

Deadlines

Stephen B Hanauer

I'm sure our journal Editor doesn't hate me (yet), but I suspect that over 90% of all my editorials over the past years as Editor-in-Chief of *Nature Clinical Practice Gastroenterology & Hepatology* have arrived within a day or two before (or after) the agreed deadline. To this end I have asked to be given an artificial deadline that's several weeks in advance of the real deadline, so as to not drive her totally insane—those of us who do a substantial amount of academic writing or grant submissions know there are flexible 'deadlines' and there are 'drop-deadlines'!

The only person I know in the field of academic medicine who absolutely respected deadlines is my mentor, Joseph Kirsner, MD. Indeed, he was well-known to drive authors (or at least their administrative assistants) nearly to tears by expecting their submissions for inclusion in his authoritative texts well in advance of the proposed deadline.

I recall from my college psychology classes that an individual's performance on a task is related to their stress level by a bell-shaped curve. We perform best in the middle of the curve when there is modest stress, and less well at extremes of low or high stress. One would anticipate that the same applies to deadlines. For in advance of deadlines there may be too little incentive (stress) for optimal performance and, conversely, as the deadline looms negative consequences accumulate to the point of hurried performance and an increased potential for editorial errors.

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SB Hanauer is Editor-in-Chief of Nature Clinical Practice Gastroenterology & Hepatology.

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The same relationship has now been demonstrated for US FDA reviews of new drug applications. The Prescription Drug User Fee Act (PDUFA) was introduced in 1992, and imposed deadlines for these reviews. Carpenter and colleagues assessed the association between PDUFA deadlines and the timing of FDA drug approval to determine whether drugs approved immediately before deadlines had more postmarketing safety problems than drugs approved at other times (*N Engl J Med* [2008] 358: 1354–1361). They found that drugs approved less than 2 months before their PDUFA deadline were more than five times more likely to be withdrawn for safety reasons. These drugs were also four times more likely to carry a subsequent black-box warning, and three times more likely to have one or more dosage forms voluntarily discontinued by the manufacturer. The authors noted that "...it appears to be the deadline, not the speed of approval, that explains the difference in the risk of such problems." Hence, the bell-shaped curve that relates performance to stress levels seems to apply to organizations as well as individuals.

As my current deadline for this editorial has come and gone, I am hopeful that my performance has not been too compromised by the hurried attention to detail [sic] and that my editorial colleagues will have sufficient time to address any omissions.