DuVal Client Alert

Passing on Tribal Knowledge of FDA Law

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2021 Retrospection Highlight

NOVEL DEVICE PROGRAM

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Novel Device Programs

FDA has two programs for novel medical devices: the Breakthrough Device Designation (BDD) and the Safer Technologies Program (STeP).

The 21st Century Cures Act defines breakthrough devices as ***(1) providing more effective treatment or diagnosis of a life-threatening or irreversibly debilitating human disease or condition, and (2) providing "breakthrough technology" or offering a treatment option when no other cleared or approved alternatives exist.*** The Breakthrough Device Designation (BDD) program has been gaining in popularity since its inception. This surge reached a high point with the hope for automated Medicare coverage through the CMS Medicare Coverage of Innovative Technologies (MCIT) program which was repealed before it began in 2021. This arguably would have been the most significant benefit from achieving BDD. Without it, the benefits of prioritization in the review queue, an additional, faster, communication pathway (sprint discussions), and management oversight throughout the review process remain important benefits.

In 2021, a little sister was born to the BDD program – the Safer Technologies Program (STeP). This program is very similar in concept to the BDD program but does not have the backing of regulation. As a result, we do not expect this program to be adopted as readily as the BDD program has been. ***The STeP program provides a pathway for products that are not eligible for the BDD program because they are used for a less serious disease or condition.*** Despite strong similarities between the BDD and STeP program, the advent of the STeP program left an important gap in the programs by not allowing eligibility for products that are not eligible for the BDD program for another reason (e.g., products that are intended for use with life threatening or irreversibly debilitating diseases or conditions) but may be safer but not more effective or fail to meet one of the secondary BDD criteria. We hope that this gap will be rectified, either formally through an update to the STeP

program, or at least informally through acceptance of these products in the STeP program.

Unfortunately, FDA does not publish metrics for either of these programs, so it is difficult to know exactly how many have been submitted, accepted, and ultimately cleared or approved for commercialization. From our internal experience and research, we have not seen any STeP authorizations through late 2021. With respect to the BDD program, it appears a vast majority of requests for BDD have required some amount of clinical data. Of the 155 requests that we have been involved in or tracked, 111 (71.6%) are confirmed to have included clinical data, and only 8 (5.2%) are confirmed to have received the designation with no clinical data. Of those supported by clinical data, the majority included more data than what could be considered feasibility or first in human. *Unless metrics start to be published on the actual benefits of this program, interest in the program may begin to dwindle. Last year, we hoped for improved transparency. We reaffirm that sentiment this year.*

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Drug, Device and Food Law

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