The Political Economy of Biotechnology: Innovation and Politics in an Emerging Industry

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An obscure piece of federal legislation enacted in the beginning of the 1980s has become both the focus of innovative efforts as well as the source of political fragmentation in the U.S. biotechnology industry as it moves into the 1990s. In the fall of 1982, Congress approved the Orphan Drug Act. The Act was designed to entice pharmaceutical manufacturers to develop drugs for diseases which have small patient populations and thus do not provide the type of profit incentives which would direct markets to respond to these life-saving demands. In an effort to promote this innovation, Congress developed legislation which promised both tax credits and government grants to support private sector development, testing, and marketing of these so-called "orphan drugs."

The history of this legislation, from its inception and through continuing efforts to amend the Act, provides an informative glimpse into the role which government plays in the innovation process in the United States. It also provides a case study in understanding the relationship between business and government in the late twentieth century.

Although we have numerous studies about episodes of government regulation (and deregulation) we have had few studies which actually examine the individual strategies and activities of both business and government and their interaction in the context of a particular issue. I am completing such an examination of business-government relations in the U.S. biotechnology industry and the orphan drug battle is one episode in this story. This paper presents the conceptual framework I am using to help explain this history.

James Q. Wilson explains that we can understand business-government relations by examining how each stakeholder affected by a particular issue perceives the distribution of benefits and costs of a proposed policy which addresses that issue. Each arrangement of perceived benefits and costs, either being narrowly concentrated or widely distributed, produces a different type of political activity: concentrated benefits and costs leads to interest group politics; concentrated benefits and distributed costs leads to clientele politics; distributed benefits and concentrated costs leads to entrepreneurial politics; and widely distributed benefits and costs leads to a majoritarian politics [3].

As Wilson observed, these benefit-cost distributions shift over time. Yet, he did not explain what would cause such shifts and, subsequently, shifts

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in the nature of the politics of the issue. Richard Vietor provided an explanation by showing that changes in market structure and changes in supply and demand conditions would alter the perceptions and, in turn, the political conflict. Vietor characterized these types of conflict as intraindustry, interindustry, intragovernmental, and business reform--roughly corresponding to Wilson's four types of political activity [2].

In the history of the Orphan Drug Act, we see in the first stage an initial perception of widely distributed benefits and costs which directed the politics leading to the creation of the Act. The subsequent implementation of and amendments to the Act altered the market structure of the orphan drug industry and led to a perceived redistribution of concentrated benefits and costs. This perception promoted interest group or interindustry politics in the second stage which is characterized by the competitive behavior between strategic industry groups.

The benefit-cost approach is a good heuristic device, but obviously each policy history necessitates more than simply fitting a story in the proper box and relating the appropriate political tale. This is clearly evident with the Orphan Drug Act which shows how each set of business and government actors failed to understand fully the economic and political implications of the Act and, in turn, initially misperceived the distribution of benefits and costs of this public policy.

Let's look at the first stage. The purpose of the Act was to stimulate innovation so that patients with diseases of small populations would receive a concentrated set of benefits, while the costs of grants and tax credits (to cover industry research, testing, and production expenses) would be widely distributed to all tax payers. This distribution should have led to a clientele-based politics (e.g., price supports for dairy farmers) in which legislators would expect some rewards (e.g., money for reelection) from a satisfied interest group. Yet the patients of orphan diseases were hardly in a financial position to establish their own political action committees.

The biotechnology industry, which would eventually become a primary beneficiary (along with the patients) of orphan drug legislation, was not to be seen in the debates leading to its enactment. The few biotechnology firms that were politically active in the late 1970s and early 1980s were in an unusual position of both challenging efforts to regulate the research activities that used the newly discovered techniques of genetic engineering and, at the same time, trying to capture advantages from a government which was promoting the biotechnology industry in international competitiveness terms. Because of these demands, the biotechnology community did not perceive that there would be significant benefits to be derived from orphan drug legislation and it was not seen as an area to devote either industry or individual firm resources.

With the absence of the emerging biotechnology firms, the drug industry position was represented by the Pharmaceutical Manufacturers Association. The PMA reflected the interests of the established corporate drug producers rather than the particular interests of the biotechnology firms. The firms which the PMA represented were neither interested in nor demanded special legislative and tax provisions for orphan drugs. In fact, the

PMA opposed the legislation because they perceived that the legislation would impose two tangible, political costs. The first was ideological. Supporting the act would be an admission that the market could not respond to all consumer demands and the industry publicly rejected the orphan drug advocate's arguments primarily on this basis. As PMA President Lewis Engman testified before Congress,

> ... let me stress our belief that the private sector can work effectively to meet the challenge posed by rare diseases. The pharmaceutical industry is prepared to work with interested private and public groups to define the issues more clearly, improve mutual understanding, and remove impediments to the development of more service drugs [4].

They perceived a second cost which their representatives were reluctant to admit publicly but that nevertheless influenced the PMA's public position. The industry wanted to deregulate the entire drug approval process and this was their major political objective for the early 1980s. They feared that approving the orphan drug legislation, which would also ease the drug approval requirements for this special class of drugs, would reduce the momentum for the overall, deregulatory effort as noted in the following exchange between industry representative, Peter Barton Hutt, and Rep. Bob Whittaker (Republican-Kansas):

> Mr. WHITTAKER. Do you believe part of your reservation to support our legislative solution could be based, in part, on a belief that if we provide relief from FDA regulation in the area of orphan drugs, it might detract from your industry's overall effort to obtain relief from the FDA regulations for all new drugs?
> Mr. HUTT. That could be a bad byproduct of it, but it does not get to the heart of the problem.... the best way to look for drugs for rare diseases is to look at all drugs for all diseases.... when you look at drugs for common diseases you will find drugs for rare diseases. Anything that will stimulate new drug development is going to help the discovery of drugs for rare diseases [5].

In spite of these perceived costs, however, the industry was not about to publicly lead a visible fight against providing drugs for orphan diseases. Thus, it left a political situation which could have pitted one set of interests (the patients) against another (the pharmaceutical industry), but instead the political reality displayed the characteristics of an issue with diffused benefits and diffused costs. This distribution generally inhibits political activity because it lacks the intensity of an interest group (with available financial resources to reward supportive legislators) being harmed or benefitted in a substantial manner. This left it to the chair of the subcommittee which would eventually create and oversee the legislation, Henry Waxman, to develop the political will for Congress to enact this public interest legislation.

A clear perception of benefits and costs was also lacking on the part of government actors. The Congressional supporters of orphan drugs were

convinced during the first stage that these drugs were never going to be profitable and that the market would, thus, never provide the research, testing, and marketing to serve these select populations. Because of this, their energies were devoted to creating incentives to alleviate these market failures. Initially this meant tax credits for research and testing and grants to academic researchers (whose work would eventually be used by industry). After President Reagan signed the Orphan Drug Act into law in early 1983, the PMA became an advocate and suggested additional industry incentives for the government to provide. In response, the Congress amended the Act in 1984 to define which drugs qualified to earn the "orphan drug" designation. The Congressional intent, once again, was to stimulate innovation and not worry about the potential market distortions. But, in doing so, the Congress replaced absence of these needed drugs with drug monopolies in the form of "marketing exclusivity" privileges and set in motion the shift to the second stage of this story.

The Food and Drug Administration was not an early advocate of the original legislation. Yet after it was enacted the FDA was given the administrative responsibilities for implementing the Act, and became, not surprisingly, a key advocate for their new programs. The FDA, however, was put into the position of not only being an industry social regulator (by establishing drug approval procedures for orphan drugs); it also became a definer of markets, an economic regulator. It did so by implementing the seven-year marketing exclusivity provisions to the firm which was the first to complete the applications with the required test results. And these firms turned out to be not the established pharmaceutical corporations but the newly emerging biotechnology companies.

It was the marketing exclusivity designations that turned the Orphan Drug Act into an instrument for individual biotechnology firms to strategically use this public policy. This, in turn, led to stage two and the political fragmentation of the industry.

Although it did not formally issue regulations to implement the 1983 Act until February 1991, the FDA proceeded to grant orphan status to drugs for research purposes (and, subsequently, tax benefits)--there was no restriction to the number of firms who could qualify--and then to grant orphan status to market drugs to the first firm to complete all the research and testing requirements. Through the end of the decade, the FDA had granted seven-year market exclusivity to the makers of nearly fifty drugs.

In all but three cases all participants agreed that the Act was working as it was originally intended, i.e., government-induced innovation had been successful. But these three highly visible exclusions--Amgen's Erythropoietin (EPO) for end-stage renal disease anemia, Genentech's Human Growth Hormone (hGH), and Lyphomed's aerosol Pentamidine for AIDS-related pneumonia--turned the Act into a political battleground pitting individual biotechnology firms (as well as a few established drug companies which had alliances with these firms) and the two biotechnology trade associations (the Industrial Biotechnology Association and the Association of Biotechnology Companies) against each other.

What had happened was that these three drugs had become "blockbuster" drugs in terms of their earnings potential. Although each qualified for orphan status, less than 200,000 patients for the designated medical condition, something had happened which was not anticipated. These three drugs were generating significant monopoly profits. Not surprisingly, the prospects of such profits had motivated both a race to qualify for orphan marketing status (by using the loopholes available in the approval process which, for example, allowed drugs which were chemically different from ones already granted orphan status) and political and judicial battles to eliminate the marketing exclusivity provisions in the law. In other words, these orphans were being fought over by many potential, doting parents.

Thus, in stage two, the provisions allowing for marketing exclusivity (seven-year monopoly privileges) significantly redistributed the benefits and costs from their original position. The new alignment was a classic, interest group, standoff of "haves" and "want-to-haves" ("have-nots"), i.e., concentrated benefits and concentrated costs. The "haves" (whose interests were represented by the IBA) were the firms which had been granted exclusive marketing rights to the three drugs; the "have-nots" (who were represented by the ABC) were the firms who wanted a piece of the market, in particular, Serono which had its own human growth hormone and Genetics Institute which had a competing version of EPO. In this new alignment the patients and their advocates were in the uncomfortable position of supporting a law which created their life-saving drugs, but for which they were charged monopoly prices. (In the case of two of the three drugs, the federal government was paying for the medication.) Because of this dilemma they were rendered politically "neutral" in the battles.

In the traditional theory of economic regulation, an industry coalesces politically around government activities which either impose concentrated costs or provide concentrated benefits to the firms in that industry. However, the traditional theory is not helpful in understanding business behavior when the benefits and costs of these policies is not distributed equally within the industry. This describes the situation that evolved with orphan drugs. In order to examine this behavior, one must approach the subject from the perspective of firms using public policy to achieve strategic goals. In this instance, dedicated biotechnology firms endeavoring to bring to market a product (in many instances their first product) that would provide the necessary profits to achieve the firm's other strategic goals, including both gaining a competitive advantage over other firms in the industry and also ensuring, for a few years at least, the very survival of the firm.

With these strategic purposes in mind, it explains the serious nature of the political battles the firms waged over these three drugs. The firm's tactics included intense Congressional lobbying, establishing political action committees (PAC's), establishing allies in the executive branch, e.g., within the Office of Management and Budget (OMB), pursuing court challenges, creating coalitions with other firms, and taking control of industry trade associations.

As William Becker reminds us, however, we must also examine the strategy and behavior of the government agencies involved [1]. In doing so we find that the institutional arrangements encompassing the Orphan Drug Act

provide both parallel and conflicting strategies with which the business strategies must interact. These agency strategies involve both ideological and interest group influences and only by incorporating them into our analysis are we able to comprehend more clearly the nature of business-government relations in the biotechnology industry.

References

1. William H. Becker, *The Dynamics of Business-Government Relations: Industry & Exports, 1893-1921* (Chicago, 1982).
2. Richard H. K. Vietor, *Energy Policy in America Since 1945: A Study of Business-Government Relations* (Cambridge, 1984).
3. James Q. Wilson, ed., *The Politics of Regulation* (NY, 1980).
4. U.S. Congress, House Of Representatives, "Health and the Environment, Part 2: Orphan Drugs," hearings before the Subcommittee on Health and Environment of the Committee on Energy and Commerce, March 9, 1981.
5. U.S. Congress, House of Representatives, "Health and the Environment, Part 7: Orphan Drug Act," hearings before the Subcommittee on Health and Environment of the Committee on Energy and Commerce, March 8, 1982.