



Pharmaceutical Research and Manufacturers of America

Response

to

Written and Oral Submissions

by the

Generic Pharmaceutical Association

on

Implementation of the Hatch-Waxman Act

by the

U.S. Food and Drug Administration

Submitted to:

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Introduction

The public health objective of the Hatch-Waxman Act requires a combination of clear procedures to (1) protect presumptively valid patents from allegedly identical generic copies, and (2) provide an abbreviated approval procedure to permit generic manufacturers to demonstrate the safety and effectiveness of their products by using the pioneer's data.

Accordingly, the Hatch-Waxman Act created a process to permit generic drugs to establish safety and efficacy based on the proprietary data of the pioneer manufacturer and to be approved following the expiration of any relevant patents and data exclusivity, and the resolution of any patent issues.

The fundamental premise of the abbreviated approval process is that the generic manufacturer makes the same (identical) drug as the pioneer. The identity between the products justifies the use of data collected on the pioneer's product to demonstrate safety and effectiveness for the generic copy. When the requirement for identity is compromised, there can be no assurance that the pioneer's data is relevant to the generic product, and there can be no assurance that the public health will be protected. Moreover, the sameness of the products defines the boundaries within which the pioneer company's data can be used and the boundaries within which the pioneer should expect competition from other drug manufacturers who have a defined

right to reference its otherwise proprietary data. As the requirement for sameness is compromised, FDA distorts the Hatch-Waxman balance away from the innovation of new and better drugs for poorly treated and untreated diseases and towards making copies of drugs that bear less and less identity to the innovator reference medicine.

In addition, the fundamental patent law principle that the Hatch-Waxman Act respects is that all issued patents are presumed to be valid. In combination with the fundamental principle of sameness for generic drugs, the Hatch-Waxman Act procedures are designed to protect a presumed valid patent from infringement by a product that is claimed to be identical. Accordingly, the Hatch-Waxman Act includes many procedures for protecting the patent rights that generic manufacturers do not challenge and for the orderly resolution of any patents that generic manufacturers do challenge.

Moreover, vigorous defense of these procedures and challenges to FDA's implementation of these procedures cannot be considered abuse. Adherence to these procedures is essential for protecting the intellectual property rights of the pioneers. Any suggestions by the generic industry that would eliminate or hinder the ability of pioneer manufacturers to protect their intellectual property rights should be rejected as inconsistent with the statute.

These principles provide the context for the response of the Pharmaceutical Research and Manufacturers of America (PhRMA) to the positions asserted by the Generic Pharmaceutical Association (GPhA) in its written and oral submissions to FDA in connection with the January 30, 2002 briefing of Chief Counsel Troy.

In particular, PhRMA makes the following points in its reply submission:

- The 30-month stay applies to each patent for which an ANDA applicant makes a Paragraph IV Certification *and* the innovator brings a patent infringement lawsuit within the statutory 45-day period;
- The Hatch-Waxman procedures require the listing of all presumptively valid patents that relate to the pioneer product to prevent infringement by an allegedly identical generic drug;
- GPhA’s proposed restrictions on three-year data exclusivity would violate the statute;
- Neither Section 505(b)(2) nor the proposed “Paper BLA” is authorized under the statute for the approval of follow-on biological products; nor are they sufficient to protect the Public Health;
- FDA’s delays in handling ANDAs are best addressed by increasing agency resources; and
- Current enforcement tools are effective at regulating promotional activities that are alleged to be false and misleading.

These points are described more fully below.

I. THE 30-MONTH STAY APPLIES WHENEVER AN ANDA APPLICANT MAKES A PARAGRAPH IV CERTIFICATION AND IS SUED FOR PATENT INFRINGEMENT WITHIN THE STATUTORY 45-DAY PERIOD.

GPhA admits that a paragraph IV certification initially included in an ANDA gives rise to a 30-month stay (if infringement litigation is brought within 45 days), but it argues that a paragraph IV certification later included in an amendment to an ANDA cannot do so. This construction is flatly inconsistent with the statute, FDA's implementing regulations, and congressional intent, and would lead to bizarre results.

A. The Statute Provides the Right to a Stay for Each Paragraph IV Certification and Notification, Including Those in Amendments.

The Hatch-Waxman process for protecting the rights of innovator companies is straightforward. An ANDA must contain a certification with respect to each patent submitted to FDA for listing. 21 U.S.C. § 355(j)(2)(A)(vii). If a certification is made under paragraph IV alleging that the patent is invalid or not infringed, the applicant must include in the ANDA a statement that it will provide notice to the patent owner and NDA holder, which includes a detailed statement of the basis for the ANDA applicant's allegations. 21 U.S.C. § 355(j)(2)(B). If patent infringement litigation then is instituted within 45 days of receipt of that notice, approval of the ANDA is stayed for 30 months while the litigation is pending, subject to modification by the court. 21 U.S.C. § 355(j)(5)(B)(iii).

Understanding GPhA's argument – and why it is without merit – requires careful review of the precise words used by Congress in establishing this process. The notice provision, section 355(j)(2)(B), is as follows:

(B)(i) An [ANDA] applicant who makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give the notice required by clause (ii) to [the patent owner and NDA holder]. . . .

(ii) The notice referred to in clause (i) shall state that an application, which contains data from bioavailability or bioequivalence studies, has been submitted . . . to obtain approval . . . before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

(iii) If an application is amended to include a certification described in subparagraph (A)(vii)(IV), the notice required by clause (ii) shall be given when the amended application is submitted.

21 U.S.C. § 355(j)(2)(B).

The process thus embodies four distinct but unified elements. First, the ANDA must contain a certification under paragraph IV that the applicant believes the patent to be invalid or not infringed. This is required by subparagraph (A)(vii)(IV) and is not in dispute. Second, the ANDA must contain a statement that the applicant will provide notice of the certification. This is required by clause (i) of paragraph (2)(B). Third, the ANDA applicant must provide notice of the certification to the patent owner and NDA holder. The notice is required by clause (ii) whenever there is a statement required by clause (i). Finally, if an ANDA is amended to include a paragraph IV certification, the notice must be given when the amended application is submitted. This is required by clause (iii).

The provision on timing of ANDA approval states as follows:

If the [ANDA] applicant made a certification described in clause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i)

21 U.S.C. § 355(j)(5)(B)(iii).

GPhA's argument is that the reference to "paragraph (2)(B)(i)" in this provision means that only paragraph IV certifications in original ANDAs can trigger the 30-month stay, and not paragraph IV certifications in amended ANDAs. According to GPhA, notice of an amended certification is made under clause (iii) of paragraph (2)(B), not clause (i), and thus the 30-month stay does not apply.

This argument does not bear scrutiny. Clause (i) requires that any ANDA with a paragraph IV certification include a statement that the ANDA applicant will provide notice to the patent owner and NDA holder. It is not limited by its terms to original ANDAs, and it thus applies to amended ANDAs as well. Moreover, nothing in clause (iii) limits clause (i) to original ANDAs. Indeed, clause (iii) does not refer at all to the statement required by clause (i). It refers only to when the notice is to be given. Clause (iii) affects the timing of the notice; it does not affect the procedural rights that arise from the notice.

In other words, clause (i) requires that when an ANDA is amended to include a new paragraph IV certification, it also must include a new statement that the ANDA holder will provide notice of the certification under clause (ii). The content of the notice is governed by clause (ii). And the timing of the notice is governed by clause (iii), *i.e.*, it must be provided "when the amended application is submitted." So when paragraph (5)(B)(iii) refers to the "notice provided under paragraph (2)(B)(i)," there is no basis whatsoever for distinguishing notice of a paragraph IV certification in an original ANDA from notice of a certification included in an amended ANDA. In either case, the notice is provided pursuant to a statement required by paragraph (2)(B)(i).

The statutory language may not be simple, but it is clear on this point. Had Congress intended to apply the 30-month stay only to paragraph IV certifications made in original ANDAs, it would have begun paragraph (5)(B)(iii) with language such as “If the applicant made a certification described in subparagraph (IV) of paragraph (2)(A)(vii) in its original application . . .” or words of similar import. The words Congress actually chose, however, do not admit that construction.

B. FDA’s Regulations Confirm That There is a Right to a Stay Under These Circumstances.

FDA’s regulations are entirely consistent with PhRMA’s interpretation set forth above and directly contrary to GPhA’s view. The regulations require, consistent with clause (i), that a paragraph IV certification “shall be accompanied by a statement” that the applicant will provide notice to the patent owner and NDA holder. 21 C.F.R. § 314.94(a)(12)(i)(4). This same provision governs amended applications. See 21 C.F.R. § 314.95(d) (referring to circumstances in which an ANDA “is amended to include the certification required in § 314.94(a)(12)(i)(4)”). In other words, when an ANDA is amended to include a new paragraph IV certification, it must include the statement required by clause (i) of the statutory provisions discussed above. The regulations also address timing of the provision of notice. For an original ANDA, the notice must be sent when the applicant “receives from FDA an acknowledgement letter stating that its [ANDA] is sufficiently complete to permit a substantive review.” 21 C.F.R. § 314.95(b). For an amended ANDA, consistent with clause (iii) of the statute, the notice must be sent “at the same time that the amendment to the abbreviated application is submitted to FDA.” 21 C.F.R. § 314.95(d).

The regulations further provide that whenever a paragraph IV certification is made and an infringement case is brought within 45 days, approval of the ANDA will be stayed for 30 months. 21 C.F.R. § 314.107(b)(3)(i)(A). No distinction is made between a paragraph IV certification in an original ANDA and one in an amended ANDA.

Finally, to dispel any doubt on this point, the regulations expressly address the situation in which there is more than one paragraph IV certification: “If the applicant has submitted certifications under . . . § 314.94(a)(12) for more than one patent, the date of approval will be calculated for each certification, and the approval will become effective on the last applicable date.” 21 C.F.R. § 314.107(b)(4). Again, FDA’s regulations make no distinction between original and amended ANDAs. An amendment containing a new paragraph IV certification thus gives rise to a new 30-month stay if infringement litigation is brought within the 45-day period. See also 59 Fed. Reg. 50338, 50340 (Oct. 3, 1994) (ANDA applicant must amend its application with respect to timely-listed new patents either to certify under paragraph III, and wait for patent expiration, or to provide a “paragraph IV certification and therefore initiate the procedure set out at section . . . (j)(4)(B) [since renumbered (j)(5)(B)]. This procedure requires that the agency wait at least 30 months . . .”).

C. The Legislative History Supports FDA’s Regulations.

None of the legislative history cited by GPhA addresses the question presented here. On the other hand, there is one statement that does, and it directly supports PhRMA’s position: “In the case where the patent certification is amended in an ANDA to allege invalidity or non-infringement of a patent, the FDA may not make the approval effective within the 45 day period that [sic] an action for patent infringement may be brought.” H.R. Rep. No. 857, 98th Cong., 2d Sess., part 1, at 28 (1984). The 45-day provision is part and parcel of the same

provision dealing with the 30-month stay. There is no way that the 45-day provision could apply without the 30-month stay then being triggered by infringement litigation brought during the 45-day period. So when Congress made clear that the 45-day period applies to amended ANDAs with paragraph IV certifications, it became equally clear that the 30-month stay applies as well.

D. GPhA's Construction Would Lead to Absurd Results.

Under GPhA's theory, any paragraph IV certification made in an amended ANDA would not give rise to a 45-day notice period or 30-month stay. If that were true, however, it effectively would eliminate the 30-month stay altogether. All that an ANDA applicant would need to do would be to submit its original ANDA with a paragraph III certification, or even no certification at all, and then amend the ANDA a few days later to include a paragraph IV certification. For example, an ANDA could be submitted without any patent certification, leading to an FDA refusal to accept the application on the ground of a facial deficiency, and then an amendment of the ANDA to correct the deficiency. See 21 C.F.R. § 314.101(b)(3)(ii).

According to GPhA's reading of the statute, this would be done in an amendment under clause (iii), not clause (i), and thus there would be no opportunity to litigate under a 30-month stay for any patents at all. Similarly, an amendment to an ANDA to add a new formulation or strength, with accompanying paragraph IV certifications, would provide no right to a 30-month stay. Any such reading is simply inconsistent with the text and intent of the statute. Amendments to add paragraph IV certifications must give rise to the same opportunity for a stay as paragraph IV certifications in original ANDAs.

II. THE HATCH-WAXMAN PROCEDURES REQUIRE THE LISTING OF ALL PRESUMPTIVELY VALID PATENTS THAT RELATE TO THE PIONEER PRODUCT TO PREVENT INFRINGEMENT BY AN ALLEGEDLY IDENTICAL GENERIC DRUG.

GPhA believes that the prospect of receiving the initial 30-month stay, combined with FDA's current policy permitting successive 30-month stays provides brand-name companies with an enormous incentive to submit patents for listing in the Orange Book, even if the patents do not satisfy the listing criteria contained in the Hatch-Waxman Act.

GPhA makes these assertions with no acknowledgment of the existence of (a) the prohibition on submitting false information to a governmental agency – including the submission of a false Orange Book listing to FDA; (b) the prohibition on frivolous litigation, under the Federal Rules of Civil Procedure; and (c) the severe sanctions that can be imposed for patent misuse. Moreover, under the federal rules of civil procedure, GPhA cannot demonstrate any pattern of Orange Book listings that do not meet the criteria in the Hatch-Waxman Act. GPhA's complaints focus on differences in interpretation of patent claims and the application of those claims to a specific product – the precise matters that the Hatch-Waxman Act leaves to the courts to decide.

A fundamental provision of the Hatch-Waxman Act is its procedure for litigating patent disputes prior to FDA approval of a product that is alleged to be an identical copy of the pioneer. Thus, in accordance with this provision, NDA holders are required to list all patents in the Orange Book that relate to the product. ANDA applicants must notify the NDA holder and patent holder if they seek approval prior to expiration of the listed patents. If the patent holder

sues the ANDA applicant after receiving such notice, FDA is prohibited from approving the ANDA involved until the patent litigation is resolved, all the listed patents have expired, or 30 months have passed, whichever is earlier.

Since the applicability of this procedure depends on whether a patent is listed in the Orange Book, there has been substantial controversy over what patents may be listed. The statute requires NDA applicants to list any patent “which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.”

A. The Hatch-Waxman Act limits the FDA’s Role in Orange Book Listings.

To overcome what GPhA believes are serious patent listing violations GPhA proposes a revised declaration in which the patent holder describes in detail how the claims of the patent cover the approved drug. GPhA proposes that FDA go beyond its ministerial role in the Orange Book listing process to determine whether the claims in the listed patents actually cover the drug that is the subject of the application. If FDA makes a determination that such claims do not cover the drug that is the subject of the application, FDA can refuse to list the patent, or delist the patent if appropriate.

GPhA reiterates that such a detailed review is within FDA’s administrative expertise, and is necessary to particularize the general requirements of a statute to facilitate compliance and thereby carry out the intent of Congress. See GPhA II at 13. To support this premise, GPhA states that FDA has the necessary expertise to decide what is the subject of an NDA. *Id.* However, it extrapolates this expertise in determining the subject of a NDA to an

unproven expertise to determine the metes and bounds of a valid patent so as to determine whether the listed patents cover the approved drug. This would drag FDA into areas outside its proven competence and outside its statutorily mandated realm of regulatory powers.

To further bolster its argument that FDA has the authority to review patent claims and thereby list or delist a patent, GPhA states that the Orange Book listing standard is in the Federal Food, Drug, and Cosmetic Act (the FDCA), and not in the patent statute. GPhA believes that although the listing standard may relate to patents, it is in the FDCA, has consequences germane to the FDCA, and because it is part of the NDA, an area which is exclusively within FDA's area of expertise, it must be subject to FDA review. See GPhA II at 14. However, GPhA overlooks the fact that FDA's statutorily mandated role with respect to listing of patents was limited by Congress.

Congress enacted the patent listing provisions to provide clear notice to potential generic developers of the patents (other than process patents) that cover the product and may reasonably be asserted by the innovator against the generic drug manufacturer. Congress did not contemplate FDA review of the substance of the listed patents other than that FDA should not list process patents. Clearly, Congress's inclusion of the paragraph IV certification (that allowed generic drug developers to contest *in court* the validity of the patent, or assert that such patent had not been infringed – and any subsequent patent infringement suits brought by the patent holder) requires that contentious issues surrounding patent claims remain outside the ambit of FDA review.

GPhA is confused about the standards by which FDA must review safety and effectiveness information for a drug and thereby publish and maintain a list of approved drugs, and the statutory standard by which it is required to publish patent information provided by the

applicant. FDA has a statutory mandate to review the safety and effectiveness of drugs. FDA does not have such a mandate to review the substance of valid patents and determine whether a product comes within the ambit of the claims of such a patent. Congress directly granted FDA the right to approve or deny applications on the basis of safety and effectiveness, but in its wisdom precluded any judicially based review of patents from FDA's jurisdiction. Thus, GPhA's attempts to extend FDA's right to review patents is baseless.

B. GPhA's Proposed Remedy Would Require FDA to Make a Determination of Patent Infringement -- an Issue Only Within the Competence of the Courts.

Contrary to the assertion by GPhA, the determination of whether a patent "covers" a particular product is analogous to a determination of patent infringement. In each case, the task is to determine if the product lies within the metes and bounds of the claims, *i.e.*, if the product is adequately described by the claims so as to infringe the patent. Neither FDA nor the Patent and Trademark Office is competent to make such a determination; this determination must be made by the courts.

GPhA's proposed solution to "strengthen" the patent listing declaration adds no additional information regarding the compliance of the listings with the statutory and regulatory requirements. The additional information merely requires the patent owner to disclose certain information that is most useful in the patent litigation context, (*e.g.*, identifying specific claims that cover the product and identifying the earliest effective filing date for each claim). The appropriate place for this information is not in Orange Book listings with FDA, but in federal court discovery in the context of a patent infringement case. Moreover, the proposed

requirement to certify that the declaration is submitted under penalty of perjury is redundant to requirements that already make it a criminal violation to knowingly submit false information to the government.

As further indication that GPhA's proposal would drag FDA into areas outside its experience and expertise, FDA is being asked to determine which product-by-process patents are “appropriate” for listing in GPhA's view. The correct view of which product-by-process patent listings are “legitimate” seems to lie solely in the eyes of GPhA.

Contrary to what GPhA states, product-by-process patents are product patents and not process patents in disguise. In a product by process claim, the inventor claims a product made by a specific process, especially when such a product cannot be claimed by more traditional patent claims involving structure, chemical formulae, etc. GPhA's belief that product-by-process claims provide the same patent coverage for the product that is provided by the composition claims is not consistent with the requirements of patentability that are administered by the Patent and Trademark Office (PTO). If the product is not new, the examiner at the Patent and Trademark Office will reject the claim and prompt the inventor to prove how the product made by this method is different from the previously known product. If there is no significant difference, the inventor loses the claim. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Accordingly, the GPhA concern about product-by-process patents is unwarranted.

Finally, GPhA erroneously asserts that there are no product-by-process patents in the pharmaceutical industry that are anything but process patents in disguise. GPhA believes this to be the case based on its incorrect assumption that such patents do not claim a new drug product or a new drug substance. First, as stated above, a product-by-process patent is not a

process patent; it is a patent that claims a product. Second, numerous drug products, for example, natural products (especially biotechnology products made by fermentation), may be adequately patented only by product-by-process claims. Third, with the application of well-established biotechnology based processes to drugs, and the advent of new drugs that may be patented only with respect to how they were produced, it would be a disservice to the brand-name companies that make these products to preclude the listing of product-by-process patents.

C. GPhA's Concerns About Inappropriate Orange Book Listings are Unfounded.

GPhA believes that as long as FDA refuses to look at what is being submitted, brand-name companies can continue to list just about any patent in the general vicinity of an NDA drug. In making this assertion, however, GPhA does not provide any evidence about whether this is a problem endemic to the industry. Brand-name companies are aware that it is a criminal violation to knowingly submit false information to a federal regulatory agency. Thus, brand-name companies are required to take seriously their statutory responsibility to submit only those patents that cover the drug, or else face severe penalties.

Furthermore, as PhRMA stated in its submission to FDA, the courts are adequately addressing any problems concerning spurious patent listings.¹ GPhA misrepresents the decision in *Andrx* to rebut PhRMA's suggestions that the courts are addressing the problem.²

¹ See "White Paper On Implementation Of The Hatch-Waxman Act By The U.S. Food And Drug Administration," Pharmaceutical Research and Manufacturers of America, submitted to FDA on January 18, 2002 (hereinafter "PhRMA I").

² (GPhA I at 12, citing *Andrx Pharmaceuticals Inc. v. Biovail Corp.*, No. 01-6194-CIV-Dimitrouleas (S.D. Fla. March 6, 2001), Omnibus Order, at 9).

The court in *Andrx* merely stated that there was no provision in the Hatch-Waxman Act that would allow a court to prevent a patent from being listed and that in contrast to the court, it was FDA's job to list or delist a patent. The court was right in making this distinction. Nevertheless, FDA's role in listing and delisting patents remains a narrow one, limited by statute.

D. The Hatch-Waxman Act does not Require the Listed Patents to Claim the Approved Drug "In All Respects."

Finally, in its attempt to rewrite the law, GPhA asserts that the patents listed in the Orange Book must claim the FDA-approved drug in "all respects." However, this standard is neither clear in its intended meaning nor supported by statutory or regulatory language. (The identical erroneous suggestion by the Federal Trade Commission is no more compelling and does not add any clarity.)³ As long as a composition or method of use patent can reasonably form the basis for a patent infringement claim against the generic version of a product that could be claimed by the ANDA applicant to be the "same," then the patent is appropriately listed in the Orange Book. Any limitation suggested by requiring the patent to claim the approved-drug "in all respects" is neither permitted by statute nor warranted by the intended operation of the Hatch-Waxman Act. At bottom, what GPhA wants is the freedom to assert that variations in their products can be the same for ANDA purposes, but *not* for patent purposes; this is fundamentally wrong, and inconsistent with the statutory scheme.⁴

³ Citizen Petition, No. 01P-0248 at 3 (May 26, 2001), available at <http://www.fda.gov/ohrms/dockets/dailys/01/May01/052901/cpa.pdf>.

⁴ This proposal, among others, apparently arises from GPhA's belief that market protection for innovator products is increasing. GPhA provides no evidence for this assertion. In fact, market protection for innovator products has decreased since the enactment of the Hatch-Waxman Act. FDA has limited the circumstances in which five-year data exclusivity is available based on its interpretation of "new chemical entity" as "active moiety." Similarly, for products qualifying for any patent term restoration, the remaining period of the original patent term was found to average only 8.2 years following product approval. Moreover, for these products, the average period of patent term

III. GPhA's PROPOSED RESTRICTIONS ON THREE-YEAR DATA EXCLUSIVITY WOULD VIOLATE THE STATUTE.

The Hatch-Waxman Act grants three years of exclusivity to certain changes in previously approved products to encourage innovation. GPhA has proposed various interpretations restricting the availability of this exclusivity that would violate the statutory provisions.

A. Three-Year Exclusivity Is Not Limited to "Important" Innovations.

GPhA's argument that three-year exclusivity is available only for "important" innovations is wholly inconsistent with the statute and must be rejected. The only statutory requirement to qualify a product for exclusivity is that the applicant conducted or sponsored new clinical investigations (other than bioavailability studies) that were essential for approval of the product's application.⁵ There is simply no language in the statute that could be interpreted as disqualifying applications that otherwise qualify if they are not for "important" innovations.

In a footnote, GPhA quotes statements from the legislative history that supposedly support its position.⁶ Although the statements indicate that exclusivity would not be available for minor innovations, they make clear that the need for a clinical trial defines an innovation that is not minor. Thus, Representative Waxman stated that exclusivity would not be available for "some minor change to a chemical entity that is already approved, but a change that is significant enough to require clinical trials." And Senator Hatch stated that exclusivity would be awarded

restoration was only 3 years. Accordingly, even for products eligible for restoration, the effective useful patent life has been only approximately 11.2 years; not the term of up to 18.5 years that every other product enjoys. Sheila R. Shulman, Joseph A. Dimasi & Kenneth I. Kaitin, Patent Term Restoration: The Impact of the Hatch Waxman Act on New Drugs and Biologics Approved, 1985-1995, *J. of Biolaw and Bus.*, Vol. 2, No. 4, 1999.

⁵ See FDCA § 505(c)(3)(D)(iii)-(iv), (j)(5)(D)(iii)-(iv).

for changes “which require considerable time and expense in FDA required clinical testing.” The bill’s sponsors were explaining the statutory requirement that exclusivity would be awarded only if a clinical trial was required, not attempting to engraft additional criteria onto the statutory text as GPhA would have it.

B. There Is No Authority for Generic Drug Labeling To Omit “Any Aspect” of the Reference Drug Labeling Protected By Patent or Exclusivity.

GPhA is concerned about recent congressional action that has undermined FDA’s position, and asks that FDA reaffirm its unsupported position that an ANDA product may omit any aspect of the innovator’s labeling protected by patent or exclusivity (unless the resulting labeling renders the product less safe or less effective for the remaining, unprotected conditions of use). The recently enacted Better Pharmaceuticals for Children Act (“BPCA”) included a provision permitting generic drug labeling to omit a pediatric indication or other aspect of labeling pertaining to pediatric use when the omitted material is protected by patent or exclusivity.⁷ As the GPhA paper implicitly admits, the fact that Congress enacted legislation specifically permitting generic drugs to omit protected labeling related to pediatric use is inconsistent with FDA’s previous position that the statute already permits omissions for labeling related to any type of use.

Apart from the implications of the BPCA, there is no statutory basis for FDA’s position that generic drug labeling can omit any aspect of the innovator’s labeling that is protected by patent or exclusivity. The statutory provision on which FDA relies — the language allowing labeling differences based on the innovator and generic drugs’ having different

⁶ GPhA paper at 26 n. 16.

⁷ Pub. L. No. 107-109, § 11 (adding subsection (o) to section 505A of the FDCA).

manufacturers or distributors — cannot properly be interpreted as allowing differences resulting from the generic drug manufacturer’s lack of legal rights to use aspects of the innovator’s labeling. Despite the differences in labeling, FDA’s practice is to rate the two products as equivalent and, thus, freely interchangeable. Accordingly, FDA’s interpretation of the permitted differences in labeling substantially undermines the incentives for innovation in new use indications.

IV. NEITHER SECTION 505(B)(2) NOR THE PROPOSED “PAPER BLA” IS AUTHORIZED UNDER THE STATUTE FOR THE APPROVAL OF FOLLOW-ON BIOLOGICAL PRODUCTS NOR ARE THEY SUFFICIENT TO PROTECT THE PUBLIC HEALTH.

GPhA tries to make a case for the approval of generic biologics by incorrectly assuming that drugs and biologics may be approved under the same statutory mechanism. The historical record shows that Congress never intended for drugs and biologics to be approved under similar mechanisms.

Drugs and biologics have historically been regulated under different statutory and regulatory schemes based upon sound scientific, intellectual property and public health rationales. Federal regulation of biologics predates and differs significantly from federal regulation of drugs, thereby reflecting the distinct role that biologics have played in the prevention and treatment of diseases. Traditional biologics, such as vaccines, have been responsible for the eradication of diseases such as small pox, diphtheria and polio.

Existing regulatory mechanisms do not permit the approval of generic versions of biologics. In addition, neither the science, the practicalities of manufacturing, nor the statutory authority support the position that biologics and drugs should be regulated in the same manner or that biologics can be subject to generic competition in the way that drugs are. Biologics are

regulated under Section 351 of the Public Health Service Act instead of under FDCA Section 505. Thus, statutorily they do not qualify as new drugs. FDA clearly lacks the authority to approve generic versions of products that are regulated as biologics.

A. Biologics and Drugs Raise Different Scientific and Regulatory Concerns.

The first traditionally defined dichotomy between drugs and biologics is based on their respective definitions. The term drug means “(A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnostic, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clauses (A), (B), or (C) of this paragraph.”

The term biologic means “a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product . . . applicable to the prevention, treatment, or cure of diseases or injuries of man.” Thus, biological products are often derived from living organisms, as distinct from drugs, which are often (if not always) chemical compounds. In lay terms, biologics can be described as products that are derived from cells and bodily fluids. In some circumstances, products that are biological products may also be considered drugs or medical devices as defined under the Federal, Food, Drug, and Cosmetic Act (“the Act”). However, biological products may be considered drugs for certain purposes, such as enforcement, but they are not considered “the same” for purposes of the requirements for an approved new drug application, grant of market exclusivity, or eligibility for abbreviated applications.

There has been some recent activity at FDA to harmonize the administrative systems for approval of biologics and drugs. This activity has led to the belief in some segments of the generic pharmaceutical industry that FDA is attempting to create regulatory mechanisms by which generic biologics may be approved. A case in point is the creation of the Biologics License Application (“BLA”) under the Federal Food and Drug Administration Modernization Act (“FDAMA”). From 1944 until 1997, biologics manufacturers, unlike drug manufacturers, were required to obtain two licenses – one for the manufacturing facility (the establishment license application or the ELA) and another for the product itself (the product license application or the PLA). This requirement was established for safety reasons. When a licensed product was made in a new establishment, or was made by a new manufacturing process, FDA required clinical trials to show that the new product has the same safety, purity, and efficacy as the old product. Although the two licenses have recently been combined into a single BLA for administrative efficiency, the biologics application still addresses the same safety issues as its two predecessors. Thus, this method of regulation remains unchanged even today.

GPhA asserts that Section 123(g) of FDAMA authorizes an abbreviated approval system for biologics. Based on this loose interpretation of Section 123(g), GPhA assumes that under this authority, a Section 505(b)(2) application may be used for the approval of generic biologics. This is patently incorrect. Section 123(g) of FDAMA was based on the regulatory changes that FDA made between 1994 and 1996 under the Public Health Service Act, and builds on them and directs the Agency to continue its administrative harmonization efforts. However, nothing in this provision suggests any direction to over-rule the longstanding statutory and regulatory framework under which abbreviated biologic application are not permitted. It is ludicrous to suggest Congress could have addressed such a momentous change in such an off-

hand manner. FDAMA repealed the statutory requirement of an ELA for biologics and replaced it with a BLA covering both the product and facility. Although section 123(g) required FDA to take measures to minimize differences in the review and approval of products required to have approved BLAs and products required to have approved NDAs, such a change was limited to the submission of a single BLA application for biologics much in the same way that a single NDA may be submitted for a drug. Thus, in place of the ELA, a company would be required to prepare and submit additional information for inclusion in a single biologics license application, which would be the same as the information included in the “Chemistry, Manufacturing and Controls” section of an NDA. However, as stated above, these are merely efforts to harmonize internal administration procedures for the approval of new drugs or biologics.

Thus, although GPhA makes much of FDAMA’s directive that FDA “take measures to minimize differences in the review and approval of drugs and biologics,” this directive does not and has not created a legal basis for the filing of a 505(b)(2) application or an ANDA under Section 505(j) (and use of the pioneer product’s data) for a biologic. Both these proposals lack any statutory basis.⁸

⁸ Congress effectively quashed any such interpretation of Section 123(g) by the passage of a House resolution as well as a letter from two key Senate conferees, Senators Jeffords (R-VT), and Kennedy (D-MA), clarifying that the status of biological products was not changed by FDAMA. This Congressional resolution was based primarily on a Congressional understanding of the safety issues that an abbreviated system for the approval of generic biologics entails. FDA responded in a letter that it concurred that FDAMA had not changed its authority with respect to biologics. Moreover, it would constitute a taking of property under the Fifth Amendment of the U.S. Constitution to upset the settled expectation that safety and efficacy data submitted for biologics approvals would remain confidential and protected from unauthorized use by FDA to approve another applicant’s product.

B. Section 505(b)(2) Provides No Authority to Approve Generic Biologics.

GPhA attempts to create a statutory basis for the applicability of Section 505(b)(2) to the potential approval of generic biologics by taking advantage of the multiple meanings of the word “drug” in the FDC Act. However, the only meaning of the word “drug” under Section 505(b)(2) is a new drug that is approved under one of the provisions of Section 505. Since new drugs are different from biologics, GPhA is incorrect in assuming that a statutory basis exists to allow a 505(b)(2) application to be used as a vehicle for the approval of a generic biologic.

Moreover, the 505(b)(2) procedure only applies to drugs covered by the FDC Act. FDA has stated that its regulations in 21 CFR 314.54 would permit a 505(b)(2) applicant to rely on FDA’s finding of safety and effectiveness for an approved drug, but only to the extent that such a reliance would be permitted under the generic drug approval provisions under Section 505(j). This policy precludes approval for generic biologics under 505(b)(2). See *Guidance for Industry: Applications Covered by Section 505(b)(2)*, Draft Guidance, October, 1999, available at <http://www.fda.gov/cder/guidance/2853dft.pdf>. Section 505(j) procedures apply only to generic versions of drugs approved under section 505(b)(1) and (2). Accordingly, FDA has no authority to approve under 505(b)(2) biologic products that would otherwise need to be licensed under Section 351 of the Public Health Service Act.

Furthermore, GPhA’s reliance on a reading of Section 505(b) together with Section 505(j) and Section 505(l) is fundamentally flawed. GPhA assumes that because Section 505(l) authorizes the disclosure of safety and effectiveness information relied upon by a Section 505(j) applicant, a generic drug applicant under Section 505(b)(2) may avail of such publicly disclosed information to which it has not obtained a right of reference or which it has not conducted or sponsored. However, GPhA’s theory conflicts with FDA practice and the

applicable law and regulations. Accordingly, FDA does not routinely disclose safety and effectiveness data in approved NDAs, even after ANDAs have been approved, because those data retain commercial value and hence cannot lawfully be disclosed.

GPhA also argues that safety and effectiveness data in approved biologics license applications can be disclosed and that this may provide the basis for some type of “paper BLA.” Here again, however, FDA does not in fact release this type of data. Historically, the legal basis for the regulation authorizing disclosure was that, in 1974, the “data afford no competitive advantage because, unlike the situation with new drugs, no competitor can utilize it to gain approval for his product.” In other words, “[t]here is no such thing as a ‘me-too’ biologic.” 39 Fed. Reg. 44602, 44641 (Dec. 24, 1974). Any use of this data today to support approval of a follow-on product through a “paper BLA” or any other mechanism would be fundamentally inconsistent with the entire premise on which the data could be released in the first place, i.e., that the data could not be used to support a follow-on approval. If the data could be so used, FOIA exemption 4 would apply, and the data could not be released. Thus, if such information contains confidential information, it is subject to Exemption 4 under the Freedom of Information Act (“FOIA”). See 5 USC § 552(b)(4). (A complete analysis of Section 505(l) is enclosed as Appendix A.)

Finally, although GPhA encourages FDA to exceed its statutory authority to adopt a “paper BLA” policy, there is no support in the Public Health Service Act that authorizes the submission of published literature to support the safety and efficacy of a biologic. The establishment of such a policy would be no more legal than the “paper NDA” policy that was also adopted by FDA without statutory authorization.

C. The Public Health Will Not Be Served by Forcing Approval of Non-Identical “Generic” Biologics.

The primary basis for precluding an approval system for generic biologics has been public safety. Public safety cannot be guaranteed by the “comparable” standard proposed by GPhA.

The fundamental issue that GPhA ignores is the requirement under the Hatch-Waxman Act that the pioneer drug and the generic drug be the same. The sameness requirement justifies the use of the data from the pioneer drug to support the safety and effectiveness of the generic product. Moreover, the sameness of the products allows FDA to approve generic products (and to characterize them as interchangeable with the pioneer drug) with no theoretical risk to the public health. Despite the requirement in the Hatch-Waxman Act that the generic drug is the same as the pioneer, GPhA proposes that FDA approve generic biologics that are only “comparable” to an approved product.” This lesser standard of “comparability” for biologics cannot guarantee the level of safety and effectiveness possible by the “sameness” standard for drugs, because of fundamental scientific and technical constraints inherent in the manufacture of biologics.

In its attempts to interpret legislative and regulatory tools, GPhA has overlooked the basic scientific and technical reasons that render an abbreviated approval system for biologics unsafe and unsound. There exist significant technical difficulties in demonstrating “sameness” between follow-on biologics and innovator products.

Numerous scientific factors contribute to the difficulty in achieving sameness, let alone comparability between biologics made by different manufacturers. Most biologic products tend to be substantially larger than most drug molecules with very complex structures. Thus,

they are not easily reproduced from manufacturer to manufacturer, with few, if any, reported complete homology across manufacturers. Because of the higher molecular weight and complexity of biologics, there is a major emphasis placed on systems, on processes and validations. Thus, for these biologic products, the process, in large part, defines the product. Processes include the complex biological culture systems with which the compounds are made, the gentle purification schemes they require, the degradation-inducing freeze-thaw that is necessary for liquid storage of the products, and their passage through various biological assays used to confirm their 3-D structure and activity. Furthermore, the source of such biologics, whether produced from particular strains of microorganisms, recombinant or otherwise, is a determining factor that characterizes the final product.

As GPhA conceded in its oral presentation on January 30, the best relationship that can be achieved between two biologic products is that they are somehow “comparable.” However, even minor differences are relevant to the clinical impact of the follow-on biologic product. Accordingly, comparability is different in kind (not just different in degree) from the “sameness” that is required under the Hatch-Waxman Act, required for interchangeability, and required as a prerequisite condition for assuring the protection of the public health.

V. FDA’S DELAYS IN HANDLING ANDA’S ARE BEST ADDRESSED THROUGH INCREASING AGENCY RESOURCES.

GPhA complains that FDA fails to comply with the statutory requirement to decide ANDAs within 180 days. It urges FDA to comply with that deadline and, further, to issue a guidance stating that the filing of a citizen petition will not stay consideration of an ANDA beyond the statutory deadline.

The innovator industry is sympathetic to complaints that FDA does not comply with statutory deadlines. Long before Hatch-Waxman, the FDCA required FDA to act on NDAs within 180 days,⁹ but FDA has rarely met that requirement. In fact, courts will generally not exercise their discretion to enforce the 180-day deadline,¹⁰ or other statutory deadlines for that matter,¹¹ if the agency lacks the resources to accomplish its duties. In the case of innovator drugs, the industry addressed this problem by supporting a program of user fees to provide additional resources to FDA,¹² and this program has improved agency processing times for NDAs. The establishment of user fees for ANDAs could reap similar benefits for the generic drug industry.

GPhA's recommendation that FDA issue a guidance stating that citizen petitions do not stay the 180-day deadline is unnecessary and threatens only to undercut the positive public policy aspects of the citizen petition process. Citizen petitions are beneficial to the agency, because they lead to a more rigorous agency decision making process which allows FDA to better articulate its position in advance of any court challenges and to better defend itself if necessary in court. FDA's regulations already provide that the filing of a citizen petition does not

⁹ FDCA § 505(c)(1).

¹⁰ See *In re Barr Laboratories, Inc.*, 930 F.2d 72 (D.C. Cir. 1991), certiorari denied by *Barr Laboratories, Inc., v. Sullivan*, 502 U.S. 906 (1991) and *National Ass'n of Pharmaceutical Mfgs. v. Sullivan*, 502 U.S. 906 (1991).

¹¹ See, e.g., *In re United Mine Workers of American International Union*, 190 F.3d 545, 555-56 (D.C. Cir. 1999) (court allowed the Mine Safety and Health Administration (MSHA) to have more time to determine final regulations on diesel engine exhaust in mines, despite the fact that the MSHA had clearly missed the 90-day deadline specified in the statute); *Western Coal Traffic League v. Surface Transportation Board*, 216 F.3d 1168, 1175-77 (D.C. Cir. 2000) (court allowed the Surface Transportation Board to preserve the 15-month moratorium that the agency had placed on filing railroad merger applications, despite the fact that the moratorium would ensure that statutory timeframes would be violated).

¹² FDCA §§ 735 & 736.

“stay or otherwise delay any administrative action” unless FDA or a court affirmatively stays the action, or a statute requires that the matter be stayed.¹³ Thus, there is no need for the guidance requested by GPhA.

VI. CURRENT ENFORCEMENT TOOLS ARE EFFECTIVE AT REGULATING PROMOTIONAL ACTIVITIES WHICH ARE ALLEGED TO BE FALSE AND MISLEADING.

GPhA complains about promotional campaigns undertaken by innovator companies directed at certain generic products. These complaints are irrelevant to the Hatch-Waxman Act, which contains no provisions related to promotional activities. Instead, these are typical issues that are addressed initially by the Division of Drug Marketing, Advertising and Communication (DDMAC).

In any event, GPhA’s argument that FDA has been lax in regulating false and misleading promotional campaigns by innovators that raise brand-generic comparisons is incorrect. FDA has issued a string of regulatory letters on this issue, as cited by GPhA. GPhA’s implicit complaint that regulatory letters are ineffective is without basis. Innovator companies take such letters very seriously, and FDA has other available enforcement tools for use as necessary. Companies understand that non-compliance with the terms of such a letter could lead to further enforcement action.

The fact that FDA did not recommend court enforcement action in three situations cited by GPhA does not mean that enforcement in this area is lax. It simply means that FDA exercised its enforcement discretion in each case to issue regulatory letters rather than seek court action. The agency has recently re-affirmed that it makes enforcement decisions, including those related to promotional issues, on a case-by-case basis where it must weigh a number of factors,

¹³ 21 C.F.R. § 10.35(d).

such as the public health interest at stake, the statutory interest to be served, the potential deterrent value of the action and the likelihood of a successful conclusion.¹⁴

GPhA seeks to carve out special enforcement remedies for alleged promotional violations involving innovator-generic comparisons, including the draconian position that the innovator's product "must be removed from the market." This approach would not only strip the agency of its enforcement discretion, but it would also compromise public health. FDA recently echoed this concern when it noted that, while there is authority to remove a product from interstate commerce as a result of a promotional violation, such an action "would undermine the strong public health interest in maintaining the availability of the product for its approved uses."¹⁵ The more measured response would be to focus on the violative promotional statements.

If the issue of innovator-generic comparisons has any relevance to the debate surrounding the Hatch-Waxman Act, it is because, as previously discussed, the generic industry seeks approvals for generic drugs that are not exact copies of innovator products. If FDA had adhered to statutory requirements, there would be no basis for disputes about innovator-generic comparisons, since the products would be identical. Under the current circumstances, however, there may be real differences in the products, including differences that could have clinical impact, even though FDA may assign a generic product an "A" rating, thereby making the pioneer and the non-identical generic product interchangeable.

¹⁴ FDA Response to Citizen Petition filed by the Washington Legal Foundation (Jan. 28, 2002)(Docket No. 01P-0250) (hereafter FDA Response).

¹⁵ FDA Response at 3, n.8.

An innovator company has a First Amendment right to provide truthful, nonmisleading information about such differences. FDA has conceded that it has no authority under the FDCA to prohibit such truthful, nonmisleading speech.¹⁶ Thus, while FDA has authority to take action against false or misleading comparisons, it must be careful to insure that it does not impair First Amendment rights with respect to truthful speech.

Conclusion

The research-based pharmaceutical industry remains concerned that actions by FDA – particularly efforts to compromise the standards for sameness – are upsetting the balance between innovation and generic drug marketing, undermining the legislative contract with the innovative pharmaceutical industry, and jeopardizing the public health. GPhA’s assertions of abuse in the operation of the Hatch-Waxman procedures are unfounded, and its proposals for change exceed FDA’s statutory authority. GPhA’s proposals would create uncertainty in the mechanisms that were designed to preserve the incentives for innovation. PhRMA and its member companies urge FDA to implement the Hatch-Waxman Act in the way that creates certainty in the mechanism for protecting presumably valid patents from infringement by allegedly identical generic drugs. The public health will benefit from certainty in FDA’s implementation of these procedures that preserve the incentives for innovation.

¹⁶ FDA Response at 2.

APPENDIX A

SECTION 505(l) DOES NOT OVERRIDE FOIA EXEMPTION 4.

Section 505(l) of the FD&C Act provides in pertinent part as follows:

Safety and effectiveness data and information which has been submitted in an application under subsection (b) of this section for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, *unless extraordinary circumstances are shown* –

* * * *

(5) upon the effective date of the approval of the first application under subsection (j) which refers to such drug

21 U.S.C. § 355(l) (emphasis added). GPhA argues that this provision supports its view regarding section 505(b)(2) applications, apparently on the theory that safety and effectiveness information in an NDA is routinely made public following approval of ANDAs referring to the same drug. Putting aside the dubious relevance of section 505(l) to section 505(b)(2) in the first place, GPhA’s theory conflicts with FDA practice and the applicable law and regulations. FDA does not routinely disclose safety and effectiveness data in approved NDAs, even after ANDAs have been approved, because those data retain commercial value and hence cannot lawfully be disclosed.

A. FDA Has Always Interpreted “Extraordinary Circumstances” To Include A Showing That Specific Records Come Within FOIA Exemption 4.

Prior to the enactment of the Hatch-Waxman Amendments, FDA regulations provided that information contained in abandoned, unapprovable, and withdrawn NDAs would be disclosed to the public unless “extraordinary circumstances” could be shown. FDA interpreted the phrase “extraordinary circumstances” (a term of its own invention) to include a showing that specific records contain confidential commercial information within FOIA exemption 4. Thus, if a showing of confidentiality under FOIA exemption 4 could be made with respect to these NDAs, the data and other records contained therein would not be disclosed to the public. This FDA interpretation is demonstrated by the regulations themselves, as well as statements made by FDA officials during Congress’s consideration of the “extraordinary circumstances” language in 1984.

1. The 1974 regulations

After Congress enacted FOIA in 1967, federal agencies were charged with promulgating implementing regulations. 5 U.S.C. § 552(a)(3). In 1974, the FDA published final regulations implementing FOIA. 39 Fed. Reg. 44602 (Dec. 24, 1974). The regulations provided that, once an NDA was abandoned, withdrawn, or determined not to be approvable, safety and effectiveness data contained therein that were “not previously disclosed to the public [would be] available for public disclosure.” 21 C.F.R. § 314.14(f) (1975). On March 4, 1976, FDA amended section 314.14(f) to correct an inadvertent omission in its language. After this correction, section 314.14(f) stated what FDA had intended for it to state in 1974: with regard to such NDAs, “all safety and effectiveness data and information not previously disclosed to the public are available for public disclosure *unless extraordinary circumstances are shown.*” 41 Fed. Reg. 9317 (March 4, 1976) (emphasis added).

Two critical points emerge from FDA’s lengthy preamble accompanying promulgation of the 1974 regulations. First, FDA confirmed the competitively sensitive nature of information in NDA files, which therefore would ordinarily fall within FOIA exemption 4. *See, e.g.*, 39 Fed. Reg. at 44634 (referring to the “tremendous economic value” of drug safety and effectiveness data). The agency refused to interpret FOIA to authorize the routine release of this information, since that could adversely affect “the incentive for private pharmaceutical research.” *Id.* The question of expanding the circumstances under which drug safety and effectiveness information could be released thus presented “an important public policy issue” within the purview of Congress, not FDA. *Id.*

Second, FDA made clear that, under its “extraordinary circumstances” test, records within FOIA exemption 4 would remain confidential. In other words, FDA did not intend for its administratively promulgated test to override the statutory exemption from disclosure under FOIA.

FDA made this point clear in two ways. First, the regulations themselves provided that any record within a FOIA exemption would not be released even if it would otherwise be disclosable under one of FDA’s regulations. *See* 21 C.F.R. §§ 4.60(a), 4.100(a) (1975); 21 C.F.R. § 20.60(a), 20.100(a) (1998); 39 Fed. Reg. at 44621 (“all of the exemptions

from disclosure” under FOIA apply “to each of the specific categories of records” addressed in FDA’s regulations). Thus, whether a manufacturer can meet the “extraordinary circumstances” test is irrelevant so long as it satisfies FOIA exemption 4.

Second, FDA’s explanation of the “extraordinary circumstances” test makes it the practical equivalent of FOIA exemption 4 in any event. FDA made clear in the preamble that “extraordinary circumstances” includes a showing that competitive harm would flow from release of the records:

[S]hould a specific instance arise in which a competitive advantage can be demonstrated in concrete terms, a manufacturer is permitted to support nondisclosure of such information under the ‘extraordinary circumstances’ exemption provided in the final regulations.

39 Fed. Reg. at 44633. This standard is no different from the test for nondisclosure under FOIA exemption 4.

2. The congressional testimony by FDA’s Chief Counsel

At a hearing before the Senate Committee on Labor and Human Resources on June 28, 1984, Senator Hatch noted that “[c]oncern has been expressed over the possibility that,” under the bill that became the Hatch-Waxman Amendments, “FDA might be required to release safety and efficacy data for drugs which are subject to ANDA’s, which data may be commercially valuable” for use in foreign markets. Drug Price Competition and Patent Term Restoration Act of 1984: Hearing Before the Senate Comm. on Labor and Human Resources, 98th Cong., 2nd Sess. 32 (June 28, 1984). (The bill, S. 2748, included at this time language identical to what ultimately was enacted as section 505(l).) In light of the concern over release of competitively significant data, Senator Hatch asked the FDA to explain its “current practice,” which, he noted, “makes use of an ‘extraordinary circumstances’ concept.” *Id.*

FDA’s Chief Counsel, Thomas Scarlett, responded. He said that the agency had refused to release safety and effectiveness data, even if they no longer had competitive significance in the United States, because FDA “found an extraordinary circumstance to exist, in that the data could be submitted to a foreign government in support of an application for approval to market the product there.” *Id.* at 33. He expressed concern, however, that “the ‘extraordinary circumstance’ exception in this legislation, if it is enacted, would probably lead to litigation,” in which FDA’s view might not prevail. *Id.*

For that reason, Mr. Scarlett recommended that Congress’s intent be clarified. “One possible approach to clarifying the term ‘extraordinary circumstance,’” he suggested, “would be in legislative history.” *Id.* He also indicated that another alternative would be to follow an approach that FDA was pursuing at the time through a proposed rulemaking generally rewriting the NDA regulations, which would have referred specifically to the exemption 4 standard for disclosure of information in abandoned NDA files. *Id.*; *see* 47 Fed. Reg. 46622, 46642 (Oct. 19, 1982) (proposed change “reflects better the exemption in the Freedom of Information Act”). Congress chose the former alternative – legislative history – and FDA later deemed the proposed change to its rules moot in light of the legislation. *See* 50 Fed. Reg. 7452, 9490 (Feb. 22, 1985).

In sum, FDA’s Chief Counsel explained that FDA considered the potential for competitive harm – use of data by a competitor in a foreign country – an “extraordinary circumstance” within the meaning of its regulations. Congress proceeded with the legislation based on this understanding.

3. The letter from FDA Commissioner Young to Senator Hatch

If there were any remaining doubt as to FDA’s interpretation of the term “extraordinary circumstances” at the time the Hatch-Waxman legislation was being considered, it was dispelled in a letter from FDA’s Commissioner, Frank Young, to Senator Hatch on September 12, 1984. In this letter, Commissioner Young confirmed Senator Hatch’s understanding that the “extraordinary circumstances” test encompasses FOIA exemption 4:

[T]he understanding expressed in [Senator Hatch’s statement] about the meaning of “extraordinary circumstances” in the bill is the same as the proposed revision in FDA’s regulations. That revision, which is meant to conform the agency’s disclosure standard with that of [FOIA] exemption (4), *also reflects FDA’s current interpretation of the term “extraordinary circumstances.”*

130 Cong. Rec. S10988 (daily ed. Sept. 12. 1984) (emphasis added).

Commissioner Young also characterized Chief Counsel Scarlett’s earlier testimony as making clear that “the agency interprets the term ‘extraordinary circumstances’ as including a situation in which safety and effectiveness data have commercial value as confidential business information.” *Id.*

Thus, the FDA Commissioner made clear on the record – on the very day that Senate voted to pass the bill and send it to the President for signature – that FDA interpreted “extraordinary circumstances” to include a showing that the records are within FOIA exemption 4.

B. Congress Intended To Codify FDA’s Policy Under Which “Extraordinary Circumstances” Includes FOIA Exemption 4.

So, Congress understood that FDA included FOIA exemption 4 within its “extraordinary circumstances” test. The legislative history further shows that Congress intended to codify precisely that understanding when it borrowed the same term for purposes of section 505(l).

1. The House report

Committee reports are the most reliable sources of legislative history because they represent “the considered and collective understanding of those Congressmen involved in drafting and studying proposed legislation.” *Garcia v. United States*, 469 U.S. 70, 74 (1984); *see also Thornburg v. Gingles*, 478 U.S. 30, 43 (1986); *Solite Corporation v. EPA*, 952 F.2d 473 (D.C. Cir. 1991). Here, the only committee report to address the issue stated that it was Congress’s intent to codify FDA’s interpretation of the term “extraordinary circumstances.” Accordingly, FDA’s interpretation of the term, as explained to Congress at the time, to encompass confidential information within FOIA exemption 4 must prevail.

The report of the House Committee on Energy and Commerce explained section 104 of the House bill, H.R. 3605 (which added section 505(l) in terms identical to the final legislation), as follows:

These conditions under which such safety and effectiveness data shall be released upon request, unless extraordinary circumstances are shown, are merely a restatement of the current regulation. *The Committee intends that all terms in new section 505(l) be given the same meaning that they have in the regulation.* It is not the intent of the Committee to alter the rights of the public under the Freedom of Information Act. . . . Finally, except as provided in this section, the Committee does not intend to change other regulations regarding Freedom of Information Act requests, trade secrets, and confidentiality of IND, NDA and master file safety and effectiveness information and data.

H. Rep. No. 857, 98th Cong. 2nd Sess., part 1, at 35-36 (1984) (emphasis added and footnote omitted). Thus, it is clear from the committee report that Congress intended to adopt FDA's interpretation of its own regulations. That interpretation, as explained above, included FOIA exemption 4 within "extraordinary circumstances."

2. Pre-enactment floor statements

Pre-enactment floor statements made by each of the bill's sponsors confirm the view expressed in the committee report. Congressman Waxman stated that, "with the exception of subsection (1)(5) [dealing with the release of information following approval of abbreviated new drug applications], the provision in section 104 statutorily codifies the current FDA regulation pertaining to disclosure of this type of information." 130 Cong. Rec. H 9114 (daily ed. Sept. 6, 1984). Similarly, Senator Hatch stated that, "under current practice, which will be the practice under this bill, *extraordinary circumstances are present for example when the information is trade secret or confidential commercial or financial information.*" 130 Cong. Rec. S10912 (daily ed. August 10, 1984) (emphasis added). Senator DeConcini concurred that this was also his understanding. *Id.*

Senator Hatch reaffirmed this view on September 12, 1984, after reading into the record the letter from FDA Commissioner Young discussed above, in which Commissioner Young endorsed the view expressed by Senator Hatch on August 10, 1984. In this letter Commissioner Young also reiterated FDA's position that "extraordinary circumstances" included a showing of confidentiality under FOIA exemption 4. After reading this letter, Senator Hatch confirmed that it was his intent to ratify FDA's present interpretation of the extraordinary circumstances regulation. *See* 130 Cong. Rec. S10988-89 (daily ed. Sept. 12, 1984).

President Reagan signed the Hatch-Waxman Amendments into law on September 24, 1984. Significantly, at this point, *every* piece of legislative history, from the hearings to the floor statements to the committee report, indicated that Congress's intent was to codify current FDA regulatory policy. The only reasonable reading of "extraordinary circumstances" is as a codification of FDA's past practice, which was to equate the term with a showing of competitive injury or other impact that would bring the information within a FOIA exemption.