Opportunities Missed, Warnings Ignored: Re-discovering the History of Drug Safety in Great Britain following the Thalidomide Disaster 1961

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Abstract
Following the thalidomide disaster 1961 many accounts of pre-thalidomide drug safety history appeared. Some identified events which represented missed opportunities or ignored warning signs. This paper reviews three assertions made in these accounts; that an opportunity to introduce a spontaneous reporting system for suspected adverse drug reactions in 1893 was missed; that concerns about dangers of drugs in pregnancy identified in 1904 were ignored; and that a proposal to establish a drug regulatory body made in 1914 was abandoned. The paper concludes that even if all had been acted upon it is unlikely that the thalidomide disaster could have been entirely avoided.

Key words: Thalidomide; safety; Britain; history; drugs

Resumo
Após o desastre da talidomida em 1961 surgiram muitos relatos de histórias de segurança de medicamentos pré-talidomida. Alguns casos identificados representaram oportunidades perdidas ou até mesmo sinais de alerta que foram ignorados. Este trabalho revisita três casos nestas condições: uma oportunidade perdida de introduzir um sistema de notificação de suspeita de reações adversas em 1893; que as preocupações sobre perigos de medicamentos na gravidez, em 1904, foram ignoradas; e que uma proposta de criação de um órgão regulador dos medicamentos feita em 1914 foi abandonada. Este estudo conclui ainda que, mesmo que todos os casos anteriores tivessem sido colocados em prática, é pouco provável que o desastre da talidomida pudesse ter sido totalmente evitado.

Palavras-chave: talidomida; segurança; Grã-Bretanha; história; medicamentos
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The thalidomide disaster of 1961 was the major watershed in the history of drug safety, not only in Great Britain but throughout the world. Following the tragedy governments everywhere tightened legislation concerned with the regulation of medicines and introduced systems for their approval and monitoring. The tragedy prompted much soul-searching in Parliament, in the industry, and in the medical professions. Developments in its aftermath included rapid expansion of research and teaching in clinical pharmacology; and new drug-focussed disciplines emerged, including pharmacoepidemiology, pharmacoeconomics and pharmacovigilance.

After the initial surge in activity some of those most closely involved in these processes began to reflect on their experiences, and a re-appraisal of the history of drug safety took place. Whilst many of these accounts were highly selective in their choice of earlier incident, some made serious assertions about missed opportunities, about warning signs and about historical precedents. To date these have received limited attention from historians. This paper reviews post-thalidomide observations on the history of drug safety, identifies key missed opportunities and early warnings identified by these authors, and explores the background to them and the reasons effective action was not taken at the time.

Introduction

The thalidomide disaster came to the attention of the world at the end of 1961. On 16 December a letter was published in *The Lancet* from W.G. McBride, headed ‘thalidomide and congenital abnormalities.’ It soon became apparent that around 10,000 children had been affected. The story of thalidomide has generated a massive literature (see for example, *Suffer the Children* 1979 and *Dark Remedy* 2001), and indeed continues to do so (see for example *Silent Shock* 2015). The review of medicines regulation which the disaster triggered continues to reverberate around the world. The new order was to see the transformation of medical specialties such as clinical pharmacology, the creation of new regulatory bodies and the growth of new fields of expertise such as regulatory affairs and post-marketing surveillance.

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