FDA Book Title and Chapter Outline

Reputation and Power:
Organizational Image and Pharmaceutical Regulation at the FDA

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2007

Chapter Outline

Excerpt from the Introduction

The Gatekeeper

Quem patronum rogaturus, cum vix justus sit securus?
-- Mozart, Requiem Mass in D Minor.

Regulation and law currently place United States citizens at second remove from therapeutic drugs. In order to use most pharmaceuticals, citizens must obtain a prescription from a licensed and qualified medical authority, usually a physician. Yet before a doctor can prescribe, the U.S. Food and Drug Administration must approve. No prescription drug can be legally marketed in the United States unless the Administration has explicitly declared it "safe and effective" for its intended uses. This authority renders the FDA the gatekeeper of the American pharmaceutical marketplace, and it sustains a battery of vast powers. Among these are the power to define medical research and shape scientific careers, the power to limit advertising and product claims, the power to govern drug manufacturing, the power to enable drug firms to generate vast riches and the power to chase them from the marketplace, and ultimately the power to influence the lives and deaths of citizens. Some of those citizens may use hazardous or ineffective therapies that the FDA has approved. Other citizens may suffer or die waiting for the agency to approve a potentially effective cure. Still others, perhaps most, may happily use a drug whose form, dosage, and label have been carefully honed and well discerned through the scrutiny that regulation brings. Whatever the outcome, the FDA has shaped the lives of one and all. Among the thousands of people who daily give painstaking attention to the agency's every utterance and movement, there is considerable disagreement about the Food and Drug Administration – it is venerated in one corner and bemoaned in another; it is targeted for expansion by one voice and for evisceration by a second – but there is no serious doubt about its reach or significance.

The Administration's formal powers engender a broader and more opaque set of informal forces. From one vantage, the agency's formal authority is limited to the jurisdictions and territories of the United States. It legally tends the boundaries of only one nation. From another vantage, however, the FDA rules the entire global pharmaceutical market. The United States is among the world's wealthiest nations and its pharmaceutical market is, at this time, by far the world's largest. The contemporary United States is, furthermore, the only major world economy without explicit pharmaceutical price controls or national health insurance. Because admission to the U.S. market is the preeminent site of profit for the world's drug companies, the FDA's veto power over entry into the American health care system translates into global economic and scientific reach. Beyond this, the Administration carries a stature that other agencies in foreign nations consciously emulate or resist. Pharmaceutical regulators in Australia, Brazil, Egypt, Germany, Great Britain, India, Israel, Japan, South Korea, Switzerland, and dozens of other countries and regions model themselves upon the FDA, and in some cases contrast themselves against it.

In a nation supposedly as anti-bureaucratic as the United States, the FDA's power over the therapeutic marketplace is odd and telling. It is odd because the authority of an established business firm to develop and market a product is essentially subject to veto by a federal regulatory agency. It is telling, I think, because the accretion and use of this gatekeeping power intimate a politics of reputation that suffuses numerous government agencies – regulatory, military, security, policing, welfare – yet is rarely recognized.

The oddity is one of economic regulation and government power. While other agencies of government have the authority to regulate a product or a firm *after* it has set foot in the marketplace – the ability to constrain a product's price, to remove large quantities from circulation by seizure, to compel factories to reduce pollution, to issue monetary fines to companies large and small – very few government agencies have the authority to restrict products from entering a market in the first place. Among those that do – government licensors, permitting regulators – few if any have the discretion, authority and power of the FDA. The difference between pre-market (*ex ante*) and post-market (*ex post*) regulatory power is crucial. With fewer resources than most other government agencies, the FDA can leverage its veto authority into much greater sway over the pharmaceutical marketplace, global clinical research, multimillion-dollar advertising campaigns, everyday medical practice, and other realms of the modern world.

The telling irony concerns the politics of reputation. The Food and Drug Administration exercises the power it does in large measure because it possesses a reputation that inspires praise and fear. One facet of that reputation is a warm public image as a protector of patients and consumer safety. Another, related facet of the agency's image is its reputation for scientific accuracy. These positive faces of the agency's reputation have not held uniformly. Over the past half-century the FDA has been subject to withering and persistent criticism from many quarters – political, scientific, medical, and economic. Indeed, the FDA's reputation for citizen protection has waned in recent years, having faded in a way that casts much of the past half-century in stark relief. Yet over the past seventy years, the FDA has generally received praise for its consumer safety work from broad and often surprising quarters. Perhaps most telling, politicians, firms, doctors and organized interests have consistently tried to use the FDA's "protector" reputation as a rhetorical tool to advance their policy objectives. In so doing they unconsciously testify to the reputation's stability, and they reproduce its basic symbols and beliefs.

A reputation is a complex, intangible, many-faced thing. The FDA's positive public image is accompanied by another, fiercer image that its officials often project to pharmaceutical firms and physicians in its capacity as a cop of the American health care system.

This book is about the interplay between reputation and power, between the gatekeeper and its images. Power supports the agency's reputation, and reputation feeds the power. At times, the reputation becomes a form of power itself, as the agency relies upon different facets of its ambiguous but feared image to induce certain patterns of behavior by pharmaceutical companies, by physicians and clinical researchers, and by regulatory agencies worldwide.

There is nothing false or mythical about the relationship between power and reputation. To say that reputation upholds a government agency's power is not to say that such power is ill-

founded, unconstitutional or illegitimate. Quite the opposite, I would argue. In a democratic republic where there is ultimately some relationship between popular sovereignty and the powers of the regime, it is a plausible claim that a powerful government agency should have a reputation characterized by trust and expertise.

So too, to argue that the Food and Drug Administration has power is not to say that it is too powerful, or that it is more powerful than the industries and companies it regulates. I am rather interested in whether the FDA is more or less powerful over the course of time. I am interested in whether the Administration bears more power vis-à-vis regulated firms, compared to other national agencies that govern the same companies. I am interested in the Administration's power compared to what it might have been, under plausibly and slightly different circumstances. The statements about power advanced in this book are historical. They are comparative across nations and organizations. They are at times counterfactual.