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FDA Challenges: Reputation and Results

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The news earlier this year that the FDA had approved aducanumab (Aduhelm™) for the treatment of Alzheimer's Disease in conflict with its own Advisory Committee recommendation raised a considerable furore in industry and political circles, leading to a Congressional investigation and then a partial roll-back of the label to a more restricted population just four weeks after the initial approval.

Similarly, the delayed approval of new or extended labelling in psoriatic arthritis, atopic dermatitis and ankylosing spondylitis indications for several members of the important immunomodulatory JAK inhibitors class – upadacitinib (Rinvoq™), tofacitinib (Xeljanz™), baricitinib (Olumiant™) and the new abrocitinib – while the Agency ponders a more aggressive labelling approach in recognition of increased concerns about cardiovascular safety, is causing concern about the effectiveness of the review system.

However, while the concerns of drug developers and industry watchers may be heartfelt and legitimate, to what extent do decisions like this affect the sharp end of health care? Do clinicians care or even notice such matters? Do they affect patients?

Some indication of clinician views has emerged from an extensive survey of 252 specialists most obviously impacted by these recent issues, across nephrology, neurology, dermatology, rheumatology and gastroenterology. Overall, the key concerns related to the unpredictability and lack of transparency of FDA actions in recent times, and the survey revealed that confidence in the FDA within the group has fallen over the past year for between 32% and 84% of respondents – with neurologists heading that figure on the back of the aducanumab decision.

The net result of this is that more clinicians are considering ignoring FDA recommendations and 'going it alone' to make up their own minds on the data – even though this will inevitably delay uptake of new treatments in areas of considerable unmet need, to the detriment of patient care.

While all can sympathise with the challenges the FDA faces – not least, the likely impact of the COVID-19 pandemic over the last 18 months on their operational capabilities – it is clearly

essential that it rebuilds/retains the confidence of the clinical community, otherwise the whole basis for the regulation of the development, approval and sale of pharmaceuticals will be undermined.

Further reading:

1. Aducanumab: Breaking through, or moving the goalposts…? https://www.transcrip-partners.com/news/aducanumab-breaking-through-or-moving-goalposts
2. Series of delayed FDA reviews signals latest trouble for JAK inhibitors in the autoimmune space https://www.pharmaceutical-technology.com/comment/delayed-fda-reviews-jak-inhibitors/
3. 'Erratic' FDA and inconsistent drug decisions put doctors off new meds: survey https://www.fiercepharma.com/marketing/erratic-fda-and-inconsistent-drug-decisions-confound-specialty-physicians-changing?mkt_tok=Mjk0LU1RRi0wNTYAAAF-sFfbWya0ArnlFLXGLX88_9Lg2Pq7t_WP0QnVIaQNk_dhP9hGY_Y8oo7Rx3dcuGgyqm0wJgn_sZwvWXQaT27E0XK9D0iMKQ-eOxsgLkyk4IcBXhuoncA&mrkid=135527860