EXECUTIVE OFFICE OF THE PRESIDENT
COUNCIL ON ENVIRONMENTAL QUALITY
722 JACKSON PLACE, N. W.
WASHINGTON, D. C. 20006

9:30
Friday

July 18, 1978

MEMORANDUM FOR MEMBERS OF THE SUBCOMMITTEE ON TRADE SECRETS AND DATA CONFIDENTIALITY

FROM: Robert B. Nicholas (RN)

SUBJECT: Safety and Efficacy Data Paper

Attached is the latest draft of the Subcommittee's paper concerning disclosure of health, safety, and efficacy data. It will be sent to the members of the Toxic Substances Strategy Committee for their review in advance of the Strategy Committee meeting next Tuesday, July 25.

We plan to send the paper to the Strategy Committee by Thursday morning, and would appreciate your comments and/or revisions by Wednesday afternoon, July 19, if possible. Please contact Suzanne Mager at 633-7111 with your comments.

Attachment

9:00
New executive Off. Bldg. Rm 2008

Study of
Industrial Innovation

Trade Secret Protection for Health, Safety or Efficacy Data -- Is it in the Public Interest?

SUMMARY

Health, safety, and effectiveness data are submitted to federal agencies in the contexts of premarket licensing or notification and testing requirements, rulemaking, as well as for other regulatory purposes. Such studies, tests, and similar information bear on a chemical's effectiveness or safety as the chemical affects the public health and environment, and the data frequently play a pivotal role in government decisions; for example, providing a basis for an agency to grant or withhold a new drug application, or to take similar regulatory action. In determining whether health, safety, or efficacy data are entitled to confidential treatment and protection, federal agencies are faced with the dilemma of balancing the economic interests of the industries which have developed a new chemical or a new use for a substance with the interests of the public in participating in and reviewing government decisionmaking, and in having full access to information which could disclose potential health and environmental hazards.

This paper's discussion will be limited to studies which an agency has the authority to require to be submitted, and will not include studies submitted voluntarily, where no authority exists. Information developed by the government itself, or by a contractor under government contract, is also excluded from this paper's scope as it would be fully and freely available to the public, in the absence of national security considerations. For purposes of discussion, the Subcommittee has selected language similar to that in the pending amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as adopted by the conference committee, to describe the subject matter included within "health, safety, and efficacy data." Such data would include all information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a toxic substance or its separate ingredients, impurities, or degradation products, and any information concerning the effects of such toxic substance in the environment, including, but not limited to, data on safety to humans and mammals, fish and wildlife, plants, and soil, or studies on persistence, translocation and fate in the environment, and metabolism.

This paper summarizes the treatment provided confidential information, health and safety studies, and safety and effectiveness data under existing toxic substances laws, and examines agencies' interpretations of their statutory authority to balance competing needs and interests. It outlines the policy considerations involved in both granting trade secret protection for this information or eliminating such protection. Finally, alternative disclosure options are presented for consideration by the Toxic Substances Strategy Committee.

Many submitters of health, safety, and effectiveness data maintain that this data constitutes valuable property, which is entitled to protection, while the health regulatory agencies maintain that health, safety, and effectiveness information acquired by the federal government should be exempt from traditional trade secret protection. The Subcommittee believes that the ideal disclosure policy would accomplish several goals:

-- protect and promote public health and the environment;

-- protect and promote research and innovation;

-- permit extensive public participation in the decisionmaking process;

-- promote submission of high quality data;

-- reduce duplicative research; and

-- reduce administrative burdens.

In developing recommendations for a disclosure policy for safety and efficacy data, the Subcommittee evaluated the value attributed by industry to its safety and efficacy data, as well as examing recent legislative and judicial trends in balancing the public and private interests involved in information disclosure or protection.

In light of its evaluation, the Subcommittee's preliminary recommendation is for full public disclosure of all safety, health, and efficacy data, as defined above, which the federal government has the authority to require private industry to submit. In a licensing context, a system providing a pioneer firm with a period of exclusive use of the data it has developed appears to offer the necessary protection to a firm's commercial and economic interests, which is essential to assure continued innovation and development within industry.

The Subcommittee is interested in receiving comments on this and other mechanisms by which corporate investments could be protected, such as direct financial compensation by a company relying on a pioneer firm's data, or tax incentives, as well as comments on non-licensing situations which might justify a system of compensation for disclosure of data. The Subcommittee would also appreciate comments on recommended minimum standards for the degree of detail required for summaries of health, safety, or effectiveness tests or studies, if certain situations would require something less than full disclosure of all underlying data.

The Subcommittee does not propose specific methods of implementation of its recommendations at this time, pending review of public comments on the Subcommittee's preliminary recommendations.

ISSUE

What is the extent to which health, safety, or efficacy data submitted to a federal agency should be disclosed to the public?

INTRODUCTION

The Toxic Substances Strategy Committee was established in response to the President's request that the Council on Environmental Quality develop, among other programs, an interagency program to eliminate overlaps and fill gaps in the collection of toxic chemical data. One of the major areas identified by the Committee for examination concerned data and information gathering and utilization. A Subcommittee on Trade Secrets and Data Confidentiality was established to consider, among other things, whether health, safety, and efficacy data submitted to a federal agency should be excepted from trade secret protection. The Subcommittee considered also the question of what conditions on the public disclosure of the data, if any, should be imposed if a policy advocating disclosure were adopted.

The treatment accorded health, safety, and effectiveness data was selected for evaluation by the Subcommittee because of the substantial problems posed by the increasing presence of toxic chemicals in the environment generally and in the workplace. The issue is important also, because of the general lack of availability of information about these chemicals and the difficulties involved in their regulation when viewed in the light of the undisputed rights of citizens to participate as fully as possible in government

decisionmaking and to know to what hazards they are or could be exposed. Federal policy, either government-wide or within each agency, determining the degree of confidentiality to be granted to such information fundamentally affects the public's ability to exercise its basic right to review and participate in government decisions having direct impact on every citizen.

In general, the issue of whether information submitted to a federal agency should be protectable as a trade secret is controversial and is receiving active consideration in Congress and the courts. Current government policy is often ambiguous and is inconsistent among agencies and, sometimes, among individual programs within a single agency. The issue assumes added significance with respect to federal regulation of technology-intensive toxic substances because of the pre-market approval regulatory process, private industry's financial investments, and the public's right to be able to assess the risks of potential hazards posed by substances to which the public is or may be exposed. The scope of this issue is restricted to information acquired by the government under mandatory authority from private industry, and does not pertain to information voluntarily submitted in the absence of governmental authority to collect such information, nor to information developed by the government itself or through its contractors.

The Subcommittee defines health, safety, and efficacy data to include:

> all information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a toxic substance or its separate ingredients, impurities, or degradation products, and any information concerning the effects of such toxic substance in the environment, including, but not limited to, data on safety to humans and mammals, fish and wildlife, plants, and soil, or studies on persistence, translocation and fate in the environment, and metabolism.

THE EXISTING SYSTEM

There is no federal law which attempts to categorize what information may be claimed as a trade secret. Trade secret status is determined under the law of each state under varying criteria. Major cases establishing and

defining trade secret protection emerge primarily from private actions based on tort or property concepts, usually involving corporate theft, industrial espionage, or some breach of a fiduciary relationship resulting in an ill-gotten economic gain.

The majority of jurisdictions have over the years adopted a definition provided by the Committee on Torts of the American Law Institute in their Restatement of the Law on Torts:

> A trade secret may consist of any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it. It may be a formula for a chemical compound, a process of manufacturing, treating or preserving materials, a pattern for a machine or other device, or a list of customers.

Under the Restatement definition any "compilation of information" may qualify as trade secret if (1) the information is used in one's business and provides a competitive advantage, and (2) others do not know or use the information, i.e., it is in fact a "secret." In order to establish and maintain information as a secret, a business must establish security procedures to restrict access to the information, and insure that it is not freely disseminated. Thus, information is not a trade secret solely because of its type or class. A business must take affirmative action to establish and maintain a trade secret.

Most recent federal trade secret litigation has arisen in the context of the "(b)(4)" exemption of the Freedom of Information Act (FOIA), which grants a federal agency authority to withhold from public disclosure information that is trade secret or which is commercial or financial, obtained from a person, and privileged or confidential. 5 U.S.C. § 552(b)(4). To varying degrees, the Restatement definition of trade secrets has been applied in federal cases arising under FOIA. The leading case interpreting FOIA's (b)(4) exemption, National Parks and Conservation Ass'n v. Morton, 498 F.2d 765 (D.C. Cir. 1974), has modified the traditional Restatement test to include the requirement of a showing that significant harm to the information submitter's competitive interest would likely result from public disclosure of the information. (An alternative test established by National Parks recognizes the possible impairment of the government's ability to obtain information

in the future if information already submitted were released to the public. The court limited this consideration, however, to information not submitted "pursuant to statute, regulation or some less formal mandate." 498 F.2d at 770. This test, therefore, is inapplicable to this paper's discussion.) Under the Restatement definition or under the courts' interpretation of the Freedom of Information Act's (b)(4) exemption, health, safety, and efficacy data submitted to a federal agency, especially if submitted in order to obtain pre-market approval, might qualify for confidential treatment.

Numerous federal statutes concern trade secrets. In general, these statutes merely state that "trade secret information" obtained by the government shall not be disclosed to the public. However, some statutes provide for disclosure in particular circumstances, and others mandate disclosure of specific types of information which might otherwise qualify as a trade secret under the Restatement of Torts definition. Summarized below are the pertinent data provisions of the toxic substances statutes considered by the Subcommittee.

Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. § 301 et seq.

- Expressly prohibits using to personal advantage or revealing any information acquired by the agency concerning any method or process which is entitled to trade secret protection.

- FDA has consistently interpreted its statute as permitting trade secret protection for safety and efficacy data arising from animal and human testing submitted in conjunction with new human drug applications.

- FDA's Public Information Regulations, which establish general rules governing the confidentiality of specific categories of information, provide that agency-prepared summaries of safety and efficacy data submitted with new drug applications as required by law may be disclosed, but that the raw data are entitled to trade secret protection, if claimed.

- Safety, effectiveness and functionality data concerning human antibiotic drugs and food color additives are publicly available.

Occupational Safety and Health Act, 29 U.S.C. § 651 et seq.

- Information obtained in connection with any inspection or proceeding and which contains or which might reveal a trade secret is required to be considered as confidential.

Consumer Product Safety Act, 15 U.S.C. § 2051 et seq.

- All information reported to or otherwise obtained by the Commission which contains or relates to a trade secret shall be considered confidential and shall not be disclosed.

Poison Prevention Packaging Act of 1970, 15 U.S.C. § 1471 et seq

- Does not contain specific trade secret provisions.

Federal Hazardous Substances Act, 15 U.S.C. § 1261 et seq.

- Expressly prohibits using to personal advantage or revealing any information which is entitled to trade secret protection.

Marine Protection, Research and Sanctuaries Act, 33 U.S.C. § 1401 et seq.

- Does not contain specific trade secret provisions.
- Information received as part of an application or in connection with any permit granted is available to the public as a matter of public record.

Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 135 et seq.

- Information, including safety and efficacy data submitted to support a registration, may not be made public if, in the judgment of the Administrator, it contains or relates to trade secret or commercial or financial information which is privileged or confidential.
- If trade secret protection is not claimed for safety and efficacy data required for registration, a second applicant seeking to register the same pesticide may rely on the data submitted by the first applicant provided the second offers to pay the first reasonable compensation for producing the data.

Clean Air Act, 42 U.S.C. § 1857 et seq.

- All records, reports, or information which contain trade secret information are required to be maintained in confidence and may not be disclosed to the public.
- Emission data is excepted from the general policy and such data must be disclosed.

Clean Water Act (Federal Water Pollution Control Act), 33 U.S.C. § 1351 et seq.

- Upon a satisfactory showing that information if made public would reveal trade secret information, such information shall be maintained in confidence.
- Effluent data is excepted from the general policy and must be disclosed.

Safe Drinking Water Act, 42 U.S.C. § 300(f) et seq.

- Upon a satisfactory showing that information if made public would reveal trade secret information, such information shall be maintained in confidence.

Resource Conservation and Recovery Act, 42 U.S.C. § 6901 et seq.

- Upon a satisfactory showing that information if made public would reveal trade secret information, such information shall be maintained in confidence.

Toxic Substances Control Act, 15 U.S.C. § 2601 et seq.

- The general policy provides that information exempt from disclosure under the trade secrets exemption of the Freedom of Information Act shall be maintained in confidence.
- An exception to the general policy permits disclosure of any information when necessary to protect health or the environment against an unreasonable risk of injury.
- Data from health and safety studies is excepted from the general policy and may be disclosed.
- The Administrator may require that testing be conducted on chemical substances or mixtures to develop data on their health and environmental effects.

- An exemption to the testing requirement is permitted if the substance or mixture is equivalent to one for which data has been, or is being, submitted, and the Administrator determines that additional data would be duplicative.

- The person or persons receiving an exemption must provide fair and equitable reimbursement to the person or persons who incurred costs in developing the data.

Hazardous Materials Transportation Act, 49 U.S.C. § 1806 et seq.

- Does not contain specific trade secret provisions

Although not exclusively applicable to toxic substances, two additional statutes must be included in this list.

Freedom of Information Act, 5 U.S.C. § 552(b)(4)

- Discretionary authority to withhold from public disclosure trade secrets and commercial or financial information obtained from a person and which are privileged or confidential.

Act of June 25, 1948, 18 U.S.C. § 1905

- Provides a fine or imprisonment or both for any federal employee who discloses trade-secret information learned during the course of his or her employment.

Thus, while the general policy expressed by Congress in laws such as the Freedom of Information Act, the Government in the Sunshine Act, and the Federal Advisory Committee Act has been that the public is entitled to the fullest information regarding the decisionmaking process of the federal government, Congress recognized that exceptions to this general policy are necessary. Laws relating to toxic substances generally follow this scheme, but create, in addition, categories of data which are excluded from confidential treatment, presumably because of the overriding public need for such information.

PENDING LEGISLATION

Three bills pending in Congress deserve specific mention. One is the Drug Regulation Reform Act of 1978 (S. 2755, H.R. 11611) which would revise and reform the federal laws applicable to drugs; the second, a bill to revise the Federal Insecticide,

Fungicide, and Rodenticide Act (S. 1678); and the third, the Criminal Code Reform Act (S. 1437) would provide sanctions against a government employee who reveals private information submitted for a government purpose in addition to those available under 18 U.S.C. § 1905.

The Drug Regulation Reform Act would amend current procedures within FDA for issuing and approving new drug entities. Upon the filing of a petition for a new drug monograph, a report in summary form adequate to disclose the basis on which the petitioner concluded that the drug is effective and has been assessed for risks becomes publicly available.

At the time of filing a petition, all of the safety and effectiveness data, i.e., the actual data, not summaries, may be disclosed to, but not copied by, any person who seeks the information solely for the purpose of participating in any public hearing concerning the petition. The person must demonstrate that he will not use the information for commercial purposes and that he or she is not acting on behalf of any person who would be able to use the information for commercial purposes. The person obtaining the safety and effectiveness data must establish also that he or she will take security precautions respecting the storage and the further disclosure of the information obtained until such time as the information becomes available to the public.

Once a new drug monograph is approved and issued, the public has access to a report containing a detailed description of each investigation concerning the effectiveness and risks of the new drug, as well as a full report of all data and information from each investigation, including data not considered by the petitioner as relevant to safety and effectiveness. However, notwithstanding full public disclosure, a second applicant may not rely on the published data to obtain a drug product license under the monograph during a period of five years following the date on which the monograph first became effective unless the pioneer firm which established the monograph authorizes use of the data, or the applicant provides information which, independently of the data and information submitted by the pioneer firm as part of the petition to issue the monograph, would be adequate to support a determination that the drug is safe and effective.

Under the pending pesticide bill, a House-Senate Conference Committee recently reached an agreement which would provide that all test data submitted on or after January 1, 1970, for the purposes of registering a new pesticide, would be compensable for 15 years from the date the data are filed. The conference compromise further provides that the original data submitter shall have ten years from the date of registration of exclusive use of the data supporting registration.

The Criminal Code Reform Act as passed by the Senate would strengthen the sanctions available against a public servant who reveals "private information submitted for a government purpose." The new provision would cover information submitted solely to comply with a duty imposed by law or by requirements for the application for a patent, license, or other benefit. Release pursuant to the Freedom of Information Act, however, would constitute an affirmative defense. At present, the only government-wide sanctions available for disclosure of trade secret data are under 18 U.S.C. § 1905, which is rarely used.

POLICY CONSIDERATIONS

This section will discuss the policy considerations that favor granting trade secret protection to health, safety, and efficacy data or that favor full public disclosure of the data. The following section will discuss alternatives to these polar positions.

Considerations for Granting Trade Secret Protection

o Preserve the Incentive to Innovate

This consideration is most applicable to drugs, pesticides, and some other toxic substances which, because of pre-market approval or testing requirements and the large capital investment required, present a unique problem. Each industry is subject to a regulatory scheme which may require submission of safety and efficacy data to obtain pre-market approval of new products. This data is expensive and time-consuming to generate. As such, it is a valuable economic property to the companies which developed it when it poses a barrier to entry to the market for companies which have not developed such data, indicates research trends for those seeking to duplicate the information or develop new uses for the drug or pesticide, provides the basis for more effective marketing of the product, or otherwise provides a legitimate and substantial competitive advantage.

Traditionally, trade secret rights have provided economic incentives to industry to invest in needed research and development of new products, since by statute safety and efficacy data are not subject to patent protection. Adequate incentives to new research and development is necessary as most new product research occurs in the private sector. Industry argues that absent trade secret protection, or some other method of appropriate protection, their anticipated return on research and development investment and their market share could be diminished because competitors could market the same product with far less development cost and less financial risk, although it is recognized that the effects of reduced trade secret protection are still highly uncertain.

Incorrect + misleading PDAC study

o Patent Protection is Inadequate

Patent protection is available for any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof. Patent protection is not available for the raw data obtained from laboratory testing. The only protection currently available for the data is under trade secret laws. As recently as 1974, the Supreme Court considered the relationship of patents and trade secrets and concluded that there is no real possibility that trade secret law will conflict with the federal patent laws. Kewanee Oil Co. v. Bicron Corp, 416 U.S. 470 (1974).

An interim report of a review panel evaluating FDA's trade secret policies[1] concluded that "the present patent system seems ill-suited to reward innovation in drug research." Patents are applied for generally immediately after identification of a potentially important new chemical entity. The 17-year patent term begins on the grant of the patent, an average of 19 months after the application is received. However, because of the requirement to obtain pre-market approval in the drug and pesticide area, and because the regulatory approval process is time-consuming, effective patent protection may be diminished by five or more years. In addition, although patent infringement provides the patent holder with a federal cause of action, litigation is expensive and lengthy.

and unpredictable while trade secret is predictable.

It is argued by those who would exclude safety and efficacy data from trade secret protection, however, that patent protection together with an exclusive use or compensation scheme would reward the inventor and provide adequate incentives for continued R & D investment.

No equivalent counter arguments re public disclosure section

Considerations for Public Disclosure

o Public Interest in Information Concerning Health, Safety, and Efficacy

The increasing presence of toxic chemicals in the environment and the resultant need for adequate risk assessment, together with the well-recognized right of citizens to receive information that is of concern to them, combine to underscore the importance of public access to data reflecting on the safety or health effects of a chemical to which the public is or could be exposed.

when?

1/ Review Panel on New Drug Regulation, Interim Report, "An Evaluation of FDA's Trade Secrets and Freedom of Information Policies," Department of Health, Education, and Welfare, 1976.

Additionally, the citizen seeks, either individually or through representatives such as public interest groups and consulting scientists, to participate in and review government decisions. Without extensive disclosure of the information on which these decisions are being based, the public would be unable to actively participate in the process by which these decisions are reached or to adequately evaluate the soundness of agency decisions. Additionally, such evaluation and participation is desirable as it would promote acceptance of agency decisions and permit discussion and critique of controversial decisions.

- o Disseminate Scientific Knowledge and Promote Submission of Data of High Quality

Health, safety, and efficacy data have both a scientific value and an economic value. Trade secret protection preserves the economic value, but eliminates the scientific value, as this information is not available to the general scientific community. Safety, health, and efficacy data should not lie outside the accepted scientific process providing opportunities for replication of studies or tests and for challenge of the results or conclusions. Those reviewing the data may provide fresh insight into the data's evaluation as the result of the reviewers' different approaches.

The scientific process in general would be stimulated by opportunities for agency scientists to review and discuss the studies they evaluate with members of the scientific community outside the agency or federal government.

- o Reduce Duplicative Testing

This consideration is primarily applicable to the drug and toxic chemical areas where the pre-market approval process requires submissions of a substantial amount of safety and efficacy data. After this data is developed by a pioneer firm, if it were available to a second firm which wanted to obtain market approval for a substantially identical drug or pesticide, the second firm would not have to duplicate the testing done by the pioneer firm. It is maintained that this would eliminate the inefficient use of limited scientific resources and, especially in the drug area, reduce the unnecessary risks associated with repeated clinical trials.

Industry counters this argument with the assertion that unnecessary duplicative testing rarely occurs, and that additional scientific investigation which does occur serves legitimate scientific purposes by increasing the validity of knowledge as a result of the broader data base established.

Reducing duplicative testing also promotes administrative efficiency in each agency because it could eliminate the need to evaluate the same data several times.

OPTIONS

The Subcommittee considered the following options for a comprehensive federal policy concerning disclosure of health, safety, and efficacy data:

(1) no disclosure of the data;

(2) disclosure of summaries of the data;

(3) full disclosure of all data; or

(4) full disclosure of the data with compensation, or other limitations on its use.

The option of not disclosing the data would be inappropriate based on the considerations set out above. Similarly, the Subcommittee believes release of summaries of the data would be insufficient because of the resultant inability of reviewing scientists to adequately analyze the studies' conclusions or methodologies without having access to the underlying data, and because of the summaries' unevenness of detail and quality.

In response to public comments received by the Subcommittee, and in light of the considerations of the public and private interests involved, the Subcommittee recommends full release of health, safety, and efficacy data submitted pursuant to the authority of a federal agency. In situtations where the data confers a competitive advantage upon the submitter by virtue of its value in obtaining pre-market approval, a system providing compensation or restricted use would seem appropriate. However, even in a pre-market approval context, if the data submitted to the agency demonstrated a substantial hazard or unreasonable risk to the public, that information should be freely available to the public without restriction.

It is important to recognize that arguments favoring public disclosure of health, safety, and efficacy data are severable from the arguments concerning the need to stimulate the private sector to develop new chemical compounds and to protect manufacturers' competitive advantage. A properly designed disclosure system could provide adequate protection of manufacturers' economic interests and stimulate innovation in the private sector, as well as allow full public access to all health, safety, and efficacy data.

It should also be emphasized that although certain safety, health, and efficacy data could qualify for confidential treatment under existing case law, substantial support can be found in a number of federal statutes for public disclosure of information of this type, notwithstanding its otherwise confidential nature. The Toxic Substances Control Act (TSCA), the most recent federal legislation passed which pertains to disclosure of safety and health data, recognizes the public's compelling interest in access to health and safety data and mandates public disclosure of all such data submitted pursuant to TSCA. Similarly, the Clean Air Act exempts emissions data from claims of confidentiality, the Clean Water Act exempts such claims for effluent data, and the Safe Drinking Water Act provides for full public disclosure of information relating to contaminants in drinking water. To an extent, all of these types of data constitute public health data, in that they pertain to potentially hazardous substances to which the public is exposed. Therefore, although TSCA's data disclosure provisions are the broadest, Congress has long recognized the need for delineating certain types of data as being unsuitable for confidential treatment. The proposed FIFRA amendments and the Drug Regulation Reform Act also resolve this issue in favor of public disclosure.

Under the Freedom of Information Act's (b)(4) exemption to mandatory public disclosure for trade secrets and confidential commercial and financial information, the courts also have recognized the need to balance the public and private interests involved. Within the context of proposed disclosure of proprietary data, a federal circuit court held that under certain circumstances "[i]t may well be that there is no other alternative than releasing this information and subjecting the [information submitters] to the financial loss that such disclosure would entail." Penzoil Co. v. Federal Power Commission, 534 F.2d 627 (5th Cir. 1976).

The Toxic Substances Control Act's solution to the potential harm of public disclosure of health and safety data is through a compensation scheme, minimizing the burden to the data submitters. In situations where the sole or primary economic value of the data is that it prevents market entry by a competitor who has not produced the data, a compensation or restricted use approach as proposed could probably obviate the need for trade secret status of such data.

If the decision is made to publicly release health, safety, and efficacy data, the following questions must be addressed: in what form should the data be released; when should it be released; and under what, if any conditions?

In What Form?

Those who advocate the need for public disclosure of data generally adopt the position that all the data submitted in a pre-market approval or notification process must be released in order to permit meaningful public participation in and review of government decisions, and to facilitate an agency's development of criteria for making its decisions. An alternative to full disclosure would be data in summary form.

In light of the scientific and public interest considerations discussed above, and particularly the inability for adequate review of such data in summary form, the Subcommittee's preliminary recommendation is for public disclosure of all health, safety, and efficacy data.

When?

The Subcommittee recommends that, in general, health, safety, and efficacy data should be released to the public upon receipt by the agency.

Data submitted for pre-market approval presents different considerations with regard to the timing of public disclosure. The data could be released:

(1) as soon as it is received by the agency. This permits prompt disclosure, but the data may be incomplete or later modified;

(2) prior to proposed approval, providing an adequate time for meaningful public review, thus permitting public comment before a decision becomes effective;

(3) concurrent with approval; or

(4) a specified period after approval.

In conjunction with exclusive use or compensation provisions, the Subcommittee recommends the second option as being most consistent with the policy goals outlined at the outset. Public participation in decisionmaking is effectively denied by the third or fourth options, while the second option allows necessary public involvement, while at the same time protecting corporate investment.

Under What, If Any, Conditions?

The Subcommittee recommends that, in general, all health, safety, and efficacy data be released without restriction. In a pre-market approval context, however, if the data provides a unique competitive advantage to the submitter, a system designed to protect submitters' economic interests would probably be appropriate.

If all data is publicly disclosed, the disclosure could be accompanied by conditions which might ameliorate its effect on incentives for innovation. Disclosure could be accompanied by restrictions on competitive use (e.g., a period of exclusive use), such as proposed in the Drug Regulation Reform Act. A compensatory scheme could be devised to reimburse the pioneer firm for the costs and risks of basic development. This approach, which has been followed in the FIFRA amendments (S. 1678) and in TSCA, could involve substantial administrative burdens, but on balance appears to hold the most promise for an equitable federal disclosure policy. The FIFRA proposal also provides for a limited period of exclusive use of the data by a pioneer firm.

CONCLUSION

The Subcommittee believes that the ideal policy concerning disclosure of health, safety, and efficacy data will:

-- protect and promote the public health and environment;

-- protect and promote research and innovation;

-- permit extensive public participation in the decisionmaking process;

-- promote submission of high quality data;

-- reduce duplicative research; and

-- reduce administrative burdens.

In non-licensing situations, measured against the objectives of an ideal policy, the Subcommittee believes that a policy of full public disclosure of health, safety, and efficacy data would not impair incentives to private investments or innovation.

The Subcommittee recommends a policy of full public disclosure upon agency receipt of health, safety, and efficacy data submitted pursuant to an agency's authority. In the pre-market approval or notification context, full disclosure combined with a mechanism for restrictions on competitive use of the data would appear to represent a reasonable compromise of the need to protect and preserve investment incentives and the need for public availability of the data. The Subcommittee further recommends that such release in a licensing context be prior to any final agency approval, but after the data have been submitted to the agency in final form.

At this time, the Subcommittee is not proposing a specific method of implementation of the above recommendations. The eventual passage of the pending amendments to FIFRA and the Drug Regulation Reform Act could obviate the need for further substantial federal action. However, upon review of public comments, especially those concerning methods of compensation, the Subcommittee may recommend comprehensive legislation as the most effective method of implementation of the Subcommittee's final recommendations.