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PERSPECTIVES

Smoke and Thalidomide

Dr Edward Nik-Khah

May 2016

14

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Edward Nik-Khah is an Associate Professor of Economics at Roanoke College (USA). He has completed research on interactions between the Chicago School of Economics, the pharmaceutical industry, and pharmaceutical science; the neoliberal origins of economics imperialism; the distinctive role of George Stigler as architect of the Chicago School; and the tensions emerging from economists' assumption of a professional identity as designers of markets. His forthcoming book on the history of knowledge and information in economics (with Philip Mirowski) is entitled *The Knowledge We Have Lost in Information*.

Editing: The Whitlam Institute

ISBN: 978-1-74108-387-3

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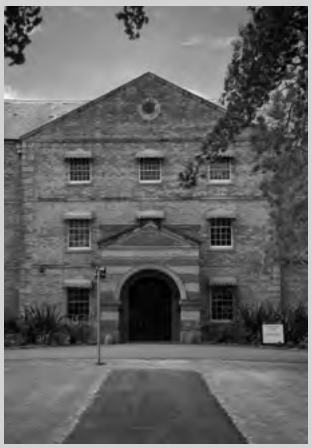

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Foreword

It was a little while back that Dr Nik-Khah sent through the first draft of this paper. I was intrigued from the moment I saw the name of the attached file: 'Smoke and Thalidomide'. What on earth could he be getting at?

I will leave you to discover that for yourself.

I would simply say by way of introduction that Dr Nik-Khah draws on a deep well of historical knowledge to offer us what in many respects is a cautionary tale. As in the best narrative traditions he concentrates our attention on a single strand then draws our eyes to the patterns formed as a means of observing how the world works.

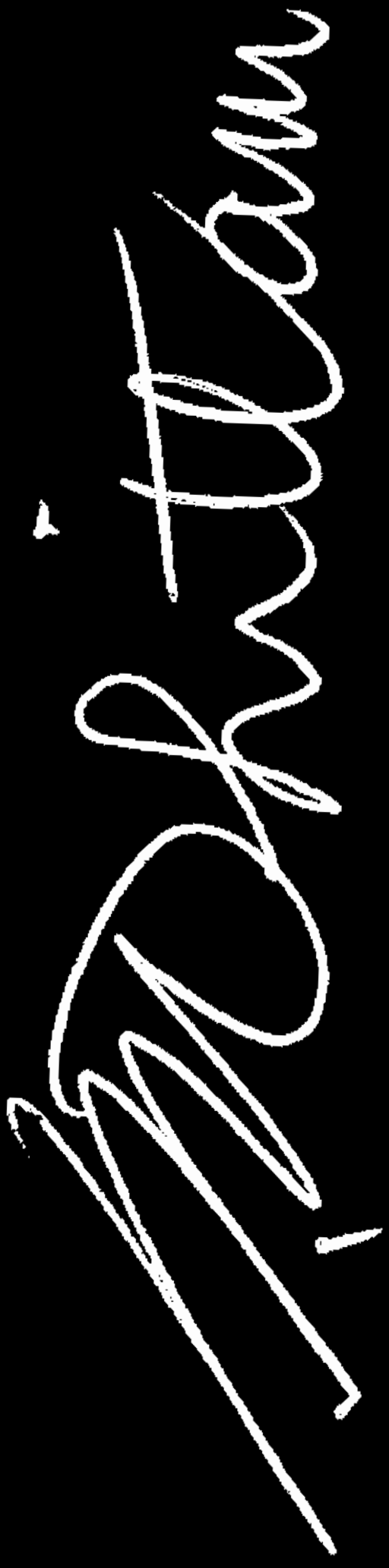
In this paper the evolution of policy settings governing drug pricing and the medical marketplace in the United States is at the centre of the story. It will have a familiar ring for Australian readers but it is a story that is still playing out in this place. It can be seen in the debates around Intellectual Property and the scope and application of patents; critical issues, for example, when considering the potential impact of the Trans Pacific Partnership. It suggests a need for the critical assessment of claims regarding private investment in the development of new drugs. It raises the flag on the risks inherent in diluting rigorous and independent scientific appraisal of new drugs in controlled conditions and who bears those risks. That's the cautionary bit.

The beauty of Dr Nik-Khah's paper is that it allows us to see what lies beneath the surface of these debates.

This story traces its roots back to 1947 and earlier still but it is a paper that is utterly relevant and contemporary. There is much at stake: the integrity of information; the nature and role of knowledge, specifically whether it is dispassionate and free of vested interest; the primacy of the public interest in a genuinely democratic society. As highfalutin as this may sound, its impact is evident in our daily lives: our health, security and well-being; our ability to be genuinely informed and to be involved in decision-making processes that count.

At its heart Dr Nik-Khah's paper highlights conflicting visions of what's important in our society, how it should work and to whose benefit.

Eric Sidoti
Director, Whitlam Institute



Smoke and Thalidomide

In the early 2000s, one of the most pressing health policy issues in the US concerned the effects of escalating drug prices on the elderly. News coverage of this issue cast light on a number of curious features of the US medical marketplace: images of the elderly taking bus trips to Canada (where prescription drug prices were lower) invited questions about why US citizens were paying more than Canadians for drugs; reports of the elderly having to choose between medicine and food only seemed to underscore the urgency of the need to address the problem. The political solution arrived at, in 2003, was the Medicare Prescription Drug, Improvement, and Modernization Act; that this law passed during a Republican administration, with both houses of congress controlled by Republicans gives some sense of the political salience of escalating prescription drug prices in the US.

One noteworthy aspect of the debate leading up to passage of the Medicare Prescription Drug Act was the way that certain expert testimony came to be aligned with the strategic goals of the pharmaceutical industry. One of the most heated debates pertained to the amount to be paid by Medicare for drugs: would the government merely accept "market prices?" Or would it negotiate for quantity discounts? The pharmaceutical industry staunchly opposed the latter option, and in support of its position cited a study that seemed to demonstrate that drug development was a risky and expensive business: the president of Merck announced in December 2001 the existence of a yet-unpublished study demonstrating that it cost over $800 million to bring a drug to market; a year later the *Journal of Health Economics* gave its imprimatur to this figure.[1] Soon after publication of this article, it became clear that the pharmaceutical industry enjoyed a cosy relationship with academic economists. During the runup to the passage of the Medicare Act, *New York Times* reporter Robert Pear revealed that PhRMA (Pharmaceutical Research and Manufacturers of America, the lobbying arm of the "research-based" pharmaceutical industry) had allocated $1 million towards deploying "an intellectual echo chamber of economists—a standing network of economists and thought leaders to speak against federal price control regulations through articles and testimony, and to serve as a rapid response team."[2] The memo's use of the term "echo chamber," and especially of a "*standing* network of economists and thought leaders" [author's emphasis] suggested a familiarity with the economists in question—that this was no one-shot deal; the reference to a "rapid response team" elicited ideas of the modern political campaign, aided by the techniques of marketing; and although $1 million was paltry compared to the aggregate profits of PhRMA members, neither was it anything to sneeze at: it suggested that there was a certain level of confidence in the ability of these economists to broadcast PhRMA's preferred message. In sum, the memo exhibited the belief of PhRMA that it could at a moment's notice call upon a group of economists who could deliver a finely tuned message to achieve a political goal, and that they could be depended upon to do so because they had done so before.

PhRMA did achieve its political goal: the new Medicare law forbade the government from negotiating discounts for drugs, and from establishing a formulary of medicines. It was a victory over three decades in the making. Beginning in the early 1970s, the pharmaceutical industry, economists of the US "Chicago School", and other "thought leaders" first began to forge close connections with one another; through assiduous efforts they engineered a set of doctrines to safeguard the medical marketplace from unwarranted interventions of the state, developed institutions to generate these doctrines, and executed a highly sophisticated strategy to bring about the desired result.

It seems obvious what the pharmaceutical industry had hoped to accomplish in financing these efforts; it may also seem clear what economists enrolled in the effort hoped to get in return for their efforts, given the figure of $1 million. But the size of this figure may serve to distract from the political goals of the economists, foreclosing consideration of this incident's most important lessons, ones that have not remained confined either to the issue of pharmaceutical pricing policy or to the US jurisdiction. These goals had something to do with privileging markets, but had little to do with the "*laissez faire*" slogan often attributed to the profession.

The Mont Pèlerin Connection

Our story begins with the creation of the Mont Pèlerin Society (MPS). Organized by the Austrian economist Friedrich Hayek in 1947, the MPS was a group of individualists devoted to reformulating liberalism by creating a "neoliberalism" as a counterblast against "collectivism": socialism, institutional reformism, social welfare liberalism, and Keynesianism. Significantly, the MPS was an obligatory passageway for those most heavily involved in constructing

1 Joseph DiMasi, Ronald Hansen, and Henry Grabowski, "The Price of Innovation: New Estimates of Drug Development Costs", *Journal of Health Economics*, 22(2), pp. 151-185, 2003.

2 Robert Pear, "Drug Companies Increase Spending on Efforts to Lobby Congress and Governments." *The New York Times*. June 1, 2003. It is revealing that the term "echo chamber" was coined by John Scruggs for his employer Philip Morris, and refers to the strategy of producing a stream of seemingly independent studies for the purpose of advancing narrow economic and political interests.

the postwar Chicago School of Economics, including Milton Friedman, George Stigler, and Allen Wallis.[3] Importantly, neoliberals also rejected classical liberalism, and sought instead to rethink its intellectual foundations by recasting the market as an information processor more powerful than any human mind. They called not for *laissez-faire* but for an *activist* state; they developed methods to control the state and fostered think tanks, which would stand at the ready to exert such control.[4] Economists played crucial intellectual and organizational roles in this effort, but viewing neoliberalism as merely a set of economic doctrines would be a mistake: neoliberals developed a set of political and philosophical ideas to instruct the activities of scholars across the disciplines.

Chicago neoliberals found (what they perceived to be) the encroachment of collectivism on economic and political life to be alarming, and the support given to collectivism by academic disciplines such as law and political science especially so. As Robert Van Horn and I have argued elsewhere, Chicago neoliberals responded by sustaining efforts to colonize law, political science, and other disciplines—an activity aptly called "economics imperialism."[5] Two of the most significant efforts undertaken by Chicago scholars were Aaron Director's Antitrust Project (carried out at Chicago's Law School) and George Stigler's Governmental Control Project (carried out at Chicago's Graduate School of Business). The motivation for these imperialistic efforts was to change the policy approach of the state; they addressed many areas, including competition policy, patent law, consumer safety regulation, finance, and—most importantly from the present standpoint—pharmaceuticals.

Director's project was the brainchild of Hayek, who in his *Road to Serfdom* called for study and promotion of the "competitive order" by providing an effective framework for competition.[6] Hayek delegated this project to Director, Friedman, and others at Chicago. Under the leadership of Director, this project subsequently found fault with existing legal wisdom, and sought to displace it with one more in keeping with the need to promote the competitive order—focusing in particular on antitrust law and, later, patents. As a result, a generation of Chicago scholars came to believe that the problems of monopoly for capitalism were exaggerated, there was no need for a vigorous policy of antitrust, and that patents conveyed no worrisome monopoly power.[7]

Stigler led a complementary effort.[8] Shortly after Stigler's 1958 acceptance of the Walgreen Chair at Chicago, he initiated a project to study the "causes and consequences of the governmental control of economic life."[9] Stigler believed that misguided views about the performance of markets and the capacities of democracy supported these unnecessary invasions of personal freedom. According to Stigler, existing academic studies of the government encouraged unrealistic views of the capacities of democracy, and therefore supported the growth of collectivism. Stigler called for studies to displace the "public interest" view of the government with one that regarded problems with governmental control as endemic. An important element of them was a portrayal of people as acquiring information through markets, whether in connection with the more conventional market activity of purchasing goods, or in the "political market." Stigler's portrayal of politics as a market formed the conceptual basis for an attack on governmental regulation on the grounds that regulation was a poor substitute for privately produced information. One intended lesson was that as *consumers* people were able to collect all the information they need through the marketplace (or at least are able to hire others to do the same) to make informed decision about what to consume. But, as *citizens*, Stigler argued albeit paradoxically that acquiring information through the marketplace of ideas would often fail to yield a correct judgment about regulation.[10] As a result of this project, Chicago scholars came to believe that regulation would not achieve its publicly declared goals. As with the Antitrust Project, Stigler's aim was to change the policy approach of the state, for example by producing methods of auditing regulators to be carried out by professional bodies purged of public interest beliefs.

Stigler used his control of the well-heeled Walgreen Foundation (a privilege that came with his acceptance of the Walgreen Chair) to fund studies of students and faculty at Chicago, recruit like-minded faculty to Chicago, and organize conferences on topics related to

3 This historical interpretation of the Chicago School was first developed in Robert Van Horn and Philip Mirowski, "The Rise of the Chicago School of Economics and the Birth of Neoliberalism," in *The Road from Mont Pèlerin*, Harvard University Press, 2009 and elaborated in Edward Nik-Khah, "George Stigler, the Graduate School of Business, and the Pillars of the Chicago School," in *Building Chicago Economics*, Cambridge University Press, 2011.

4 This observation was first made, of course, by Michel Foucault in his 1978–1979 Collège de France Lectures (later published in translation as *The Birth of Biopolitics*).

5 Edward Nik-Khah and Robert Van Horn, "Inland Empire: Economics Imperialism as an Imperative of Chicago Neoliberalism, *Journal of Economic Methodology*, 19(3), 2012.

6 Robert Van Horn, "Hayek's Unacknowledged Disciple," *Journal of the History of Economic Thought*, 35(3), 2013.

7 Robert Van Horn, "Reinventing Monopoly and the Role of Corporations," in *The Road from Mont Pèlerin*, Harvard University Press, 2009; Robert Van Horn and Matthias Klaes, "Intervening in Laissez-Faire Liberalism: Chicago's Shift on Patents," in *Building Chicago Economics*, 2011; Nik-Khah and Van Horn, 2012.

8 This discussion of Stigler draws heavily from Nik-Khah, 2011 and Nik-Khah and Van Horn, 2012.

9 Stigler explicitly related this project to concerns about collectivism:

> …the most fundamental issue posed by the increasing direction of economic life by the state [is] the preservation of the individual's liberty…If it can be shown that in important areas of economic life substantial and unnecessary invasions of personal freedom are already operative, the case for caution and restraint in invoking new political controls will acquire content and conviction. (George Stigler, *The Citizen and the State*, University of Chicago Press, 1975, pp. 5-18.)

10 The difference between these activities, according to Stigler, was that instincts of the vast majority of people informed incorrect beliefs about markets and government, leading the public to support unwarranted encroachments of democracy into areas best left to market actors. For Stigler, the baleful effects of culture could never be entirely wiped away. See Edward Nik-Khah, "What Is 'Freedom' in the Marketplace of Ideas?" *Neoliberalism and the Crisis of Public Institutions*, Working Papers in the Human Rights and Public Life Program, Whitlam Institute within Western Sydney University , 2015, Nik-Khah, 2011.

governmental control.[11] In 1972, along with other Chicago scholars, he turned their attention to pharmaceutical regulation. Eleven years earlier, evidence came to light that thalidomide, a popular sedative that had nearly been cleared for marketing in the US, had caused thousands of birth defects in Europe and Australia.[12] In the context of considerable public concern, the US Congress passed the Kefauver-Harris Amendments to the Federal Food, Drug, and Cosmetic Act (hereafter, 1962 Amendments), granting the US Food and Drug Administration (FDA) power to restrict advertisements, establish standards for clinical trials, and requiring drug manufacturers to provide proof of efficacy. By 1970, the pharmaceutical industry had become alarmed by the implementation of the 1962 Amendments, and proved willing to provide moral, intellectual, and financial support for efforts to countervail FDA policy. Consequently, Stigler and his colleagues organized the Conference on the Regulation of the Introduction of New Pharmaceuticals (hereafter, Pharmaceuticals Conference) for the express purpose of attacking the 1962 Amendments.[13] Stigler arranged for his former student Sam Peltzman to produce a paper on the "costs" of the 1962 Amendments, pledged funds from his Walgreen Foundation to finance Peltzman's research, and oversaw its progress. Richard Posner, another luminary of the Chicago School, assumed responsibility for supervising the efforts of Edmund Kitch, who wrote on the economics of intellectual property. Kitch was an important member of the Chicago Law and Economics Program, which was an outgrowth of the Antitrust Project; Peltzman was a member of Stigler's project to study governmental control.

In his contribution, Peltzman provided a critical examination of FDA regulation.[14] Peltzman's primary complaint about the 1962 Amendments was that while it was supposed to have reduced the costs of producing information about drugs (by substituting FDA sanctioned information for drug companies' promotional activities and doctors' experience with medicines), it had actually decreased the value of information available to consumers. The reason, Peltzman argued, was twofold: the laborious process of gaining the sanction of the FDA for their claims had increased the cost incurred by pharmaceutical companies to provide information to drug consumers, and doctors would be more wary of prescribing drugs for off-label (i.e., non-sanctioned) uses. Both would tend to reduce the amount of available information on drugs. Peltzman argued that one could observe the consequences of the 1962 Amendments in consumers' drug purchasing behaviour: this decrease in information had led consumers to reduce their demand for new drugs. Hence, in attempting to substitute "publicly" produced information for "privately" produced information, the 1962 Amendments artificially restricted the demand for new drugs, resulting in a decrease in consumer welfare: "The 1962 Amendments assume implicitly that it is 'worth' sacrificing some potential return from an innovation for reduced risk. Our estimates imply that if any trade would be profitable, it would be toward more risk."[15] By developing a technique to audit a regulator (the FDA), and conceiving a criterion for audit that fits the idea of an ideal market for information, Peltzman was operating well within the framework of the Governmental Control Project. By seeking to displace the kinds of judgments made by clinical scientists, Peltzman's technique conformed to the methods and purpose of the Governmental Control Project.

For his contribution to the Pharmaceuticals Conference, Kitch addressed the appropriate level and scope of patent protection.[16] He argued that the 1962 Amendments had likely reduced the rate at which new drugs were being introduced, due to the increased costs of satisfying the marketing requirements of the FDA and a reduction in period of patent protection (due to the increased time required to comply with the marketing requirements). Both reduced the flow of revenues to the pharmaceutical firm, and therefore eroded the incentives to innovate. Kitch then focused on the role of patents in ensuring returns to investment for pharmaceutical companies, and argued that the patent system had become unreliable and was "faltering." In particular, he identified three aspects of the patent system that were of specific concern to the pharmaceutical industry—that a patent could not be granted for the investigation of known substances, that the invention must be non-obvious to skilled practitioners in the field, and that patents granted for therapeutic uses might be invalid. He argued that the current legal definition of "process" prohibited the patenting of biological processes for much the same reason that (at that time) a computer program could not be patented: ideas and algorithms were not patentable. In sum, he argued, the pharmaceutical industry's reliance on the patent system had become unstable. He noted that some aspects of the FDA's New Drug Application (NDA), by keeping secret information disclosed therein, had operated as an ineffective and costly substitute for the patent system. In that paper, Kitch then proposed modifying the NDA to formally convey a property right as a quick and dirty way

11 Stigler had served since 1958 as director of the Walgreen Foundation, a position which carried with it considerable discretion over how to spend its sizeable funds. The story of the Walgreen Foundation and Stigler's construction of a distinct research program at Chicago's Graduate School of Business can be found in Nik-Khah, 2011.

12 In late 1961, Widuken Letz of West Germany and William McBride of Australia independently announced finding a link between thalidomide and phocomelia (Carpenter, 2010, p. 240).

13 In addition to Stigler, faculty advisors included Kenneth Dam, Harold Demsetz, Milton Friedman, Reuben Kessel, and Richard Posner. Far from viewing the patronage of pharmaceutical companies as a necessary evil, Stigler and others at Chicago argued that it would *improve* knowledge about drugs and drug policy, by helping give a voice to pharmaceutical manufacturers' claims. While such participation might introduce a certain bias into scientific activities, one of Chicago's distinguishing features as an academic formation has been to celebrate donor participation in their activities. When it comes to appreciating the virtues of the market, top quality "leaders of the market place," as Stigler was wont to call them, were the most reliable guardians of intellectual freedom. See Nik-Khah, 2015.

14 Sam Peltzman, "The Benefits and Costs of New Drug Regulation," In *Regulating New Drugs*, Chicago University Press, 1973, p. 131.

15 Peltzman, p. 194.

16 Edmund Kitch, "The Patent System and the New Drug Application," In *Regulating New Drugs*, Chicago University Press, 1973.

of improving intellectual property protection. By stressing the beneficent aspects of expanding intellectual property, suppressing market power implications, and connecting this discussion to a concern for the gradual encroachment of the state on economic life, Kitch was operating well within the framework established by the Antitrust Project.

One participant in the Pharmaceuticals Conference yet unaffiliated with the Chicago School (but thoroughly vetted by members) was the "renegade clinical pharmacologist" Louis Lasagna, once a public champion for FDA regulation, but now in the midst of transmogrifying into its most strident scientific critic.[17] Lasagna's comments were relatively brief, but in them one may catch an early glimpse of how thoroughgoing his, and Chicago's, critique would eventually become. Lasagna advocated for a "pluralistic, fallibilistic approach" to pharmaceutical regulation and complained about "undue emphasis on 'controlled trials' by experts and the denigration of more 'naturalistic trials' by ordinary practitioners."[18] He lamented what was in his view a "nihilistic" bias of academic researchers, and argued the best way to judge the effectiveness of medicines was "performance in the marketplace." By enlisting the efforts of Lasagna, Chicago hoped to craft a critique that would appeal to scientists and up a new front in the fight against drug regulation.

Neoliberalism on Drugs

The immediate aftermath of the Pharmaceuticals Conference saw a flurry of activity devoted to establishing special purpose think tanks, led by conference participants. In 1974 the American Enterprise Institute (AEI) established the Center for Health Policy Research, with the heavy participation of scholars that participated in the Pharmaceuticals Conference and their students: Sam Peltzman's PhD student (at UCLA) Robert Helms served as the first director and Louis Lasagna served on the advisory committee. In 1976, Lasagna organized the Center for the Study of Drug Development (CSDD), which brought together neoliberal economists, clinical pharmacologists, and members of the pharmaceutical industry. Soon a steady stream of book-length studies, collections of papers, and pamphlets issued forth from these think tanks—often referring to each other's works.

Through the AEI, the CSDD and other institutions, the pharmaceutical industry and pro-market advocacy foundations sponsored efforts that brought together members of the original Pharmaceuticals Conference, linking the various critiques advanced there, fostering further explorations of neoliberal themes by sympathetic scholars, and promulgating the results. The AEI Center's very first publication was a book-length treatment of Peltzman's work on the 1962 Amendments. Kitch's definitive view of intellectual property came soon after his participation in the Pharmaceuticals Conference, with his 1977 publication of "The Nature and Function of the Patent System."[19] In this work, Kitch introduced his "prospect theory" of patents, which argued that it would be optimal to grant patents early in the innovation process for "prospects," interpreted in the same fashion as for mineral exploration. Kitch argued that early issuance of patents centralizes research activities, but that it does not limit research nor reduce competition. Indeed, it prevents "wasteful duplication." The close connection of his work on prospect theory to his earlier contribution to the issues pertaining to the pharmaceutical industry becomes apparent in a paper he delivered to the Conference on the *International Supply of Medicines*, which was sponsored and later published by the AEI.[20] In that piece, Kitch more explicitly argues for the indispensable role of the patent-holding multinational pharmaceutical firm as an efficient "international coordinator" of drug development and marketing, and for the preservation and enhancement of this role by harmonization of regulation and patent protection. Unfortunately from his perspective, many developing countries proved reluctant to delegate research and pricing decisions entirely to multinational firms, and so Kitch would later respond with the argument that since patent reform was far too important to entrust to democracy "outsiders can play a constructive role by insisting that the issues be addressed within a larger and principled framework," in particular by the use of forum shifting to remove intellectual property and trade negotiation from the UN World Intellectual Property Organization (WIPO) to the framework established by the General Agreement on Tariffs and Trade (GATT).[21] The focus on patents was particularly attractive for a pharmaceutical industry that had coalesced around the issue of intellectual property.[22] As with Peltzman, "The Nature and Function of the Patent System" was reprinted by the AEI, and like Peltzman's piece, Kitch's paper became an obligatory reference at the AEI and complementary think tanks; by now, Kitch's work has come to be regarded as a classic contribution to the theory of patents.

17 On Lasagna as a "renegade," see Daniel Carpenter, *Reputation and Power*, Princeton University Press, 2010, p. 377.

18 Louis Lasagna, "Comment on Toward Better Systems of Drug Regulation," In *Regulating New Drugs*, University of Chicago Press, 1973.

19 Edmund Kitch, "The Nature and Function of the Patent System," *Journal of Law and Economics*, 20(2), 1977, pp. 265-290.

20 Edmund Kitch, "The Political Economy of Innovation in Drugs and Drug Regulation Reform," in *The International Supply of Medicines: Implications for US Regulatory Reform*, American Enterprise Institute, 1980.

21 Edmund Kitch, "The Patent Policy of Developing Countries," *UCLA Pacific Basin Law Journal*, 13, 1994, pp. 166-178. Shifting from the WIPO to GATT enabled developed nations to tie expanded IP to trade access to their domestic markets. Since then, pharmaceutical corporations, industry lobbying groups, and sympathetic governments (such as the US) have repeatedly utilized forum shifting to push through what Susan Sell accurately calls "ever-higher standards of property protection." The negotiation surrounding the Trans Pacific Partnership (TPP) is the latest instance of such forum shifting. See, Susan Sell, "TRIPS Was Never Enough: Vertical Forum Shifting, FTAs, ACTA, and TPP," *Journal of Intellectual Property Law*, 18, 2010, pp. 447-478.

22 To select but one example, Michael Novak's book on the morality of patents was directly commissioned by Pfizer and published by the AEI; the argument for the efficiency of patents contained therein relies heavily on Kitch's prospect theory. Michael Novak, *The Fire of Invention, The Fuel of Interest: On Intellectual Property*, American Enterprise Institute, 1996.

The CSDD gave Lasagna the opportunity to further develop his critique, and a platform to put it into practice. Lasagna argued that academic scientists were *biased*, in that they expressed too much skepticism toward the claims of pharmaceutical companies, a problem best addressed by placing control of drug research entirely in the hands of pharmaceutical corporations. Moreover, he argued against relying on a single "approved-or-not" answer to the question of drug safety and efficacy, on the grounds that judgments about the best regimen are too 'complex' for scientists to answer. Best in his view to allow all parties to promulgate their claims for drugs, and let the public sort out the claims and counterclaims. Lasagna's arguments were clearly consistent with the emergent Chicago policy position, but his influence would go well beyond the policy realm. He led the CSDD, which viewed its mission as providing study of and guidance in economic, legal, public policy, and scientific issues. These efforts, which included advising pharmaceutical firms on the best method of commercializing research and providing its own commissioned research, should be understood as an attempt to take neoliberal ideas into the heart of scientific practice.

Chicago School neoliberals, then, had produced a multidirectional attack on the use of academic science to inform regulatory policy. All of those enrolled in this effort viewed the public as dangerous, too susceptible to the rare tragedy (such as the thalidomide disaster), and too prone to support unwarranted transgressions into the pharmaceutical industry. But they differed on how to address this problem. One could construe the critique as calling for the abolishment of the FDA. Friedman made such an argument in his *Newsweek* column, and it did attract considerable attention, but this was only the crudest of Chicago's proposals.[23] Others argued that it may be better to keep the FDA in place, and to focus efforts on developing performance measures to audit and thereby control it. Such was Stigler's motivation for assigning Peltzman to study the "costs" of drug regulation. Kitch argued for empowering the pharmaceutical industry to coordinate research, via the expansion and globalization of intellectual property. And Lasagna sought to change impressions about who should perform this science, and how one should interpret its results. The task of discerning truth about drug efficacy should be delegated to the market, a suggestion informed by a presumption that the power of markets to create and use knowledge was unsurpassed, a hallmark of neoliberal thought.

Lost in the Echo Chamber

By 1985 at the very latest the "echo chamber" was a fait accompli; the roster would eventually expand to include the Competitive Enterprise Institute, and the Manhattan Institute, among other institutions. Interlocking directorates and shared memberships connected academic departments (the Chicago School of Economics), transnational efforts (the MPS), general-purpose think tanks (The AEI, the Competitive Enterprise Institute, the Manhattan Institute), and special purpose institutions (the CSDD).[24] In the years immediately preceding the PhRMA memo, it became possible to catch a glimpse of this echo chamber acknowledging how it worked, if you knew where to look. One paper surveyed the work of economists affiliated with the AEI, the Cato Institute, the Competitive Enterprise Institute (CEI), the Independent Institute, and the Foundation for Economic Education, and declared a consensus among economists "against" the FDA. It sanctioned one specific purveyor of data:

> A chief source of information about drug development and approval is the Tufts Center for the Study of Drug Development. Their information is often mined and analyzed from a libertarian perspective by researchers at the Competitive Enterprise Institute.[25]

This observation, from an academic economist who is also affiliated with the CEI, provides something of an insider's perspective on the echo chamber tactic. Recent years have seen the development of yet more specialized projects devoted to producing and circulating skeptical studies of the FDA's performance. For example, the Manhattan Institute's Project FDA has one active and one previous member of the CSDD on its board, and has published work authored by CSDD scholars.[26]

In mentioning an "echo chamber," it seems likely that the leaked PhRMA memo of 2003 was referring to these think tanks. And, indeed, the echo chamber did prove successful in that specific instance: the CSDD produced the "$800 million drug" study; the echo chamber kicked into gear publicizing this number, floated it as an alternative explanation to market power for the high prices of drugs, whereupon it was used as a primary reason for preventing the government from negotiating with pharmaceutical companies for lower drug prices.[27] The network of think tanks provided an additional method of ratifying knowledge about drugs. Consider Lasagna: occasionally, someone has levelled the charge that he was merely a "hired gun"; but neither the emergence of this perception, nor his loss of stature among academics following his controversial critiques of the role of clinical science in regulation mattered in the least. The phalanx of institutions constituting the echo chamber supported the works produced and, to some extent, conditioned them.

Contrast the reception given the Chicago position on drugs with that of a rival approach advanced by the MIT economist

23 Milton Friedman, "Frustrating Drug Advancement." *Newsweek*, January 8, 1973, p. 49.

24 To take but one example, The CSDD advisory board included Henry Grabowski and Austin Ranney of the AEI; Lasagna served on the advisory boards of both the CSDD and the AEI Center for Health Policy Research.

25 Klein, 2000, 100n5.

26 The board members, Joseph DiMasi and Henry Grabowski, were two of the authors of the *Journal of Health Economics* '$800 million pill' study, discussed above. A similar project is the Independent Institute's FDAReview.org.

27 Merrill Goozner, *The $800 Million Pill*, University of California Press, 2009. For a critique of the CSDD study, see Donald Light and Rebecca Warburton, "Demythologizing the High Costs of Pharmaceutical Research," *BioSocieties*, 6(1), pp. 34-50, 2011.

Peter Temin.[28] For the present purposes, Temin's approach can be summarized in two points. First, there was considerable market power within the pharmaceutical industry. For Temin, pharmaceutical companies enjoyed excessively high profits, which they secured by using all the tricks in the imperfect competition book.[29] Firms used patents as a method of securing monopoly profits, and devoted their research efforts to producing chemically similar "me too" drugs of questionable value. But as firms introduced chemically similar drugs, the result was not lower prices stimulated by greater competition, but an increase in efforts to engage in product differentiation—and likely *higher* prices. Insofar as these efforts merely allocated market share, rather than increased the knowledge of consumers or producing new breakthrough products, then they should be viewed as socially wasteful.[30] Temin therefore strongly suggested that pharmaceutical companies are not doing a good job of allocating either research or marketing resources effectively, pointing the blame at the way patent laws had been used to establish and hold on to market power. Second, because imperfect information pervaded the pharmaceutical industry, it was necessary to make sure that adequate information was available. Patients did not understand the available information, and doctors did not have enough experience with all drug types to collect information on behalf of their patients;[31] doctors would then rely on custom in prescribing medicine, but this served only to perpetuate market power. Therefore, Temin presented a view of the pharmaceutical industry that differed remarkably from Kitch's and Peltzman's. Whereas Kitch viewed the patent system as a method of promoting the efficient use of resources devoted to innovation, Temin concerned himself with the market power bestowed by patents. And whereas Peltzman viewed pharmaceutical firms as low-cost producers of information, Temin argued that absent some method of rationalization, the flood of information would prove too confusing for doctors and their patients.

The network of neoliberal think tanks did not treat Temin's work, or that of those whose work resembled his, as worthy of promulgation, a fact that constituted a distinct disadvantage for his approach. Whereas think tanks trumpeted the results of Peltzman and Kitch (and Lasagna), Temin's concerns about market power were resolutely ignored. Therefore, compatibility with the business strategies of the multinational pharmaceutical firms was an important determinant of the research promoted by think tanks: one could surmise that a rallying cry, 'reduce the market power of pharmaceutical companies' was hardly likely to find support from a pharmaceutical industry intent on impacting regulation, and indeed it did not.[32] Temin did have one piece published by the AEI, but in it there was nary a mention of the market power of pharmaceutical companies, and Temin's criticism of the performance of the pharmaceutical industry was purged from Klein's review of economists' attitudes towards the FDA.[33] In sum, Temin's approach has generally not been viewed by think tanks as relevant to pharmaceutical policy as that offered by Chicago.

Consequences, Unintended and Otherwise

The appearance of the term "echo chamber" in the PhRMA memo suggests that those activities held significance well beyond pharmaceutical pricing policy. The structure of the pharmaceutical echo chamber has some potentially significant parallels to the "Tobacco Strategy" identified by Naomi Oreskes and Erik Conway, a set of techniques developed to produce confusion about the state of tobacco science, generated by think tanks, misguided scientists, and economists, and deployed to forestall a negative regulatory judgment in cases ranging from global warming to DDT.[34] Similar techniques to befog the public and its representatives were employed in the pharmaceuticals case. For example, CSDD estimates of the cost of bringing a drug to market seem designed less to advance academic discussions of pharmaceutical research and development than to achieve a specific policy result.[35] Lending credence to this interpretation is the participation of the American Enterprise Institute, the Competitive Enterprise Institute, the Cato Institute, and the Independent Institute, *many of the very same institutions highlighted by Oreskes and Conway*. That the think-tanks composing the pharmaceutical echo chamber were battle-tested by their experience in anthropogenic global warming and tobacco-caused cancer denial would surely have increased the confidence of its pharmaceutical industry patrons in their ability to successfully use obfuscation to arrest regulation.

Hence, maintaining absolute control over US drug pricing may be only the tip of the iceberg. For example, John Abraham and Tim Reed have shown how in the UK

28 The MIT School of Economics was a primary American neoclassical rival to the Chicago School of economics; traces of this rivalry (in style, if not always in substance) persist in quips about "freshwater versus saltwater" economics. To be clear, the point in attending to the fate of Temin's program is not to argue in favor of the "saltwater" approach; instead it is to draw attention to the importance of the infrastructural conditions aiding the triumph of Chicago's approach.

29 Peter Temin, "Technology, Regulation, and Market Structure in the Modern Pharmaceutical Industry," *Bell Journal of Economics*, 10(2), pp. 429-446, 1979, p. 432. See also Peter Temin, *Taking Your Medicine,* Harvard University Press, 1980.

30 Temin, 1979, p. 444

31 Peter Temin, "Physician Prescribing Behavior: Is there Learning by Doing?" In Drugs and Health, *American Enterprise Institute*, 1981, pp. 179-180

32 The exception comes in the form of a grant from the Nonprescription Drugs Manufacturers Association (now, the "Consumer Healthcare Products Association"), an organization of producers that had been excluded from the Pharmaceutical Manufacturers Association (because they produced generic medicines), and not exactly in the same lobbying league as PhRMA.

33 Temin, 1981; Daniel Klein, "Policy Medicine Versus Policy Quackery: Economists Against the FDA," *Knowledge, Technology, and Policy*, 13(1), pp. 92-101, 2000, p. 99

34 Naomi Oreskes and Erik Conway, *Merchants of Doubt*, Bloomsbury Press, 2010.

35 Several features of the data upon which the CSDD study was based raised serious questions. For example, the firms were self-selected, and there is no evidence that the data they provided were subjected to any critical scrutiny. See Donald Light and Rebecca Warburton, "Demythologizing the High Costs of Pharmaceutical Research," *BioSocieties*, 6(1), pp. 34-50, 2011.

commercial and political considerations have displaced technical standards in pharmaceutical regulatory science, providing cover for regulatory actions that would otherwise be regarded as illegitimately biased toward commercial interests.[36] Clinical science has gone private and global, leading to the early termination of trials for economic reasons, delayed publication of results, and pharmaceutical industry control of research outlets.[37] Government regulatory bodies have given up even trying to monitor the trials undertaken across the world.[38] At the same time, regulators have relaxed premarketing testing requirements for an increasing number of cases, in favor of postmarketing surveillance of adverse effects.[39] These are but some of the practices that have resulted in surplus ignorance about the effects of taking drugs.[40]

We are currently living through a period where withdrawals of drugs from the market have become routine and adverse effects from taking drugs have risen to epidemic levels.[41] But are these problems not merely unavoidable—in the worst cases tragedies to be sure, but an unfortunate consequence of the irreducible uncertainty and danger of taking pharmaceuticals? One wonders. Let us return to 1973:

> It turns out that the cost [of drug regulation] is far in excess of the costs of having a thalidomide tragedy ... I will have to say, how very shocking it might seem, that we don't have enough thalidomide tragedies in the United States today.[42]

This long-forgotten BBC interview of Sam Peltzman, fresh off participation in the Pharmaceuticals Conference, offered a pithy statement of aims for the medical marketplace: the medicine consuming public would gain by "trading" risk for accelerated drug innovation (a benefit that failed to materialize[43]).

That the public should be *forced* to make this trade is neoliberalism's calling card.

36 John Abraham and Tim Reed, "Progress, Innovation, and Regulatory Science in Drug Development: The Politics of International Standard-Setting," *Social Studies of Science*, 32(3), pp. 337-369, 2002.

37 See, for example, Joel Lexchin, "Sponsorship Bias in Clinical Research," *The International Journal of Risk & Safety in Medicine* 24(4), pp. 233-242, 2012 and Lexchin, "Those Who Have the Gold Make the Evidence: how the pharmaceutical industry biases the outcomes of clinical trials of medications," *Science and Engineering Ethics* 18(2), pp. 247–261, 2012.

38 See Adriana Petryna, *When Experiments Travel*. Princeton, NJ: Princeton University Press, 2009.

39 Patients therefore assume the increased health risks of taking medicines with unknown effects, but receive neither credit nor compensation for doing so. See Melinda Cooper and Catherine Waldby, *Clinical labor: Tissue donors and research subjects in the global bioeconomy*, esp. chapter 8. Duke University Press, 2014. That it is nevertheless maintained that innovation requires the protection of pharmaceutical companies' intellectual property to be expanded gives some indication of the exact nature of neoliberalism's bias.

40 There are other methods. See, David Michaels, *Doubt Is Their Product*. New York: Oxford, 2008.

41 Donald Light et al, "Institutional Corruption of Pharmaceuticals and the Myth of Safe and Effective Drugs." *Journal of Law, Medicine & Ethics* 14(3), 590-610, 2013.

42 Read into record, US Senate Subcommittee on Monopoly, Hearings on the Present Status of the Competition in the Pharmaceutical Industry, Part 23, p. 9831, 1973.

43 On the lack of pharmaceutical innovation, see, e.g., Light et al, 2013.

Author's Note

An earlier version of this paper was delivered at the Whitlam Institute in Western Sydney University. I am grateful to Eric Sidoti, Rob Van Horn, Anna Yeatman for their thoughtful suggestions. Portions of this paper are adopted from Edward Nik-Khah. (2014) "Neoliberal Pharmaceutical Science and the Chicago School of Economics," *Social Studies of Science*, 44(4), pp. 489-517.

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