Health Law Daily Wrap Up, PHARMACEUTICAL NEWS—Is FDA expedited review encouraging less-innovative drugs?, (Sep. 25, 2015)

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The increasing reliance on expedited development and review procedures by the FDA are being driven less by drugs that provide "noticeable clinical advances," and more by drugs that are not first in class and are less innovative, according to a study published in the BMJ. This conclusion was drawn based on an analysis of FDA approval of drugs in the last two decades, which focused specifically on drugs that were subject to "special expedited development and review pathways" made available by the FDA.

**Expedited reviews.** The notion of expedited processes to obtain FDA approval of a certain drug product grew out of the desire to minimize delay of widespread access to drugs that treat rare and serious or life-threatening diseases. According to the BMJ, four programs for expedited review were created in response to this issue:

1. the Orphan Drug Act (P.L. 97-414), which establishes tax breaks and market exclusivity periods for drugs that treat conditions that are considered too rare for large randomized clinical trials;
2. fast track designation, which allows for approval of drugs after an abbreviated clinical trial phase for products that treat life-threatening or severely debilitating diseases;
3. the accelerated approval pathway which allows drugs treating life-threatening or severely debilitating conditions “to be approved on the basis of surrogate endpoints reasonably likely to predict patient benefits;” and
4. priority review designation, or guaranteed review for new drug applications within six months, for drugs that appeared to offer “a therapeutic advance over available therapy.”

In general, these pathways and designations were to be offered on a limited basis and were to be reserved for those products that seemed to offer “the greatest promise of therapeutic advance to patients with no other reasonable therapeutic choices.”

**Study.** The study was focused on “approved novel therapeutics” between the years 1987 and 2014. In that time period, the BMJ found that 774 total drugs were approved. In terms of type of expedited review, priority review was the most popular path of expedited approval while accelerated approval was the least popular. The BMJ observed that there was a 2.6 percent increase in “the number of expedited review and approval programs granted to each newly approved agent… and a 2.4 [percent] in the proportion of drugs associated with at least one such program.”

**Conclusion and policy implications.** According to the BMJ, the results dictated that the increase in the use of expedited pathways was not simply the result of the increase in the number of innovative drugs over the studied period of time. Instead, the findings indicated that the expedited processes are increasing being driven by fewer first-in-class drugs, and other less-innovative drugs The BMJ noted that rather than recognize the danger associated with this trend, Congress is continuing to allow for additional expedited review and approval pathways. In fact, the 21st Century Cures Act, which was recently approved in the House, creates another pathway for expedited approval without the requisite conventional clinical trials for new antibiotics and antifungals.

Companies: The BMJ