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Incentivizing Industry to Advance Pediatric Medical Device Development

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Abstract: *The limited profits afforded to pediatric device manufacturers do not incentivize the industry to develop treatments for these populations. Existing incentives, in the form of patent protections, marketing thresholds, and development grants indicate modest potential for future development of these devices.*

Keywords: ADHD, drug shortages, generic drugs, mental health

Introduction

Pediatric medical devices have crucial life extending impacts. However, as children are generally a healthy subpopulation, the market for such devices is limited.[1] The small market size weighed against the high costs of research and development do not justify sufficient commercial profit for industry investment.[2] As a result, existing pediatric medical devices, such as surgical tools, have remained largely unaltered for the last 40 years.[3]

In an effort to stimulate the development of medical devices for neglected pediatric populations, Congress authorized the Humanitarian Device Exemption (HDE) in 1990.[4] This exemption established a marketing approval requirement that required manufacturers to demonstrate evidence that the probable benefits of the device outweighed the risks involved.[5] At the time the HDE was authorized, pediatric manufacturers were not allowed to make a profit off these devices, known as Humanitarian Use Devices (HUDs), intended to treat rare diseases affecting less than 4,000 individuals a year.[6]

Issue: Pediatric Devices Are Not Afforded Equivalent Incentives as Pediatric Drugs

Patent Protections

Pediatric devices are not afforded equivalent patent protections as pediatric formulations.[7] Pediatric formulations are afforded seven years' market exclusivity.[8] Conversely, no such incentive exists for pediatric medical devices.[9] Further, efforts to provide similar incentives would be insufficient, as the typical life cycle of a medical device is only 18 months.[10] Unlike approved drugs, which are sold for decades without being modified, medical devices are consistently being modified, rendering this type of incentive ineffective for industry involvement.[11] Secondly, this incentive lacks industry impact in that medical device patents are granted for specific components of devices and not the entire object.[12] Hence, the patent protections that encourage development in pediatric pharmaceutical drugs are insufficient with medical devices.[13]

FDA Amendments Act of 2007 (FDAAA)

The conduction of appropriate pediatric clinical trials requires critical adjustments to device design.[14] Medical devices currently utilized by children must be adjusted from adult versions and clinicians often lack access to crucial technical data to assist this process.[15]

In an attempt to solve this problem, the Federal Drug and Administrative Act of 2007 was enacted.[16] FDAAA enabled four non-profit pediatric device consortia to manage the development process by awarding them in 2009 and 2019 with close to 5 million dollars in grant money.[17] This funding provides statistical data and modeling techniques for targeted subpopulations and connects inventors and physicians too much needed data.[18] According to industry stakeholders, these recent efforts have assisted in clarifying issues in the market approval process. Of the 107 assisted pediatric projects, 73 were reported as currently in active development in the recent a GAO report.[19] In addition to development grants, another category of incentives have been established.[20] As part of The Federal Drug and Administration Act of 2007, Congress removed prior profit restrictions for pediatric-labeled HDE devices as part of the Pediatric

Medical Device Incentive Act, and instructed the GAO provide results of the impact of this incentive by 2012.[21]

GAO Report

The recently released GAO report indicates some progress in the development of pediatric medical devices. Specifically, stakeholders indicate that removing the restriction to generate profit on HUDS has assisted in the approval process.[22] Indeed, GAO results indicate modest potential in future development of devices. Prior to passing FDAAA, an average of 1 HUDs a year designated for pediatric use were approved by the FDA and after the enactment of FDAAA, there have been on average, five requests per year, in the past five years.[23]

Conclusion

The FDAAA provisions enabling device manufacturers to recover profits in pediatric devices represents a modest first step in accelerating development to neglected populations. Existing incentives, in the form of patent protections, marketing thresholds, and development grants indicate some potential for future development of these devices.

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[6] *Id.*
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[10] *Id.*
[11] *Id.*
[12] GAO, *supra* note 1.
[13] Field, *supra* note 9.
[14] *Id.*
[15] *Id.*
[16] Bleicher, *supra* note 2.
[17] *Id.*
[18] GAO, *supra* note 1.
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] *Id.*
[23] *Id.*

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