Bulletin of
Health Policy and Law

FDA Generic Drug User Fee Proposal Aims to Enhance Safety, Access, and Transparency in the Generic Drug Market

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Abstract: *The FDA has established three goals in establishing the Generic Drug User Fee Act: (1) improve safety through consistent, high quality standards; (2) enhance access to low-cost generic drugs by expediting the review process and making the drugs available in the market faster; and (3) increase transparency by identifying facilities involved in the manufacture of generic drugs.*

Keywords: FDA, generic drugs, user fees

Introduction

In mid-January the Food & Drug Administration (FDA) sent proposals to Congress for a new Generic Drug User Fee Act (GDUFA) based on agreements reached between the FDA and the generic drugs industry last year.[1] Under the GDUFA, the FDA will collect $299 million in new fees from pharmaceutical companies to help expedite the review process for generic drugs.[2]

Issue: Costs and Benefits

Under the agreements between the FDA and the generic drug industry, 30% of the new $299 million in fees will come from application fees while the remaining 70% will be collected through facility fees from manufacturers. In exchange, the FDA will aim to review 90% of generic drug applications within 10 months.[3] The FDA has outlined three primary goals of the GDUFA: safety, access and transparency.[4] While these goals are all meant to improve the generic drug market, the GDUFA, as currently written, has sparked general concerns about its effect on the cost of generic drugs for consumers and the cost of competing in the drug market for manufacturers.[5]

The first of GDUFA's three primary goals is to ensure safety by holding the industry to consistent high quality standards.[6] With user fees supplementing funding from Congress, the FDA will have additional financial resources to conduct more inspections and safeguard the quality of the generic drugs.[7] The FDA wants foreign and domestic parity central to its safety goal, meaning that they will "aim to conduct foreign and domestic inspections at an equal frequency" and in a comparable manner.[8] The FDA plans to inspect manufacturing plants every other year.[9] Overall, the GDUFA is expected to increase the number of facility inspections.[10]

The FDA's next primary goal is to enhance access to low-cost, high-quality generic drugs by expediting the review process and making the drugs available in the market in a timelier manner.[11] The GDUFA would help the FDA clear its backlog of over 2,000 applications.[12] Faster review times would enhance access to generic drugs without increasing generic drug prices.[13] The FDA asserts that user fees may eventually lower the cost of generic drugs by reducing development times and making the review process more manageable for drug manufacturers.[14]

Finally, the GDUFA is expected to increase transparency by identifying the manufacturing facilities for generic drugs and API's.[15] This goal is manifested largely in the facility fees that will comprise 70% of the user fee funding.[16] Several concerns have arisen regarding the facility fees, including the effect that it will have on API's and contractual manufacturing organizations (CMO's) that work with generic drug makers.[17] Specifically, it is unclear whether the API's and CMO's will absorb the fees or pass them to the generic drug makers.[18] Additional concerns have been raised regarding the effect of the facility fees on overseas manufacturers; facility fees for manufacturers outside the U.S. will be between

$15,000 and $30,000 more than a U.S. based facility.[19] Some question whether "CMOs in highly regulated regions, such as Europe, should be forced to pay for countries with poorer quality standards."[20] Despite these concerns, many recognize that earlier entry into the market will compensate for the increased business costs.[21]

Conclusion

Although there are concerns about the proposed GDUFA, the FDA's goals are clear: safety, access and transparency. While the FDA and the generic drug industry were able to reach a fundamental agreement, it is now up to Congress to approve the proposals and changes to the GDUFA as currently written.

Competing Interests: None reported
Acknowledgments: None reported

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References (Bluebook)

[1] Karen Finn, *US Generic Drug User Fee Proposals Mean More Facilities Inspections*, Securing Pharma (Jan. 24, 2012), http://www.securingpharma.com/us-generic-drug-user-fee-proposals-mean-more-facilities-inspections/s40/a1172/.
[2] *FDA Unveils User Fee Program for Generic Drugs,* USA Today, Jan. 15, 2012, http://yourlife.usatoday.com/health/healthcare/story/2012-01-13/FDA-unveils-user-fee-program-for-generic-drugs/52538458/1.
[3] Kurt R. Karst, *FDA Proposes Generic Drug User Fee System and Performance Goals*, FDA Law Blog (Dec. 7, 2011), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2011/12/fda-proposes-generic-drug-user-fee-system-and-performance-goals.html.
[4] *Id.*
[5] Robert Kennedy, *GDUFA: Who Will Benefit?*, CHEManager (Jan. 13, 2012), http://www.chemanager-online.com/en/topics/pharma-biotech-processing/gdufa-who-will-benefit.
[6] Karst, *supra* note 4.
[7] Silverman, *supra* note 3.
[8] *Id.*
[9] *Id.*
[10] Karst, *supra* note 4.
[11] *Id.*
[12] David Belian, *GPhA: Generic Drug User Fee Act will Increase Accessibility of Generic Drugs; Urges Broad Congressional Support,* GPhA (Dec. 7, 2011), http://www.gphaonline.org/media/press-releases/2011/gpha-generic-drug-user-fee-act-will-increase-accessibility-generic-drugs-u.
[13] *Id.*
[14] Karst, *supra* note 4.
[15] Silverman, *supra* note 3.
[16] Gil Roth, *GDUFA and CMOs: Will a New User Fee Affect CMOs and API suppliers?,* Contract Pharma (Jan. 23, 2012), http://www.contractpharma.com/issues/2012-01/view_features/gdufa-and-cmos/.
[17] *Id.*
[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] *Id.*

e-ISSN: 2168-6513