



Generic Pharmaceutical Association

1620 I Street, NW • Suite 800 • Washington, DC 20006
202-833-9070 • Fax: 202-833-9612 • Email: info@gphaonline.org

7357 00 SEP 19 19 26

**Prescription Drug User Fee Act (PDUFA)
FDA and Stakeholders Public Meeting
September 15, 2000**

Panel IV – Presentations by Industry Groups

Good afternoon. My name is Chris Pelloni and I am Vice President for Generic Research and Development at TevaUSA. I am also co-chair of the Science Committee of the Generic Pharmaceutical Association (GPhA) which was recently formed from the unification of the Generic Pharmaceutical Industry Association and the National Pharmaceutical Alliance. GPhA members provide the products with which ninety percent of all generic prescriptions (new and refills) are filled. On behalf of GPhA, I want to thank the FDA for the opportunity to participate on this panel and to provide a generic industry perspective on the collection of user fees to fund FDA review activities.

As a “non-participant” in the current user fee program, the generic industry is not qualified to comment on the details of the PDUFA program as outlined in the questions which the Agency has posed. However, I would like to provide GPhA’s perspective on the impact of the program on non-PDUFA funded activities, specifically the review and approval of generic drug applications. I will then briefly address the position of GPhA members on the very controversial subject of generic user fees.

Although little, if any, hard data is available to us, certain information (anecdotal and otherwise) indicates that resources are sometimes allocated, or re-allocated, within CDER to facilitate achievement of PDUFA goals at the expense of non-PDUFA activities, such as the review of ANDAs and related supplements. For example, in 1993, when the PDUFA program went into effect, a total of 448 FTEs were allocated to the generic drug program; in 2000 that number had dropped by 16% to 372 FTEs. During this same time period, however, *appropriated* (non-PDUFA) dollars for salaries and expenses *increased* by 39%. Where did this increase in appropriated S & E funds go? Might it be that these funds were disproportionately allocated to the new drug program to supplement PDUFA dollars at the expense of non-PDUFA activities such as the generic drug program? Did PDUFA funds fully cover the close to 50% *increase* in FTEs for new drugs that occurred between 1993 and 2000? There have been reports of pre-approval inspections for NDAs receiving priority over those for ANDAs when both types of applications compete for resources. There has been concern that even those funds appropriated by Congress specifically for the Office of Generic Drugs are being diverted to some extent as a consequence of PDUFA demands.

Often we in the generic industry are told that the answer to all our problems is “user fees”. It is sometimes tempting to naively start down this path when we are frustrated with delays in review and approval far beyond statutory mandate, when we take a backseat to PDUFA funded activities, or when we see funds diverted because of PDUFA demands on the regulatory system. Review times, in fact, are significantly longer, on average, for ANDAs than for NDAs.

00N-1364

137

However, the benefits of user fees for the generic industry are not as clear cut as they may be for the brand industry. The success of the user fee program for the brand industry cannot *a priori* be extrapolated to the generic industry.

Why not? While the focus of user fees is on the reduction of review/approval times for product applications, "reduction in review/approval time" is simply a surrogate for the desired endpoint, "reduction in time to market." In the case of new drugs, the surrogate marker closely approximates the desired endpoint. This is often not so for generic drugs. For generic drugs, application review, or even approval, is not necessarily the rate-limiting step for getting to market. Hatch-Waxman provisions for paragraph IV certification and related 30-month stay, for 180-day exclusivity, for patent extensions, for exclusivities, etc. are more often the determinants of time to market. Achieving the statutory-mandated time (six months) for approval is not a sufficient outcome for generics. Can user fees address the non-review delays in time to approval and launch? Can we expect that user fees will preclude delays caused by citizen petitions, last minute patent extensions, eleventh-hour pediatric exclusivities, and the never-ending listing of new patents? What is the value of a 6-month review if launch is routinely delayed another 2 or 3 years because of other factors? What has the sponsor bought with his fee? Brand products, by definition, reap the benefits of a monopoly when they enter the market. For generics, what is a meaningful fee vs expected margin when 10 or 12 ANDAs for the same product are approved at the same time? Clearly, "user fees" for generic drugs is a very complex issue. An in-depth analysis of the entire review, approval and launch processes, and their related statutory, regulatory, and legal constraints, would be required before any attempt is made to develop a meaningful proposal, if indeed a user fee program which will achieve the desired outcome (timely access for consumers to affordable generic drug products) is feasible.

Any drug user fee program, whether for the brand industry or the generic industry, should have clear, measurable, goals and objectives, directly related to the review, approval, and launch of a drug product, only. User-fee funded activities should be the exception, not the rule. The allocation within the Agency of appropriated funds, as well as user fees, should be fully transparent to all stakeholders and the continuation of user fee programs contingent on the appropriateness of this allocation.