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Neoliberal technocracy: Explaining how and why the US Food and Drug Administration has championed pharmacogenomics

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ABSTRACT

By 2004 the FDA had emerged as a champion of pharmacogenomics as an exemplar for novel approaches to drug development. This was made clear in 2004 when the agency released a wide-ranging report which positioned pharmacogenomics at the heart of a broader regulatory reform agenda. The Critical Path initiative addressed declining productivity of drug development by suggesting that the problem was a mismatch between the rapid pace of discovery in post-genomic biomedicine and the antiquated development process for new drugs. Framing their work in this context, FDA officials reconceptualised their role in the innovation process, in what was the first programmatic statement of a shift from a strictly gate-keeping role to a more collaborative or facilitative role as enablers of innovation. This paper situates the FDA's emergence as a champion of pharmacogenomics in the broader politics of pharmaceutical regulation in the USA. In making a contribution to the pharmaceuticalisation literature this paper will draw on the work of John Abraham who has argued that one of the primary drivers of pharmaceuticalisation has been "deregulatory state policies" and on Williams and colleagues who have argued that the changing relationship between regulatory agencies and the pharmaceutical industry is an important dimension of pharmaceuticalisation. This paper links this to the promotion of pharmaceutical futures such as pharmacogenomics and explores how this shift is also closely related to the trend towards a risk management approach to pharmaceutical regulation. The role of Bush appointees in the development and promotion of the Critical Path agenda is also examined.

1. Introduction

In 2009 Margaret Hamburg, Commissioner of the US Food and Drug Administration gave a speech at the American Association for the Advancement of Science. She spoke in visionary terms about the expectations which surrounded the genomic turn in the life sciences and about its potential impact on pharmaceutical regulation:

> This first decade of the 21st century began with the decoding of the human genome—a scientific achievement that we knew had the potential to transform our understanding of health and disease and revolutionize our fundamental approach to medicine …
>
> In these, the early days of the genomic age, we are trying to adapt our thinking, our regulatory system, our models of drugs development, research, clinical trials and the very way we look at, gather and analyze data to a new reality. (Hamburg, 2009)

In setting out the potential positive impact of genomic science, Hamburg was echoing what had become a well-established position in the FDA. Pharmacogenomics is the use of genomic science to study human variability in drug response. Proponents of pharmacogenomics suggest that it will lead to a new era of personalised medicine through a fundamental transformation in the drug discovery and development process. Whilst currently clinical trials are designed to observe effects in populations, the use of pharmacogenomics will provide information on inter-individual variation in drug response. Although trial enrichment and population stratification are not novel, the promise of genomic biomarkers is that they will encourage the widespread systematic use of such techniques, both in discovery and development but also in clinical practice where the use of pharmacogenomic tests will help to identify those patients most or least likely to benefit from a drug.

In her 2009 speech Hamburg went on to link the science of genomics to the regulatory science practised by the FDA, and her argument echoed a thesis advanced many times by a variety of

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actors: the fruits of the Human Genome Project would include both health benefits and economic growth:

> A robust, state-of-the-art regulatory science discipline is essential to FDA's work. But more than that, it represents an important driver of our nation's health, the health of our health care industry, and the health of our economy. It is a field of endeavor that must be fully embraced by academia, industry and government.

What relevance does this have for scholarship on pharmaceuticalisation? In their 2011 review Williams et al. highlight a number of current trends which they see as critical to pharmaceuticalisation. One is the lowering of regulatory standards and the transformation of regulatory agencies into facilitators of innovation. Another is the creation of pharmaceutical futures, a trend which they exemplify with the example of pharmacogenomics. Williams et al. do not link these two trends, but in this paper I seek to bring them together. I argue that the FDA's articulation of its new role as agent of innovation was inextricably linked to its vision of a genomic future for pharmaceutical R&D, and that the framing of this policy was, to a significant extent, shaped by a neoliberal policy agenda of permissive regulation, an orientation not new to the Agency, but amplified by the appointment of pro-industry officials to senior positions in FDA by the Bush administration in 2001, just at the time when FDA staff were beginning to articulate the agency's policy towards pharmacogenomics. Subsequently, when the Vioxx scandal brought political pressure for a reversal of the policy of permissive regulation and a return to a more stringent approach to protection of public health, senior FDA officials presented pharmacogenomics as a technocratic solution to the political tensions inherent in the exercise of their regulatory authority. Finally, I suggest that the FDA's advocacy of a pharmacogenomic future must be understood as an expression of the broader ambitions of the US government to maintain its competitive advantage in the global bioeconomy.

2. Methods

My initial research in this area was conducted in a series of projects between 2004 and 2008 including commissions from Health Canada for an overview of global developments in the regulation of pharmacogenomics. Desk research took the form of a literature review encompassing regulatory guidance documents, scientific papers, and grey literature including policy reports, commercial industry surveys and industry news publications. Field research took the form of expert interviews with industry executives, regulatory officials and clinicians and participation in scientific meetings and industry conferences. Since then participation in industry and scientific conferences, and a variety of policy fora, in Europe, North America and Japan have provided further opportunities to garner evidence on the elaboration of public policy and commercial strategy in this area. More recently I have supplemented this field work with additional interviews with industry and regulators and have conducted a further literature review of outputs from regulatory agencies including new guidance documents, regulatory decisions, minutes and transcripts of regulatory advisory committees, presentations to conferences and media interviews, as well as other grey literature and scientific papers.

2.1. Conceptual framework and historical background

A substantial body of scholarship informs our understanding of the history and contemporary operation of the FDA's regulatory regime for pharmaceuticals, but in this paper I engage primarily with recent work from four scholars: Daniel Carpenter's highly detailed history of FDA's regulation of pharmaceuticals, which spans around seventy years from 1938–2008 (Carpenter, 2010); John Abraham and Courtney Davis more contemporary analysis which focuses on the last thirty years (Davis and Abraham, 2013) and Edward Nik-Kah's historical exegesis of the role of the Chicago school of economics in the late sixties to early 1980s.

Davis and Abraham's corporate bias theory posits an intimate relationship between public policy and commercial interests, in which representatives of the pharmaceutical industry are granted "privileged access to the state, over and above any other interest groups … setting the agenda for regulation" (2013, p 33) In recent decades, *neo-liberal* corporate bias has been characterised by the pursuit of deregulatory reforms justified by the assumption that the interests of patients are aligned with those of industry in seeking acceleration of the approval process as part of a broader relaxation of regulatory standards. Although their work posits that industry demands have become increasingly influential in shaping the regulatory regime over the last two to three decades, they distinguish their neoliberal corporate bias theory from the established regulatory capture model. Corporate bias theory does not privilege the relationship between regulatory agency and regulated firms; industry's strategic access to the policy-making process encompasses executive and legislature, as well as the regulatory administration.

If the narrative arc of Abraham and Davis's work is the decline in FDA's power, Carpenter, by contrast, seems more interested in understanding how the agency has retained so much of its authority. He offers a more pluralist model of the regulatory regime, in which a greater diversity of actors is accorded influence, because his model centres on reputation management as the critical driver of organisational behaviour of regulatory agencies, and the management of reputation requires attention to multiple audiences including:

> … the political and judicial authorities who endow organizations with power; interest groups and civic associations; organizations of professional and scientific expertise; media syndicates in print and broadcast, the mass publics who digest the information produced by these syndicates; the companies, corporations, and citizens who are governed by agencies; the clienteles who rely upon agencies for benefits and for order. (Carpenter, 2010, p 34)

Carpenter also emphasises how the FDA's reputation as a *scientific* organisation was rooted in dense networks of association: "between the agency, its committee system, universities and clinical researchers, pharmaceutical firms, and specialized medical and scientific societies and their members." (Carpenter, 2010, p 303)

2.2. From the Kefauver Amendments to the era of permissive regulation

Although there are important conceptual differences between the work of Carpenter and that of Abraham and Davis, they agree that since the enactment of the 1962 Kefauver Amendments to the FDCA which defined contemporary pharmaceutical regulation, the FDA has been under increasing pressure to adopt a more permissive and less stringent approach to regulation, a critical point of departure for this paper.

Developed as a response to what was perceived as a profound crisis in drug safety following the international scandal surrounding the drug Thalidomide, the 1962 Kefauver Amendments provided the legislative framework through which the three critical components of the contemporary pharmaceutical regulation regime were