
Fabienne C. Meier-Abt

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First Advisor
Dr. Bruno Strasser

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Dr. Naomi Rogers

Abstract
BALANCING SAFETY AND AVAILABILITY: A HISTORICAL PERSPECTIVE ON THE PACE OF DRUG APPROVAL, 1950s-2009. Fabienne C. Meier-Abt and Bruno J. Strasser. Department of History of Medicine, Yale University, School of Medicine, New Haven, CT. Over the course of the past 50 years, drug approval processes have ranged from 42 days to more than 10 years. What are the consequences of slow or rapid drug approvals on drug safety and drug availability? How slow is too slow? How fast is too fast? These questions have engaged the public, the government, physicians and the pharmaceutical industry for decades. This essay adopts a historical approach to examine the search for the right balance between drug safety and drug availability in the changing political climates of the past 60 years. Before 1962, the discovery of life-saving antibiotics fostered an emphasis on drug availability and the rapid marketing of drugs. On the background of the thalidomide crisis in the early 1960s, however, the drug approval process was reframed. The 1962 Kefauver-Harris Amendments ensured a new focus on drug safety rather than drug availability. Efficacy standards were introduced and safety standards raised, and as a result drug approval and drug marketing times increased. During the 1970s, the term drug lag was coined and rapidly endorsed by pharmaceutical companies, physicians and by conservative parties. The term referred to the unnecessary suffering of American patients as a result of the delayed market introduction of life-saving drugs in the United States. On the background of general consumer movements and as illustrated by the case of sodium valproate, patients, too, used the notion of drug lag as a political weapon to fight government regulations on the pharmaceutical industry. In the context of the Reagan Administrations emphasis on economic deregulation and of the public health crisis caused by the emergence of AIDS, the political pressure on the Food and Drug Administration rose, and the drug review process was revised to emphasize drug availability rather than drug safety. In the late 1980s and throughout the 1990s, several measures were introduced, intended to reduce drug approval and drug marketing times, especially for drugs targeting life-threatening diseases. Finding the right balance between drug safety and drug availability has been a controversial task. As illustrated by the case of gefitinib, the current system depends very heavily on postmarketing studies and on trust in the pharmaceutical industry's ethical behavior. So far, however, the drug industry has not proven to deserve such trust, as exemplified by cases like rofecoxib. Hence, in 2009, the drug approval process awaits to be reframed again. A renewed focus on drug safety with more careful pre-approval studies and more thorough drug reviews seems warranted.

Recommended Citation
What is interesting from a historical perspective is how society, through a requirement for widespread literacy and an increasing scrutiny of educational performance, amongst other imperatives, has structured dyslexia in particular ways. Their work set the tenor for much research to come, broadening accounts to consider children and thus the developmental aspects of dyslexia; countering the notion that brain injury or disease caused the condition; and setting up, for the first time, the idea that dyslexia, as a specific difficulty with reading and writing, was independent of broader intelligence. In the early 20th century, there was a lull in dyslexia research in the UK, although work continued elsewhere, including Denmark and the United States.