Allied Against Reform: Pharmaceutical Industry-Academic Physician Relations in the United States, 1945-1970

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Summary

During the 1960s, the drug industry was the subject of two congressional investigations into its business practices and pricing policies, and in 1962, passage of the Drug Amendments mandated greater FDA authority over pharmaceutical development. In this article, I examine the industry's efforts to circumvent these political challenges by drawing on its long-standing relationship with academic physicians and the American Medical Association. Utilizing the medical profession's shared concern about expanding government oversight over therapeutic practice, the industry called on academic physicians to join forces with them and establish an expert advisory body to guide government officials on pharmaceutical policy. Drawing on research in the archives of the University of Pennsylvania and the National Academy of Sciences, and a careful reading of the trade and biomedical literature and congressional documents, I argue that by positioning themselves as pharmaceutical experts, this industry-academic alliance gave industry a seat at the policy table and enabled them to challenge the efforts of pharmaceutical reformers to further increase the government's role in drug development.

Keywords: pharmaceuticals, drug industry, industry-academic relations, drug regulation, Food and Drug Administration, health care reform

> [T]he pharmaceutical industry and the medical profession have stood shoulder to shoulder in the past and will continue to do so in the future, wherever the health of the public is at stake. We are both dedicated to pursue our chosen fields in the public interest. We both seek the same goal – better health for the American people.[i]

The 1960s was a decade of crisis for the American pharmaceutical industry. In Congress and the press the industry was berated for its high profits, its marketing strategies, the high cost of drugs, and the abundance of so-called "me-too" drugs.[ii] As a way of curbing the high cost of prescription drugs and putting a break on escalating health care costs, pharmaceutical reformers in Congress, together with labor leaders, consumer groups, and disease-based organizations, sought to secure passage of legislation that would increase the federal government's control over pharmaceutical development, distribution, and practice.

In 1962, pharmaceutical reformers scored their first and most significant success. That summer, reports that thousands of babies had been born in Europe with severely shortened limbs because their mother's had taken thalidomide during pregnancy brought home to Americans the dangers of taking potent pharmaceutical agents and the potential limits of the regulatory system in the United States. Coming in the midst of a congressional investigation led by Senator Estes Kefauver into the pricing and business practices of American drug firms, the tragedy spurred support for pharmaceutical reform. In October that year, Congress passed the Drug Amendments to the Federal Food, Drug, and Cosmetic Act, giving the Food and Drug Administration (FDA) greater authority over the testing, manufacture, and marketing of new drugs.

Passage of the 1962 Drug Amendments followed the legislative pattern of earlier drug regulations, where a health hazard precipitated public demand for more rigorous drug laws. The 1906 Pure Food and Drug Act (which prohibited false and misleading labeling, and adulteration, of food and drug products) was signed into law after a series of muckraking articles and Upton Sinclair's The Jungle exposed the sometimes dangerous practices of food manufacturers. And the 1938 Food, Drug, and Cosmetics Act (which for the first time required manufacturers to prove

the safety of their drug products before the FDA would approve marketing of those drugs) passed following the death of 107 people who had taken the sulfa drug, Elixir Sulfanilamide.[iii] Indeed, Kefauver's reform bill was all but dead until news of the thalidomide tragedy in Europe reached the U.S.[iv]

Although it is well understood by medical historians that Kefauver's investigation and the thalidomide disaster led to major reform of the pharmaceutical industry, a history that has yet to be told is how the industry fought back and retained control in the new regulatory environment.[v] Indeed, while the Drug Amendments increased the safety provisions of clinical testing, required for the first time proof of efficacy of all drugs, and mandated the use of generic drug names in all pharmaceutical advertising, the pricing and profit structure in the industry remained unchanged. Even as pharmaceutical reformers continued through the 1970s to push for even tighter control over pharmaceutical practices, drug prices and the industry's profits remained high, and companies continued to develop "me-too" drugs in large numbers. Today, these same concerns dominate the public and press critique of the industry.[vi]

Based on research in the archives of the National Academy of Sciences and the University of Pennsylvania, the publications of the Pharmaceutical Manufacturers Association, the published biomedical and trade literature, and congressional documents, I examine how, despite the sustained attack on its practices before and after 1962, the industry prevented more significant reform of the corporate system of drug development. This reform agenda included efforts to reduce the patent term on prescription drugs; to make it mandatory for physicians to prescribe drugs by their generic names rather than by their brand name; to allow pharmacists to substitute a generic drug for any brand-name drug prescribed by a physician; and to put the federal government in charge of all pre-clinical and clinical testing of new drugs.

The industry, I argue, retained control over pharmaceutical practice and policy following passage of the 1962 Drug Amendments by forging a political alliance with academic physicians and the American Medical Association (AMA). Drawing on the medical profession's shared

concern about expanding government oversight over therapeutic practice, the industry called on academic physicians, in particular, to join forces with it and establish an expert advisory body, the Drug Research Board, to guide government officials on pharmaceutical policy. By positioning themselves as pharmaceutical experts, this alliance circumvented the FDA's new authority and challenged the efforts of pharmaceutical reformers to further increase the government's role in drug development and practice. In doing so, this alliance secured from Congress the passage of compromise solutions that preserved the authority of physicians and their autonomy in pharmaceutical practice, and protected the industry's role (and to a large extent their profits) in drug development and distribution.

Pharmaceutical Industry-Academic Relations after World War II

To understand the political alliance made between the pharmaceutical industry and academic medicine in the 1960s we must first consider the relationships between drug firms and academic physicians, and the regulatory efforts of the government in the decade after World War II. This early history shows that drug firms and academic physicians shared intellectual and economic relationships -- and held common political concerns -- before the 1960s.

As pharmaceutical historians have described, the interwar years witnessed the forging of collaborative relationships between academic biomedical researchers, clinicians, and drug companies. Through a system of consultancy arrangements, firms such as Eli Lilly & Co. and Merck & Co. had, by the early 1940s, developed elaborate knowledge networks within the academic medical community. These networks were fostered through the awarding of fellowships and grants to researchers and academic departments, as well as donations of research material to clinical researchers. At the same time, most firms maintained a cadre of academic researchers and clinicians who served as company consultants, providing firms with advice on specific developments in their industrial laboratories and on corporate research strategy. These academic

consultants also gave companies access to new knowledge being produced in academic laboratories that they would otherwise not have had access to prior to publication of that research.[vii]

During World War II these relationships intensified. When the Committee on Medical Research of the Office of Scientific Research and Development (OSRD) contracted with drug companies to develop penicillin, synthetic antimalarial drugs, steroids, and replacement blood products, the companies utilized their preexisting connections with academic researchers to meet the wartime demands.[viii] After the war, these collaborative relationships continued, resulting in the introduction of a number of so-called wonder drugs such as new antibiotics and vaccines, corticosteroids, and psychotropic drugs.[ix]

At the same time that it nurtured its intellectual relations with researchers, the industry also significantly increased its financial commitment to academic medicine after World War II. The federal government's expanding support of biomedical research in the post-war years -- primarily through the programs of the National Institutes of Health and the National Science Foundation -- raised serious concerns among academic physicians and drug company executives.[x] While drug companies had "a very real interest in certain wide fundamental fields of research," they were not, as Merck's president, George Merck resolved, "disposed to leave them to the mercies of a problematical governmental beneficence."[xi] Firms were particularly concerned that the government's involvement in the field of biomedicine would "encourage the trend toward socialized medicine."[xii]

Medical school administrators--who were struggling to meet the growing cost of medical education after the war--shared the industry's concern that too much government involvement in biomedical research would invite the government into other areas of medicine.[xiii] To avoid an over-dependence on government funds, medical schools solicited drug firms to increase their support of medical education. These school administrators were also concerned by a growing manpower shortage in biomedical research and regarded it as the industry's responsibility to help

foot the bill of biomedical education and training. After all, noted Edwin J. Cohn, chair of Harvard's Division of Medical Sciences, drug firms "depend[ed] for the fulfillment of their avowed aims" on the training of specialized researchers.[xiv]

Harvard University's administrative vice president, Edward Reynolds, for example, wrote to George W. Merck in May 1948 to suggest ways in which Merck & Co. could help advance biomedical education and research at Harvard. "One, of course, is obvious," Reynolds stated, "and that is the support of specific research that leads directly towards work [the Company's] own research and development organization can pick up. The second," he continued, " would seem to me to be support of basic research… in a field that is likely to produce new knowledge of interest to Merck & Co." This support, Reynolds' believed, should "be annual with some expectancy of renewal for a three to five year period."[xv]

Next, Reynolds recommended that Merck & Co. award "an institutional grant to a selected institution, such as Harvard, for work in a broad field of interest to Merck & Co., whether it be research or education of students." Indeed, over the previous two years, Harvard's departments of public health and medicine had solicited Merck & Co. for just such support. Reynolds conceived of such grants as being undirected funds for which the receiving institution would be free to "decide how to parcel it out among the various participating projects." And in those cases where the company supported education rather than research, Reynolds continued, "it seems to me that it can be justified, even without any commitment that Merck can or will employ any students trained in such fields in the institutions Merck supports, by the probability that we can recruit our fair share of such men by looking over the graduating class as they near the end of their education, in the same way that many large law firms now visit the last-year men in the Harvard, Yale, Columbia, and other Law Schools each year." In this way, Reynolds proposed, essentially, a recruitment pipeline that would run between Harvard and Merck & Co.[xvi]

Because of their concern over the role of the government in biomedicine, drug industry executives were receptive to the requests of medical schools.[xvii] Yet, as much as drug firms did

"not want to see institutions like Harvard falling back on federal funds, as we see quite enough of the effect of state financing in many of the big Western schools," they had very specific ideas of what shape industry support of medicine should take.[xviii] Although the industry had a stake in maintaining the standards of medical education, it was not responsible for funding either the core teaching or the "bricks and mortar" of medical schools and universities. For Merck & Co., if corporate funding would not "benefit the stockholders specifically other than as members of the general public," the company would not fund it.[xix]

In an effort to prevent the impending shortage of medical manpower, and in response to the threat of increasing government involvement in biomedical research and education, drug companies increased their support of academic medicine by expanding their pre-war fellowship programs. Before the war, drug companies had awarded fellowships in pharmaceutical-related fields only on an ad hoc, case-by-case basis to specific university departments with whom the firm had a standing relationship. After the war, however, firms such as Merck established annual, competitive, and nationally organized postdoctoral fellowship programs. These fellowships benefited universities by helping them to underwrite the cost of undergraduate and graduate education and by encouraging undergraduate, graduate, and medical students to enter the field of pharmaceutical research. The benefits were no less significant for industry: first, the fellowships introduced young researchers to the financial and intellectual benefits of working with -- and for -- industry. And second, these fellowships promoted the exchange of knowledge between academic and industrial research laboratories, as drug company sponsors retained access to the fruits of their fellows' research.

Drug company fellowships thus marked a mutually beneficial economic relationship between the pharmaceutical industry and the biomedical research community and served to intensify the knowledge networks that had been created between drug firms and academic institutions in the interwar years. Moreover, the rationale behind companies' increased investment in biomedical education and training reveals that from the end of World War II, the

industry and the medical community were troubled by the expanding role of the federal government in medicine.

The Politicization of Pharmaceuticals

Relations between the drug industry and academic physicians (and the medical profession more generally) were not, however, without tension. Since the war the American drug industry had been riding a wave of public and political support due to the significant therapeutic achievements made by it during and immediately after World War II. By the mid-1950s, however, the political tide was beginning to turn on the industry as the public and Congress grew increasingly disillusioned as several new drugs were found to cause adverse reactions, and the industry's advertising practices, its high profits, and the high cost of prescription drugs came under fire.

The first signs of trouble came in July 1956 when the Federal Trade Commission (FTC) launched an investigation of the antibiotics industry. The FTC was troubled by the high cost of antibiotics and sought to uncover how much it cost firms to develop and manufacture antibiotics.[xx] When the FTC finished its study two years later it filed a complaint alleging five firms had attempted to maintain "arbitrary, artificial, non-competitive and rigid" prices for tetracycline.[xxi]

Also in 1956 -- during an examination of the U.S. Public Health Service's polio vaccination program -- the House Subcommittee on Intergovernmental Relations discovered that several polio vaccine producers had made identical bids to the government for the vaccine contract. Disturbed by what looked like collusion among the vaccine manufacturers, the subcommittee's chair Lawrence H. Fountain (Democrat from North Carolina) began an investigation of the pricing practices of vaccine producers, including several of the largest pharmaceutical firms. And in 1957, Representative John A. Blatnik's (Democrat from Minnesota) Legal and Monetary Affairs subcommittee began investigating the promotional practices of drug

firms. Blatnik's subcommittee was concerned, in particular, with the promotional strategies used by drug manufacturers to try and persuade physicians to prescribe their products. Thus by the late 1950s, Congress had "discovered" the industry's existence.[xxii]

Many physicians—academic and non-academic alike--joined in the critique of drug advertising as being excessive, misleading, and oftentimes inaccurate. In particular, physicians were frustrated by the large quantity of advertisements they received through the mail and the hard-selling detail men that came through their offices. They deemed both wasteful and expensive and contributing to the high cost of drugs.[xxiii] The medical profession's critique of the industry, however, came at a time when health care costs in general were a subject of scrutiny in Congress and the press. For as long as the cost of medical care had been debated in the United States, a primary target of that debate had been physicians' fees. As such, industry leaders suspected that physicians were shifting the blame for high medical costs to pharmaceutical manufacturers as a way of taking their own fees and practices out of the spotlight.[xxiv]

In an effort to persuade physicians to stop shifting the blame, the drug industry launched a professional relations campaign targeted at educating physicians -- through advertisements and the work of detailmen -- on "the truth about drug costs." The goal of this campaign was two-fold: first, it explained that drug costs had increased less than any other segment of health care costs, and that by reducing patients' hospital stays drugs actually reduced the overall cost of health care. Second, the industry's campaign emphasized that physicians shared the same interest as the industry when it came to criticisms of health care costs. Any attack on health care costs, the industry warned, was an attack on the capitalist system of medical care. Thus by attacking drug costs, physicians were effectively threatening the stability of the health care system -- the very system that allowed them to treat patients with autonomy.[xxv] By situating the critique of drug costs in this way, the industry made a potentially persuasive argument, drawing on the medical profession's long-standing concern about the expanding role of the federal government in medicine.[xxvi]

Part of this concern related specifically to the authority of the FDA over pharmaceutical practice. Indeed, since passage of the 1938 Food, Drug and Cosmetics Act the FDA had been pushing to increase its authority over prescription drug labeling. Their efforts provoked a decade-long response from the drug industry as it worked to curtail the agency's authority. This effort included warning physicians of the impending socialization of medicine if the FDA was allowed to have its way and dictate to physicians which drugs they could and could not prescribe.[xxvii]

The industry and medical profession's unease over the FDA's burgeoning authority was exacerbated, through the 1950s, by their concerns about the intellectual and material weakness of the FDA. A Citizen's Advisory Committee evaluating the agency in 1955 emphasized the FDA's inadequate budget and lack of scientific prowess and called for a three- to four-fold increase in the agency's budget and the addition of a thousand new field inspectors.[xxviii] Although industry and the medical profession discussed their worries that the agency did not have the resources to adequately protect the public's health, they did little to tackle the problem.

In 1959, Johns Hopkins University clinical pharmacologist, Louis Lasagna, suggested to the Pharmaceutical Manufacturers Association (PMA) that one way of solving the FDA's manpower and intellectual crisis was for "universities and the pharmaceutical industry… [to] join forces in providing reasonable advice to government." Such a solution, Lasagna suggested, would strengthen the FDA *and* "preven[t] unwise participation of the government in drug development."[xxix] Although the PMA agreed that an industry-academic advisory body was desirable it did not act on Lasagna's recommendation. As much as industry executives agreed that intellectually strengthening the FDA would serve their interests, they were not sufficiently threatened by the agency's authority at that time. This was due in large measure to the openness that characterized relations between drug companies and the FDA and the limited degree of regulatory authority the FDA had over firms during the 1950s.[xxx] Indeed, despite the early warning signs that Congress and the public were growing increasingly disgruntled, the industry was in general slow to respond to the emerging political trouble. Rather than engaging in specific

strategies to defend itself and undercut the congressional and regulatory challenges facing it, the pharmaceutical industry preferred instead to let its past therapeutic achievements stand as its defense and focus its efforts on curtailing the medical profession's critique.

"Mutualities of Interest"

By the time Senator Estes Kefauver launched his Senate Subcommittee on Antitrust and Monopoly investigation into the alleged "administered pricing in the drug industry" in December 1959, the industry was finally taking its troubles seriously.[xxxi] In reaction to Kefauver's investigation, the PMA's president, Austin Smith, announced to an industry audience in 1959 that a successful defense against pharmaceutical reform depended on "industry using all its talents and the help of its friends, present and acquired, to pursue objectives in which there is a mutuality of interest."[xxxii] Industry's "friends in medicine" -- and specifically their shared concern over the increasing role of government in medicine -- were particularly critical to this task.

Kefauver's investigation of the business practices of the prescription pharmaceutical industry lasted almost three years and culminated, after the thalidomide tragedy spurred Congressional and public support for pharmaceutical reform with passage of the Drug Amendments to the Federal Food, Drug and Cosmetic Act in October 1962. The Drug Amendments significantly altered the political economy of drug development in the U.S. Two provisions of the amendments were particularly important for drug developers and their academic colleagues. First, prior to the Amendments, a firm could undertake clinical testing of a new drug at any time without any prior notification of the FDA. Thus it was the responsibility of the firm and its team of clinical investigators to determine whether or not it was safe to proceed from *in vitro* and preclinical studies in animals to testing in humans. The new law, however, transferred that responsibility to the FDA, requiring that firms receive approval from the FDA for their testing procedures before proceeding with clinical studies of an investigational new drug.[xxxiii]

Second, the amendments now required that a drug firm provide proof of safety *and* efficacy to the FDA (before the new law, the FDA required only evidence of safety to grant a firm marketing approval for a new drug).[xxxiv] The efficacy requirement, which mandated that all new drugs -- including those already on the market -- have "substantial evidence" of efficacy, threatened to deprive physicians of drugs they had long-held to be effective and charged the FDA with greater authority over the prescription practices of the physicians. This meant that, together with the clinical testing provisions of the new law, that clinical investigators were expected to provide a lot more documentation about the drugs they were studying. This new level of oversight raised the ire of drug firms and academic researchers alike as both parties feared the new levels of bureaucracy would deter researchers from engaging in clinical studies, hindering the development of new drugs and thereby jeopardizing the public's health.

In July 1963, less than a year after the Drug Amendments were passed, the medical director of Eli Lilly & Company, Dr. Raymond Rice, reported to an AMA audience, "that qualified investigators are indeed giving up clinical research rather than bother with all the paperwork" necessitated by the new regulations. The number of investigators registered with his company had dropped by half in the last two years.[xxxv] Earlier that year, the director of medical research at Lederle Laboratories had reported similar problems confronting his firm, noting that the time and cost of adapting to the new regulations had forced Lederle to "close out a lot of projects." The Lederle executive warned that the "increased research, testing, and development costs" incurred by the new regulations would force "industry [to] take long searching looks at all research programs before they are instituted. There will be less inclination to take the long gamble."[xxxvi]

Industry leaders also feared the added strain the Drug Amendments placed on the FDA's already limited resources. As Lilly's Rice asked an AMA audience in 1963, "how critical can be the evaluator of a new drug application within the FDA[?] I recently saw the data for one such application," he continued, "which consisted of a stack of paper six feet tall - how can one man

cope with dozens of these and how can Dr. Kelsey [director of the Division of New Drugs] supervise the evaluation of hundreds of them?"[xxxvii] Rice further warned that just as drug companies were struggling "to enlist the cooperation of qualified investigators," so too would the FDA "find it difficult to recruit men of the caliber needed."[xxxviii]

The FDA's recruitment difficulties were made worse by the agency's persistently inadequate funding, as Merck's John T. Connor noted to a group of Texan physicians: while "at the height of the thalidomide furor President Kennedy had announced a 25% increase in the FDA staff… a few months later, came Congressional action eliminating the necessary supplemental appropriation." How, Connor asked, "can an understaffed, overworked and underpaid FDA be expected to cope with this onslaught of data" produced by the new regulations? This concern extended beyond the industry. In 1962, a second Citizens' Advisory Committee of the FDA (on which Connor served) had warned of the continuing material and intellectual weakness of the FDA, and called for the agency's personnel to be upgraded and its scientific orientation and leadership improved.[xxxix]

Academic researchers were equally concerned about what the new regulations meant for clinical research, as William M. M. Kirby, professor of medicine at the University of Washington and chairman of the Committee on the Study of New Drugs of the American Association of Medical Colleges (AAMC), reported in October 1963. Based on the results of a questionnaire circulated among the deans of the country's medical schools (which included 650 replies from 75 medical schools), Kirby's committee found "that the new regulations have not been received enthusiastically by medical school investigators. Far from participating more actively in studies involving new drugs, thereby improving scientific merit as well as increasing drug safety, clinical investigators in academic institutions are likely to undertake less and less of this type of research."[xl]

While their academic colleagues were concerned about the implications for biomedical research, leaders in the non-academic medical community worried about what the new Drug

Amendments meant for the practice of medicine. As Hugh Hussey, chairman of the AMA's Board of Trustees, had argued during the hearings on the Drug Amendments, it was not the FDA's responsibility to determine the efficacy of a drug but rather the physicians because only he "has the knowledge, ability, and the responsibility to make that decision [about efficacy] in regard to that particular patient." The physician, he continued, "should not be deprived of the use of drugs that he believes are medically indicated for his patient by a governmental ruling or decision."[xli]

For Hussey and his non-academic colleagues, the increased authority of the FDA over therapeutic practice marked a dangerous trend in health care policy at a time when reformers were advocating national health insurance for the elderly. As the AMA's president, Leonard Larson, proclaimed to an industry audience six months before the amendments had passed:

> One of our mutual problems is that we suffer from the dubious benefits of too much supervision… too many people still turn around and insist they are competent to tell the physician how to practice medicine. Labor leaders, the Secretary of H.E.W. [Health, Education and Welfare]… the FDA, the Senator from Tennessee, the editor of Saturday Evening Post – all of these and others are eager to dominate the practice of medicine and the behavior of the physician.[xlii]

For Larson, the legislative efforts of Senator Kefauver and his reform-minded colleagues were part of a larger struggle confronting the health care team. As Larson continued, the attempts by pharmaceutical and health care reformers "to wreck the patent system in the pharmaceutical industry, to have the government purchase medical care for the aged, to put the FDA in charge of the clinical evaluation of drugs, and to censor drug advertising are all phases of a single effort." For Larson, these efforts signaled that the medical profession and the drug industry were "involved in a large scale war… we should recognize that there are many facets involved in what must be viewed as a broad-scale attempt to make health care a government responsibility."[xliii]

The challenges posed by the new regulations represented a mutuality of interest between the drug industry and the medical profession. Yet, the medical profession was itself divided in its position towards the drug industry. As Daniel L. Shaw, a physician with Wyeth Laboratories, explained to an industry audience in November 1964, "We must divide physicians into at least two groups: 1.The practicing physician… a friendly neutral who, if made better informed, could become one of our most prized assets." And "2. The investigator," of whom there were three kinds: "1st: Friends, 2nd: The Indifferent, and 3rd: The Academic Prigs."[xliv]

The industry's investigator-friends (friends "because they have a common goal in therapeutics with us") were the industry's "best offense if through them we can practice "third-person sell"… [to] the FDA and [to] the medical community at large." The "indifferent investigators" (those who "are content to participate in clinical pharmacology and clinical trials without becoming involved in the scientific or political problems that surround their activities") "could become a compelling force… if properly molded" by the industry. The academic prigs, however, posed the biggest problem for the industry. These, Shaw asserted, "are the therapeutic nihilists, the smallest group, but the loudest in their denouncements. They usually hold high academic appointments. Their administrative duties and their approach to life have taken them out of contact with day-to-day common programs. Yet they no longer do research, they only talk about it. They rarely see patients, yet they consider themselves, and are looked upon by others, as experts. They have status. These are our most severe critics… and must not be ignored." As experts, these were physicians who possessed a significant degree of political influence and as such were the physicians the industry was most keen to secure the support of.[xlv]

Throughout the 1960s, relations between academic and non-academic physicians had grown increasingly antagonistic. Nowhere was this antagonism more pronounced than over the question of who had the authority to evaluate the safety and efficacy of drugs. For many academicians, the practitioner did not have sufficient expertise in clinical research or pharmacology. As William Coon, professor of surgery at the University of Michigan Medical

School explained, “I feel that the practicing physician has neither the inclination, breadth of experience or background of research experience necessary for objective evaluation” of the safety and efficacy of new drugs.[xlvi] For non-academic physicians, however, academic physicians lacked the clinical expertise to make pronouncements on drug efficacy. As Sidney Merlis, director of psychiatric research at Central Islip State Hospital in New York, argued, both the industry and government suffered from “excessive acceptance and dependence on the academician;” he called on drug firms to reevaluate the role of the academician. In particular, Merlis warned that “the influence of the academician must not be permitted to extend beyond the limits of their knowledge. Their “ivory tower” position and their prestige often permit their statements to have much greater weight than experience or practical clinical data would support. The industry must make some effort to place the academic viewpoint in proper perspective.” That proper perspective would be achieved, Merlis continued, if the industry—and government committees—would balance the academic perspective with that of the practicing physician.[xlvii]

If the industry were to win the political support of all physicians, it would have to take note of these differences and build alliances where possible. Because of their political capital, the drug industry was especially keen to secure the support of so-called “academic prigs.” To do so, Shaw urged his industry colleagues to “recognize[e] these people for what they are and… [be] willing to take the time to penetrate their hard shell.” One way of doing this was to establish cooperative committees with academic researchers, such as the Greater Philadelphia Committee for Medical-Pharmaceutical Sciences (GPCMPS). Established in 1962, the GPCMPS was composed of academic and industry physicians in the Philadelphia region who met regularly to discuss and develop strategies for solving the problems facing clinical researchers in the Philadelphia region. According to Shaw, the early meetings of the GPCMPS “were quite strained and restrained. Those of us from the industry were sure we had B.O. and quite probably a police record.” But “with time-lots of time-and patience… barriers were gradually broken.” Eighteen months later, Shaw could confidently report that while not “all of Philadelphia’s academic prigs

are… on 'our side'… at least we can talk with them, we can make them aware of our problems. They in turn have learned that we can be helpful to them."[xlviii]

The experiences of industry and academic physicians on the GPCMPS reminded both groups that underneath their differences they shared certain key interests: neither group wanted the federal government to wrest further authority away from physicians, nor to circumscribe what the physician could prescribe. So too, academic physicians and the industry regarded the scientific weakness of the FDA as a very real threat to the integrity of pharmaceutical innovation and to clinical research, and thus to the public's health.

The need for alliance-building between industry and medicine grew all the more pressing during the mid-1960s as health care reformers continued to advocate for national health insurance, and pharmaceutical reformers continued to push for legislation that would reduce the cost of prescription drugs. In 1964, for example, as the AMA fought in Congress against the Kerr-Mills legislation, Senator Philip A. Hart (Democrat from Michigan) chaired a Senate subcommittee hearing into charges that U.S. drug firms were fixing the price of the antibiotic tetracycline. These hearings resulted in antitrust charges being filed against Pfizer, Bristol, and American Cyanamid.[xlix] That same year, during Senate and House subcommittee investigations into FDA procedures, the safety of pharmaceutical agents was again called into question as Senator Humphrey and Representative Fountain highlighted several instances of serious adverse reactions induced by FDA-approved prescription drugs.[l] The most publicized of these adverse reactions were those associated with the use of oral contraceptives. Although it took the FDA until late 1968 to confirm that the long-term use of oral contraceptives increased women's risk of blood clots and cervical cancer, the safety of the birth control pill had been hotly contested in the national and medical media since 1961.[li]

Congressional and public debate over the cost of prescription drugs also continued through the 1960s. As a way of reducing prescription drug prices and thus putting a break on spiraling health care costs, Senator Kefauver had pushed for legislation that would require

physicians to prescribe generically whenever a (cheaper) generic drug was available for use. The principal opponents of generic prescribing were the large research-based pharmaceutical manufacturers whose brand-name drug sales (from which they garnered most of their profit) were threatened by mandatory generic prescribing, and physicians, who saw the legislation as the government intruding once more in medical practice.[lii] They all argued that it was inaccurate and extremely dangerous to assume, as the reformers did, that generic drugs had the same therapeutic effect as their brand name equivalents. Rather, the industry and medical profession contended that because generic drugs were not as rigorously evaluated as brand name drugs and because they were usually produced by small drug firms whose reputation could not be guaranteed, you could be neither certain of their quality (and therefore safety) nor their efficacy.

Although Kefauver failed to secure passage of such legislation in 1962, Senator Gaylord Nelson (Democrat from Wisconsin) continued the push for prescription drug reform. When Nelson launched his own investigation into the "Competitive Problems in the Pharmaceutical Industry" in 1967, he placed the issue of generic drug prescription at the center of his investigation.[liii] Like Kefauver, Nelson regarded mandatory generic prescribing as the solution to rising prescription and health care costs. Nelson joined with others in Congress and in state legislatures to push for use of generic drugs for all welfare patients and to secure prescription drug benefits for seniors under Medicare. In 1967, the Secretary of Health, Education, and Welfare established a Task Force on Prescription Drugs—composed of government officials—to determine the feasibility of expanding the Medicare program to include prescription drug coverage. Part of the Task Force's study included an assessment of the benefits of using generic drugs.[liv]

The drug industry, of course, fought back against these challenges, their political mobilization during the Kefauver hearings merely a warm up for the battles that ensued. During the Kefauver hearings the PMA had hired the public relations firm, Hill & Knowlton Inc. and launched a massive public relations program that told "the drug industry story" to the American

public. This public relations effort expanded after 1962. Through the public speeches of its executives, a series of advertisements that were published through the late 1960s in national magazines such as Reader's Digest, The Saturday Evening Post, and Look, the writing of letters to news and medical editors and congressional members, and through individual in-house corporate publications, the industry presented "to the public its record of achievement in protecting health, prolonging life and lowering the costs of illness."[lv]

The industry also worked to establish a stronger political presence in Washington, D.C. In addition to hiring a cadre of lobbyists to promote the industry's interests in the halls of Congress, firms established programs that worked to get "business-oriented, free-enterprise philosophy individuals" elected in Congressional district elections instead of those congressional members who pushed for "Fabian-socialist type of government controls."[lvi] To help with this, firms sought to make connections with as many elected officials as possible, passing along information to these officials, and in return receiving information from them. The industry also sought to inculcate itself in state and local politics. At Eli Lilly & Co., for example, the company encouraged their employees to run for elective office in the Indianapolis community, seeking "such spots as precinct committee man, ward chairman, state representative, city council members, members of town boards and trustees, board of education members."[lvii]

More than anything, however, the industry's ability to draw upon the "mutualities of interest" it shared with the academic medical community proved critical to its political efforts. While the drug industry and academic medicine had shared the threat of increasing government oversight since the end of World War II, passage of the 1962 Drug Amendments -- by expanding the FDA's authority over drug development and therapeutic practice -- transformed that threat into reality. In response, the pharmaceutical industry joined forces with academic physicians to circumvent the FDA's new authority and shift the balance of power back toward industry and academic medicine.

Networked Solutions: The Commission on Drug Safety

During the summer of 1962, in response to the thalidomide disaster, the PMA created the Commission on Drug Safety, a body of pharmaceutical experts from industry and academic medicine. The Commission was charged with guiding industry and the FDA on the issues raised by thalidomide and other problems relating to drug safety. Composed of roughly half industry and half academic medical scientists and physicians, the makeup of the Commission highlighted the "revolving door" that characterized pharmaceutical industry-medicine-government relations throughout the twentieth century.[lviii] Included on the Commission were the Nobel Laureate, Philip S. Hench (who had shared the 1950 Nobel Prize in Physiology or Medicine for his work on the corticosteroids), former Secretary of Health, Education, and Welfare, Chester Keefer (then professor of medicine at Boston University School of Medicine and long-standing consultant for Merck & Co.), former Director of the Drug Division at FDA, Theodore Klumpp (then president and director of the drug firm, Winthrop Laboratories), former Surgeon General Leonard Scheele (then a senior vice-president at Warner Lambert Pharmaceutical Company), former editor of the Journal of the American Medical Association and current president of the PMA, Austin Smith, along with two additional industry executives and eight academic researchers, several of whom had ties to drug companies.[lix]

The aim of the Commission on Drug Safety was to guide industry and government on improving the policies and methods under which new compounds were tested for safety and efficacy.[lx] To this end, the Commission formed 17 subcommittees (composed of nearly 200 scientists), which evaluated each of "the critical phases of the complex problems of drug safety."[lxi] These included the study of prenatal malformations, the principles of clinical trials, and the respective responsibilities of industry, universities, and the state and federal governments regarding drug safety. The PMA's chairman, Eugene Beesley, also hoped the Commission would help undermine the image -- portrayed by the industry's critics in Congress and the press -- of the industry as greed-driven and quick to exploit the sick patient with costly and dangerous drugs, by

making “it more clear to all people that the prescription drug industry is truly going their way, seeking what they seek - the conquest of disease."[lxii]

The ad hoc Commission was in operation for 18 months, funded entirely by the PMA. At the end of its tenure, the Commission published a final report detailing 116 recommendations based on the evaluations of its 17 subcommittees. Of those recommendations, two in particular were aimed at shifting the balance of power within the political economy of drug regulation back toward academic medicine and industry. The first sought to do this by tackling the intellectual weakness of the FDA. Concerned that the FDA remain fully engaged with advances in pharmaceutical knowledge but aware of its stretched-thin resources, the Commission recommended the agency partake in “wide consultation” with leaders in pharmaceutical research. By outsourcing its scientific expertise the FDA could “take full advantage of the knowledge” of pharmaceutical experts in academia and “close the gaps in [the FDA’s] knowledge.” In particular, the Commission suggested the FDA use ad hoc advisory panels to help guide the agency in making decisions about the safety and efficacy of drugs. In this way, the Commission sought to make pharmaceutical experts outside of government the designators of regulatory requirements.[lxiii]

The second and most significant of the Commission’s recommendations went a step further and aimed to secure academic medicine and industry a seat at the policy table. As the Commission’s chairman, Lowell Coggeshall, testified in front of the 1964 Senate Subcommittee on Drug Safety, the Commission recommended the establishment of a permanent advisory body similar to the Commission on Drug Safety “composed of men whose scientific ability and integrity is not questioned – if you will, a supreme court that might serve as a reference body to all the problems that currently exist or will exist in the future.”[lxiv] Such a body was needed, explained Coggeshall, because as new and increasingly potent drugs were developed, the processes of drug development and testing were certain to grow more complex. And if a major problem or crisis was to arise, the government “should not and could not await a regrouping of ad

hoc committees to consider each" problem.[lxv] Rather, the Commission urged the government to retain an elite group of pharmaceutical experts with whom they could consult on everyday issues and should a crisis emerge.[lxvi] These experts would also guarantee that industry and academic medicine had a permanent presence in the policy arena, thus ensuring that their interests would be protected even as pharmaceutical reformers sought to further expand the government's authority over pharmaceutical practice.

Establishing "a Supreme Court" on Drug Policy: The Drug Research Board

The Commission on Drug Safety recognized that as an industry-funded entity it could not function effectively as a permanent advisory body for risk that its motives and the objectivity of its advice would be questioned. Such a body needed instead to be independent of both business and government influence. As both a non-government and non-business scientific organization with "the stature, the tradition, and the capabilities of effectively assuming an advisory function," the Commission regarded the National Academy of Sciences-National Research Council (NAS-NRC) as the ideal home for the "supreme court" of pharmaceutical experts.[lxvii] In the spring of 1963, Lowell Coggeshall approached the NAS-NRC to see about transferring the Commission's operations to the Academy and setting up a permanent advisory body.

The NAS-NRC accepted the Commission's proposal having already determined that the FDA's "woefully inadequate resources" jeopardized the public's health. And like the drug industry and academic medicine, the NAS-NRC was keen to balance the FDA's new authority with that of academic researchers. Indeed, when Coggeshall approached the NAS-NRC, its governing board was anticipating that the FDA would soon ask them to provide advisory services on a continuing basis to the agency. While the NAS-NRC agreed the FDA needed "all the scientific support that can be given," the Academy would not be "put in a position of being a shield for FDA with respect to specific drug decisions." Rather, the Academy preferred the Commission's proposal as it guaranteed the NAS-NRC the autonomy of its expert body, while

ensuring that the advisory body would also have the prestige and authority to make drug policy and practice recommendations to high-level government agencies.[lxviii]

At the end of 1963, under a three-year contract with the National Institutes of Health (at up to $75,000 a year), the Drug Research Board (DRB) was established. The primary objectives of the DRB were to evaluate "the policies, principles, and practices" of pharmaceutical research, to provide a forum for academic medicine, industry, and government to discuss "the problems, responsibilities and opportunities" of drug research and practice, and to make policy recommendations to government.[lxix]

Like its predecessor, the DRB relied on a system of subcommittees -- composed of non-Academy scientists considered experts in their field -- to evaluate and make recommendations on key issues in drug policy and practice. And like the Commission, membership on the DRB consisted of high-ranking industry and academic medical scientists; many of the latter also had affiliations with industry.[lxx] Although Congress had raised some questions about the role of industry on any such advisory body, the DRB sidestepped charges of "conflict of interest." The DRB's members insisted their industrial affiliations actually gave them the expertise to deliberate on issues of national drug policy rather than undermining their authority to speak on matters of pharmaceutical policy.[lxxi] In a statement made to the FDA in 1963, the DRB asserted, "almost inevitably, those individuals with the greatest experience in the study of the action of drugs will be found to have developed working relationships with the pharmaceutical industry."[lxxii] The Academy was confident that it "has sought out the best men for the job as it sees it, confident in the belief that one has less to fear from asking the counsel of the best men than one has to fear from rejecting their counsel because of suspected possibilities of conscious or unconscious bias."[lxxiii] The FDA agreed; its Commissioner assured the DRB that when seeking its advice the agency would not question conflict of interest in any individual selected by the Board.[lxxiv]

The DRB operated for 12 years (from 1964 through 1975), during which time it was at the center of industry and academic medicine's efforts to reshape the regulatory environment to

better serve their interests in the years after passage of the 1962 Drug Amendments. In particular, as pharmaceutical reformers in Congress pushed to further increase the government's authority over pharmaceutical practice the DRB's work proved critical in undermining these efforts. To be sure, the DRB was not a straight-forward proxy for the industry. During the DRB's tenure there was often disagreement among its members over how best to resolve the problems confronting the pharmaceutical field. The discussions and work of the DRB, however, show that in their efforts to reshape the political economy of drug regulation, the shared interests of the industry and academic physicians were far more important than their differences. Nowhere was this clearer than in the debates over mandatory generic prescribing.

The Drug Efficacy Study and the "Generic Drug Controversy"[lxxv]

In May 1967, Senator Gaylord Nelson began what would become a decade-long investigation of the American drug industry. As chair of the Senate Subcommittee on Antitrust and Monopoly, Nelson was concerned, like his predecessor Senator Kefauver had been, "with the important matter of the health and pocketbook of American citizens." In particular, Nelson's hearings examined "such matters as restraint of trade, drug pricing, scientific and technological progress in the industry, the comparative cost and effectiveness of generic and trade-name drugs, the welfare of the consumer and of small business."[lxxvi]

The question of whether or not generic drugs were therapeutically equivalent to their brand name counterparts dominated the hearings. As Nelson sought to secure passage of legislation that would reign in the presumed excesses of the pharmaceutical industry, the generics controversy—and Nelson's efforts to make generic prescribing mandatory—served as an issue around which the drug industry could galvanize the medical profession's support—academic and non-academic alike.

In general, practicing physicians did not want to see the FDA encroach any further into the domain of medical practice. As one Memphis physician asserted to readers of the Journal of

the American Medical Association in 1966, the "[t]he physician should be allowed to prescribe drugs from a pharmaceutical house that he knows is ethical and holds to high sanitary standards, even though it might cost his patient a little more money for the prescription at his pharmacy." For this physician, the "pending legislation before the U.S. Congress [that] would make… generic prescribing mandatory… is obviously not in the best interest of the patient." After all, he noted, "The next time you attend a medical convention in any large city and are on your way from the airport to your hotel, raise your eyes above the street level. In second and third floor lofts you will see many small pharmaceutical companies in very dingy surroundings with obviously poor sanitary facilities. The pharmaceuticals manufactured in some of these loft factories are sometimes a combination of dust, ground-up cockroaches, and drug. Supervision by the local health department may be desultory and two years late. Almost every week we receive catalogs of cut-rate drugs from just such pharmaceutical companies."[lxxvii]

The AMA was vociferously opposed to any legislation that threatened to further undermine the physicians' autonomy. In an editorial in The AMA News, the physician group argued that physicians prescribed drugs by brand name so that they could be confident in the drugs' quality. Any "[l]egislation that would nullify this knowledge [about quality] by removing the decision-making power from him," the AMA asserted, "clearly is not in the public interest."[lxxviii] Furthermore, based on a survey of 352 prescriptions filled at 85 Chicago drugstores, the AMA "challenge[d] the contention that generic prescribing automatically assures the patient of obtaining drugs at the lowest possible price."[lxxix]

Academic physicians had additional concerns. As Louis Lasagna explained, "the science underlying [generic legislation] and the realistic appraisals of their economic impact, are deficient." As Lasagna noted, "After many years of blind reliance on United States Pharmacopoeia [USP] standards for drug quality, biopharmaceutical experts have now realized our ancient standards for drug quality are inadequate." For example, "recently, nine brands of an important antibiotic were removed from the market when it became apparent that none of these

met the criterion of reproducible and adequate blood levels in man. All of these preparations had been batch-tested by the FDA, and had presumably passed these tests." Legislation should not be passed, Lasagna exalted, "in scientific areas where we are abysmally ignorant."[lxxx]

Even for those physicians who supported the concept of generic prescribing, their support came with qualifications. For example, prominent clinical pharmacologist, Walter Modell, testified in front of Nelson's subcommittee that "if all drugs lived up to USP standards then there should be absolutely no difference between generically named drugs and [brand] named drugs." However, Modell noted, this was not currently the situation. While "the large drug manufacturers take every precaution possible to insure that their drug lives up to proper standards… I think that there may be a tendency for smaller drug houses to cut corners because they can't afford the luxury of not cutting corners."[lxxxi]

In 1966, the matter of generic drugs had come before the DRB as part of the broader efficacy review of pre-1962 drugs undertaken by the National Academy of Sciences-National Research Council. As part of the 1962 Drug Amendments, the FDA was required to review the efficacy of all drugs marketed between 1938 and 1962, some 4000 drugs. Since passage of the legislation, the FDA had failed to act on that requirement. However, when James Goddard became Commissioner in 1966, he began to address the problem. Realizing the FDA had neither the necessary manpower nor the resources to undertake such a massive task, Goddard asked the DRB if it would fulfill the drug efficacy requirement on behalf of the FDA.[lxxxii] Despite some initial reluctance, the DRB agreed to oversee the efficacy review, and coordinated the recruitment of 30 advisory panels composed of almost 200 academic physicians deemed experts in critical areas of drug evaluation to perform the evaluations; this came to be called the Drug Efficacy Study (DES).[lxxxiii]

As was standard for government contracts, the FDA contracted the DES out to the National Research Council rather than directly to the DRB. However, the DRB and nine additional academic researchers composed the executive committee of the DES, making the DRB

-- in effect if not in name -- responsible for coordinating the DES. The DES completed the evaluations in just three years after which time the FDA decided, based on the DES's reports, which drugs were to be pulled from the market because they did not have sufficient evidence of efficacy, and which drugs required labeling changes to more accurately reflect the DES's findings. In the end, the FDA pulled some 300 drugs from the market, based on the DES data.[lxxxiv]

The DES necessarily included the evaluation of brand name and generic drugs and as such dealt specifically with the matter of the therapeutic equivalence of generic drugs. Any recommendation that the DES made to the FDA regarding the efficacy of generic drugs thus stood to influence the legislative efforts of Senator Nelson and his fellow pharmaceutical reformers. This fact was not lost on the DES's chairman, prominent Yale pharmacologist, Alfred Gilman, who warned that Nelson's pending legislation signaled the government was "more concerned with the cost rather than the quality of medical care."[lxxxv] Moreover, the problem of generics marked a double standard in the regulatory process. While "the marketer of a patent-protected drug applies to the FDA for a change in formulation, no matter how slight, a supplementary NDA [New Drug Application] must be submitted and the proof of therapeutic equivalency required by the FDA is exacting and demanding." On the other hand, the marketer of a generic drug need only supply to the FDA proof of the drug's chemical equivalence to the brand name drug for which approval had already been given. Thus by "rendering decisions on the efficacy of "generic" drugs," and "accepting inadequate "in vitro" tests as adequate evidence of therapeutic equivalency," Gilman believed the DES would violate the 1962 Drug Amendments. Without clinical data, "we have no idea of the efficacy in man of many of the generic drugs that we have declared to be effective."[lxxxvi] Until the FDA's evaluation of generic drugs was made more rigorous, the DES opposed any legislation that mandated generic prescribing.

The DES laid out its position on generic drugs in a "White Paper on Therapeutic Equivalence." In it, the DES contended that the FDA should require a modified NDA for all generic drugs. Recognizing that it would not be feasible for all generic manufacturers to repeat all

clinical studies on their drugs, the DES called for "proof of biological availability in man equivalent to that of the drug for which it claims to be a therapeutic equivalent." Any drug failing "to meet these requirements should not be allowed on the market."[lxxxvii]

In September 1967, Gilman submitted these views to Senator Nelson's subcommittee. Repeating the assertions made in the White Paper, Gilman argued, "that the present practice constitutes a kind of double standard [for] originators of compounds and those who later market alleged "equivalents."" It was imperative, Gilman contended, that "all producers, and certainly the generic houses, should be required to submit proof of the performance of their drugs in human patients before they are permitted to market them. Once that is required, and this double standard is eliminated, I believe many of the problems facing us will be reduced." Gilman also challenged Nelson's premise that mandatory generic prescribing would significantly reduce health care costs, arguing instead that if the same regulatory "demands were placed on these so-called generic equivalents," the cost of developing generic drugs would rise and "then the price differential between generic and trade-marked drugs… would be very much less. In fact, many generics would disappear."[lxxxviii]

The DES's perspective was all the more important as it directly challenged the conclusions of the Secretary of Health, Education, and Welfare's Task Force on Prescription Drugs. Established in 1967 by Secretary Gardner and composed of government officials, the Task Force was charged with determining the feasibility of expanding the Medicare program to include prescription drug coverage. Part of the Task Force's study included an assessment of the benefits of using generic drugs.[lxxxix] To this end, the Task Force had determined that "lack of clinical [therapeutic] equivalency among chemical equivalents meeting all official standards has been grossly exaggerated as a major hazard to the public health."[xc] The DES found instead that there was insufficient evidence of therapeutic equivalence among chemically equivalent drugs to justify mandatory generic prescribing.

For the next five years, Senator Nelson introduced bills calling for mandatory generic prescribing based on the assumption that generic drugs were therapeutically equivalent to their brand name counterparts. In each case, the bill failed to make it out of committee. In February 1972, however, citing the work of the Drug Research Board and specifically its "White Paper on the Therapeutic Equivalence of Chemically Equivalent Drugs," Nelson revised his generic prescription bill. While still calling for the mandatory prescription of generic drugs, Nelson acknowledged the "inadequate information… made available to the physician, the pharmacist, or the consumer by pharmaceutical manufacturers" on the biological activity of chemically equivalent drugs. Although Nelson framed his statement as an attack on the industry's failure to adequately label prescription drugs, he was clearly responding to the concerns expressed by the DRB and the DES regarding the problem of therapeutic equivalence. By calling for the "inclusion of such biological performance data by manufacturers of their new drug application and to require the inclusion of such biological performance information in the labeling which accompanies the drug," Nelson acknowledged that chemical equivalence could no longer be regarded as an adequate measure of therapeutic efficacy.[xci]

To be sure, the drug industry's campaign against generic prescription legislation did not rest solely on the work of the DES and DRB. Rather, the industry mobilized a full-scale political campaign against generic legislation. As part of this, the PMA published Compulsory Generic Prescribing – A Peril to the Health Care System and Drugs Anonymous?, two 15-page pamphlets that presented the industry's arguments against generic prescribing. Distributed in physicians offices and by pharmacists, and to Congressional members and staffers, the pamphlets warned of the dangers of making generic prescribing mandatory, asserting that such action "could and probably would bring about deterioration in the quality of medical care—through the wide sale of substandard products—by discouraging the struggle for excellence which has marked the astounding progress in the pharmaceutical field—and by impeding drug research on which future progress depends."[xcii]

During the summer of 1969, the industry was accused of pressuring the White House to withdraw its support for the appointment of a staunch advocate of generic prescribing to the position of director of the FDA's Bureau of Medicine. As the New York Times reported, John Adriani, chairman of the AMA's Council on Drugs, had accepted the position but the offer was withdrawn following his testimony to the Nelson subcommittee that May. In this testimony, Adriani had "said brand names should be abolished; they were aliases and deceptive and served no useful purpose."[xciii] While the PMA denied applying any such pressure, just a year earlier, the industry had also been accused of "pour[ing] money into Wisconsin in an attempt to defeat Senator Gaylord Nelson" in his reelection bid that fall.[xciv]

At the same time, the AMA lobbied against Nelson's bills. As Donald O. Schiffman from the AMA's Department of Drugs asserted in 1973, "Until all similar drug preparations can be equated meaningfully in terms of their bioavailability to permit the interchange of different forms of a drug on a rational basis, legalistic maneuvering," which took away the physician's prescribing autonomy, "should be vigorously opposed by the medical community."[xcv] As Schiffman later warned, passage of any "[l]aws allowing the pharmacist to exercise the right of autonomous product selection will open the door to a decrease in the physician's control over his patient's therapy. Without automatic and absolute control over the exact regimen of therapy, the physician cannot possibly utilize all of his training and ability to help the patient."[xcvi] To this end, the AMA repeatedly testified against Nelson's generic prescription legislation.[xcvii]

The efforts of Senator Nelson to enact mandatory generic prescribing (a bid that was ultimately unsuccessful), was thus an issue around which the drug industry and medical profession forged a political alliance. The effectiveness of the alliance between the industry and academic physicians was most visible in the efforts of the DES—and by extension, the DRB—to influence Nelson's legislative agenda. This, together with the legislative activism of the PMA and AMA, ultimately served to protect the interests of the drug industry and the medical profession from a bill that would have further expanded the government's role in pharmaceutical practice.

Conclusion

The 1962 Drug Amendments were a turning point in the history of drug regulation and in the history of drug industry-academic physician relations. In response to the new regulations, the drug industry drew upon the relationships it had nurtured with the academic medical community since the interwar years and created a political alliance not only with academic physicians but also with the organizations that represented the interests of practicing physicians. The Drug Research Board, with its predecessor the Commission on Drug Safety, allowed industry and academic medicine to reassert their authority in a new regulatory context that threatened to undermine them. They did this by positioning themselves as pharmaceutical experts available to advise government on matters of drug policy and therapeutic practice. In this way, the DRB aimed to see government agencies - as part of their standard practice - "invite the biomedical community to participate in the management of drugs."[xcviii] As an executive officer of the NAS-NRC proclaimed, "Surely this is good political science because it broadens the base of democratic government, increases… the permeability of bureaucracy and fosters cooperation rather than conflict."[xcix] Moreover, it ensured industry and academic medicine seats at the policy table.

As pharmaceutical experts they were able to tackle one of the major problems confronting the industry and medical profession in the 1960s: the increasing authority of the FDA over pharmaceutical development and practice. Since World War II the drug industry and medical community had feared the expanding authority of the federal government in medicine. After passage of the 1962 Drug Amendments, however, pharmaceutical reformers attempted to transform the corporate system of drug development into one in which the government played a central role. Indeed, in securing passage of the amendments Senator Kefauver had succeeded in shifting the balance of power in the political economy of drug regulation further towards the

federal government. The new regulations showed that the government was serious about correcting what critics of the industry had long viewed as the industry's exploitation of the America patient.

Through the work of the DRB—together with the political activism of the PMA and AMA—industry and medical profession were, however, able to limit some of the FDA's new authority. The provision of this industry-academic expertise coincided with the FDA's tendency in the 1960s, as Shelia Jasanoff has argued, to consult with expert advisory committees in order to shore up its own authority within the scientific community.[c] The evidence that I have presented here advances Jasanoff's argument by indicating that as much as the FDA sought cooperation with academic medicine, academic physicians were acting out of their own interests when they agreed to provide that expertise to the agency. In particular, academic physicians were seeking to secure their autonomy from government involvement and to preserve their expert-status in the new regulatory environment.

At the same time, the history of the DRB shows the importance of voluntary and purportedly independent expertise -- in addition to explicit legislation and regulation -- in shaping post-war American health care. Specifically, the DRB gave industry and academic medicine a vehicle for challenging the efforts of pharmaceutical reformers to radicalize the corporate system of drug development. The DRB continued to play this role during the 1970s. Through the 1970s, Senator Nelson, joined by his fellow pharmaceutical reformers -- Democratic Senators Edward Kennedy of Massachusetts and Russell Long of Louisiana, and Democratic Representative Paul Rogers of Florida -- continued to push for measures that would increase the government's role in drug development. In that decade, these reformers attempted successively to secure legislation that would allow pharmacists to fill prescriptions with cheaper generic drug substitutions for the brand-name drugs requested by physicians. These efforts to enact federal substitution laws threatened both the autonomy of physicians and the profits of the pharmaceutical industry and thus met with vociferous opposition from industry and the medical community. These reformers

also attempted to establish a national center of drug development within the Department of Health, Education, and Welfare, which would have made the government responsible for the preclinical and clinical testing of all new drugs.

In each instance, however, the pharmaceutical industry was able to thwart these efforts to place the industry under government control through the work of the DRB and the legislative activism of the PMA and AMA. In doing so, the industry was able to preserve the system of corporate drug development (and thus their profits). Indeed, by 1980, in spite of the continued efforts of pharmaceutical reformers to push for radical reform, there still had been no significant patent reform (except in favor of increasing the industry's period of exclusivity), no federal substitution laws had been passed (despite passage of such laws by all states by the mid-1980s), and there was still no federal center of pharmaceutical development.

The history of the relationships between the pharmaceutical industry and medical profession in the three decades after World War II sheds important light on pharmaceutical politics in the U.S today. This history challenges the tendency of many observers to vilify the American pharmaceutical industry and cast the industry as the single perpetrator of today's current health-care crisis. Rather, my research shows that the drug industry is just one of several actors -- including clinicians, biomedical researchers, the FDA, and Congress -- that has shaped the current political economy of drug development, and the health care system more generally. Today's pharmaceutical politics are a consequence of the social networks that were forged between the drug industry and physicians during the 1960s, when both groups were under Congressional scrutiny that threatened their practices and their autonomy. By identifying these social networks and understanding why and how they developed, the ways in which they adapted to regulatory challenges, and what form they take today, historians can aid policymakers in demanding greater accountability in the pharmaceutical marketplace and finding solutions to the current health care crisis.

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[i] Leonard W. Larson, "Together for the best medical care," PMA Year Book, 1960-1961, (Washington, D.C.: PMA, 1961), p. 38

[ii] "Me-too" drugs refer to drugs that have similar chemical properties and more or less identical therapeutic function.

[iii] See James Harvey Young, "Sulfanilamide and Diethylene Gylcol," in John Parascandola and James C. Wharton, eds., Chemistry in Modern Society (Washington, D.C.: American Chemical Society, 1983); Charles O. Jackson, Food and Drug Legislation in the New Deal (Princeton: Princeton University Press, 1970); Peter Temin, Taking Your Medicine: Drug Regulation in the United States (Cambridge: Harvard University Press, 1980); James Harvey Young, Pure Food: Securing the Federal Food and Drugs Act of 1906 (Princeton: Princeton University Press, 1989);

and Harry Marks, "Revisiting "The Origins of Compulsory Drug Prescriptions." American Journal of Public Health 1995, 85(1): 109-116.

[iv] Richard Harris, The Real Voice. (New York: The Macmillan Company, 1964); Richard E. McFadyen, Estes Kefauver and the Drug Industry (Ph.D. Dissertation, Emory University, 1973); and also see Julius J. Mastro, The Pharmaceutical Manufacturers Association, the Ethical Drug Industry and the 1962 Drug Amendments: A Case Study of Congressional Action and Interest Group Reaction (Ph.D. Dissertation, New York University, 1965). For the history of the thalidomide tragedy see Arthur Daemmrich, "A tale of two experts: thalidomide and political engagement in the United States and West Germany." Social History of Medicine, 2002, 15(1): 137-158.

[v] Histories of U.S. drug regulation that emphasize the importance of the Drug Amendments but fail to examine the industry's reaction to and the lasting political effects of those regulations include: Temin, Taking Your Medicine (n. 3); Philip J. Hilts, Protecting America's Health: The FDA, Business, and One Hundred Years of Regulation (New York: Alfred A. Knopf, 2003); Robert Bud, "Antibiotics, Big Business, and Consumers: The Context of Government Investigations into the Postwar American Drug Industry." Technology and Culture, 2005, 46: 329-349; Arthur Daemmrich, Pharmacopolitics: Drug Regulation in the United States and Germany, (Chapel Hill: University of North Carolina Press, 2004).

[vi] For example see Marcia Angell, The Truth About the Drug Companies, (New York: Random House, 2005); Jerry Avorn, Powerful Medicines: The Benefits, Risks, and Costs of Prescription Drugs (New York: Alfred A. Knopf, Random House, 2004).

[vii] John P. Swann, Academic Scientists and the Pharmaceutical Industry: Cooperative Research in Twentieth-Century America, (Baltimore, Johns Hopkins University Press, 1988); Louis Galambos and Jane E. Sewall, Networks of Innovation: Vaccine Development at Merck, Sharp & Dohme, and Mulford, 1895-1995, (Cambridge: Cambridge University Press, 1995); and Nicolas

Rasmussen, "The Drug Industry and Clinical Research in Interwar America: Three Types of Physician Collaborator," Bulletin of the History of Medicine, 2005, 79(1): 50-80.

[viii] On the increase in the number of drug company fellowships awarded during World War II, see Swann, Academic Scientists and the Pharmaceutical Industry (n. 7), p. 50. On biomedical research during World War II see Harry Marks, "War and Peace," The Progress of Experiment. Science and Therapeutic Reform in the United States, 1900-1990 (Cambridge: Cambridge University Press, 1997), pp. 98-128, and Nicolas Rasmussen, "Of 'small men', Big Science, and Bigger Business: The Second World War and Biomedical Research in the United States." Minerva, 2002, 40: 115-146. On penicillin see Robert Bud, Penicillin: Triumph and Tragedy (Oxford: Oxford University Press, 2007) and Gladys Hobby, Penicillin: Meeting the Challenge (New Haven: Yale University Press, 1985).

[ix] See for example, Galambos and Sewall, Networks of Innovation (n. 7); Rasmussen, "Of 'small men', Big Science, and Bigger Business" (n. 8); Nicolas Rasmussen, "Steroids in Arms: Science, Government, Industry, and the Hormones of the Adrenal Cortex in the United States, 1930-1950," Medical History, 2002, 46: 299-324; Harry Marks, "Cortisone, 1949: A Year in the Political Life of a Drug," Bulletin of the History of Medicine, 1992, 66: 419-439; Jeremy A. Greene, "Releasing the Flood Waters: Diuril and the Reshaping of Hypertension," Bulletin of the History of Medicine, 2005, 79(4): 749-794; Lara Marks, Sexual Chemistry: A History of the Contraceptive Pill, (New Haven: Yale University Press, 2001); and Mickey C. Smith, Small Comfort: A History of the Minor Tranquilizers, (New York: Praeger, 1985).

[x] For a detailed analysis of the federal government's increasing investment in medical research after World War II see Stephen P. Strickland, Politics, Science, and Dread Disease: A Short History of United States Medical Research Policy (Cambridge: Harvard University Press, 1972). For a discussion of the business community's involvement in passage of the National Science Foundation Act (including the work of pharmaceutical executives), see Daniel Lee Kleinman,

"Layers of interests, layers of influence: Business and the genesis of the National Science Foundation." Science, Technology, and Human Values, 1994, 19(3): 259-282.

[xi] George Merck letter to A.N. Richards, January 25, 1946. Alfred Newton Richards Papers, University of Pennsylvania Archives (hereafter ANR Papers), Box 19, FF 12.

[xii] H. W. Chadduck, "Memo: Contributions of industrial corporation funds toward support of scientific research, education and other related activities," March 31, 1949. ANR Papers, Box 16, FF 41.

[xiii] See Strickland, Politics, Science, and Dread Disease (n. 10), pp. 55-74.

[xiv] Edwin J. Cohn, "Training for research in the medical sciences," December 6, 1947. ANR Papers, Box 20, FF 40.

[xv] Edward Reynolds to George W. Merck, May 4, 1948. ANR Papers, Box 16, FF 34.

[xvi] Reynolds (n. 15).

[xvii] In 1946, Chemical and Engineering News published a list, compiled by the National Research Council, of research scholarships and fellowships supported by the chemical and pharmaceutical industries in the United States. As of 1946, 302 companies reported a total of 1,800 fellowships, scholarships, or research grants to academic institutions. For example, Abbott Laboratories supported 20 fellowships at $5000 each for five years, Lederle Laboratories provided 13 fellowships each with annual stipends of $1000-$1200, and Pfizer awarded two fellowships of $4700. This was contrasted to the 56 firms supporting 95 fellowships and grants in 1929. See Callie Hull and Mary Timms, "Research Supported by Industry through Scholarships, Fellowships, and Grants," Chemical and Engineering News, 1946, 24: 2346.

[xviii] G. H. A. Clowes to George W. Merck, September 15, 1947. ANR Papers, Box 16, FF 34.

[xix] Chadduck (n. 12).

[xx] Bud, "Antibiotics, Big Business, and Consumers" (n. 5), pp. 341-343.

[xxi] The companies were Pfizer, Lederle, Bristol-Myers, Squibb, and Upjohn. FDC Reports, 20(31), August 4, 1958

[xxii] FDC Reports, April 21, 1958, 20 (16): 15-16.

[xxiii] See, for example, Harry F. Dowling, "Twixt the cup and the lip." Journal of the American Medical Association, 1957, 165(6): 657-661, and Joseph Garland, "The play of the market place," New England Journal of Medicine, 1956, 255(1): 528-529. For a detailed discussion of the medical profession's ongoing critique of pharmaceutical advertising see James C. Whorton, "Antibiotic Abandon and the Resurgence of Therapeutic Rationalism," in John Parascandola, ed., The History of Antibiotics (Madison: American Institute of the History of Pharmacy, 1980), pp. 125-136; Harry M. Marks, "Trust and Mistrust in the Marketplace: Statistics and Clinical Research, 1945-1960," History of Science, 2000, 38: 343-355; and Nancy Tomes "The Fielding H. Garrison Lecture: The Great American Medicine Show Revisited," Bulletin of the History of Medicine, 2005, 79(4): 627-663.

[xxiv] FDC Reports, July 6, 1959, 21 (27): 3-5.

[xxv] See, for example, Theodore G. Klumpp, "Partners in Progress." Speech delivered to unnamed group of physicians, September 23, 1958. National Museum of American History, Papers of Sterling Drug Inc., (hereafter referred to as SDI), Record Group 4, subgroup 3, series 4, folder 04-00-03-004-0001. See also, Theodore G. Klumpp, "Medical progress and the pharmaceutical industry." Commencement address, University of Chattanooga, Chattanooga, Tennessee, June 6, 1960. SDI, Record Group 4, subgroup 3, series 4, folder 04-00-03-004-0002.

[xxvi] The drug industry had successfully used a similar strategy in the late 1940s and early 1950s, as it fought to restrict the FDA's authority to limit the use of prescription drugs, see Marks "Revisiting "The Origins of Compulsory Drug Prescriptions" (n. 3). For the history of the American medical profession's struggle against national health insurance see Ronald L. Numbers, Almost Persuaded: American Physicians and Compulsory Health Insurance, 1912-1920

(Baltimore: Johns Hopkins University Press, 1978); and Colin Gordon, Dead On Arrival: The Politics of Health Care in Twentieth Century America (Princeton: Princeton University Press, 2003).

[xxvii] Marks, "Revisiting "The Origins of Compulsory Drug Prescriptions" (n. 3), pp. 111-112.

[xxviii] John T. Connor, "Government and Industry Relationships: Their New Impact on Medicine." Address delivered to the 1963 Conference for Physicians, the Texas Medical Association, Austin, Texas, January 19, 1963. Merck Archives, Whitehouse Station, New Jersey.

[xxix] Louis Lasagna, "Gripemanship: A Positive Approach," PMA Year Book, 1959-60, (Washington, D.C.: PMA, 1960), p. 69-70

[xxx] Both of the FDA's Commissioners during the mid- to late-1950s – Charles Crawford from 1953 and George Larrick from 1954 – had an "open door" policy towards industry, as described in Hilts Protecting America's Health (n. 5), pp. 117-128.

[xxxi] Administered Prices in the Drug Industry. Hearings before the Subcommittee on Antitrust and Monopoly of the Committee of the Judiciary, United States Senate, 86th Congress, 1st Session, December 7-12, 1959.

[xxxii] Austin Smith, "Remarks of Austin Smith, M.D. (president elect)" PMA Year Book, 1959-1960, (Washington, D.C.: PMA, 1960), p.39.

[xxxiii] Section 103 (b) Section 505 (i). Drug Amendments to the Federal Food, Drug and Cosmetics Act, Public Law 87-781, 10 October 1962.

[xxxiv] Section 102. Drug Amendments to the Federal Food, Drug and Cosmetics Act, Public Law 87-781, 10 October 1962.

[xxxv] "Who likes the new drug regulations?" Medical News, July 13, 1963, p. 34-35.

[xxxvi] "Drug industry situation uncertain but hopeful." Medical News, March 14, 1964, p. 35.

[xxxvii] "Who likes the new drug regulations?" Medical News, July 13 1963, p. 34-35.

[xxxviii] "Who likes the new drug regulations?" Medical News, July 13 1963, p. 34-35.

[xxxix] Connor, "Government and Industry Relationships" (n. 27).

[xl] William M. M. Kirby, "Impact of the new drug regulations on teaching and research in medical schools." Presented at 74th Annual Meeting of the Association of American Medical Colleges, Chicago. I.S. Ravdin Papers, University of Pennsylvania Archives, UPT 50 R252, Box 175, Folder 1.

[xli] Statement of Hugh H. Hussey, Hearings Before the Subcommittee on Antitrust and Monopoly of the Committee of the Judiciary, United States Senate, 87th Congress, 1st Session, Pursuant to S. 1552 (Washington, D.C.: U.S. Government Printing Office, 1961), p. 45.

[xlii] Leonard W. Larson, "Mutual problems of the A.M.A. and P.M.A." PMA Yearbook, 1962-1963, (Washington, D.C.: PMA, 1963), p.345 (emphasis in original).

[xliii] Larson, "Mutual problems of the A.M.A. and P.M.A" (n. 39), p. 346

[xliv] Daniel L. Shaw, "Physician-Industry-FDA Relationships: III." PMA Year Book, 1965-1966, (Washington, D.C.: PMA, 1966), p. 580.

[xlv] Shaw, "Physician-Industry-FDA Relationships" (n. 41), p. 581-582.

[xlvi] William W. Coon to Duke C. Trexler, February 3, 1969. NAS Archives; Series 2 DES Panels; Folder: Membership--Comments on Topics for Final Report.

[xlvii] Sidney Merlis, "Physician-Industry-FDA Relationships: I" PMA Yearbook, 1965-1966 (Washington, D.C., 1966), p. 569. Merlis' speech was delivered at the Research and Development Section Meeting of the PMA, November 10, 1964.

[xlviii] Shaw, "Physician-Industry-FDA Relationships" (n. 41), p. 582.

[xlix] This was actually a continuation of the price-fixing allegations first made by the FTC against the tetracycline manufacturers in 1958. Samuel Mines, Pfizer… An Informal History (New York: Pfizer, 1978), pp. 198-212.

[l] Drug Safety. Hearings before the Subcommittee on Intergovernmental Relations of the Committee on Government Operations, House of Representatives, 1964; Interagency

Coordination in Drug Research and Regulation; and Hearings before the Subcommittee on Reorganization and International Organizations of the Committee on Government Operations, United States Senate, 1962-1963.

[li] Elizabeth Siegel Watkins, On The Pill: A Social History of Oral Contraceptives, 1950-1970 (Baltimore: Johns Hopkins University Press, 1998), pp. 73-102; Lara Marks, "'Not just a statistic': The history of U.S.A. and U.K. policy over thrombotic disease and the oral contraceptive pill, 1960s-1970s," Social Science and Medicine, 1999, 49: 1139-1155; and Suzanne Junod and Lara Marks, "Women's trials: the approval of the first oral contraceptive pill in the United States and Great Britain," Journal of the History of Medicine and Allied Sciences, 2002, 57(2): 117-160.

[lii] During the 1960s, the PMA had around 140 member firms (at that time there were approximately 1,200 drug companies in the U.S.). The PMA represented small- and medium-sized prescription drug manufacturing and distribution firms, and large-sized, research-based manufacturing firms. The vast majority of manufacturers of generic prescription drugs (the remaining 1000 or so firms) were excluded from the PMA. However, beginning in the 1970s, once the patents began expiring on many of their biggest selling drugs, and recognizing the market potential of the generic drug field, several of the large-research based firm began manufacturing and distributing generic prescription drugs, in addition to their brand-name drugs. Despite their entry into the generic drug field, for the largest and most powerful of the PMA's member firms, brand-name prescription drug manufacturing and distribution remained the most important aspect of their business.

[liii] "Competitive Problems in the Drug Industry." Hearings before the Senate Select Committee on Small Business. Monopoly Subcommittee, 1967-1977. Hereafter referred to as the "Nelson Hearings."

[liv] Office of the Secretary, U.S. Department of Health, Education, and Welfare, Final Report of the Task Force on Prescription Drugs. (Washington D.C., 1969), p. iii. The Task Force was composed only of government officials, several of whom had no medical or scientific training.

[lv] Pharmaceutical Industry Advertising Program, National Museum of American History, N. W. Ayers Advertising Agency Collection, Collection no. 59, Series 4, Box 67, folder 7. Part of this public relations strategy included the president of the PMA making an annual "Report to the Nation," each winter. Some 20,000 copies of the president's speech would be mailed to the media, business leaders, and public officials. For details of the PMA's public relations campaign see William Kloepfer, "Report of the Director of Public Information," PMA Year Book, 1961-1962 (Washington, D.C.: PMA, 1962), pp. 81-85.

[lvi] John F. Modrall, "Comments," PMA Year Book, 1962-1963, (Washington, D.C.: PMA, 1963), p. 98.

[lvii] Modrall, "Comments" (n. 56), p. 99-101.

[lviii] On the origins of the revolving door between drug companies, academic institutions and government agencies see Jonathon Liebenau, Medical Science and Medical Industry: The Formation of the American Pharmaceutical Industry (Baltimore: Johns Hopkins University Press, 1987)

[lix] The full membership list of the Commission on Drug Safety was Lowell T. Coggeshall (Vice President of the University of Chicago and on the Board of Directors of Abbott Laboratories), Paul R. Cannon (editor of the Archives of Pathology), Thomas Francis, Jr., (chairman of the Department of Epidemiology, University of Michigan), Hugh Hussey (director of the Division of Scientific Activities, AMA), Chester S. Keefer (Wade Professor of Medicine, Boston University School of Medicine), Theodore G. Klumpp (President and Director, Winthrop Laboratories), John T. Litchfield (Director of Research, Lederle Laboratories), Maurice R. Nance (Medical Director, Smith Kline & French Laboratories), Leonard A. Scheele (Senior Vice President, Warner-

Lambert Pharmaceutical Company), Leon H. Schmidt (Director, National Primate Cener, University of California, Davis), Austin Smith (President, PMA), Thomas B. Turner (Dean of the School of Medicine, Johns Hopkins University), Josef Warkany (Professor of Research Pediatrics, University of Cincinnati, The Children's Hospital Research Foundation), and Duke C. Trexler.

[lx] "Objectives of the Commission (As stated by Dr. Coggeshall, July 31, 1962)," NAS Archives; CDS; Folder: Commission Establishment

[lxi] "Objectives of the Commission" (n. 60)

[lxii] Eugene N. Beesley, "Address of the chairman of the board," PMA Yearbook, 1963-1964, (Washington D.C., PMA, 1964), p. 6.

[lxiii] Beesley, "Address of the chairman of the board" (n. 62)

[lxiv] Lowell T. Coggeshall to Senate Subcommittee on Drug Safety, June 19, 1964. NAS Archives; CDS; Folder: Coggeshall – Senate Hearing June 19, 1964.

[lxv] Lowell T. Coggeshall, "Strengthening the Forces of Drug Safety." PMA Yearbook, 1964-1965, (Washington, D.C.: PMA, 1965), p. 328.

[lxvi] On the government's national security strategy of maintaining an elite reserve labor force of scientists after World War II see Chandra Mukerji, A Fragile Power: Scientists and the State, (Princeton: Princeton University Press, 1989).

[lxvii] F. Douglas Lawrason, "Report of the Liaison Committee with the NRC, VA, and USPHS." PMA Yearbook, 1963-1964, (Washington, D.C.: PMA, 1964), p. 399.

[lxviii] NAS-NRC Division of Medical Sciences, "Appendix 7.2 of meeting minutes, September 29, 1963." NAS Archives; Medical Sciences; Folder: DRB, 1963.

[lxix] NAS-NRC Division of Medical Sciences "Appendix 7.2 of meeting minutes" (n. 68).

[lxx] For example, in 1972 the Roster of the DRB listed four industry executives, one FDA officer and 13 academic physicians, 10 of whom either currently or previously held affiliations with

industry. “Current Membership for Drug Research Board,” NAS Archives; Medical Sciences; Folder: DRB: Membership Biographies 1972.

[lxxi] Coggeshall (n. 64).

[lxxii] NAS-NRC Division of Medical Sciences “Appendix 7.2 of meeting minutes” (n. 68).

[lxxiii] R. Keith Cannan, “The Drug Efficacy Study of the NAS-NRC: A talk given at the Sixth Annual Briefing in Science Council for the Advancement of Science Writing, November 11, 1968.” NAS Archives; Series 1 DES; Speeches on History and Work of DES by Cannan, Gilman, and Trexler, 1966-68.

[lxxiv] R. Keith Cannan, “Inter-Office Memorandum. For the Record: Conference with Dr. Goddard and Dr. Don Estes,” March 28, 1966. NAS Archives; Series 1 DES; Folder: Beginning of Program, 1966.

[lxxv] Senator Durward G. Hall, “The ‘generic’ drug controversy,” Congressional Record, 90th Congress, 1st session, 113 pt. 10: 13071-13074.

[lxxvi] Nelson Hearings, 15 May 1967, p. 1.

[lxxvii] Edward F. Skinner, “Generic prescribing,” Journal of the American Medical Association,1966, 198(7): 792-297. See also Charles A. Ragan, “Editorial: Are We Headed for a Dark Age of Nondiscovery in Therapeutics?” Journal of the American Medical Association, 1967, 202(12): 1099-1100.

[lxxviii] Donald Janson, “AMA says brand-name drugs do not always cost more,” New York Times, 26 May 1967, p. 24.

[lxxix] Janson, “AMA says brand-name drugs do not always cost more” (n. 78)

[lxxx] Louis C. Lasagna, “What we don’t know about drugs.” Letter to editor of undisclosed newspaper, 1968. Louis Lasagna Papers, University of Rochester Archives, d302, Box 4:1.

[lxxxi] “Statement of Dr. Walter Modell, Director of Clinical Pharmacology, Cornell University Medical College, New York.” Nelson Hearings, 7 June 1967, p. 304.

[lxxxii] James L. Goddard, Memorandum to R. Keith Cannan: "Efficacy Review of Pre-1962 Drugs," March 31, 1966. NAS Archives; Series 1 DES; Folder: Beginning of Program 1966.

[lxxxiii] Governing Board, National Research Council, Minutes of NRC Governing Board Meeting, April 24, 1996, Appendix 7.2. NAS Archives; Medical Sciences; Folder: DRB: Committee on Drug Efficacy Review Ad Hoc 1966.

[lxxxiv] Throughout the 1970s, the drug industry launched legal challenges against the FDA's rulings. See Richard A. Merrill and Peter Barton Hutt, Food and Drug Law: Cases and Materials (Mineola, NY: Foundation Press, 1980), pp. 374-375; and "Drug Efficacy and the 1962 Drug Amendments," Georgetown Law Journal, 1971, 60: 185-224.

[lxxxv] Gilman was one of the most prominent pharmacologists of his time, co-authoring with Louis S. Goodman, the seminal text in therapeutics and clinical pharmacology (now in its 11th edition): Louis S. Goodman and Alfred Gilman, The Pharmacological Basis of Therapeutics: A Textbook of Pharmacology, Toxicology and Therapeutics for Physicians and Medical Students (New York City: The Macmillan Company, 1941). Quotation taken from Alfred Gilman, "Therapeutic equivalence of generic drugs and problems of drug formulation," Appendix A, Minutes, Policy Advisory Committee of the Drug Efficacy Study, No. 3., March 27, 1968. NAS Archives; Series 3 DES PAC 1968; Folder: Meetings: Third: 27 Mar.

[lxxxvi] Gilman, "Therapeutic equivalence of generic drugs and problems of drug formulation" (n. 85)

[lxxxvii] Drug Efficacy Study, "White Paper on the Therapeutic Equivalence of Generic Drugs. Draft for the Policy Advisory Committee." Minutes of Policy Advisory Committee of DES, Appendix B, March 6, 1969. NAS Archives; Series 3, DES PAC 1969; Folder: Meetings: Fourth: March 6, 1969.

[lxxxviii] Statement submitted by Alfred Gilman to Senator Nelson, Congressional Record, 90th Congress, 1st session, 113 pt. 19: 25146-25148.

[lxxxix] Office of the Secretary, U.S. Department of Health, Education, and Welfare, Final Report of the Task Force on Prescription Drugs. (Washington D.C., 1969), p. iii. Members of the Task Force were Philip R. Lee, Assistant Secretary for Health and Scientific Affairs (chairman), Dean Coston, Executive Assistant to the Secretary, James F. Kelly, Assistant Secretary, Comptroller, Alice M. Rivlin, Assistant Secretary for Planning and Evaluation, Herbert L. Ley, Jr., FDA Commissioner, Joseph H. Meyers, Deputy Administrator, Social and Rehabilitation Service, William H. Stewart, Surgeon General, and Milton Silverman, Special Assistant to the Assistant Secretary for Health and Scientific Affairs.

[xc] Final Report. Task Force on Prescription Drugs (n. 89), p. 31.

[xci] Statement of Senator Gaylord Nelson, Congressional Record, 92nd Congress, 2nd Session, 118 pt. 5: 5887-5888.

[xcii] Pharmaceutical Manufacturers Association, Drugs Anonymous? (Washington, D.C.: PMA, 1967). National Museum of American History, Parke-Davis Collection, Box 1964. For information on Compulsory Generic Prescribing – A Peril to the Health Care System, see Senator Gaylord Nelson, "Drug Quality Standards," Congressional Record, 90th Congress, 1st Session, 113 pt. 5: 5630-5631.

[xciii] E. W. Kenworthy, "Doctors suggests drug men denied him post in FDA." New York Times 26 August 1969, p. 1; E. W. Kenworthy, "Nixon criticized for withdrawing offer of FDA post to physician." New York Times 28 August 1969, p. 23.

[xciv] Senator Morse, "Drug industry seeks to defeat Senator Nelson." Congressional Record 90th Congress, 2nd Session, 114 pt. 21: 27950-27951.

[xcv] Donald O. Schiffman, "Editorial: On therapeutic equivalency and the antisubstitution laws," Journal of American Medical Association, 1973, 223(5): 552-553.

[xcvi] Donald O. Schiffman, "Editorial: Eroding the physician's control of therapy," Journal of the American Medical Association, 1973, 225(2): 164.

[xcvii] See, for example, "Statement of the American Medical Association re. S. 3441 and S. 966," before the Senate Subcommittee on Health, Committee on Labor and Public Welfare, 21 May 1974, pp. 2561-2576.

[xcviii] Cannan "The Drug Efficacy Study of the NAS-NRC" (n. 73).

[xcix] Cannan "The Drug Efficacy Study of the NAS-NRC" (n. 73).

[c] Sheila Jasanoff, The Fifth Branch: Science Advisors as Policymakers (Cambridge: Harvard University Press, 1990).