STATEMENT

ON BEHALF OF

American Home Products Corporation
Bristol-Myers Company
Carter-Wallace, Inc.
Hoffmann-La Roche Inc.
Johnson & Johnson
Merck & Co., Inc.
Norwich Eaton Pharmaceuticals, Inc.
(A Procter and Gamble Company)
Schering-Plough Corporation
Squibb Corporation
Stuart Pharmaceuticals
(Div. of ICI Americas Inc.)

BEFORE THE SUBCOMMITTEE
ON COURTS, CIVIL LIBERTIES, AND THE
ADMINISTRATION OF JUSTICE
OF THE COMMITTEE ON THE JUDICIARY
UNITED STATES HOUSE OF REPRESENTATIVES

HEARING ON H.R. 3605

June 27, 1984

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INTRODUCTORY REMARKS

Mr. Chairman and Members of the Committee:

My name is Jack Stafford and I am the President of American Home Products Corporation. We are here today to speak on behalf of 10 of the nation's leading research-based pharmaceutical companies: American Home Products Corporation; Bristol-Myers Company; Carter-Wallace, Inc.; Hoffmann-La Roche Inc.; Johnson & Johnson; Merck & Co., Inc.; Norwich Eaton Pharmaceuticals, Inc., a Procter and Gamble Company; Schering-Plough Corporation; Squibb Corporation; and Stuart Pharmaceuticals, a Division of ICI Americas Inc.

Together our companies account for approximately 50% of the pharmaceutical research dollars spent in the United States by private industry. Let there be no mistake about the public benefit of this pioneering work. Our companies have been responsible for some of the most significant pharmaceutical breakthroughs of the last several decades. Not only have we developed new drug therapies for many previously untreatable conditions, but drug innovations often provide the least expensive, most cost-effective form of medical therapy. Several recent studies establish that pharmaceuticals can lead the way in the effort to curtail health-care costs by cutting back the need for more expensive surgery and hospitalization. (Appendix A.) Moreover, the pharmaceutical industry is undeniably important to our national economy. Our group of com-

panies employ approximately three-quarters of a million workers in the United States. In 1983, the U.S. exported over $2.5 billion worth of pharmaceutical products that accounted for a net favorable trade surplus in excess of $1.2 billion. These health and economic benefits make it imperative for Congress to encourage adequate future research by restoring the effectiveness of America's patent system while maintaining our commitment to providing the world's safest and most dependable drug products.

Therefore, at the outset Mr. Chairman, we would like to commend the Congress for considering this important piece of legislation. We support its objectives. Specifically, our group favors legislation which would (1) restore some of the patent life lost to the regulatory review process for innovative drug products, and (2) accelerate the availability of safe and effective generic drug products. Although we support the goals and purposes of H.R. 3605, we believe that certain changes are essential in order to produce a bill which achieves its objectives fairly and equitably. This complex legislation must receive careful and thorough consideration.

We applaud your efforts, and those of the entire Committee to tackle these problems and we appreciate the opportunity to appear before the Subcommittee today.

As you know, this bill raises many difficult patent issues including serious constitutional questions about the elimination of patent rights for already-patented products.

In the past Representative Henry Waxman, who introduced this legislation, has said, "On first glance the proposal to restore patent term appears to be a simple and straight-forward issue of equity. But, ... it is really a complex and difficult public policy decision which requires a careful balancing of the need for incentives for pharmaceutical innovation and the societal impact of those incentives." H.R. 3605 is by far the most intricate measure of its type ever introduced, and some of its effects of pharmaceutical patent issues are not immediately clear. On careful examination, though, several flaws relating to the patent provisions become clear.

Most important, it would limit unduly the kinds of drugs and patents that would benefit from patent term restoration under the bill: products with multiple patents, significant improvements to existing products, and other worthwhile uses of the pharmaceutical research dollar all would be ineligible for restoration under H.R. 3605. The bill will encourage needless patent infringement and premature patent litigation. H.R. 3605 would also provide for the retroactive taking of important patent ownership rights without just compensation and would require the FDA to disclose valuable proprietary data to competitors both here and abroad. The bill's proposed restrictions on existing patent rights and the lengthy litany of the types of patents not eligible for patent term restoration could have far ranging adverse effects on the development of new technology in this country, including serious implica-

tions for the future of university-based research and the emerging and vitally important field of biotechnology. In addition, the bill contains narrow transition provisions that would penalize companies that invested in research in areas such as new indications, new dosage forms, and new delivery systems. We hope to be able to assist the Committee in understanding the impact this bill will have on innovation in our industry.

H.R. 3605 also raises significant public health concerns which need to be addressed before final consideration of this legislation. Our group believes and the FDA agrees that the bill restricts FDA's authority to insure that all drugs are safe and effective.

The FDA, in fact, raises a number of additional points that our group has not asserted. The FDA's "Technical Comments" on the legislation identify several of the health and safety problems which could arise if this legislation is enacted in its present form. For example, the bill would impose a number of severe administrative burdens on the FDA which could have the unintended consequence of actually thwarting the statutory objective of speedy approval of safe and effective innovative drugs. (Technical Comments, Appendix D.)

Some may have represented to you that our group, by seeking careful consideration of this legislation and its complex issues, is really trying to defeat the bill. I assure

you that this is not the case. We believe that the issues embodied in the bill deserve far more consideration than they received before the House Energy and Commerce Committee where this complex 45-page bill was entered as an amendment to a 1 1/2-page bill, and the amended bill was reported out of the Committee on the very same day it was introduced.

Today, in keeping with the Committee's expertise and jurisdiction over patent issues, we would like to use our limited time to focus the Committee's attention on several issues affecting patent rights and innovation which are raised by the legislation.

I. THE NEED FOR REAL PATENT TERM RESTORATION IS COMPELLING

The 98th Congress must deal with many difficult and controversial problems, but none are more challenging nor more crucial than the need to reverse the decline in U.S. innovation and productivity. Congress must not only be concerned with how to reverse this trend, but also must avoid unintentionally stifling U.S. technology.

- The U.S. share of world pharmaceutical R&D expenditures has fallen from greater than 60 percent during the 1950s to less than 30 percent now.
- The U.S. share of world pharmaceutical exports has fallen from greater than 30 percent before 1960 to less than 15 percent today.
- The number of new drugs entering clinical trials and owned by U.S. firms has steadily dropped from a yearly average of 60 in the mid-1960s to about 25 a year now. In contrast, the number of compa-

rable foreign-owned new drugs has remained almost constant at about 20 a year.

° The percentage of world pharmaceutical production occurring in the United States has fallen from 50 percent in 1962, to 38 percent in 1968, to 27 percent in 1978.

° Smaller U.S. pharmaceutical firms self-originate fewer new drugs than before 1960 and are increasingly dependent on foreign firms for licensing new products, though licensed products still make up less than half of drug introductions by small firms.

By any measure the pace of America's drug innovation is slowing. Unless Congress and the public are willing to provide meaningful incentives for pioneering research while insuring the safety and effectiveness of all drug products, then investment in private pharmaceutical research is likely to decline and will no longer provide the kind of products that have brought such an improvement in public health over the past 30 years.

One big step in the right direction would be to restore the diminishing effectiveness of the U.S. patent system for certain products, such as pharmaceuticals, that are subject to elaborate pre-market approval requirements by the Federal Government. Under current law, the Government grants a 17-year patent and then prohibits the pharmaceuticals from being marketed until all FDA-required tests are completed, reviewed, and approval is obtained. During this time, the life of the patent is ticking away, often for many years. For example, FDA reported that of 205 drug products approved between

1962 and 1978, 51, or 25%, had no or comparatively little, effective patent life at the time of approval. (Appendix B.)

Gradually, the time needed to complete and clear the regulatory review process has grown longer, as products and tests have become more sophisticated and the regulatory resources of agencies like the FDA have become stretched to their limit. In 1962, for example, it took approximately 2 years and $6 million to bring a new medicine from the laboratory to the marketplace. It now takes an average 7 to 10 years and about $70-85 million to complete this testing period. Thus, it is not uncommon for a drug product to have lost up to one-half of its patent life without having yet been marketed. (Appendix B.)

This phenomenon, coupled with the inability of many new products to recover their investment, discourages innovation. For example, from 1955 through 1962, an average of 46 drugs were introduced annually in the United States; today, undoubtedly for a variety of reasons, that average is only 17 drugs a year, a decline of 63 percent.

This reduction in the number of drug innovations strongly indicates that the public is being deprived of new therapies. A decline in pharmaceutical patent lives -- the result of inadvertence rather than Congressional intent -- could erode the investment research incentive provided by the traditional 17 year statutory patent term. No one could have anticipated that a testing and approval process that took

about two years in the early 1960s would take seven to ten years by 1980. Our group of companies urges that it is time to rebuild the incentives originally provided by the patent system.

We realize how difficult it is to draft a bill that accommodates all the multiple objectives touched by H.R. 3605. This is a bill that purports both to accomplish patent restoration and to promote the availability of generic drug products. But, amendments are needed to achieve these objectives.

On one hand, the patent term restoration provided by the bill is, in many cases, illusory because H.R. 3605 contains restrictions on the eligibility of patents for extensions. In fact, at least one provision would actually shrink existing patent protection. That provision, section 202, would reverse the decision recently rendered in Roche Products, Inc. v. Bolar Pharmaceutical Co., No. 84-560 (Fed. Cir. April 23, 1984), by the Court of Appeals for the Federal Circuit, which has appellate jurisdiction over all patent cases. The reversal of Bolar with respect to existing patents is clearly inequitable. On the ANDA side, the bill would create a number of new regulatory problems. Overall, we are concerned that it would reorient FDA's priorities toward approval of ANDAs and release of proprietary safety and effectiveness data and away from approval of important new drug therapies.

This result would be bad policy and could create public health problems.

We submit that encouraging research leading to new drug therapies is at least as important as streamlining the approval process for generic copies of drugs. H.R. 3605 has been described by its proponents as a politically attractive bill because, as a compromise, it has something for everyone: patent term restoration for the research-oriented pharmaceutical industry and increased availability of generic drugs from "me-too" manufacturers. However, as currently drafted, it is not a successful compromise because it severely restricts patents eligible for extension and undermines the basic principles of established patent law. Nonetheless, we firmly believe that the concept underlying this legislation is indeed attractive because both patent term restoration and safe and effective generic products serve the best interests of the consumer. Consumers benefit not only from price competition among the finite number of existing approved drug therapies, but also from the development of new cures and treatments. Obviously, unless a new drug is developed there can never be a generic copy of that drug.

U.S. pharmaceutical companies have been pre-eminent in developing and disseminating health-care products in this country and throughout the world. But this country's continued leadership in this field and its international competitiveness are in jeopardy. The bill under consideration today

could result in a decline in scientific research and innovation.

II. ANALYSIS OF H.R. 3605

A. Unfulfilled Commitment -- Discouraging Innovation by Limiting Drugs Eligible for Restoration

This bill purports to be a fair balancing between the need for swift FDA market approval for products whose patents have expired and the need to restore the portion of patent life lost to regulatory delay. However, patent term restoration as offered in the bill is, in many cases, illusory and the ANDA provisions go far beyond what is necessary to provide prompt approval for generic drug products after the expiration of valid patents. In reality, the bill effectively denies patent term restoration for a variety of new drug products. This result is accomplished through detailed and complicated restrictions on the types of patents eligible for restoration. If the objective of the bill is to restore incentives for pharmaceutical innovation, then patent term restoration must reflect the reality of pharmaceutical research and development, and apply to a broader range of drug patents.

- The Species v. Genus Patent Problem.

Section 201(a) (proposed 35 U.S.C. 156(a)(4)) of the bill prohibits patent term extension for cases in which the applicant holds, or will hold, more than one patent claim-

ing the drug in question. Many new pharmaceutical innovations will thus be ineligible for restoration because they will, in fact, be covered by more than one patent held by the same owner or exclusive licensee. As an example, many drugs are claimed both by a patent with claims of broad scope, the genus, and also by a subsequent patent claiming a specific compound, or species within the genus.

After the initial discovery leading to the genus, pharmaceutical research is ordinarily continued on families of compounds sharing similar chemical structural features and often similar biological characteristics. The objective is to study the entire family and to identify new compounds within the family that appear to provide more of a likelihood of therapeutic promise than other compounds within the genus. The R&D expenses to take a new medicine from discovery to market approval range from $70-80 million. Section 201(a) would prohibit patent term restoration on the species patent if the holder of the genus patent conducts this species research, and would allow it only if the two patents are forever held by separate owners.

For example, the Squibb Corporation obtained a patent on the genus of 9-halosteroids and later was able to develop two popular topical steroids from this genus: Kenalog (triamcinolone acetonide) and Halog (halcinonide). Wyeth Laboratories obtained a patent on a genus of anti-anxiety agents, which has led to the development of four specific drugs--

oxazepam (marketed as Serax), lorazepam (marketed as Ativan), pemazepam, and lormetazepam. Had H.R. 3605 been in effect when these patents were issued, none of these products would have qualified for restoration because each was covered under a species patent and belonged to a family identified in an earlier genus patent. This destroys much of the incentive to develop new compounds under the genus patent.

° The Split Application Problem

Another way in which a compound becomes covered by more than one patent is through division of the patent claims within the Patent Office itself. Under present law, the Patent Office can require that claims in a patent application be divided and prosecuted in separate patents. Over 80% of patent applications for chemical compounds are prosecuted in severed applications. This requirement is met as part of the patent prosecution or by the Patent Office itself upon examination of the application. At this early stage of drug development, the patent applicant is forced under this bill to choose which compound to prosecute first. Under section 201(a) of H.R. 3605 (proposed 35 U.S.C. 156(a)(4)(A)), the first-issued patent of the series would be the only patent entitled to restoration. Subsequently issued patents of the series would be precluded from restoration.

This restrictive provision is ill-advised because it unrealistically and unfairly requires manufacturers to determine in advance of FDA approval and marketing which patent in

a series will cover the valuable products and therefore be worthy of extension. Because only the first-approved application would be eligible for extension, and patent applicants rarely know at the early stages of development -- when patent applications are made -- which aspects of a new product will become most valuable at a later date, patent-term restoration becomes a game of chance. Moreover, even if the future commercial success of a new chemical compound was predictable, the patent applicant cannot assure that the patent claiming the potential successful product will be issued before the others, which is what the bill currently requires to ensure eligibility for patent term restoration. H.R. 3605 would thereby fail to provide the certainty requisite for investment and long-term research planning that will stimulate making discoveries available to the public.

° The Overlapping Patent-Product Problem.

Another exception to patent term restoration embodied in section 201(a) of the bill, proposed section 35 U.S.C. 156(a)(8), would apply where a substance is covered by multiple patents, each claiming a different use for that substance, or where a single patent covers two or more FDA-approved drugs. The term of claims in the patent covering the second FDA-approved drug could not be restored.

In the pharmaceutical industry, it is common for additional research on a patented drug product to lead to

the development of new delivery systems, therapeutic indications, or dosage forms of the original product. These later innovations contribute significantly to the safety and effectiveness of drug therapy, and the later-discovered products deserve restoration to the same extent as the initial products of a patent. Yet the bill would provide only one restoration per patent, even when a company has expended considerable resources in developing the subsequent FDA approved products. For instance, in 1972 Merck and Company, Inc. was issued a patent on a beta blocker which resulted in a product called Blocadren, a highly effective cardiovascular drug which is used in the prevention of a second heart attack, the heart attack most likely to cause death. Though widely used in Europe, it was not approved in the United States until 1981 and therefore had only eight years left on the patent once it was brought to the U.S. market.

Merck continued its research on this compound long after it was marketed in Europe as a cardiovascular drug and in 1978 received approval from FDA to market the product for a new use. Merck had discovered that the same compound which was useful in the treatment of cardiovascular disease would also decrease intraocular pressure on the eye when used as eyedrops, making it a useful drug in the treatment of glaucoma. Merck obtained a patent for the glaucoma indication in 1980 and manufactured the drug under the brand name Timoptic. Timoptic, a breakthrough drug which in many cases eliminates

the need for surgery, costs only 22 cents per dose and replaces a surgical procedure which costs approximately $800 per procedure and approximately $200 per day in hospitalization costs.

Under this proposed bill, the Timoptic active ingredient was claimed in the earlier issued patent for Blocadren, it would not be entitled to patent term restoration under subparagraph (4)(A) of section 201 of the bill. On the other hand, Blocadren was not approved in this country until 1981 while Timoptic was approved in 1978. Therefore, subparagraph (7)(A) of section 201 prevents the discoverer from getting restoration on Blocadren because Timoptic was approved first.

Schering-Plough has developed both Valisone (betamethasone valerate) and Diprosone (betamethasone dipropionate) from a single patent, and has turned the Diprosone formula into another form marketed as Diprolene, which has an improved delivery vehicle and allows lower dosages. None of the later improvements to these topical steroids would qualify for extension if H.R. 3605 were law, because they all arise under a single patent.

Just as one patent may cover two drugs, one drug or a family of drugs frequently is covered by more than one patent. Subsequent innovations to an existing drug may result in one product being covered by multiple patents. For example, the drug propranolol (Inderal) was patented in 1967 and is currently indicated for seven indications. Research continued

on the agent and a patent was obtained for the new product, Inderal LA, in 1979. The new form of the drug is considered an improved therapy for four indications, largely because it requires less frequent doses and thereby stabilizes serum levels of the drug and raises patient compliance through less frequent doses. Yet since Inderal LA is covered by both the 1967 and the 1979 patents, the drug would be ineligible for patent term restoration under section 201(a) of H.R. 3605, proposed section 35 U.S.C. 156(a)(4).

Similarly, the compound Cyclapen-W (cyclacillin) received patent protection in 1965 as an antibiotic, and the product was later improved by formulating an anhydrous version that has a longer and more stable shelf life and was patented separately in 1971. Wyeth Laboratories, which now sells only the improved anhydrous version of the drug, would be ineligible for restoration of either patent's term if H.R. 3605 had been law at the time of Cyclapen-W's discovery. These examples show how H.R. 3605 unfairly restricts the products for which patent term restoration may be available, and would deny restoration for the very kinds of new inventions and innovations it purports to encourage.

° <u>The Manufacturing Patent Problem</u>.

Section 201(a) of the bill (proposed 35 U.S.C. 156(a)(5)(A)) limits availability of patent term restoration for patents covering a method of manufacturing (not using rDNA

technology), including the limitation that no other type of patent has been or "may be issued for any known therapeutic purposes" claiming the method of using the product. New advances in pharmacological manufacturing techniques can contribute greatly to reducing the cost of drug therapy, and these innovations should be encouraged by providing for appropriate patent terms.

Furthermore, the bill contains special provisions for biotechnology and rDNA manufacturing techniques. Under proposed 35 U.S.C. 156 (a)(5)(B), the term of a process patent utilizing rDNA technology can be extended only if two tests are met: the patent holder of the method of manufacture is not the exclusive licensee or holder of the patent on the product itself (i.e., different ownership), and no other method of manufacturing the product primarily using rDNA technology is claimed in a patent having an earlier issue date. This second test would eliminate patent term restoration for much of the rDNA work being conducted, because a previously-issued dominating patent claiming rDNA technologies would exclude subsequently-issued "method of manufacture" patents from patent term restoration. This provision is overly broad, particularly where the dominating patent belongs to another party. One example of a dominating patent is the "Cohen-Boyer" patent developed at Stanford University, which covers basic rDNA manufacturing technologies. It would not take many of these broad-coverage, dominating patents to exclude almost

all future rDNA innovations from restoration of term. The existence of these dominating patents will turn the patent term extension promised in proposed 35 U.S.C. 156(a)(5)(B) into a mere illusion.

B. Encouraging Patent Infringements And Premature Patent Litigation

Under present law, a patent has a statutory presumption of validity. Under section 101 of H.R. 3605 (proposed 21 U.S.C. 505(j)(4)(B)(iii)), a competing drug manufacturer, a so-called "second-comer," can submit an ANDA on a patented drug, and give appropriate notice of this submission to the patent holder, who then has 45 days to institute a patent infringement action. Assuming such an action is brought, the second-comer is allowed to market the drug after the expiration of an 18-month period following the notice unless a court declares the patent valid within this period. This provision would institutionalize and provide incentive for a system of attacks on presumptively valid patents. It does serious damage to a patent system that generally -- apart from the regulatory system's inadvertent erosion of effective patent life -- has long served this nation well by fostering and promoting research, invention, and innovation.

Under section 101, the ANDA applicant can also force the patent holder to litigate the validity of the patent within 45 days of the initial submission of an ANDA, whether complete or not. This is in contrast to the current law which

provides that a full NDA must be complete before it is considered filed. ANDAs are often incomplete and require revision and additional work before they are accepted for filing by the FDA. The bill does not require that the ANDA submission be complete, even though there is presently a comparable requirement of "due diligence" in prosecuring an NDA imposed under the patent term restoration side of the bill upon a patent owner seeking an extension of the patent. If a patent suit can be triggered even before a complete ANDA is filed, then some companies and groups of companies will be encouraged to attack unexpired drug patents. Their risk is slight because they will not have to invest in the research required for a complete NDA.

Presumably, section 101's 18-month delay in the ANDA effective date once an infringement suit is filed is intended to permit a court to adjudicate a patent's validity before the ANDA becomes effective. However, this provision is grossly deficient. As the Subcommittee is well aware, the trial of a complex civil suit such as patent litigation is almost never completed within 18 months. Congestion in the courts and the low priority assigned to civil relative to criminal cases can stretch patent litigation out for five years or more. In fact, it has been recently reported that the completion of trials of patent actions (calendar waiting time plus trial time) average 35 months, not counting the time spent in discovery or pre-trial motions. Report of Proceedings of the Ju-

dicial Conference of the U.S., March 16-17, 1983 and September 21-22, 1983, Annual Report of the Director of the Office of U.S. Courts, table C54 (1983).

If enacted in its present form, the bill is certain to generate increased patent litigation. Owners of unexpired patents will need to respond to virtually every second-comer's notice of an ANDA submission with a suit for patent infringement. First, failure of the holder of a valid patent to litigate would permit the FDA to approve the "me-too" company's or companies' ANDAs and permit infringing commercial sales. Profits from the infringing sales could permit the initial and subsequent generic manufacturers to finance patent litigation. Second, failure of the patent owner to respond may support an estoppel or laches defense in subsequent litigation. Patent issues rarely lend themselves easily to quick summary judgment or other prompt resolution. This could result in extended and terribly costly patent litigation to the patent owner during the early stages of a patent -- precisely when unencumbered patent protection is most useful.

If the infringement occurs close to the end of the patent term, a court might eventually issue a final ruling in favor of the patent owner but mandate only payment of monetary damages, rather than also ordering the infringing product off the market. This would further encourage patent infringement and litigation, by allowing a second-comer to market competing

products before expiration of the
paying the equivalent of a licensing f

Since patents are presumed
should not get a free ride on the pi
to obtain an NDA and market a "me-too"
fully and properly decided the paten
the bill should be amended to require
ANDA filing to trigger the initial
serious patent infringement.

C. Commercial Testing During Pa

It is a long-accepted tene
unauthorized use, sale, or manufactu
during the life of the patent consti
aspect of the rights accruing to the
cored recently in the case of Roche
Pharmaceutical Co., No. 84-560 (Fed.
United States Court of Appeals for
consistent with prior rulings, that
turer may not use another company's
purposes of obtaining FDA approval
patent term. This decision is sound
vent damaging, commercially competi
substance while the patent owner is
sive rights.

The legislation under consideration [illegible] permit a commercial competitor to engage in [illegible] now constitute blatant patent infringement. [illegible] that this restriction on patent rights should [illegible] a bill intended to restore patent life and encourage [illegible] tion. The competition in today's market for [illegible] products is extremely intense. In order to encourage [illegible] search while respecting the rights of the patentee [illegible] quate patent protection such as was reaffirmed [illegible] decision is critical.

The bill would eliminate this important [illegible] not only for patents issued in the future but also [illegible] already in existence. This provision of the bill raises [illegible] ous constitutional concerns. By overruling Bolar retroactively, the bill deprives current patent holders of [illegible] erty rights and constitutes a "taking" without [illegible] Even if Congress wishes to overrule the Bolar decision, it should do so only prospectively and only for those drugs not eligible for patent extension under the bill.

We believe the provisions of the bill permitting a competitor to conduct commercial testing on an invention covered by a valid patent should be amended. It is one thing to overrule Bolar for drugs that will qualify for patent restoration provisions of the bill. It would be clearly unfair to remove existing patent protection from drugs that are ineligible for any benefit under the

event, the attempt to apply such changes to already-issued patents raises serious constitutional concerns and must be remedied.

D. Government Disclosure to Foreign Competitors Of Valuable Proprietary Information

For over 45 years the FDA has not publicly disclosed, or allowed the release for any purpose not explicitly authorized by an NDA holder, any safety or effectiveness data contained in a pioneer NDA, while these data retain any commercial value. 21 C.F.R. 20.61, 314.11, 314.14. See 37 Fed. Reg. 9128, 9130-31 (May 5, 1972); 39 Fed. Reg. 44602, 44612-14, 44633-38 (Dec. 24, 1974); 40 Fed. Reg. 26142, 26148, 26168-7 (June 20, 1975); 43 Fed. Reg. 12869, 12870 (March 28, 1978). This interpretation of the FDC Act has consistently been upheld in court. E.g., Johnson v. DHEW, 462 F. Supp. 336 (D.D.C. 1978); Webb v. DHHS, Food, Drug, Cosm. L. Rep. ¶ 38,138 (D.D.C. 1981). See also, Pharmaceutical Mfrs. Ass'n v. Weinberger, 401 F. Supp. 444 (D.D.C. 1975); Syntex Corp. v. Califano, Food, Drug, Cosm. L. Rep. ¶ 38,221 (D.D.C. 1979). Cf. Public Citizen Health Research Group v. FDA, 704 F.2d 1280 (D.C. Cir. 1983).

Section 104 of H.R. 3605 would provide for a dramatic and ill-conceived reversal of this long-standing policy, although the bill's sponsors apparently maintain it would merely codify current FDA disclosure policy regarding drugs subject to ANDAs. It has indeed been FDA policy to allow for

limited disclosure of material contained in NDAs. This policy, however, applies to pre-1962 drugs, and since adoption the regulation has applied only to data generated before 1962. The regulation was adopted before any serious consideration had been given to ANDAs for post-1962 drugs. It does not follow that a policy which may be appropriate for data which are at least 22 years old is sound for data developed relatively recently and which are of far greater commercial value. Moreover, in the course of its ongoing rewrite of the NDA regulation, FDA itself intends to revise this regulation to reflect the continuing proprietary nature of these data. The bill would negate this effort.

The bill would permit the public disclosure of all of the extensive and costly research data generated by research-based pharmaceutical companies, at least as soon as FDA approval of a generic version of the new drug could become effective, even though the data may be of significant value to foreign competitors or may retain proprietary value in the United States. Also, it is not clear in section 104 that the term "information" is limited to safety and effectiveness information as distinguished from other confidential data such as manufacturing methods and processes.

The data that would be released can retain commercial value, even though FDA would no longer require another applicant to submit the data to obtain approval for sale in the United States. These data would be commercially valuable

because they could be used to obtain approval to market the drugs in foreign countries.

Senator Orrin Hatch earlier this year drove home the value of U.S.-produced technical data during efforts to tighten the Freedom of Information Act. Senator Hatch said:

> Foreign governments and foreign competitors of U.S. companies are able to obtain very valuable unclassified technical information simply by submitting a FOIA request to the Federal agencies that have paid to have the data developed. In fact, cottage industries have sprung up to systematically obtain and catalog such technical data, which they then market throughout the world.

The data disclosable under section 104 are particularly valuable in those countries which do not recognize U.S. patents. Thus, by providing for the release of these data, the bill hands foreign competitors of U.S. drug firms information which costs many millions of dollars to obtain and which can be used to obtain approval to market drugs in competition with the U. S. owner and generator of the data. This is hardly the way for this legislation to reverse the decline in pharmaceutical innovation and maintain the competitiveness of American industry.

Under section 104, trade secret data that now cost, on average, $70-85 million to generate per new drug would be freely released to anyone requesting them, including the innovating firm's foreign competitors. Competitors will copy the data and submit them to foreign drug regulatory agencies when they request permission to sell the drug abroad. Unlike FDA,

most foreign drug approval agencies give preference in their approval decisions to firms of their own nationality. American firms can expect to lose market shares in these nations and, in some instances, watch a foreign firm get marketing approval instead of themselves.

Section 104, as presently drafted, may jeopardize U.S. pharmaceutical exports and numerous American jobs. The exports at stake are to nations that (a) require data in the application for market approval that, but for section 104, would not be publicly available, and yet (b) do not recognize product patents. (Appendix C).

In effect, under section 104 our government would give foreign firms, for merely the cost of photocopying, private U.S. commercial information needed by the foreign firms to go on the market in their home countries. It would be ironic if such a provision were enacted now, when the U.S. government is vigorously negotiating against international efforts to impose compulsory licensing requirements on U.S. patent holders.

As FDA noted, in its Technical Comments (Appendix D), this provision of H.R. 3605 also has significant resource implications for FDA. Under the FOIA, FDA is obligated to respond to requests for documents in its files, including the voluminous safety and effectiveness data, ordinarily within ten days and in special cases, within twenty days. Since the enactment of FOIA, FDA has consistently received more requests

for documents than virtually any other Federal agency. In 1983, FDA received over 39,000 FOIA requests. One hundred twenty-five "full time equivalents," many of whom are highly trained scientists and doctors, were required to process these requests. Under H.R. 3605, over twenty years of safety and effectiveness data and information for off-patent drugs will be available for disclosure immediately upon enactment. If FDA were to receive requests for even a modest part of those data, the workload and resource burdens would be staggering. It is difficult to see how the public benefits by the FDA being forced to divert scarce resources to processing FOIA requests and ANDAs at the expense of new drug applications.

Despite the toll in jobs and balance of trade, Section 104 is unrelated to the goals of the bill, namely to expedite approval of generic drugs and to restore some of the time lost on patent during regulatory review of human and animal drugs and medical devices. Mandating disclosure of trade secrets would not affect the availability or pricing of generic substitutes, nor does it relate to the type or amount of information necessary for FDA approval of generics. In the United States, generic competitors do not need access to the raw data because the bill authorizes FDA to rely upon the innovator's data in making its decisions on the approvability of the generics rather than require that the generic firm duplicate the data.

Section 104 should be amended to require FDA to make available a detailed summary of safety and effectiveness data, but not the complete raw data. Also section 104 should be clarified so that the term "information" relates only to information on safety and effectiveness.

E. Burdens On The FDA And Its Unnecessary Involvement in Patent Issues

The bill imposes a number of new administrative burdens on the FDA. While many of these bear upon FDA's traditional functions, many others involve FDA for the first time in the administration of the patent system. Contrary to the implication in the Report on H.R. 3605 of the Energy and Commerce Committee, these complex procedures and their effects on FDA have not been considered at any time. They deserve full and careful evaluation. We understand that FDA representatives are making their views known independently on some of these features of the bill and therefore we will leave it to the FDA to address important aspects of these new responsibilities. (Appendix D.)

III. CONCLUSION

In conclusion, our group supports the legislative objectives of this important bill, but we believe that there are changes which must be made to improve and clarify the legislation. We have specific amendments that we believe will improve and clarify this important legislation. Moreover, we

wish to impress upon this Subcommittee the need for careful consideration of the complex and controversial public policy questions raised by the legislation. We stand ready to work with the Committee and its staff so that a meaningful and fair bill can be enacted this session of Congress.

Thank you very much for the opportunity to address this Subcommittee.