes, and the development of judicial expertise on cost-benefit.

k. *Modification and Alternatives to Cost-benefit.* Finally, what modification or alternatives to cost-benefit should be considered, so that the issues identified can be diminished? Will use of screening models, multi-attribute analysis, and other progeny of cost-benefit reduce some of the problems of valuation? Does cost-effectiveness analysis provide a better method of simultaneously considering diverse factors in regulatory decision making and also insuring that various social-well being parameters are not breached by the regulated activities?

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[16] Citizens for Safe Power v. Nuclear Regulatory Commission, 6 E.L.R. 20095 (D.C. Cir. 1975).

nologies to provide more effective limitation of releases on the sources of such pollutants, over time. To what extent will the use of cost-benefit for establishing regulations and prescribing control technologies retard the technology-forcing function? Information on control technologies is more available to industry than to government; in the past, industry has presented pessimistic data on the feasibility and costs of new technological developments to government agencies (e.g., auto emission technologies).[13] How shall we assure the adequacy of the data and opinion on such technological developments, so that cost-benefit does not become a tool for conveniently maintaining the status quo on control technology, nor be used to stultify the forcing of new control developments?

h. *Ethical Limitations.* What constitutional and ethical limitations will be applicable to the use of cost-benefit? How will due process, equal protection and other legal and ethical concepts apply to the conduct of regulation by cost-benefit? Is it ethical to use an economic method which requires valuation in order to establish the quality of life of this and future generations?

In another hazard or safety context, that of vehicular safety regulation, it has been noted that:

> If... the principal benefits anticipated are the savings in lives and/or reductions in the frequency or severity of injuries which cannot be reasonably quantified in monetary units, serious theoretical and conceptual difficulties arise.... Virtually all cost-benefit studies involving the loss of life or limb have assigned fixed monetary values... typically obtained either by computing the discounted future income of individuals or by computing the discounted differences between future earnings and personal consumption. These concepts and approaches have been criticized on a number of grounds....
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> National Highway Traffic Safety Administration (NHTSA) has expressed a similar [critical] view. In its recent notice of proposed rule-making concerning school bus crashworthiness, the agency stated that it 'has conducted conventional cost-benefit studies on school bus safety, but the normal valuation techniques evidently do not adequately reflect general public opinion on the importance of protecting children from death or injury. *It is obvious from the voluminous mail and Congressional interest that society places a higher value on the safety of its children than a conventional cost-benefit analysis would indicate...*' [B]ecause of the major conceptual and methodological difficulties in the valuation of life and limb, cost-benefit studies will be appropriate only in the decision-making processes involving standards *not* primarily intended to save lives and reduce injuries — that is... standards to reduce property damage.
>
> Congress recognized this distinction. Under Title I of the *Motor Vehicle Information and Cost Savings Act* (P.L. 92-513, 1972) — principally intended to reduce property damage losses resulting from low-speed crashes — it included a mandatory requirement for the Department of Trans-

[13] *See* discussion in Chap. 4 of NAS-BEIR report, *supra* note 6.

fected interests and enable them to play a role in the identification process?

To what extent will it be possible to identify significant long-term effects by means of the various assessment techniques we now possess or can develop? To what extent will the characterization of effects as costs or benefits reflect establishment values and the status quo and ignore changing values and behavior (e.g., the NRC's characterization of increased energy supply as of virtually unlimited benefit at a time of increased concern about the need to conserve energy and fuel resources and move to small technologies)?

b. *Measurement and Quantification of Costs and Benefits.* Similar uncertainties arise regarding the capacity of regulatory agencies adequately to measure and value costs and benefits, particularly those which cannot be properly valued by the marketplace or economic processes. Can we measure or value such effects as carcinogenicity, mutagenicity, teratogenicity, consumer convenience, or the perpetuation of certain aspects of certain lifestyles such as mobility? Are we ready to accept the valuation of $1000 per man-rem promulgated in 1975 by the Nuclear Regulatory Commission in order to conduct its cost-benefit analyses and set standards for ionizing radiation?[10] Should such values be commonly adopted by all agencies with regulatory jurisdiction over different aspects of the same problem, such as EPA and FDA, which share with NRC to some extent control over ionizing radiation? By what legal procedure shall we set such values? To what extent shall we enable various interests to play a role in the objective measurement and subjective valuation processes? Who will represent the unborn (future generations) in the valuation of mutagenic and other future effects, which arise from standards established by NRC and EPA for radiation and toxic materials?

c. *Consideration of Distributional Effects.* Closely associated with the foregoing issues is the need to consider adequately distributional effects of agency decision making based on cost-benefit. Clearly the adverse effects of radiation emitted from nuclear power plants in accordance with NRC standards will fall most heavily on those living in the environs of the power plants, but this distributional effect pattern is not adequately recognized in the NRC's use of cost-benefit analysis. How shall we safeguard the interests of these impacted groups and others such as the poor, the primitive, and the unborn?

d. *Determination of Appropriate Weighting Factors.* A facile solution to the issues of quantification and distributional effects is the

[10] *See* NRC's Appendix I, *supra* note 6.

and operation.[6] The Environmental Protection Agency has also promulgated regulations requiring that the technique be used for the establishment of other radiation standards and for the setting of emission standards for toxic chemicals under the Water Pollution Control Act Amendments of 1972. The Consumer Product Safety Commission and several other agencies have not formally acknowledged use of the technique, but recognize that the technique or a rough equivalent is used in its decision processes.[7] Implementation of the National Environmental Policy Act by various agencies, in accordance with the *Guidelines* of the Council on Environmental Quality,[8] has brought about further adoption and use of the technique in certain agency decision-processes (Table 1).

Use of a new technique on this scale for national decision making on matters involving the management of risks may have unforeseen and undesirable implications. The time is ripe to directly address the implications of using cost-benefit in regulatory decision making, before such implications become manifest.

Issues for Evaluation

The use of cost-benefit analysis by regulatory agencies raises several issues that deserve study, so that appropriate corrective measures may be taken in time to avoid undesirable societal consequences. Discussion of these issues is briefly presented here. Note that most of these issues are inherent in any regulatory decision process, but are most urgently and clearly raised when regulation is based on cost-benefit.

a. *Identification of Costs and Benefits.* The identification of costs and benefits may appear to be a relatively simple task, but in reality is an immature art. The Leopold, Sorenson, and GSA matrices[9] are of some use as checklists of some possible effects that may attend the construction of discrete projects, but are inadequate to the task of identifying the effects of a standard (for radiation, for example) that may have national and global consequences over long time frames. To what extent will agency regulatory processes provide adequate notice to potentially af-

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[6] *See generally,* 10 C.F.R. 20, 10 C.F.R. 50, and other sections of NRC's regulations, particularly Appendix 1 to 10 C.F.R. issued in 1975. For discussion, *see Consideration of Health Benefit-cost Analysis for Activities Involving Ionizing Radiation Exposure and Alternatives,* Washington, D.C.: National Academy of Sciences (BEIR Committee), 1977.

[7] Findings based on interviews with personnel of various agencies.

[8] CEQ Guidelines, 40 C.F.R. 1500 (1973).

[9] For discussion of matrix methods, *see Review of Decision Methodologies for Evaluating Regulatory Actions Affecting Public Health and Safety,* Chap. 6, Battelle Northwest Laboratories, Report BNWL-2158 (1976).

teristics and health and environmental effects in their decision-making processes to establish standards, issue licenses, or take other agency action. This responsibility to consider such diverse factors simultaneously may be imposed by a single statute on an agency, or by a set of statutes enacted over time, all of which may apply to a single agency.

Comprehensive statutes to control externalities, such as the Federal Water Pollution Control Act Amendments of 1972, the Consumer Protection Act, the Noise Pollution Control Act, and the National Environmental Policy Act of 1970 (NEPA) are examples of Congressional enactments that call for agency consideration of such factors in decision making. Statutes governing resource development and management by Federal agencies, such as the Outer Continental Shelf and the Submerged Lands Acts, the Reclamation and the Water Resource Acts, and the Atomic Energy Act of 1954 (as amended) also impose similar requirements for decision making on the Federal departments and independent agencies.

Judicial review of agency decision making under these statutes has been particularly rigorous and has had the effect of insuring that Federal agencies comply with such multiple-criteria requirements in their decision processes. For example, NEPA and the Administrative Procedure Act,[1] which apply to all agencies, have been judicially interpreted as requiring agency use of "balancing analysis" *(Calvert Cliffs v. AEC)*[2] and "substantial inquiry" *(Citizens to Preserve Overton Park v. Volpe)*[3] by agencies in their decision-making processes, thereby requiring that all relevant factors such as economic and technical feasibility, and health and environmental effects, must be simultaneously considered.

The agencies have therefore sought to develop and apply new techniques for decision making that can satisfy these statutory and judicial requirements for balancing multiple factors, such as cost-benefit analysis.

Agency Implementation

Agencies are now turning to cost-benefit analysis in an effort to comply with statutory and judicial requirements. Cost-benefit is a relatively

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[1] NEPA (42 U.S.C. 4321-4361) and APA (5 U.S.C. 500-576) are generically applicable to all agencies of the Federal government, and similar statutes have been enacted in many states for applicability to state agency regulatory activities.

[2] In *Calvert Cliffs*, the D.C. Court of Appeals required that agencies use the results of their environmental impact assessments under NEPA in "balancing analyses" to reach their final determinations. [449 F.2d 1109 (1971).]

[3] In *Overton Park*, the U.S. Supreme Court dealt with the need for compiling a full, adequate record to support agency decisions. [401 U.S. 402 (1971).]

"food additive" under the Delaney Amendment and subject to a zero level tolerance.

The rate of cancer is highest in developed countries. With this in mind, the United States would be wise to be exceptionally careful in minimizing the incidence of carcinogens in our food.

prevention of agency discrimination in controlling carcinogens. Critics cite the great improvements since 1958 in the detection of increasingly minute amounts of such substances in food as a reason for the desirability of discretion. The argument frequently degenerates into the contentions that setting tolerance levels for carcinogens is no different from setting them for acute poisons, that not all encounters with carcinogens are equally harmful and that the tolerance levels chosen for carcinogens should be set so as to create no more than an acceptable risk to human life.[56] The problem with the rationale, whether applied to aflatoxins in milk or to additives in convenience foods (a burgeoning market of the industrial food giants who are most upset by the Delaney Amendment), is the difference between acute poisons and carcinogens. For the former, the harm of an over-the-threshhold dose is limited to harm to certain categories of persons under certain conditions. For the latter, harm also clearly increases with potency, but whether there is any threshold dose below which the harm is acceptable is not known.[57]

The FDA's decision to set an "action level" of 0.5 ppb for aflatoxin contamination was a judgment of risk that a low dosage would be safe and therefore acceptable. The action raises many questions. What would be the cost of no action level at all, that is, of banning contaminated milk from interstate commerce and spreading the cost over the remaining milk to be sold. Dairies face a similar problem now in relation to pesticide residues in milk. The model for controlling pesticide residues may be relevant for controlling aflatoxin-contaminated grain. If shipped, milk with pesticide residues can be labeled "adulterated," dairies can be prosecuted, and the milk subject to seizure. If the milk is not shipped, but destroyed, the dairies may suffer severe financial loss. However, there may be no prosecution of the dairy if, under a "good faith" provision, the dairy has received grain containing pesticide residues from second parties. The dairy can establish a guarantee signed by the person providing the grain. (This does not apply to grain produced by the dairy for its own cattle's feed.) With the guarantee, the dairy can get an indemnity payment for dumping pesticide-contaminated milk. The entire provision is cited as an improving technological experience which has been used much

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[56] Blank, *id.*

[57] Environmental Defense Fund, Inc. v. United States Dep't of Health, Education and Welfare, 428 F.2d 1083 (1970), included testimony to the effect that scientifically there was no way to determine a "safe" level for a substance known to produce cancer in animals.

duced by fish but is acquired through the external food supply of the fish.[47]

The analogy between mercury-contaminated fish and aflatoxin contaminated milk is clear. Both contaminants have existed for centuries. Both are in the food source of the contaminated substance or, in the case of aflatoxin-contaminated milk, in its product. The analogy breaks down insofar as there is no control over what chubs and swordfish eat, but there is control over what cows producing contaminated milk eat. The argument for banning aflatoxin-contaminated milk is even stronger because cows' feed can be controlled, while that of swordfish cannot be controlled.

Milk, although denominated as a raw agricultural commodity by the FDA, after processing could be held to the standard for processed foods, *i.e.*, pesticide residues in manufactured dairy products come within the definition of "food additives" and are subject to food additive regulations. There are no tolerances or exemptions from tolerances for pesticides in milk or dairy products. Thus, when they contain pesticide residues in any amount, they are defined by statute as unsafe and therefore adulterated.[48]

It seems incongruous that chemical pesticides should be subject to zero tolerance in milk while a known carcinogen should be permitted at an "action level." There has been criticism of the FDA's concepts of "no residue" and "zero tolerance" by, among others, the National Academy of Science, which finds those concepts untenable in light of finer measurements. The Academy suggests the use of terms like "permissible residue" or "negligible residue," a "safe" use or a "no effect" level. However, with respect to carcinogens, the Academy says that to approve such a compound for use when it might leave a residue on food would require the "most extraordinary" justification. It considers insufficient data on a safe tolerance a reason for using zero tolerance.[49] It could be argued that there is insufficient data on a safe tolerance level for aflatoxin in milk.

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[47] An earlier ruling in *Vita Food* was in direct contradiction to the later ruling in the *Swordfish* case. The court in *Vita Food* held that while fish were adulterated within § 402(a) (2) (C) by additives of DDT and Dieldrin, the company did not actually "add" these to their product. They therefore were accidental and not "food additives" under the Act. United States v. Vita Food Products, Inc., 356 F.Supp. 1213 (D.C.Ill. 1973), 21 ALR Fed. 302, *rev'd on other grounds,* 502 F.2d 715.

[48] Fistere, *Pesticide Residues – Legal Aspects,* 20 FOOD DRUG & COSM. L.J. 684, 685 (1965).

[49] National Academy of Science, *No Residue and Zero Tolerance,* 20 FOOD DRUG & COSM. L.J. 608, 614-22 (1965).

directly with the extent of their presence. The effect can be plotted on a continuum in relation to concentration of the substance and degree of exposure to it, considering attendant variables such as whether the substance is degraded or metabolized, stored or excreted, etc. The body can tolerate some amounts of some poisons, such as metholmercury, the substance found in swordfish,[37] with no apparent ill effects. The body excretes methylmercury at a rate which eliminates one half the amount present in about 70 days, the substance's biological half life. At low levels of consumption, intake and elimination balance to maintain an equilibrium of low toxic levels in the body. The equilibrium level is the scientific basis for calculating safe rates of consumption.[38] It is on this basis that tolerance levels are set "limiting the quantity as necessary to protect the public health."[39] In a similar situation, that of pesticide chemical levels (DDT), the court in *United States v. Ewig Bros. Co.*,[40] said, "Scientists seem to agree that if the DDT level is high enough, the food should not be consumed by [hu]man[s] and, conversely, if the amount is sufficiently small, ingestion of DDT may be harmless." The level set should be generally recognized among qualified experts as safe.[41]

It should be kept in mind that some may consider arbitrary the tolerance levels selected in ppm or ppb. Ideally, the levels are to be based on the best available scientific information and not merely on economic or political motivations or fragmentary data. The ideal, unfortunately, is not always achieved. Because rapid progress has been made in measuring techniques in the past ten to twenty years, it is now possible to detect the presence or substances at increasingly minute levels. That the presence of a poison is detectable in many cases does not per se indicate a food is not safe. "A thing is safe if the risks are judged to be acceptable," not if it is completely "free from risk."[42]

Aflatoxin-contaminated milk presents a special problem because aflatoxin is a carcinogen. As explained above, if aflatoxin were to be considered a "food additive" under Section 409 of the FDCA instead of a "poisonous ingredient" under Section 408 or a "naturally occurring poison" under Section 402, aflatoxin contaminated milk would be au-

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[37] An Article of Food Consisting of Cartons of Swordfish, 395 F.Supp. 1184 (D.C.N.Y. 1975).

[38] *See* page 5 in text and *The FDA Ban on Swordfish, supra* note 36, at 1027.

[39] Sec. 408; 21 U.S.C. § 346.

[40] 502 F.2d 715 (7th Cir. 1974).

[41] *Id.* at 718.

[42] W. LOWRANCE, OF ACCEPTABLE RISK at 8 (1976).

Food, Drug and Cosmetic Act (FDCA) governs food additives.[24] Section 402 governs adulterated food including naturally occurring poisonous ingredients; Section 408 governs tolerance for poisonous ingredients in food; and Section 408(a) governs tolerances for pesticide chemicals in or on raw agricultural commodities. "What's in a name" has determined the fate of a number of foods marketed in this country in the past few years. Depending on the category used, either tolerance levels have been accepted or the equivalent of a ban has been imposed.

If aflatoxin in milk is labeled a "food additive" under Section 409 of the FDCA, that milk must be restricted from interstate sale.[25] Aflatoxin is a known carcinogen. Under the Delaney Clause to Section 409 there is *no* acceptable level of carcinogenic contamination.[26] The milk would be held adulterated as a matter of law under Section 402.[27]

If, on the other hand, aflatoxin-contaminated milk is held to the standard for "poisonous ingredients" under Section 408[28] or to the standard for "naturally occurring poisonous ingredients" under Section 402(1)(a),[29] it may be permissible for it to be sold. Section 408 indicates, with respect to added substances, that if the poisonous substance cannot be avoided by following good techniques of processing, tolerance levels may be established. If there are no tolerance levels established, the substance *may* be held adulterated under Section 402.[30] Section 408 turns on the avoidability of the poisonous substance.

At present there are no tolerance levels established under Section 408 for aflatoxin contamination in food, but the FDA could promulgate a tolerance level if it so desired.[31] The FDA's avoidance of the issue is evidenced by its December 1977 ruling that since there were no tolerances established under Section 408 for aflatoxins, it was establishing something called an "action level" of 0.5 ppb for aflatoxin M_1 contamination of milk.[32] This could be taken as good news or as

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[24] Food additives are defined in § 201(s); 21 U.S.C. § 321(s).

[25] Sec. 409; 21 U.S.C. § 348.

[26] Sec. 409(c) (3) (A); 21 U.S.C. § 348 (c) (3) (A).

[27] Sec. 402; 21 U.S.C. § 342.

[28] Sec. 408; 21 U.S.C. § 346.

[29] Sec. 402 (1) (a); 21 U.S.C. § 342 (1) (a).

[30] Sec. 408; 21 U.S.C. § 346.

[31] *Id.*

[32] *See* Aflatoxin Contamination of Milk, *supra* note 3.

the age of three years, a group consuming a high percentage of milk, are the most vulnerable, but adults having longer exposure time may also be in jeopardy.[19]

Human milk can become contaminated as well. It has been found that fetal tissue may be much more sensitive to the effects of carcinogens than adult tissue; in some cases, only 1% of the doses necessary to produce cancer in adults has produced cancer in fetuses.[20] Even though some products in the United States, including milk, are contaminated at very low levels (most often 1 part per billion), human health risks may still exist particularly for infants.[21]

To reliably prevent contamination of milk requires the ability to detect even minute quantities of aflatoxin in grains consumed by dairy cattle. The presence of aflatoxin cannot be determined with certainty except by analysis for the toxins. Although cereal grains are known to be the most important food source naturally contaminated, little data on the natural occurrence of aflatoxin in cereals exists because of the lack of precise chemical assays. Two methods now used in the United States have serious limitations. The "CB" method has a sensitivity of 1-3 ppb, but the difficulty of obtaining a truly representative sample of an entire lot makes the method problematic. The other method, thin layer chromatography, provides another analytical approach, but it must always be backed by a confirmatory test since fluorescence is not always indicative of aflatoxins.[22] One of the most pressing practical needs in aflatoxin research is for a rapid screening method for detection at grain elevators and mills.[23]

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[19] Campbell & Stoloff, *supra* note 12, at 1006-15.

[20] J. CORBETT, CANCER AND CHEMICALS 19 (1977). Carcinogens can interact with the fetus and produce cancer later in life as in the DES cases.

[21] Rodricks, *supra* note 2, at 13. The number of human carcinogens known is becoming larger as more research is being done in this area. For example, stilbestrol in 1971, methyl chloromethyl ether in 1973 and vinyl chloride in 1974. The incubation time requires for chemical carcinogenesis in humans is relatively long. An induction period of 10, 20 or even 30 years is not uncommon. It is a scientific fact that many chemical carcinogens become chemically (covalently) bound to DNA, RNA and proteins of the cells in certain susceptible tissues. It has become common knowledge that cancer is induced by these chemical carcinogens as a result of this binding to these macromolecules. Aflatoxin is one of those chemicals that induce cancer by this mechanism. It has also become axiomatic that most chemical carcinogens must be metabolized (changed chemically) by the body before they become carcinogenic. Aflatoxin is not an exception. Heidelberger, *Chemical Carcinogenesis,* 44 ANN. REVS. OF BIOCHEMISTRY 79-126 (1975).

[22] Hesseltine, *supra* note 2, at 142-6.

[23] *Id.* at 146. Chromatography involves fluorescence under U.V. light; "CB" utilizes a mini column technique.

and pesticides may have to be balanced against the risk of aflatoxin contamination.[11]

Aflatoxins can be found in food that is obviously moldy. More importantly, they can be found in food taken from stocks which, upon visual inspection, seem to be sufficiently high in quality to be used directly as human food. Therefore, removal, the second technique of avoidance, has limited practical value. It can provide protection only against acute aflatoxicoses. Acute human aflatoxicosis is unlikely in a country like the United States because most people here can afford to avoid moldy food. In countries where widespread food shortages exist, consumption of moldy food is not uncommon.

More likely sources of aflatoxin contamination for this country are outbreaks of veterinary mycotoxicoses which continue to be reported in agriculturally advanced nations. Animals tend to reject feeds severely contaminated with aflatoxin mold unless sweetened, but the ingestion of less heavily contaminated feeds probably lies behind the reports of aflatoxin-contaminated milk in four southern states.[12]

Processing Methods of Detoxification and Removal. In addition to prevention and removal, processing methods that detoxify or remove aflatoxins in contaminated raw foods have been utilized with varying degrees of success. Several methods have successfully inactivated or removed aflatoxin from peanuts and cottonseed. Solvent extraction is one such method. Detoxifying agents, including oxidizing agents (5% NaOCl, 10% Cl_2), alkalies (NaOH, Na_2CO_3), ammonia, and heat plus moisture have at least partially inactivated aflatoxin in oilseed meals. Although aflatoxins are relatively stable to heat under anhydrous conditions, a reduction has been achieved in peanut meal using steam pressure, *i.e.,* autoclaving for four hours.

Some procedures offer promise for other protein sources such as grains. To date, however, there have been no major breakthroughs. It is important to note that while several of these studies have resulted in apparent aflatoxin inactivation, few have been concerned with nutritive value which would be a definite concern with milk.[13]

Aflatoxins in milk are apparently not destroyed by boiling or by any other simple means. Studies on aflatoxin recovery from pas-

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[11] Hollis, *supra* note 9, at 4. Hollis considers the production of food in a hungry world the first goal of "pest management," minimizing hazards to humans and the environment as the second.

[12] Campbell & Stoloff, *Implications of Mycotoxins for Human Health,* 22 (6) J. AGR. & FOOD CHEMISTRY 1006 (1974); *See also* Rodricks, *supra* note 2, at 12 & 13; and Wogan, *supra* note 7, at 936.

[13] Wogan, *supra* note 7, at 937.

The relatively recent discovery of the existence of the problem in this country gives rise to a multitude of policy questions, particularly for the Food and Drug Administration (FDA) as the chief governmental guardian against unfit food. Although the highest levels and incidence of alflatoxin contamination are in tropical or semitropical regions, where the climate favors the growth of the producing fungi, it has also been found in foods produced in more temperate zones as far north as Canada. There is probably no populated region of the earth where some aflatoxin contamination of food does not take place. In this country, aflatoxin contamination in milk is considered a potentially serious public health problem in at least four southeastern states.[4] Its presence in meat and eggs as well as in milk is likely to be even more common than limited studies have determined.

The Delaney Amendment to Section 409 of the Food, Drug and Cosmetic Act bans "food additives" found to be carcinogenic irrespective of the amount of carcinogen present.[5] However, with aflatoxin the question arises whether it is a "food additive." Notwithstanding the carcinogenic danger, the FDA has held aflatoxin in milk is not a food additive. Instead, the FDA has treated aflatoxin as a "poisonous ingredient" for which a tolerance level can be established under certain circumstances and to which the Delaney Amendment does not apply. Thus the label attached to aflatoxin determines whether food containing it is proscribed or permitted. The FDA has set a tolerance level, referred to as an "action level," below which aflatoxin-contaminated milk can be and is sold.

This treatment is indefensible both in policy and according to legal precedent. The sale of contaminated milk should not be permitted where control or elimination of the source of the carcinogen, feed ingested by dairy cattle, is feasible. (The wiser policy would turn attention to the source of the health danger, cattle feed, and to the scientific data base for ending it.) Moreover, the Court of Appeals for the Seventh Circuit, in a case concerning fish contaminated with DDT, has ruled that even where the food source for fish cannot be controlled or avoided, DDT in such processed fish is to be considered a food additive and the fish to be adulterated as a matter of law.[6] If DDT in processed fish is a food additive, then aflatoxin in processed milk must be so considered.

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[4] *See generally* Human Health and the Environment — Some Research Needs, 77 DEP'T OF HEALTH, EDUCATION AND WELFARE PUB. 83, 84 (1977); and JAY, *supra* note 1, at 401; Rodricks, *supra* note 2, at 13; and Hesseltine, *supra* note 2, at 148.

[5] Section 409, 21 U.S.C. § 348.

[6] United States v. Ewig Bros. Co. Inc., 502 F.2d 715, 718 (7th Cir. 1974).

Conclusion

Uncertainties are inherent in identifying as well as in regulating environmental carcinogens. However, regulatory decisions will continue to be made on the basis of imperfect evidence. The best hope is that such regulatory decisions are made in a consistent way, on the best available evidence and with the regulatory discretion to overturn a decision as scientific and economic analyses improve. Present procedures rely too much on the ability of scientists and economists to quantify risks and benefits. Policymakers should recognize this fact, open up the process to public discussion, and spread the responsibility for making decisions on issues with increasing impact on our technology-oriented society.

conclusions on experimental findings rest on subjective, quasi-scientific beliefs. One reviewer believes that rare but statistically insignificant tumors are proof of carcinogenicity. Another believes that they were spontaneous and are insignificant. One reviewer believes that positive short-term tests tip the finding of equivocal results in a particular animal experiment toward proof of carcinogenicity. Another will find that the two types of tests are not related. What emerges is the lack of consistency in interpretation of test results from the same data source (short-term tests, animal tests, and epidemiologic studies), and in the relationships between data sources.

Systematic attempts are of course being undertaken. The effort of the OSHA to classify carcinogens in terms of the types of test results is one example. OSHA's proposal would place each carcinogen or suspected carcinogen into one of three categories, allowable exposure levels correlating to these classifications. For example, a "confirmed" carcinogen would be based on evidence in any of the following categories:[57] (1) humans; (2) two mamallian test species; (3) one mammalian species, if the results are replicated in the same species in a separate study; and (4) a single mammalian species, if the results are supported by multitest evidence of mutagenicity.

Similar systematic attempts should be undertaken to judge the reliability of the experiments themselves. The NCI guidelines for animal testing set forth criteria for judging whether or not a particular test was properly conducted. Even these guidelines, however, are a little confused. One of the criteria listed is that the chemical should be administered by a route that mimics human exposure. This criterion is not related to the validity of test conditions, but rather to the applicability of test results to human exposure. Cancers in test animals, if the other conditions were met, would be taken as proof that carcinogenicity was shown. There would still be a question of whether the chemical would produce cancer in humans if the route of exposure were different from the test conditions. This latter question would not have bearing on the validity of the animal tests, only on their relevance to human risk.

Recommended animal test protocols now take three years to perform and the guidelines are constantly being revised. Some practical solution must be found if we are to avoid either the rigid stance of ignoring tests that do not meet current guidelines or the current approach where reviewers of completed tests often abide by their own rules of what is significant and what is not. Weighting scales could be

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[57] *See supra* note 52.

line extrapolation model, using the no-threshold assumption. Most agencies reported great interest in the use of short-term tests and expressed a desire to have the methodology and validation of such tests given attention.

Although there are problems associated with the assessment of risks, such assessment is an advanced science when compared to benefits assessments. All of the regulatory agencies and their supporting scientific agencies have expressed dissatisfaction with the methodologies used in the second half of the risk-benefit equation. Benefits of a substance include positive benefits due to use and the avoidance of costs which would accrue if the substance were not available. The most common "benefit" to be measured and weighed against risk, according to the statutes, is economic impact. How the agencies perform these assessments is something of a mystery, often to the agencies themselves. By that is meant that the analysis conducted on one substance may be entirely different from the analysis conducted on another. No published guidelines are used systematically in regulating carcinogens.

In short, assessment of benefits by the regulatory agencies is largely an ad hoc process. Although agencies are not satisfied with the product of these analyses, they cite methodological problems, lack of guidance from Congress, and the basic difficulties involved in quantifying measures of social value or utility in defense of their processes.

Although both benefits and risks must be quantified in order to conduct a risk-benefit analysis, regulatory decisions are not usually made by merely choosing the course (banning, setting allowable exposures, etc.) indicated by the numbers. The EPA, for example, has risk analysis conducted by its Cancer Assessment Group and the benefit assessment by an economic analysis unit.[55] The two groups submit their individual results in the case of action being considered under the TSCA to the Office of Toxic Substances. That Office then makes a recommendation to the EPA Administrator based on a balancing of the risks versus the benefits. By the office's own admission, this is not a straightforward mathematical decision. It is a subjective weighing of assessments which, for all their attempts to use common measures, are not equivalent in terms to those measures. For example, x thousand lives lost or to be lost may be balanced against y million dollars in economic impact, and a decision made as to which is more important to society. The decision is not based on x

[55] *See supra* note 42.

tives, drugs and cosmetics. Thus, the scientific criteria will vary according to the substance and the type of evidence available rather than according to whether the substance is new or established.

Assessment of risks and benefits. Three of the most perplexing aspects of the regulation of carcinogenic substances are: (1) The assessment of the risks to health care due to exposure; (2) The assessment of the benefits to health, the economy, the environment, etc., due to continuing use of the substance; and (3) The comparison of the results of the above assessments to reach a decision on whether the risks outweigh the benefits or vice versa.

Not all the applicable statutes require or even permit this type of analysis. The Delaney Clause for food additives and the Delaney-like clauses for color additives and residues of animal drugs found in foods, do not allow balancing of risks and benefits. The provisions on cosmetics in effect presume that no benefit to health will accrue as a result of their use and do not allow assessment of economic or other benefits either. Therefore when a cosmetic, or an ingredient in a cosmetic, is shown to present a danger to human health, the substance is not allowed on the market.[49] The drug sections of the FDCA, however, *require* that risk-benefit analyses be conducted.[50]

Risk-benefit analysis is *permitted* by the Clean Air Act, the Water Pollution Control Act, the Safe Drinking Water Act, the Federal Insecticide, Fungicide, and Rodenticide Act, the Federal Hazardous Substances Act, and the Occupational Safety and Health Act.

Such analyses *must* be performed under the Consumer Product Safety Act,[51] the Toxic Substances Control Act,[52] and the sections of the FDCA mentioned above. Implementing regulations for the Occupational Safety and Health Act also make risk-benefit analysis mandatory. Thus, most of the statutes either require or permit the balancing of risks and benefits. However, Congress has given the agencies little guidance on how to perform the assessments or the balancing.

Some of the problems in assessing risks to health from use of or exposure to carcinogenic substances have been discussed above. Two of the primary underlying problems are deciding how much weight to give to results of the often numerous tests performed on a substance, and how to interpret what the test results mean in terms of human

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[49] *See supra* note 35, at § 361; and T. Quinn, Food and Drug Administration; Personal Communication, 1977.

[50] *See supra* note 1 and T. Byers, Food and Drug Administration; Personal Communication, 1977.

[51] *See supra* note 27, at § 9.

[52] *See supra* note 24, at § 6(c).

stances, however, under the same rule-making authorities of the TSCA as are applicable to toxic chemicals in general.

Thus, with the exception of the provisions of the FDCA and the TSCA, all major federal statutes applicable to control of carcinogenicity derive from the regulation of general risks to health from toxic substances. Only the FDCA contains provisions which explicitly direct a mandatory action, a total ban.

New versus established substances. The statutes vary greatly on whether a new[37] substance is to be regulated differently from an established one. The key distinction is whether an agency can require pre-market testing to determine if the substance is to be allowed on the market.

A peculiar case is the Consumer Product Safety Act (CPSA)[38] which permits the Consumer Product Safety Commission to require that information on the health dangers of new products be provided to the Commission before marketing. That agency, however, does not have the authority to take action until the product is on the market![39] However, those chemical products regulated by the CPSA after they are on the market, might be regulated under the TSCA which has pre-market regulatory powers.[40] TSCA could cover such substances if they were not covered by CPSA; and since they are not covered by CPSA *until* they reach the market, the TSCA may apply.

The EPA has authority to require submission of data on the safety of new and established chemical substances.[41] If such data proves insufficient for a determination of the chemical's safety, the EPA may then require further testing. Sidney Wolfe of the Ralph Nader-affiliated Health Research Group believes that the EPA's authority to require pre-market testing is discretionary rather than mandatory. According to Wolfe, when that fact is added to the Act's complicated procedures for requiring testing, the result is likely to be that adequate pre-market testing is the exception rather than the rule.[42] A differing view is held by Devra Davis of EPA's Office of Toxic Sub-

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[37] A "new" substance for our purposes will mean both a substance which has not yet been significantly used, a substance which has had substantial use but which is to be used for a different purpose, under different conditions or exposures, etc.

[38] *See supra* note 27 at § 13 (a).

[39] R. Brown, Consumer Product Safety Commission; Personal Communication, 1977.

[40] *Id.*

[41] *Id.*

[42] Wolfe, *Standards for Carcinogens: Science Affronted by Politics*, in ORIGINS OF HUMAN CANCER.

TABLE I: FEDERAL REGUL

	(a) Administered By:	(b) Type of Substances Regulated	(c) Specific Procedures for Regulating Carcinogens?	(d) If "c" Does Not Apply, How are Carcinogens Regulated?
1(a) Federal Food, Drug, and Cosmetic Act — food provisions	Food and Drug Administration, DHEW	Foods, food additives, other substances or residues in food	Yes, in several sections (food additives, color additives, residues of animal drugs)	For other sections general safety is the criterion
1(b) Federal Food, Drug, and Cosmetic Act — drug provisions	Food and Drug Administration, DHEW	Drugs and substances in drugs	No	Carcinogenicity is considered as a risk of the drug; used in weighing safety against usefulness
1(c) Federal Food, Drug, and Cosmetic Act — cosmetic provisions	Food and Drug Administration, DHEW	Cosmetics and substances in cosmetics	No	Action is taken on the basis of adulteration (unsafe or injurious)
2. Toxic Substances Control Act	Environmental Protection Agency	Substances such as foods, drugs, cosmetics, tobacco are not covered; all non-excluded substances are covered but if other Acts cover such substances those Acts take precedence	Carcinogenic and certain other substances are to receive priority attention; a ruling must be made on carcinogens within a specified time; but regulatory action is based on texicity	Toxicity; cancer regarded as a priority class of toxicity
3-6 Clean Air Act; Water Pollution Control Act; Safe Drinking Water Act; Federal Insecticide, Fungicide, and Rodenticide Act	Environmental Protection Agency	Pollntants in the respective areas of the environment	No	As environmental pollutants posing danger to public health; toxicity
7. Consumer Product Safety Act	Consumer Product Safety Commission	Substances used by consumers (at home, in recreation, etc.)	No	As hazardous products, or imminent hazards
8. Federal Hazardous Substances Act	Consumer Product Safety Commission	Hazardous substances (in effect, it primarily covers honsehold products)	No	As hazardous substances; toxicity is criterion
9. Occupational Safety and Health Act	Occupational Safety and Health Admin., Dept. of Labor	Hazardous substances in the workplace	No	As texic substances there are proposed implementing regulations dealing specifically with carcinogens

*There is some judicial opinion that for animal drug residues, *if regulated under general safety* some risk/benefit analysis must be even if carcinogenicity is indicated.

Source: Congress of the United States, Office of Technology Assessment. *Cancer Testing Technology and Saccharin.* Washington, D.C.: U.S. Government Printing Office, 1977.

often difficult to tell exactly where one agency's responsibility ends and another's begins. The result is that no one agency has the responsibility or resources to serve as a focus for action. The Commissioner of the Food and Drug Administration (FDA) has recognized this problem and has initiated efforts to consolidate the procedures of the different federal regulatory agencies in developing (1) compatible testing standards and guidelines, (2) a common approach to assessing health risks from chemicals, (3) better coordination of compliance and enforcement efforts, (4) coordination of public education programs on chemicals, and (5) review of all mutual research efforts.[23]

The current federal regulatory 'framework" for controlling exposure to carcinogenic substances consists of nine primary statutes administered by four agencies, with technical advice from at least three other agencies. The statutory provisions under which carcinogens are regulated are usually contained within statutes covering toxicity in general. Except for the Federal Food, Drug, and Cosmetic Act[24] and the Toxic Substances Control Act,[25] the relevant statutes do not explicitly discuss carcinogenicity.

The FDCA generally takes precedence over other laws in the regulation of substances that may be ingested. Health hazards in the workplace (implicitly including carcinogenic substances) are covered by the Occupational Safety and Health Act,[26] which is administered by the Occupational Safety and Health Administration of the Department of Labor. Those substances to which consumers are likely to be exposed (other than foods, drugs, cosmetics, and other excluded substances regulated under different authorities) are regulated by the Consumer Product Safety Act[27] and the Federal Hazardous Substances Act.[28] The Environment Protection Agency (EPA) administers four relevant statutes covering specific areas of the physical environment: The Clean Air Act;[29] the Water Pollution Control Act;[30] the Safe Drinking Water Act;[31] and the Federal Insecticide, Fungicide, and Rodenticide Act.[32] EPA also administers the

[23] Greogory, *Washington Scene,* 5 LEGAL ASPECTS OF MED. PRAC. 54 (1977).

[24] Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301.

[25] Toxic Substances Control Act, 15 U.S.C. § 2601 *et seq.* (1976).

[26] Occupational Safety and Health Act of 1970, 29 U.S.C. § 651 *et seq.*

[27] Consumer Product Safety Act of 1972, 15 U.S.C. § 2051 *et seq.*

[28] Federal Hazardous Substances Act, 15 U.S.C. § 1261 *et seq.*

[29] Clean Air Act, 42 U.S.C. § 300 (1963).

[30] Federal Water Pollution Control Act, 33 U.S.C. § 1251 (1952).

[31] Safe Drinking Water Act; 42 U.S.C. § 300 (1977).

[32] Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136 (1975).

tested first. The second method is grouping chemicals according to structure. All chemicals can be divided into approximately 18 subgroups. Within each subgroup chemicals judged more dangerous would be tested first. An advantage to this approach is that the proportion of each subgroup already tested or being tested could be readily ascertained. As of January 1978 the Subgroup on Chemical Selection was actively considering both methods as well as a combination of the two.

The Subgroup on Data Evaluation and Risk Assessment analyzes and evaluates the results of completed tests, including some 300 to 400 tests of chemicals already performed at or for the NCI. The evaluation of this "backlog" of tests is expected to be completed by early 1978.

As final reports are received, they are assigned to a member of the Data Evaluation Subgroup for primary review. After discussion, the Subgroup votes on whether or not to accept the report. Each accepted report contains a conclusion that the tested chemical is or is not a carcinogen under the test conditions. Acceptance of the report does not mean that the subject is closed, however. The mandate of the Subgroup does not include evaluation of all animal experiments on the chemical tested, only those performed by or for NCI. Thus, the Subgroup makes a judgment on whether or not specific experiments show carcinogenic effects and whether or not those experiments demonstrate human risk. And, as the following description of a meeting of the Subgroup on Data Evaluation and Risk Assessment shows, acceptance of a report does not necessarily mean that the acceptance is conclusive.

Eight reports were evaluated at a recent meeting of the Subgroup.[22] One chemical was declared a human risk; another was declared to be non-carcinogenic without reservations. In two cases the results were declared equivocal. The unusual nature of the tumors precluded a decision about human risk in another case. Another decision was made to ignore admittedly treatment-related tumors because doubt was expressed that a human risk assessment could be made on the basis of a carcinogenic response in only one strain and one sex. Finally, in two decisions, reports with admittedly weak test protocols were accepted as demonstrating no carcinogenic response. A brief description follows of the discussion on one of these latter reports, that on the insecticide dichlorvos.

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[22] National Cancer Institute, Minutes, Fourth Meeting of the Data Evaluation/Risk Assessment Subgroups of the Clearinghouse on Environmental Carcinogens, (typescript) July 25, 1977.

the market because of positive carcinogenic tests in rats fed a mixture of cyclamate and saccharin, the predominant mode of use of these artificial sweeteners at the time. Despite the fact that these results were not repeated when testing only cyclamates, and despite the subsequent evidence that saccharin is a carcinogen,[17] scientific reviews of the potential of cyclamate as a carcinogen have called for more studies and have not overruled this questionable positive test in light of the subsequent negative tests.[18] Consequently, petitions to remarket cyclamate are being carefully examined. The issue will probably be ultimately decided by the courts and not by reliance on the conclusive findings of a body of scientific experts.

Disagreements concerning the significance of positive results in one test classification and negative results in another have been mainly between positive animal tests and negative epidemiologic studies. The initial basis for the disagreement was the belief that carcinogenicity in animals was irrelevant to carcinogenicity in humans. This skepticism has now largely dissipated. However, additional confusion has occurred because of the failure to distinguish those situations described above in which the animal tests predict a human response lower than that which could be detected by epidemiologic studies. The controversy is now shifting towards the relationship between short-term tests and animal experiments, *i.e.*, how to interpret positive short-term tests and negative animal tests. Investigators are presently accumulating empirical evidence to show a relationship between dose levels in short-term tests and expected carcinogenic response in test animals. This is being done to ultimately demonstrate a relationship between short-term tests and human exposure.[19]

The Clearinghouse on Environmental Carcinogens

The National Cancer Institute (NCI) has established a Clearinghouse on Environmental Carcinogens to provide direction to the Institute on its testing of suspected chemical and physical carcinogens. The Clearinghouse receives nominations of suspect agents, ranks them on a priority scale for testing, selects the most important, has them tested, and evaluates the tests to determine what human risks were shown.

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[17] Congress of the United States, *supra* note 1.

[18] National Cancer Institute, Report of the Temporary Committee for the Review of Data on Carcinogenicity of Cyclamate, Washington, D.C.: National Cancer Institute, February 1976.

[19] Meselson, & Russel, *Comparisons of Carcinogenic and Mutagenic Potency* in ORIGINS OF HUMAN CANCER (H. Hiatt, J. Watson, J. Winston eds. 1977).

that a causal relationship can be shown between it and the effect observed. The problem is that the chemical to be tested may itself alter the experimental environment especially when living systems (cell cultures, animals) are used and doses are increased. Thus, efforts must be made to prove that these secondary changes are themselves not responsible for the observed effect.

The test animal selected is crucial, and at least two species must be tested.[9] Test animals are very specialized and in-bred. In addition, even species of the same ancestry might have very different characteristics. Test results are often difficult to compare because the animals may not be from the same source across experiments, and because certain animal strains have a propensity to develop tumors.[10] Although these tumors might be of a certain type and limited to specific body sites, tumor site and type in test animals are not necessarily correlated to similar types and sites in humans.[11] Additionally, for some sites such as the bladder, certain test animals harbor parasites which in turn are known to cause tumors.[12]

The use of high doses in current procedures assumes that there is no threshold for the carcinogenicity of a particular chemical. If a carcinogenic effect is shown with very high doses, then a carcinogenic effect is assumed even at very low doses, the difference being in the number of cancer cases to expect.

High doses are also used to compensate for (1) the strength of the carcinogen, (2) the exposure level or dose, and (3) the number of animals exposed.[13] But high doses, resulting in "metabolic overload," can affect the metabolism of the chemical and the physiological state of the test animal which in turn are possible cancer causes.[14]

The diet of test animals is usually a standardized formula. However, consumption cannot be standardized because of the varying effects on appetite by different chemicals, and the individual appetite variations among animals. Amount of diet can be standardized by

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[9] National Cancer Institute, *supra* note 6.

[10] National Cancer Institute, General Criteria for Assessing the Evidence for Carcinogenicity of Chemical Substances, Report of the Subcommittee on Environmental Carcinogenesis, Typescript, June 2, 1976.

[11] National Academy of Sciences, *supra* note 5.

[12] Chapman, *Infection with Trichosomoides crassicauda as a Factor in the Induction of Bladder Tumors in Rats Fed 2-Acetylaminofluore*, 7 INVEST. UROL. 154 (1969).

[13] See *supra* note 7.

[14] National Cancer Institute, *supra* note 11.

be potentially carcinogenic in humans. In practical terms this means that chemicals known to cause cancer in animals remain suspect no matter how many studies are conducted on other animals or humans with negative results.

Current National Cancer Institute guidelines for animal testing are as follows:[5]

> (1) Groups of 50 animals of one sex and one strain should be started on the experiment at 6 weeks after birth or at weaning. Control groups should also contain 50 animals. (In practice 100 animals (50 M, 50 F) should be used at each dose.)
>
> (2) The chemical should be administered by a route that mimics human exposure.[6]
>
> (3) At least two doses, MTD (maximum tolerated dose) and MTD/2 or MTD/4 should be administered.
>
> (4) Treatment should be continued long enough (in practice generally 24 months) to produce a maximum response.
>
> (5) Animals should be sacrificed (usually at 24 months) and necropsied according to detailed pathology procedures.
>
> (6) Tests should be conducted in two species, and the results of the more sensitive one given greater consideration.

Additionally, a subcommittee of the National Academy of Sciences has recommended that:[7] "(7) Exposure to the chemical for two generations should be considered. (This procedure exposes the animals of the second generation to the substance *in utero,* which may represent the most sensitive stage of the animal's life.)"

These guidelines provide criteria for deciding whether or not the experimental conditions were valid. They do not provide a basis for standardizing the interpretation of the results of any particular experiments, *i.e.,* whether or not the experiment shows cancer induction.

Human studies, which, for ethical reasons, cannot be controlled as animal experiments, always contain an element of speculation. Epidemiologic studies presume that there are multiple causes for a specific type of cancer. The problem is to isolate one cause. This can be done only if a population which is exposed to a particular chemical shows an increase of cancer over that which is present in a

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[5] National Cancer Institute, *Guidelines for Carcinogen Bioassay in Small Rodents,* DHEW (NIH) Publ. No. 76-801 (Feb. 1976).

[6] This criterion is a little anomalous, because it really addresses the issue of applicability to human experience, not the integrity of the conditions of the specific experiment.

[7] National Academy of Sciences, *supra* note 5.

confused by the seeming ubiquitousness of carcinogens in every facet of our lives.

In this paper, the authors describe cancer testing technology, the federal authorities that regulate environmental carcinogens, and the links between the two processes in which uncertainties are inherent. The authors' primary purpose is to identify these areas of uncertainty so that policymakers have a common basis for developing future approaches on (1) how to be more consistent in evaluating the scientific evidence for carcinogenicity and framing it in a way useful for regulation, (2) specific methods of coordination between the scientific and regulatory communities, and (3) how the regulatory process should be reorganized.

Current public policy largely delegates decisions on what to do about environmental carcinogens to the scientific community and the regulatory agencies. Our purpose is not to examine the wisdom of this placement of responsibilities, but rather to openly discuss the problems this placement poses, the uncertainties that cannot be avoided, and the value judgments that must continue to be made. Our hope is that an open discussion of these issues will lead to better understanding by the public and its representatives and a more ordered approach by scientists and regulators in dealing with these uncertainties.

Determining Carcinogenicity

The problem is to identify the carcinogenic potential of substances before they have been shown to cause cancer in humans. This task is primarily one of estimating the degree of risk to humans through indirect methods. In addition to validating the carcinogenic effects that have been shown in experimental conditions, relationships must be established between these effects and the potential for causing cancer in humans.

In determining whether a substance is a potential carcinogen the conditions under which a substance acts are as important as its molecular structure. Whether a particular substance causes cancer in humans is a separate question from whether or not it causes cancer under experimental conditions.

General criteria for assessing the evidence of carcinogenicity can be classified according to the source of data: (1) data from human studies, (2) data from animal experiments, (3) data from short-term tests.

The rationale behind short-term tests is the assumption that the observed effect is related to carcinogenesis. Such tests include an array of procedures ranging from the observation of chromosomal

even under those facts, a court might find that any inference of forfeiture would be rebutted by a showing that the public would still benefit from the issuance of the patent.[67]

If the second inventor were to file a patent application, the rights of the first inventor would be determined in a priority dispute with the second inventor.[68] Forfeiture would not be applicable as such since the rights of the inventors in this situation would be determined by statute.[69]

C. Forfeiture By Delaying the Issuance of a Patent. A rather extreme factual situation is needed for a court to find that an inventor has forfeited his right to a patent by delaying its issuance. In the CCPA, at least Judge Rich believes that "[c]ase law 'doctrines' are no more."[70] Only in cases like *Ex parte Hull, supra, Wirebounds, supra,* and *Vitamin Technologists, supra,* where the applicant was either (1) abusing USPTO practice by filing a continuing application to obtain patent claims which he would only obtain by way of reissue,[71] or (2) positively attempting to conceal the invention within the USPTO by filing one or more continuing applications,[72] would a court be likely to find forfeiture.

The case for a forfeiture conclusion obviously improves as the number of unjustified continuing applications increases. However, if each continuing application could be justified on the basis of (1) the presentation of new arguments or evidence to rebut USPTO rejections, or (2) an attempt to obtain greater claim protection, it would appear that the applicant is merely doing what he is statutorily permitted to do. Case law doctrines should not interfere with these statutory rights.

The theory underlying the forfeiture doctrine in the context of deliberate delaying of the issuance of a patent is apparently that the applicant should not be allowed to "have his cake and eat it too" by securing an early filing date for the purpose of avoiding § 102 bars, yet delaying the issuance of the patent for the sole purpose of developing a better market for the invention. It is doubtful whether such a theory is correct, however. The patent system which is, in part, based

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67 Moore v. United States, *supra* note 2, at 427.

68 *See* note 3, *supra.*

69 *See* text accompany note 63, *supra.*

70 *Id.*

71 *See* Wirebounds Patents Co. v. Saranac Automatic Mach. Corp., *supra* note 41. *See also* Moore v. United States, *supra* note 2, at 435.

72 *See* Vitamin Technologists, *supra* note 40; *Ex parte* Hull, *supra* note 39. *See also* Moore v. United States, *supra* note 2, at 435.

that the § 102(c) issue *always* arises *after* a patent application has been filed. If an inventor were able to "recapture" or rediscover an abandoned invention merely by showing his interest in the invention by filing a patent application, the abandonment issue would almost *never* arise.[61]

However, a court may look at the reasons why an inventor filed his patent application. If he was "spurred" into action by the activities of another, then the first inventor would probably be held to have abandoned his invention. Since he filed a patent application only because of the influence of the activities of another, then it could be said that he did not possess the invention himself if possession, *i.e.,* lack of abandonment, is defined as including the realization of the value or worth of the invention. However, if the first inventor reduced to practice his invention, discarded it, then several years later discovered on his own the real value of his invention, and filed a patent application, a court may consider this evidence as competent to show that he never really abandoned his invention in the first place. In this latter situation, the inventor himself not only possessed the inventive concept but also appreciated the value of the invention, albeit several years after his reduction to practice. Thus, courts might weigh the inventor's new-found interest along with the evidence of his initial disillusionment and conclude that he never actually abandoned the invention.

B. Forfeiture By Delay in Filing a Patent Application. As a defense, forfeiture, like abandonment, is rarely applicable, although more frequently raised. Although it has been raised in the past when the activity in question would be sufficient to constitute a § 102 bar,[62] it is clearly not needed in such a situation.

Judge Rich even attempted to sound the death knell for the forfeiture doctrine in his concurring opinion in *Young v. Dworkin, supra,* when he stated in a § 102(g) interference context:

> The issue is, therefore, not forfeiture or estoppel or anything other than whether Young suppressed or concealed, since no question of abandonment has been raised. The only reason we have to look to prior cases is to

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[61] Another kind of abandonment may result if a patent applicant allows a patent to issue when that patent discloses an invention which is not claimed. Upon the issuance of the patent, the unclaimed subject matter is presumed by the USPTO to be dedicated to the public. This presumption may be rebutted, however, by the patentee filing a reissue application claiming that subject matter when the reissue application is filed within one year of the issue date of the original patent. *In re* Gibbs, 437 F.2d 486, 168 U.S.P.Q. 578 (C.C.P.A. 1971).

[62] *See* Macbeth-Evans, *supra* note 27, and Metallizing Engineering, *supra* note 23.

garage), told his attorney that he wanted to patent it if a market should develop, but otherwise forgot about it.[54] These activities did not prove an implicit intent to abandon.

Even if an inventor were to put his invention aside for a very long period of time, forget about it, and then several years later be spurred into activity by the activities of others, this would not *necessarily* imply abandonment since the mere fact that he did not destroy or give away his invention is inconsistent with and thereby rebuts any such implication.

An intention to abandon an invention is likely to be implied only in the following kind of factual situation: After an invention is made, including a conception of "utility" in a patent law sense, the inventor ("Inventor A") concludes that it is nevertheless worthless (for example, a notebook entry reads "not worthwhile" or "no good"). Accordingly, he destroys or throws away virtually everything associated with the invention, *e.g.*, physical embodiments of the invention, drawings associated with its conception, etc. He never expressly states that he is abandoning the invention, however.

Later, another inventor ("Inventor B") either conceives or reduces to practice substantially the same invention and, unlike Inventor A, realizes its value. After learning of Inventor B's activity, Inventor A recalls the details of his invention and files a patent application on it.

If Inventor B also files a patent application, then Inventor A's rights will be determined in a priority contest with Inventor B.[55] Under these facts, Inventor A would have some difficulty in proving that he neither "abandoned, suppressed, or concealed"[56] his invention. Thus he may be deprived of the benefit of his early reduction to practice.

If Inventor B does not file a patent application, then the question is whether Inventor A abandoned his invention within the meaning of 35 U.S.C. § 102(c). Whether B files or not, however, the issue of A's abandonment would arise only *after* A filed a patent application.[57]

If Inventor B does not file a patent application and the issue of A's abandonment arises in a validity context, a court is likely to find that A implicitly intended to abandon his invention. That abandonment

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[54] Levinson v. Nordskog Co., *supra* note 30, at 589, 163 U.S.P.Q. at 53.

[55] 35 U.S.C. § 102(g).

[56] *Id.*

[57] It should be noted that abandonment of a patent application does not necessarily imply abandonment of the invention under 35 U.S.C. § 102(c). A patent applicant who is very interested in his invention may find that he does not have the financial ability to continue the prosecution of his patent application.

In *Wirebounds*, the inventor filed a continuing application to obtain claims which were broader than those already contained in an issued patent. The court concluded that since he could legitimately obtain these claims only by filing a reissue application, the delay of more than two years after issuance of the patent constituted laches. As a result, the applicant lost whatever rights he might otherwise have had.

In *Moore*, the court found that the first four CIP applications were needed to overcome the examiner's objections. Only in the fourth CIP application did Moore receive any "indication that his application contained allowable claims."[44]

Moore then attempted to add claims directed to an embodiment using flowable rubber.

> The Patent Office not only refused to allow the new claims in this application, but, as well, rejected the six claims that had previously been allowed. Finally, Moore failed yet another continuation-in-part application, Serial No. 165,456, on January 10, 1962.
>
> In Serial No. 165,456, the Patent Office allowed the six claims previously allowed in Serial No. 818,254, plus two additional claims. No claims to the flowable rubber embodiment were, however, allowed. This application issued as Patent No. 3,135,634.
>
> Moore, however, persisted in his attempts to patent his flowable rubber embodiment and, therefore, before allowance of the 3,135,634 patent and, specifically, on May 20, 1963, he filed continuation-in-part application 281,748. The continuation-in-part application 281,748 was directed to the flowable rubber embodiment as well as others. When the Patent Office refused to allow claims in this continuation-in-part, Moore filed still another continuation-in-part application, No. 422,056, eventually was abandoned with no claims indicated as being patentable, and the chain of continuity terminated. In the meantime, on May 19, 1965, Moore filed an application to reissue his 3,135,634 patent. That application not only included the eight claims of his patent, but also added the additional claims.[45]

The court thus found that Moore's conduct was different from that found objectionable in *Vitamin Technologists, supra, Wirebounds, supra,* and *Hull, supra.* Accordingly, it held that Moore had not forfeited his right to a patent by delaying the issuance of his patent.

Analysis

The clear result of the *Moore* decision is that the United States Supreme Court decision in *Bates v. Coe*[46] is still the law of the land,

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[44] *Id.* at 434.

[45] *Id.*

[46] *See* note 34, *supra.*

though the court's holding in *Levinson* mentions only the five year delay, more than mere delay was actually involved.

> After being advised in September 1962 of American Airlines' interest in his idea, plaintiff in September 1963 filed an application for a patent.
>
> It also appears, however, that in the meantime defendant by at least December 4, 1962, was seeking to sell a device which plaintiff contends infringes his patent.[32]

The court then carefully analyzed each of the cases cited by the *Levinson* court in arriving at its conclusion that a mere delay of five years constitutes forfeiture. Judge Colaianni found that "none of the cases cited indicate that it has been applied to a situation which involves pure and simple delay — regardless of the length or duration of the delay — between the time that an inventor reduces his invention to practice and the time that he files for a patent application."[33] Furthermore, he cited *Bates v. Coe*[34] for the proposition that mere delay is not sufficient per se for forfeiture to occur.

> Inventors may, if they can, keep their invention secret; and if they do for any length of time, they do not forfeit their right to apply for a patent, unless another in the meantime has made the invention, and secured by patent the exclusive right to make, use and vend the patented improvement. Within that rule and subject to that condition, inventors may delay to apply for a patent . . . .[35]

A more recent commentary on the effect of mere delay on an inventor's right to a patent states:

> Furthermore, the patent laws do not require that an application be filed within a reasonable time after the completion [actual reduction to practice] of the subject invention. Instead, a patent application may be filed on a secret invention at any time as long as it is filed within a year after the invention has been placed in commercial use.[36]

Judge Colaianni then looked to *Young v. Dworkin*,[37] a case involving 35 U.S.C. § 102(g) where Judge Rich, in a concurring opinion, distinguished forfeiture of the right to a patent and forfeiture of the right to rely on an actual reduction to practice in a priority dispute.

> I cannot agree with the hoard that the question in this case is whether Young 'forfeited his *right to a patent.*' But for Dworkin's conflicting claim,

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[32] Moore v. United States, *supra* note 2, at 431.

[33] *Id.* at 432.

[34] 98 U.S. 31 (1878).

[35] *Id.* at 46.

[36] Adelman, *Trade Secrets and Federal Preemption – The Aftermath of Sears and Compco*, 49 J. PAT. OFF. SOC'Y 713, 727 (1967).

[37] 489 F.2d 1277, 180 U.S.P.Q. 388 (C.C.P.A. 1974).

duction to practice and the filing of a patent application was inadequate to meet that burden for either defense.

B. Abandonment. The court held that Moore did not abandon his invention because he lacked the requisite intention to do so. That intent could be express or implicit, but in either case Moore's activities belied such an intent. Delay alone was not sufficient to constitute an express abandonment. Furthermore, Moore did not implicitly intend to abandon his invention because the intention to abandon had to be "the only reasonable explanation of [his] 'inaction'."[20] On the contrary, Moore's drafting and retaining of two patent applications and his attempt to interest the Navy and several corporations in his invention all contradict any implicit intent to abandon his invention.

C. Forfeiture By Delay in Filing a Patent Application. The court found that Moore did not forfeit his right to a patent. Unlike abandonment, "forfeiture appears to be grounded more on what Judge Learned Hand . . . characterized as '[T]he fiat of Congress that it is part of the consideration for a patent that the public shall as soon as possible begin to enjoy the disclosure'."[21] The court distinguished the factual situation in *Moore* from all other cases where forfeiture was found. In each of these other cases either "the invention was in the public domain because of acts by the inventor which are now proscribed by 35 U.S.C. § 102 or because during the inventor's delay others working independently made the same or substantially the same invention."[22]

The forfeiture doctrine has its roots in *Metallizing Engineering Co. v. Kenyon Bearing & A.P. Co.*[23] In that case, acts which today would constitute a 35 U.S.C. § 102(b) bar were found to constitute a forfeiture of the right to a patent. In dictum, however, Judge Hand stated that the § 102(b) activities might not even be necessary.

> But if he goes beyond that period of probation, he forfeits his right regardless of how little the public may have learned about the invention; *just as he can forfeit it by too long concealment, even without exploiting the invention at all.*
>
> It is indeed true that an inventor may continue for more than a year to practice his invention for his private purposes or his own enjoyment and later patent it. But that is, properly considered, not an exception to the doctrine, for he is not then making use of his secret to gain a competitive advantage over others; he does not thereby extend the period of his

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[20] 194 U.S.P.Q. at 428.

[21] *Id.*

[22] *Id.* at 433.

[23] 153 F.2d 516, 68 U.S.P.Q. 54 (2d Cir. 1946), *cert. denied,* 328 U.S. 840, 69 U.S.P.Q. 631.

from disclosing the subject matter of the patent application to others not cognizant of the invention prior to the date of the secrecy order. The interest of the United Mine Workers ended shortly thereafter."[9] The secrecy order was lifted on April 2, 1957. Moore's original patent, U.S. Patent No. 3,135,634, issued following a series of CIP applications. The original patent was reissued as the patent in suit.

In December 1939, Moore had prepared and notarized a patent application directed to the explosive composition and method which he had conceived as early as 1939. This application was never filed with the USPTO. Moore also had prepared a second patent application concurrently with the delivery of the test sample to the Navy in 1948. This second application was the one which Moore filed in 1955.

The court found that from 1941 to 1955 Moore was "financially, physically, and mentally capable of filing an application on the invention in issue."[10]

The Government's Contentions

Although the government's position was that the patent in suit was invalid because of abandonment and/or forfeiture, its brief did not clearly distinguish between the two. It appeared to present three interrelated validity defenses. The first two stem from allegations that Moore "unduly delayed filing of an application for a patent on his invention." Consequently, Moore either abandoned his invention or forfeited his right to a patent. The third defense was that Moore, by filing several CIP applications, forfeited his right to a patent because he unduly delayed the issuance of his patent.

Opinion of the Trial Judge

At the outset, the trial judge noted that an analysis of the pertinent case law indicated that the "hoped-for line of demarcation between what has been characterized as acts of abandonment and/or forfeiture does not exist."[11] He then focused on the constitutional basis[12] for the patent laws and found that "the historical purpose for the granting of patents is to encourage a public disclosure of new scientific and tech-

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[9] *Id.* at 426.

[10] *Id.* The record shows that Moore filed and prosecuted several other patent applications in the period between 1941 and 1955.

[11] 194 U.S.P.Q. at 426.

[12] Art. I, § 8 of the Constitution of the United States states that "[t]he Congress shall have power . . . [t]o promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."

in acts which were proscribed by 35 U.S.C. § 102[3] (such as public use or sale) or that substantially the same invention was created by another working independently during the thirteen-year period of delay. Furthermore, the court believed that the public could still benefit from the patent disclosure, thus justifying an allowance of the patent.

Finally, the court held that Moore's filing of a series of continuation-in-part (CIP) applications to overcome objections raised by the United States Patent and Trademark Office (USPTO) and to increase patent coverage was not an abuse of USPTO practices and did not constitute a forfeiture of Moore's right to a patent.

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[3] 35 U.S.C. § 102 reads as follows:

Conditions for patentability; novelty and loss of right to patent. A person shall be entitled to a patent unless —

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

(c) he has abandoned the invention, or

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or

(f) he did not himself invent the subject matter sought to be patented, or

(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

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