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Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Supplemental Comments of the Generic Pharmaceutical Association regarding Docket FDA-2013-N-0500: Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products.

The Generic Pharmaceutical Association ("GPhA") acknowledges and appreciates FDA’s efforts regarding Docket Number FDA-2013-N-0500, and re-opening of the comment period following the March 27, 2015, public meeting on labeling changes for approved drugs and biological products. We thank you for the opportunity to share our thoughts on this important public health issue, which are in addition to the comments GPhA submitted on March 13, 2014.

GPhA represents the manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. Our members manufacture more than 90% of all generic pharmaceuticals dispensed in the U.S., and their products fill more than three billion prescriptions every year. Generics represent greater than 86% of all prescriptions dispensed in the U.S., but only 27% of expenditures on prescription drugs. GPhA is the sole association representing America’s generic pharmaceutical sector in the U.S. While this letter represents the views of the association, the comments may not reflect the positions of all member companies.

Introduction

GPhA shares the goal of ensuring both the promotion and protection of public health Congress established for FDA. See 21 U.S.C. §393. The generic drug industry also shares FDA’s and the other stakeholders’ concerns regarding implementation and distribution of the most current data and safety information regarding approved drug products. Changes to pharmaceutical product labeling, however, not only must be prompt and accurate, in the case of generic drug products, it must be made to maintain uniformity, but also must be accurate. Specifically, and in keeping with longstanding FDA requirements, changes to product labeling should be effected only when “there is reasonable evidence of a causal association with a drug.” 21 C.F.R. §201.57(c)(6). A system that creates an environment encouraging or even allowing disparate, inconsistent, and
potentially inaccurate information from multiple manufacturers does not satisfy FDA’s goals of promoting and protecting the public health.

NDA and ANDA holders are active participants in the surveillance, receipt, and submission to FDA of pharmacovigilance data. They each currently submit adverse event data to FDA in 15-day, quarterly, and annual reports. Once a product(s) become multi-source, NDA and ANDA holders are unable to determine whether the information they possess truly is “new,” because no individual applicant holder has access to all the available data – the proprietary data from clinical studies conducted by NDA holders, and/or the data held and/or provided by each individual applicant holder. Unlike individual applicant holders, FDA possesses all the significant clinical trial data on a pharmaceutical product and all the adverse event and periodic reports from all manufacturers. In addition, FDA has enhanced its position as the primary repository of safety information for pharmaceutical products through creation of the Sentinel System (recently transitioned from the mini-Sentinel pilot program). The Sentinel System is FDA’s national electronic system that is utilized to track the safety of marketed drugs, biologics, and medical devices. Active surveillance by the Sentinel System allows FDA to identify an increased risk of common events that healthcare providers may not suspect are related to medical products. Therefore, public health can be protected more effectively by FDA using the Sentinel System and relying far less on the historical passive reporting processes. The historical approach is limited by both a lack of data precision and an inability to perform signal identification.

According to the FDA’s Sentinel program:

“The Food and Drug Administration has the responsibility of regulating medical products—overseeing the development, approval, and postmarket monitoring and surveillance of the drugs, biologics, and medical devices that the American public relies on to maintain and improve their health. FDA must also ensure that information about the performance of a medical product is available to both healthcare professionals and their patients so they can make fully informed choices and use these medical products as safely and effectively as possible.”

The Sentinel program in its current form is established for the use of FDA, not pharmaceutical manufacturers, as many have claimed. The data used by the program “will be accessed, maintained, and protected by the Sentinel System’s data partners, as part of a ‘distributed system.’ In a distributed system, data remain in their existing secure environments, rather than being consolidated into one database.” The structure allows FDA’s robust use of this important tool, in conjunction with others, to evaluate post marketing safety information. The Agency does not have possession of the data but can query with data holders as needed. Additionally, other members of the marketplace do not have easy access to any of the data for their company’s post marking pharmacovigilence.

FDA has long recognized that ANDA applicants do not have all necessary data from clinical trials as do NDA applicants. Nonetheless, FDA is proposing to blindly impose label changing requirements on multi-source applicants. “Newly acquired information” encompasses “data, analyses, or other information not previously submitted to the agency.” 21 C.F.R. §314.3(b). Accordingly, “newly acquired information” is the very type of information that requires careful consideration in light of all available data – especially clinical data. FDA’s proposal to use the CBE-0 process to implement the proposed rule by multi-source application holders that do not possess the most relevant data on which to analyze “newly acquired information” is both unrealistic and contrary to FDA’s statutorily-charged missions and goals, which mandate that safety comes first. The EAR process would replace the Changes Being Effected (CBE-0) process for safety-related labeling changes in 21 C.F.R. §314.70(c)(6)(iii). The EAR proposal also contemplates that FDA would issue a guidance document on the identification and submission of “new safety information” to define NDA and ANDA holders’ responsibilities in the process coincident with implementation of the EAR process.

**Expedited Agency Review (“EAR”) Process**

The Expedited Agency Review, an alternative proposal supported by GPhA and the Pharmaceutical Research and Manufacturers of America (PhRMA) – as well as numerous healthcare stakeholders – satisfies FDA’s objective to strengthen and expedite the labeling process and does so without the potential unintended safety consequences for patients, providers, taxpayers and payors. Under the EAR process, defined time parameters would be established for FDA to take action on a label change made (1) following FDA’s receipt and review of “new safety information” from either an NDA or an ANDA holder; or (2) following review of data received by FDA through the Sentinel System and/or other databases including global sources that are suggestive of a need for a label change.

An EAR can be triggered in either of two ways. First, NDA and ANDA holders, who submit expedited and periodic reports and who believe data they are submitting to FDA might constitute “new safety information,” can request an EAR. Second, FDA can determine that it is in possession of “new safety information” from all the resources available to it and begin an EAR on its own initiative. Once an NDA or ANDA holder requests an EAR or FDA determines on its own initiative that an EAR should be undertaken, FDA must make a decision on the appropriateness of a label change within 45-60 days (or sooner if FDA determines the circumstances warrant more expedited action). During that 45-60-day period, FDA engages the NDA and ANDA holder in discussions regarding the potential label change. Once FDA determines whether a label change is required, FDA immediately notifies the NDA and all ANDA holders of the decision. If the decision is to implement new labeling, NDA and ANDA

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3 “New safety information” has the definition provided in the Guidance for Industry: Safety Labeling Changes – Implementation of Section 505(o)(4) of the FD&C Act, dated July 2013.

4 As an expedited review, 45-60 days is a reasonable amount of time.
holders would be required to implement the change within 30 days (or sooner if FDA determines the circumstances warrant more expedited action).  

The EAR proposal is in accord with current agency practice as reflected in the various electronic mechanisms FDA has established over the past decade to promptly and accurately notify the public – both healthcare practitioners and consumers – of potential or known adverse effects of approved products.  

In addition, the EAR proposal is in accord with and compliments adoption of FDA’s proposed e-labeling technology to promote the availability of new information expeditiously and in real time. Paper labeling often results in a delay of months (or even a year or more) for the new product containing the revised labeling to appear on pharmacy shelves even for labeling changes implemented immediately upon approval by FDA. These are the factual dynamics of the commercial distribution channels. In short, the EAR reinforces the basic goals set forth in FDA’s e-labeling proposal by assuring that all application holders meet their responsibility of reporting safety-related information and making newly-evaluated safety information available to practitioners and the public as soon as possible. Furthermore, the combination of the EAR proposal and e-labeling will promote not only the goals of prompt dissemination of new labeling, but also assures that different labels will not exist in the marketplace at the same time. The public health benefit of e-labeling is clear as it will speed up the availability of accurate, real-time, and consistent labeling of marketed products for pharmacists, physicians, and patients.

The EAR Process Is Consistent With the Pathways Utilized by Regulatory Authorities Outside the United States

Regulators across the globe make key label changing decisions that impact patient safety in their jurisdictions. An analysis of the labeling processes in place in Canada, Australia, and the European Union reveals that all three jurisdictions share the requirement for a generic drug product to follow the lead of an innovator. When an innovator changes a label, generic versions are required to follow the changes initiated by the innovator. Other jurisdictions have pathways in place for generic application holder(s) to submit a recommendation, even if that recommendation is limited by available data. That recommendation is considered carefully, along with the data the regulatory body has compiled over the course of the application and post-marketing processes for all products. As is true of FDA, those regulatory bodies are the only entities with sufficient data to make a decision grounded in patient safety.

5 “New safety information” has the definition provided in the Guidance for Industry: Safety Labeling Changes – Implementation of Section 505(o)(4) of the FD&C Act, dated July 2013.
6 See FDA website, Safety, Subscribe to MedWatch Safety Alerts, available at http://www.fda.gov/Safety/MedWatch/ucm228488.htm (permitting subscriptions to the MedWatch E-lists to receive e-mail notifications titled “FDA Updates for Health Professionals,” “Consumer Education about Medicine,” “Recalls, Market Withdrawals and Safety Alerts,” and “Press Releases” to name a few; permitting the public to follow MedWatch via twitter; and to sign-up for MedWatch RSS feeds).
The EAR would provide a regulatory pathway for labeling changes proposed by generic applicants and would align with practices by other global regulators’ systems. It would establish a formal process through which generic applicants could initiate FDA regulatory review of “new safety information,” while maintaining the scientific integrity of labeling decisions and ensuring that such decisions are not made by persons who are not in possession of the most relevant data from clinical studies. The EAR also satisfies Congress’s mandate in the FDCA, as part of FDA’s statutory mission, to reduce regulatory burdens and harmonize regulatory requirements with those employed by foreign regulatory authorities. See 21 U.S.C. §393(b)(3).

Concerns Related to the Innovator’s Inability to Unilaterally Change Labeling Are Illusory and Focused on an Impermissible Goal of Creating Civil State-Law Liability

During the public hearing, there were questions and comments regarding the ability of the NDA holder under the EAR proposal to make immediate label changes. The apparent concern is that the NDA holder no longer would have the ability to implement a label change unilaterally to reflect newly acquired information. The concern is, at best, illusory. Under the EAR process, either FDA or the sponsors (either NDA or ANDA) can initiate an EAR. In either instance, if the new information, in FDA’s estimation, raises truly new safety concerns, electronic dissemination easily can be employed to circulate the information to a much wider audience than ever would be reached by the NDA holder using traditional paper-initiated changes. Indeed, such broader electronic dissemination of information already occurs when the NDA holder makes or proposes a label change of any significance.

It is apparent that FDA’s concern regarding an NDA holder’s inability to make an immediate label change under the EAR process is the same as the concern that instigated FDA’s proposed rule in the first instance – FDA is concerned about the potential erosion of state tort liability systems. Congress was explicit when it defined FDA’s mission. That definition does not include the creation, support, or enablement of civil state-law causes of action. Instead, Congress defined FDA’s mission as follows:

(b) The [FDA] shall—

(1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;

(2) with respect to such products, protect the public health by ensuring that—

(A) foods are safe, wholesome, sanitary, and properly labeled;
(B) human and veterinary drugs are safe and effective;
(C) there is reasonable assurance of the safety and effectiveness of devices intended for human use;
(D) cosmetics are safe and properly labeled; and
(E) public health and safety are protected from electronic product radiation;
(3) participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements; and

(4) as determined to be appropriate by the Secretary, carry out paragraphs (1) through (3) in consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.

21 U.S.C. §393(b). Notably, Congress’s definition of FDA’s mission endorses the EAR process which, like Congress’s mandate, calls for FDA to “promptly and efficiently review[,] clinical research and tak[e] appropriate action on the marketing of regulated products in a timely manner.” Id.

The Proposed Rule Would Increase Litigation Involving Generic Drug Companies

Numerous commentators have suggested that the proposed rule will not result in increased levels of litigation involving generic drug companies or cause significant economic burdens on those companies, for some, to the extent of forcing them from the marketplace. In fact, some commentators claim that even in light of the litigation that pre-existed *Mensing*, generic drug companies continued to thrive. In support, the commentators cite to the growth of generic drug sales in the country.

First, citing the generic drug growth rate as an indicator that the industry continued to thrive even with litigation pending against it is misleading at best. The fact that generic drugs now account for 86% of the prescriptions filled does not equate to a conclusion of any kind about the amount of profit earned on sales of generic drugs. Generic drugs sales represent only a fraction of prescription drug spending in the U.S and the margins for many generic drugs are very small.

Second, the onset of mass litigation involving generic drugs is a fairly recent phenomenon. It must be noted that Hatch-Waxman was enacted in 1984 and FDA did not finalize its regulations implementing the Act until 1992.7 Prior to that time, there were very few ‘generic’ drugs on the market.

One of the earliest mass litigations involving a generic drug was the fenfluramine/phentermine (fen/phen) litigation, which began in the mid- to late-1990s. The litigation alleged personal injuries from the combination use of fenfluramine (including Pondimin, approved in 1973; and Redux, approved in 1996) and phentermine (approved in 1959). At FDA’s request, both Pondomin and Redux were withdrawn from the market in 1997. See Rheingold, Paul D., *Litigating Mass Tort Cases*, Volume 1, Washington, D.C.; ATLA Press, and St. Paul, Minn.:
Thomson/West, 2006, supp. 15-4; Studdert, David M., et al., “Medical Monitoring for Pharmaceutical Injuries: Tort Law for the Public’s Health?” *Journal of the American Medical Association*, Vol. 289, No. 7, Feb. 19, 2003, pp. 889-94. The lawsuits alleged failure-to-warn claims involving predominantly two injuries – valvular heart disease and primary pulmonary hypertension. Eventually, the litigation involved tens of thousands of lawsuits in federal and state courts. The vast majority of the lawsuits were filed against the companies that manufactured and distributed the brand-name fenfluramine drugs. Although the manufacturers of generic phenetermine also were named as defendants in the lawsuits, over the course of the litigation it was established that phentermine was not associated with the alleged injuries and tens of thousands of lawsuits against the generic drug company defendants were dismissed without indemnity payments – but, not before vast amounts were expended in litigation costs. Notably, it was learned after the brand-name company spent billions of dollars settling the numerous fen/phen lawsuits that substantial numbers of the claims were brought on behalf of plaintiffs who suffered no injuries relevant to the litigation or for whom the severity of the injury was substantially exaggerated.8

Following the fen-phen litigation, litigation involving phenylpropanolamine emerged. Generic drug companies were involved in that litigation to only a limited extent. However, by the early 2000s, as the generic industry began to grow, so too did the plaintiffs’ bar’s sophistication and coordination of mass litigation mature. Generic drug companies became larger targets for the plaintiffs’ bar as evidenced by the thousands of lawsuits filed involving hormone replacement therapy (HRT) products, which again was based on the combination use of two products – progestin and estrogen. Following closely behind the HRT lawsuits, came lawsuits aimed at Reglan and its generic equivalent metoclopramide; Accutane and its generic equivalent isotretinoin; Fosamax and its generic equivalent alendronate; Yaz and Yasmin and their generic equivalents drospirenone and ethinyl estradiol; and Darvon and Darvocet and their generic equivalent products containing propoxyphene. In total, there were many thousands of cases.9

All those cases were filed and pending in courts nationwide during the time Mensing wound its way through the courts to finally reach and be decided by the United States Supreme Court.

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9 Of course, the filing of those thousands and thousands of lawsuits severely impacts the usefulness and integrity of FDA’s adverse event report database as each lawsuit is reported to FDA by each company named in the lawsuit, if not also by attorneys as documented in a recent article. In “Alleged Isotretinoin-Associated Inflammatory Bowel Disease: Disproportionate reporting by attorneys to the Food and Drug Administration Adverse Event Reporting System,” by D.J. Stobaugh, et al., published May 16, 2013, in the *Journal of the American Academy of Dermatology*, the authors analyzed 3.3 million(+) cases filed in the FAERS database between 2003-2011 using the query “for IBD cases reported with Isotretinoin for a usage indication of acne.” The authors found that [t]here were 2,214 cases of IBD resulting from Isotretinoin. Attorneys reported 1,944 (87.8%) cases, whereas physicians reported 132 (6.0%), and consumers reported 112 (5.1%) cases (P value <.01). For the entire FAERS, only 87,905 of the total 2,451,314 cases (3.6%) reports for all drug reactions during the same time period were reported by attorneys (P value .01). The signal inflation factor for IBD with Isotretinoin for attorney-initiated reports was 5.82 signifying a clear distortion.
As the early focus in most of those litigations was the brand-name drug product, very few lawsuits involving generic drugs either were settled or reached trial, although they did cause industry to spend exorbitant amounts in litigation costs. In short, the threat litigation posed to the generic drug industry was growing at the time the Supreme Court decided Mensing and eventually may well have had a devastating impact on the industry but for Mensing.

FDA’s proposed rule threatens to place the litigation against generic drug companies that never reached its apex back into the courtroom. The threat of litigation is not exaggerated, nor is its cost. While prior to Mensing, the generic drug industry was burdened with the costs of defending the lawsuits, those costs seldom included the “transfer costs” of indemnity payments to the plaintiffs. Instead, the costs were “social costs” – extra costs that would not, and do not, exist except in the presence of product liability claims. Revitalizing lawsuits against generic drug companies will result not only in saddling the companies with future litigation costs in defending lawsuits, but also will add the additional social costs associated with settlements or verdicts for alleged non-economic injuries.

The potential for increased litigation posed by FDA’s proposed rule is not illusory. Indeed, the scope and breadth of the litigation will be exponentially expanded through FDA’s proposed rule. As GPhA explained in its March 2015 comments, the proposed rule will encourage companies to change labeling aggressively and to publish that labeling quickly in an effort to insulate themselves from lawsuits. The result likely will be that different companies will add different adverse events to labeling at different times creating a landscape in which plaintiffs can, and will, pit the varying labels against each other as alleged inadequacies based on the other. All the while, FDA will be faced with varying labels accompanied by varying purported “newly acquired information” to support the changes and will be tasked with sorting through “information” to determine what, if any, change should be approved. Meanwhile, the marketplace will be left to puzzle which of the competing labels to rely upon in making healthcare decisions. In the process, FDA’s recent goal of reducing the number of listed adverse events on drug labeling will take a major step backward.

**There Are No Statistics to Support the Representations that Brand-Name Companies Exit the Market Following Introduction of Generic Versions**

Several commentators contend that the withdrawal of the innovator product from the market following introduction of generic versions supports the proposed rule because withdrawal of the innovator leaves no one responsible to monitor postmarketing safety information. Those contentions are based on fiction and unsupported by any statistical information. In fact, generic companies are required to review, evaluate and submit postmarketing safety information. Additionally, considering the litigations discussed above that involved generic versions of the drugs, and where the NDA products have been the subject of considerable litigation, demonstrates there is no merit to the contention. Aside from the fenfluramine products (Pondimin and Redux) and the propoxyphene products (Darvon and Darvocet), which FDA requested the brand-name manufacturer to withdraw from the market, only Accutane (the brand-
name version of isotretinoin) has been withdrawn from the market. Reglan (metoclopramide), Premarin and Preempro (HRT), Fosamax (alendronate), and Yaz and Yasmin (drospirenone and ethinyl estradiol) all remain on the market today. Notably, Accutane was withdrawn from the market and the sponsor asked FDA to withdraw the NDA because of the unceasing litigation aimed at the company over use of the product and not because of any safety or efficacy concerns. (See “Determination that ACCUTANE (Isotretinoin) Capsules, 10 Milligrams, 20 Milligrams, and 40 Milligrams, Were Not Withdrawn from Sale for Reasons of Safety and Effectiveness, 75 Fed. Reg. 39024 (July 7, 2010).) That litigation, which has been pending for approximately ten years and has involved thousands of cases, was held to be without merit. (See In re: Accutane Litigation, Civil Action No. 271 (MCL), Superior Court of New Jersey, Law Division: Atlantic County, April 2, 2015 (finding Accutane’s label post-2002 adequate as a matter of law).) There are no statistics to support the proposition that the innovator products are withdrawn from the market following generic entry and the commentators who have cited this reason have provided none.

**FDA Always Has Taken Responsibility for Product Labeling When the NDA Product Leaves the Market**

Another concern related to the withdrawal of the innovator product from the market voiced by commentators is the responsibility for labeling after withdrawal. As an initial matter, although many commentators speak in terms of “withdrawal of the NDA product,” others refer to “withdrawal of the RLD.” Commentators referring to the latter are confusing the distinction between the NDA product and the product designated as the reference listed drug (“RLD”). As FDA is aware, although the NDA and RLD often are one and the same, that is not always the case. “RLD” (or listed drug) is a moniker developed to refer to the drugs FDA was charged with listing in a publication to identify drugs approved for safety and effectiveness. That publication, the Orange Book, identifies drug products and their eligibility for generic versions. A generic version must be the “same as” the RLD/listed drug. See 21 U.S.C. §355(j). After Hatch-Waxman was enacted, FDA explained how the drugs that would be the RLD for existing approved drugs would be designated. (See 57 Fed. Reg. 17958 (“FDA will designate all reference listed drugs. Generally, the reference listed drug will be the NDA drug product for a single source drug product. For multiple source NDA drug products or multiple source drug products without an NDA, the reference listed drug generally will be the market leader as determined by FDA on the basis of commercial data.”) For products approved after that time, the NDA product routinely is the RLD for generic versions. If the NDA product is withdrawn from the market, FDA will designate another product as the RLD for purposes of new ANDAs. In addition, FDA is charged with evaluating whether the product was removed from the market for safety or efficacy reasons. See 21 C.F.R. §314.161.

Since the passage of Hatch Waxman, when an innovator has withdrawn from the market, FDA has worked with generic companies and in some cases has taken responsibility for the labeling of the generic equivalents on the market and has advised industry that it would apprise them of any need for a change in labeling. The product designated as the RLD after removal of the innovator
does not step into the innovator’s shoes and subsequently become responsible for initiating label changes. FDA’s notice on the withdrawal of Accutane provides an example. In the notice, FDA found that Accutane was not removed for safety or effectiveness reasons and, therefore, would not initiate procedures to withdraw approval of ANDAs that refer to Accutane. (See 75 Fed. Reg. 39025.) FDA also advised additional ANDAs for isotretinoin may be approved if relevant legal and regulatory requirements were satisfied and that “[i]f FDA determines that labeling for isotretinoin capsules should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.” (Id.; see also, e.g., 73 Fed. Reg. 11121-01 (finding Minocin was not withdrawn for safety or effectiveness reasons and stating “[i]f FDA determines that labeling for this product should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.”) In short, concerns related to withdrawal of the NDA product have no merit whatsoever. FDA routinely has accepted responsibility for labeling changes when NDA products have been withdrawn from the market.

The Differences That Naturally Occur Between Brand-Name Drug Labels and Generic Drug Labels Following an Approved Change to the Brand-Name Drug’s Labeling Is Not Comparable to the Differences that Will Result from FDA’s Proposed Rule

Commentators have been critical of the concern raised by GPhA, industry members, and other stakeholders regarding the differences in product labeling that FDA’s proposed rule will engender. Those commentators claim the situation will be no different than what currently exists following an approved change to the brand-name drug’s label. That simply is not so.

Under the current regulations, there inevitably is some lag time between approval of a change to the innovator labeling and the adoption of the approved change by the generic drug companies. However, under the current system, confusion does not arise in the marketplace for at least three very important reasons. First, healthcare practitioners know the label that will include the most up-to-date information is the label for the innovator product. Second, when an important change is approved for an innovator product, the change is widely publicized by FDA and the product manufacturer. Third, the reality is that physicians and many other healthcare providers rarely, if ever, review a label for a generic drug product.

In contrast, under FDA’s proposed rule, healthcare practitioners will have to sort through the various proposed product labels without any clear understanding of the changes or reason for them. In addition, the proposed rule contemplates placing all changed product labels on an electronic site pending FDA review and approval. It is unlikely any public announcement regarding any proposed change would be made until FDA reviewed the data and made its determination as to whether a change should be approved, which of perhaps several competing proposed changes should be made (if any), whether a completely different change from any proposed should be approved, or whether no change should be made at all. Meanwhile, all the versions will be in circulation both in electronic and paper form. That scenario is a far cry from the one that exists with the current system and the inevitable time lag that occurs between approval of an innovator’s change and the adoption by the generics. The confusion that will
result not only will cast doubt on the general equivalency and safety of generic drugs, but also may prompt healthcare providers to steer away from a particular drug where there is labeling confusion or an unwarranted warning of a risk and employ an alternative therapy to preclude a future malpractice claim, even if the drug product is the superior choice.

In fact, a random survey conducted by GPhA and the National Coalition on Healthcare of 300 healthcare providers and 150 pharmacists regarding the proposed rule revealed an overall negative assessment of the proposed rule. Of those surveyed, 81% believe that label changes should go through the FDA, and 90% believe access to safety data should be required prior to changing generic product safety labels. In addition, 76% were concerned that using different labels for the same drug would be confusing to patients, and 60% say the proposed rule would have at least “some” impact on their willingness to prescribe generic drugs in the future.10

Conclusion

GPhA appreciates the opportunity to continue our dialogue on the FDA proposed rule on labeling. It is important that any final rule ensures patient and practitioner access to consistent, science-based information to best inform treatment decisions. Patient safety is both the Agency’s mission and expertise. The proposed rule’s intent to address liability is the sole purview of Congress and exceeds the Agency’s authority.

Respectfully submitted,

Ralph G. Neas
President and CEO

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