

In NAMI's view, PDUFA IV should help FDA progress toward being an agency that:
Engages in effective pre-market review of products,
Fosters expedited drug development,
Moves toward rapid progress for fully automated drug reviews,

NATIONAL ALLIANCE ON MENTAL ILLNESS

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□ Invests in full funding and staffing of the Critical Path Initiative (this agreement is a first step toward that goal), and
Brings about a transformed post-market drug safety system at the agency.

It is on this final goal that NAMI believes PDUFA IV makes important progress. It is clear that additional resources are needed to address the increasing volume of adverse event reports. In NAMI's view, the FDA simply cannot keep pace with this increase in volume by relying solely on an expectation that Congress increase appropriated funds over the short term. Clearly, additional resources beyond appropriated funds are in order for the agency to engage in effective post-market safety beyond the current limited 3-year window. PDUFA IV moves us toward making sure that the agency has the resources to engage in this important safety review activities.

As the FDA moves forward to enhance post-market safety review, NAMI urges that the agency, and members of Congress that fund and oversee the agency, not lose sight of what is the greatest risk for people living with severe mental illness and their families, not being able to access available treatments. NAMI strongly supports individuals living with mental illness being able to access the full array of available treatment options. They should be able to work with their physician to weigh efficacy, side effects, patient and family history and other factors to make an individualized treatment decision. NAMI's hope is that PDUFA IV will move toward an environment in which those treatment options are broadened.

In commenting on this PDUFA IV agreement, NAMI would make the following observations:

There is widespread agreement that the FDA has been hampered by a lack of resources, both in terms of financial resources and human capital. PDUFA IV is a significant step forward in terms of drug development, drug safety and information technology. NAMI also feels strongly that Congress must also step forward with additional appropriations for the agency.

Since the early 1990s, PDUFA has succeeded in expanding the drug review process, what was once a 3-4 year process has been reduced to less than a year in many instances.

People living with mental illness and their families - like other patients who live with significant chronic illness - understand that there are risks associated with any prescription medication. What patients and their families want most is to have a variety of treatment options and clear understanding of the risks and benefits of each treatment option and to make an informed decision in consultation with their doctor. PDUFA can, and should, help expand and illuminate these important treatment decisions.

Finally, NAMI would like to go on record with concerns about the process for enactment of legislation in Congress that is needed to make this agreement a reality. NAMI recognizes that this process of passing legislation is beyond the control of the agency. Nonetheless, it is important to go on the record with a clear statement that the Commissioner should work hard with Congress to ensure that the reauthorization process not be delayed. Such delays have enormous potential to derail drug reviews, hurt agency morale and in the long run, limit access to new medications. NAMI urges the FDA and Congress to move the reauthorization process forward expeditiously.

Thank you for your attention in this important matter.

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- 0 / ÉVw²0^0"xL0 . Fŕŕ 0~ñS
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2007N-0005-EC16-Attach-1.txt

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 æIòf>çßùÄIÍß/èvé<gÈ-Ö-è[]Aqþ¿YfE B-ÜgÈOüÄmfíproó[þpÈÉUáé-ùwþq.òòìi[]ò[]mÄfžMh\5½±òð-‘[]
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 }[]|š@÷Íkù68;ò±·ç,,H!<H²X,, æ@æys½:ä“!þ|üÄò_ã-µ[]8yüi->vòæ.[]Ky@ßÈ±
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 ·ç*ü’ä ÈßéÈE¥ycÈv1iüE[]<ž!NÑçv5fc¹\$æã-òó’[]Nó[]ç[]È[]‘žH³>ò¾±×Xìù%æ] (,°w-À_ò[[]è[]xýbá°%
 %[]ò[]m3ç_òòì¼y 80iüujIüßi°0Yé6
 ”ÜH-wóš»[]äš ežžðf[]F@ù+y 90ý 8yüüäK8oð?+þRA[]æÄ[]È[]~þ>ù@ã s[]°æa...Ià3ížlØÆ’4ÜN«ó
 a°iš¼-|~]GÍš[][]_È.o ^«x[]n(r[]-þwþMüzþK-kówEzt1
 »K-Y,6’i%Iè[]láuxçßüáþ,±mīç -ã[]Æ0 µ3Üš/cédòCÜNç[]qíwþ~³y
 8<dòA|y[]\ó[]ò[]_[]ßMñiæÈ ?¼æ² e”!Üx![]IYÍZ<éy ”ßóšß”ß èi[]m{[]>ÜAI`µ[]°*
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 |usÈ02ßj[]±°~F*±æ []žFç^÷’>4þEý ÍZy
 ÍM~n[]Ie~Rèþf³¿ò?ä±ç°™\~_ü°äç[]Æ’dž<{}@«Je@y°[]Äü9÷;6lýðüù,,>jó[][òç~òg[]%][K»³häVðáxèPÜ
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 ó<[]U÷ä[]\$|[]I[]K~YyÖPç[[]HÓNj-¶¼a4ðFóYVãFX~<OÆ[]ð[]N’ò|üøy YþyÄæ-[]È¿0%:¿áíiìt>gó>¹
 Ä>PÖY ‘KÞÈ Yl[]ç[]I[]yIóKíüßpscóiy 9&°è_-Ü°ÈšùrÈð0³
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