

## THE AMERICAN MEDICATION NATION: 1980 TO PRESENT

By

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“We hate big pharma, but we sure love drugs,” wrote Geoffrey Colvin in 2004. Colvin asserts that despite the American public’s antipathy towards the drug industry, the United States has nevertheless entered a pharmaceutical era of medicine and become the world’s number one “medication nation.”<sup>1</sup> As disturbing as it sounds, Colvin’s assertion is largely correct. Americans consume more prescription drugs than citizens of any other country, although France is close. In 2004, global pharmaceutical sales stood at \$500 billion and the U.S. market accounted for nearly half of that spending. With less than five percent of the world’s population, the U.S. accounted for almost fifty percent of global sales.<sup>2</sup> The amount of money spent on pharmaceuticals was the fastest growing part of total U.S. healthcare expenditures, at 12% per year. Additionally, in 1980, U.S. prescription drug expenditures were \$12 billion, accounting for 4.9% of total healthcare spending, but by 2003 it had escalated to \$184.1 billion or 11% of total healthcare spending. Prescription drug spending also grew an annual rate of between 10-14%.<sup>3</sup> During this time span, the pharmaceutical industry was America’s most profitable industry.<sup>4</sup>

Meanwhile, social scientists and medical practitioners have articulated concerns about the medicalization of human behaviour, the U.S. drug industry’s excessive but disguised influence on the parameters and definitions of sickness, and the modern industry’s

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<sup>1</sup> Geoffrey Colvin, “We Hate Big Pharma, But We Sure Love Drugs,” *Fortune*, 27 December 2004: 56.

<sup>2</sup> Andrea Tone and Elizabeth Siegel Watkins, *Medicating Modern America: Prescription Drugs in History* (London: New York University Press, 2007), 4.

<sup>3</sup> Monali J. Bhosle and Rajesh Balkrishnan, “Drug Reimportation Practices in the United States,” *Therapeutics and Clinical Risk Management* 3, no. 1 (2007): 41-46.

<sup>4</sup> Marcia Angell, *The Truth About Drug Companies: How They Deceive Us and What to Do About it* (New York: Random House, 2004), 86-88.

formidable lobbying power in Washington, D.C. These issues have incited studies from academics of all fields and this developing body of literature – unmistakably interdisciplinary in nature – has challenged us, as historians, to think more critically about health care and drugs in the twenty-first century.

Professor Francis Fukuyama, a prominent political and social commentator from the academy, is one individual who has questioned the pharmaceutical industry’s ascendant position in the United States. Mainly recognized for his famous 1989 “End of History” theory and his rejection of neoconservatism and the invasion of Iraq, Fukuyama’s *Our PostHuman Future: Consequences of the Biotechnology Revolution* problematizes the U.S. drug business and the life sciences more broadly. Published in 2003 in the wake of the Human Genome Project and tremendous sales for such drugs as Prozac and Ritalin, *Our PostHuman Future* argues that American policymakers, doctors, and patients need to reassess the remarkable power of the pharmaceutical industry. Citing George Orwell’s and Aldous Huxley’s chilling visions of a dreadful dystopian future, Fukuyama strongly urges American academics and laypersons to cast off intellectual ennui and identify the pitfalls associated with an unchecked pharmaceutical industry. According to Fukuyama, it is imperative to probe the antecedents of the medication nation and unpack the bond between technology and democracy.<sup>5</sup>

What follows is based on Fukuyama’s challenge: a broad-based examination of the U.S. drug industry between 1980 and the present. In offering this analysis, this essay provides a description of drug approval and a snapshot of the watershed years – the early Reagan years – when the drug industry grew enormously. I will then discuss the concerns cited earlier: the evolving diagnostic boundaries of certain illnesses and the increased usage

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<sup>5</sup> Francis Fukuyama, *Our PostHuman Future: Consequences of the Biotechnology Revolution* (London: Profile Books, 2003). Various other authors besides Fukuyama have challenged the academy to probe the impact of breakthroughs in biotechnology and pharmaceuticals in American society. Some examples include: Erika Dyck’s *Psychedelic Psychiatry: LSD From Clinic to Campus* (Baltimore: Johns Hopkins University Press, 2008), Lawrence Schmidt and Scott Marratto’s *The End of Ethics in a Technological Society* (Montreal: McGill-Queen’s University Press, 2008), and Greg Critser’s *Generation RX: How Prescription Drugs are Altering American Lives, Minds, and Bodies* (New York: Houghton Mifflin, 2006).

of certain classes of drugs. Colvin's assertion is accurate: Americans embrace pharmaceutical products while maligning the companies that provide them. Addressing Colvin's subject, what he labeled the medication nation, is a complex task demanding an interdisciplinary approach. Such analysis has the potential to contribute to the current discussion about the health care system and health care outcomes in the United States.

## The Tangle

Prescription drugs are not ordinary consumer goods. As U.S. Senator Debbie Stabenow (D-MI) proclaimed: "It's not like buying a car or tennis shoes or peanut butter."<sup>6</sup> Many Americans owe their good health, their livelihood, even their lives to innovative drug technologies that emerge from this industry on a regular basis. Yet many Americans also owe their health problems, including the loss of family members, to this same industry. Recognition of this fact provoked historian Peter Temin to write, "Those who think or write about drugs therefore have to thread their way through a tangle of alternative criticisms from different and conflicting viewpoints."<sup>7</sup> Unsurprisingly and lamentably, the literature on this subject is often bizarrely bifurcated, as in the case of Doug Bandow's *Demonizing Drugmakers* and Jerome Kassirer's *On the Take*, which adopt wildly divergent positions on the role of pharmaceuticals in American society.<sup>8</sup>

The tangle, as Temin so artfully put it, looks even thicker and thornier when you consider the difficulty inherent in developing and approving a drug. To be begin with, according to Paracelsus, a sixteenth century alchemist, "All medicines are poisons...the right dose differentiates a poison from a remedy."<sup>9</sup> Dr. Robert Temple, one-time FDA Director

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<sup>6</sup> Quoted in Angell, *The Truth About Drug Companies*, xxvii.

<sup>7</sup> Peter Temin, *Taking Your Medicine: Drug Regulation in the United States* (London: Harvard University Press, 1980), 2.

<sup>8</sup> Doug Bandow, "Demonizing Drugmakers: The Political Assault on the Pharmaceutical Industry," *Policy Analysis* 475: 1-55 and Jerome Kassirer, *On the Take: How America's Complicity with Big Business Can Endanger Your Health* (New York: Oxford University Press, 2005).

<sup>9</sup> Jerry Avorn, *Powerful Medicines: The Benefits, Risks, and Costs of Prescription Drugs* (New York: Alfred A. Knopf, 2004), 72.

of Research and Review, informed Congress that no drug is completely safe.<sup>10</sup> These are significant reminders of how difficult it is to evaluate and approve such medicines for both safety and efficacy. Federal drug officials must be rigorous so as to minimize the dangers as much as possible; they must be honest so that unethical drug companies do not corrupt the process. Yet critics contend that these employees must also be speedy and efficient and prioritize the drugs of most significance. The job is both intricate and essential and a delicate equilibrium must be found between promoting innovation and safety, a balance which is calibrated to meet the needs of consumers, various other stakeholders, and, finally, industry. Getting this balancing act correct remains an ongoing struggle.<sup>11</sup>

The marketing of a new drug, from its birth in the research lab to FDA approval, is a protracted, arduous, and pricey process. According to historian Barry Werth, “new drugs are exceedingly rare; novel ones still rarer.” This is due to the cost and risk associated with the research and development (R&D) cycle as well as the approval process.<sup>12</sup> Companies must perform preclinical testing in the lab and on animals. This usually takes three to four years. A company then files an Investigational New Drug Application (IND) with the FDA and, if not disapproved in thirty days, the company may move forward with a three stage test of the compound in human subjects. Phase I, which takes about a year, involves under a hundred healthy volunteers, and determines the compound’s pharmacokinetics and correct dosage level – how the drug is absorbed, distributed, metabolised, and excreted, as well as how much of the drug is safe to administer. Phase II trials evaluate the efficacy of the drug in a larger group of volunteer patients suffering from the targeted illness or disease; these tests

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<sup>10</sup> Committee on Government Operations, *Oversight of the New Drug Review Process and FDA’s Regulation of Merit: Hearing Before the Intergovernmental and Human Resources Subcommittee of the Committee on Government Relations*, 99<sup>th</sup> Congress, May 22, 1986, 15.

<sup>11</sup> Committee on Government Operations, *FDA Proposals to Ease Restrictions on the Use and Sale of Experimental Drugs*, 100<sup>th</sup> Congress, 1<sup>st</sup> Session, April 29, 1987, 89-90. This struggle was particularly difficult for the Food and Drug Administration and the American public during the height of the HIV/AIDS crisis in the late 1980s and early 1990s. FDA Commissioner Frank Young commented that the danger inherent in rushing new drugs to market had to be weighed against the danger of failing to act. “I believe first and foremost,” Young said, “there is broad public consensus acceptance and earnest support for the goal of providing promising new drugs to desperately ill patients.”

<sup>12</sup> Barry Werth, *The Billion Dollar Molecule: One Company’s Quest for the Perfect Drug* (New York: Touchstone, 1995), 216.

often take two years. Lastly, Phase III clinical trials, conducted using thousands of patients across the United States (and sometimes abroad), take three years and are designed to pinpoint contraindications, also known as adverse reactions. Only then may the drug company file for a New Drug Application (NDA) with the FDA.<sup>13</sup>

## The Watershed Years

America's love/hate relationship with the pharmaceutical industry truly flowered in the 1970s and 1980s. These were turbulent political, economic, and social times, the effects of which cut across a broad spectrum of industries, demographics, and government agencies. Franklin Delano Roosevelt's New Deal consensus, built in the 1930s, was corroding as the U.S. economy slumped. Various American industries, especially manufacturing in the so-called Rust Belt states, suffered. So too did Americans' faith in their established institutions. Inflation was persistently high, yet levels of unemployment inched upward as well. And economists, perplexed by the absence of the Phillips Curve, the trade-off between inflation and unemployment, invented a new term. Stagflation represented a frightening confluence of diminishing productivity and creeping inflation. Besides these worrying events, American prestige, specifically its military power, also seemed to wane, as communist groups made inroads in Laos, Mozambique and Angola, and Iranian terrorists in Tehran held Americans hostage. Amid this tumultuous climate, President James Earl Carter lost a close election to Republican Ronald Reagan, an appealing candidate who promised low taxes, widespread deregulation, and a restoration of a halcyon era.<sup>14</sup>

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<sup>13</sup> Dave Collins, "Lawyer challenging reported Pfizer settlement," *Washington Post*, 26 May 2009, <http://www.washingtonpost.com/wp-dyn/content/article/2009/05/26/AR2009052601303.html>. See also Angela Beth Ritzert, *Essays on the Development and FDA Approval of Pharmaceutical Drugs*, Unpublished PhD Dissertation (University of Kentucky, 1999), 8.

<sup>14</sup> For a fuller, more comprehensive account of the political economy during the 1970s see Robert M. Collins's *More: The Politics of Economic Growth in Postwar America* (Oxford: Oxford University Press, 2000), James Patterson's *Restless Giant: The United States from Watergate to Bush v. Gore* (Oxford: Oxford University Press, 2006), John Sloan's *The Reagan Effect: Economics and Presidential Leadership* (Lawrence: University Press of Kansas, 1999), and Michael J. Boskin's *Reagan and the Economy: The Successes, Failures, and Unfinished Agenda* (San Francisco: Institute for Contemporary Studies, 1987).

While a resounding failure for the Democratic Party, the year 1980 was nonetheless a successful and significant year for pharmaceutical firms. With Ronald Reagan's victory against incumbent Jimmy Carter, the drug industry and the press envisaged a pharmaceutical industry boom in the near future. The *New York Times* reported in 1981's "The Drug Business Sees a Golden Era Ahead" that pharmaceutical trade associations and stock holders were positively giddy. In 1980, the same paper had printed: "The FDA: Too Slow." Authored by Rep. James Scheuer (D-NY), the opinion-editorial denounced the Food and Drug Administration's stultifying assiduousness and emphasized the need for immediate, meaningful reform. Moreover, think tanks such as the Heritage Foundation and American Enterprise Institute promulgated the transformation of the FDA's mission as a means of unleashing the once-mighty American pharmaceutical industry.<sup>15</sup>

The industry itself was subject to a paradigm shift in the early 1980s. It was a heady, revolutionary time for U.S. drug makers, as Americans in university labs, corporate boardrooms and government circles grew increasingly conscious of a burgeoning biopharmaceutical industry. Nothing less than a radical change in technological research and development was underway in 1980. The signature moment saw drug research switch from a chemical to a biological basis, a new approach to pharmaceutical research and development which rested upon a superior understanding of the intricate functioning of the human body, specifically the molecular and chemical actions and pathologies of the brain. This shift affected both private pharmaceutical firms of varying size and state sponsored scientific institutions.<sup>16</sup> According to Hugh D'Andrade, the senior vice-president of the Schering-Plough corporation, innovation and success during the period depended on managers

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<sup>15</sup> "The Drug Business Sees a Golden Era Ahead," *New York Times*, 17 May 1981, F1 and James Scheuer "The FDA: Too Slow," *New York Times*, 22 May 1980, A35.

<sup>16</sup> Alfonso Gambardella, *Science and Innovation: The US Pharmaceutical Industry in the 1980s* (Cambridge: Cambridge University Press, 1995).

recognizing the shift: "...I think that a pharmaceutical company has to be both a biological company and a chemical company."<sup>17</sup>

Prior to this technological transition, the American pharmaceutical industry was flagging relative to its foreign competitors. Domestically, detractors of big government complained that this was to blame, not company policy or insufficient R&D. It was, critics trilled, inefficient, hidebound bureaucrats and their rigid regulatory posture which retarded growth and inevitably led to a drug lag. The Food and Drug Administration, regulator of the U.S. drug industry, was especially singled out for its role in this decline. "...I have been increasingly alarmed over the past several years at the disastrous effects FDA regulations and their administration have had on drug research and development in this country," pronounced Dr. Louis Lasagna, a member of Rochester University's Medical School and an expert on the drug approval process.<sup>18</sup> Denying innovative technologies to Americans was, in his estimation, tantamount to protecting American consumers to death.<sup>19</sup>

In many experts' estimation, the lag contributed to the diminishing competitiveness of the American pharmaceutical industry – and of the larger economy as well. "Future competitive performance in a dynamic Schumpeterian industry like pharmaceuticals will be significantly affected by national policies influencing the technological and economic opportunities for drug innovation," noted a report by the Comptroller General in 1980.<sup>20</sup> In short, as drug companies were delayed by government approval wait times, the effective patent life of new chemical entities (NCEs) decreased and pre-market expenditures rose. Moreover, critics deplored how R&D expenditures in Western Europe and Japan had been

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<sup>17</sup> Hugh D'Andrade Interview. Chemical Heritage Foundation Oral History Collection, 25-26.

<sup>18</sup> Testimony of Louis Lasagna, M.D. on Drug Regulation Reform Act of 1978 before the Subcommittee on Health and Scientific Research and Committee on Human Resources (Rochester, New York: The Center for the Study of Drug Development, 12 April 1978) 2

<sup>19</sup> Committee on Science and Technology, *FDA Drug Approval – A Lengthy Process that Delays the Availability of Important New Drugs: Report to the Subcommittee on Science, Research, and Technology, House Committee on Science and Technology*, May 28, 1980, 59-60.

<sup>20</sup> *FDA Drug Approval – A Lengthy Process that Delays the Availability of Important New Drugs*, Comptroller General's Report, 5-6.

mounting quicker than in the United States; and the pharmaceutical industries in such places, which had already evolved rapidly from the 1960s, would pose a grave challenge to U.S. pharmaceutical dominance in the future. Consequently, calls for policy change rang loudly in Washington, D.C.<sup>21</sup>

The rise of regulatory reform paralleled fears about future U.S. economic competitiveness and the budding technological transformation in the American pharmaceutical industry. Historian Edward Berkowitz has argued that deregulation in the 1970s transcended the nation's ideological divide. According to him, "the seventies was a time in which people rediscovered the power of the marketplace and individual responsibility and raised questions about the effectiveness of regulation to change behavior in a desired way."<sup>22</sup> "Deregulation," he continued, "represented one of the era's few successful liberal-conservative collaborations" – and this included the pharmaceutical industry.<sup>23</sup> Regardless of political creed, Americans on the whole were willing to countenance some measure of deregulation of business and industry if it would provide economic growth.

For instance, President Reagan, who had promised to limit the size and scope of government and extolled the virtues of an unshackled marketplace, made it a top priority to reshape and reform the FDA, the gatekeeper of the nation's drug supply. Accordingly, he appointed moderate deregulators to oversee the FDA and its parent, the Department of Health and Human Services (HHS). Commissioner Hayes at the FDA and Secretary Schweiker at HHS subsequently promoted the Reagan deregulatory agenda, modified the status quo, and helped foster a robust, cooperative relationship between the drug industry and the FDA. Reagan took further steps, however. He signed Executive Order 12291, a rule

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<sup>21</sup> Henry Grabowski, "An Analysis of US International Pharmaceutical Competitiveness in Pharmaceuticals," *Managerial and Decision Economics* (10): 27-33.

<sup>22</sup> Edward Berkowitz, *Something Happened A Political and Cultural Overview of the Seventies* (New York: Columbia University Press, 2006), 10.

<sup>23</sup> *Ibid.*, 166.



which codified cost-benefit analysis and effectively slowed the promulgation and passing of new drug regulations.<sup>24</sup> Additionally, Reagan allowed the FDA to suffer budget shortfalls and dwindling staff levels.<sup>25</sup> According to Mary Frances Lowe, writing in *Food Drug Cosmetic Law Journal*, a faith in regulatory reform at the elite level of the U.S. government undoubtedly facilitated pharmaceutical growth, as well as breakthroughs in research and development.<sup>26</sup> Reagan was truly instrumental in molding the conditions and settings of the modern drug industry.

Nevertheless, the watershed years were also influenced by the U.S. Supreme Court and Congress. For example, in June 1980, five months before the election of Reagan, the Supreme Court held in *Diamond v. Chakrabarty* that living organisms engineered by scientists were potentially patentable under existing statutes. Seemingly innocuous, this decision sparked a period of speculative frenzy over genetic engineering. On 14 October 1980, biotech company Genentech went public. Within minutes of the opening bell, investors on the New York Stock Exchange had purchased one million shares and the stock prices jumped from \$35 to \$89, raising \$38.5 million and becoming the largest initial public stock offering to date.<sup>27</sup>

Moreover, the passage of the Bayh-Dole Act in 1980, the crucial legislative initiative named for Senator Birch Bayh (D-IN) and Robert Dole (R-KS), served to revolutionize the legal environment for the nascent biotechnology and bio-pharmaceutical industry. Encouraging federally funded researchers and university sponsors to license their patented discoveries by giving them clear titles to the patents, the Bayh-Dole Act was a product of both the Republican and Democratic Party. Designed to advance American competitiveness

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<sup>24</sup> Edward P. Fuchs and James E. Anderson, "The Institutionalization of Cost-Benefit Analysis," *Public Productivity Review* 10 (1987): 29-30.

<sup>25</sup> Mary Olson, "Substitution in Regulatory Agencies: FDA Enforcement Alternatives," *Journal of Law, Economics and Organization* 12 (1996): 389.

<sup>26</sup> Mary Frances Lowe, "Pharmaceutical Regulatory Policy: A Departmental and Administrative Perspective," *Food Drug Cosmetic Law Journal* 39 (1984): 504-509.

<sup>27</sup> Sally Smith Hughes, "Making Dollars Out of DNA: The First Major Patent in Biotechnology and the Commercialization of Molecular Biology, 1974-1980," *Isis* 92 (2001): 569.

in the global pharmaceutical trade, it was another crucial component of the watershed years and the burgeoning medication nation.

### **Pandering Sickness**

Another indispensable piece of the story behind Colvin's medication nation is the purported promotion of sickness. Recently, critics have contended that the drug industry seeks to expand the boundaries of certain chronic diseases. Such books as Merrill Goozner's *The \$800 Million Pill*, Jackie Law's *Big Pharma* and Ray Moynihan's and Alan Cassel's *Selling Sickness* have asserted that companies develop and promote new sicknesses for the American marketplace. Historian Howard Kushner articulates a broader and more sinister perspective: in the early 1980s, medical knowledge itself was commercialized.<sup>28</sup>

Depression serves as instructive example of this critique. The psychotropic class of drug which dealt with depression grew out of a deeper understanding of the biochemical nature of the brain and its mental processes.<sup>29</sup> Once the American medical establishment and pharmaceutical industry developed a firmer understanding of the brain, it was only a matter of time before new drugs like Prozac were developed and manufactured. Prozac (fluoxetine) of the selective serotonin reuptake inhibitor (SSRI) class, blocks the reabsorption of serotonin by the nerve synapses and hence serves to increase the levels of serotonin in the brain. Low levels of serotonin are associated with poor impulse control, uncontrolled hostility aimed at improper targets, and ultimately depression.<sup>30</sup> Unfortunately, depression

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<sup>28</sup> Howard I. Kushner, "The Other War on Drugs: The Pharmaceutical Industry, Evidence-Based Medicine and Clinical Research" *Journal of Policy History* (19): 49-70.

<sup>29</sup> It was called a neurotransmitter revolution, and it was strengthened by the increase in scientific knowledge about serotonin, dopamine, and norepinephrine. It was discovered that neurotransmitters controlled and regulated the firing of nerve synapses and the transmission of signals across the neurons in the brain. It was also discovered that the specific levels and interactions of these neurotransmitters directly influenced a given person's subjective feelings of well-being, self-esteem, and fear.

<sup>30</sup> A lack of serotonin is considered to lead to depression, aggression, and suicide. Prozac is therefore believed to affect that most central of emotions, the feeling of self-worth, our self-esteem. Depression, though, has been around since Hippocrates, is largely considered the most common psychiatric complaint, and is extremely variable from person to person. It is an affliction, marked by sadness and inactivity. It can be fleeting or permanent, acute or chronic. Moreover, depression has myriad social causes, ranging from the loss of one's parents to the loss of one's job; but

has been suffered by everyone in one form or another – at one time or another – and because one cannot fathom a life-situation completely absent occasional bouts of sadness, this affords drug companies a lucrative opportunity.

As chronicled in David Healy’s *Let Them Eat Prozac: The Unhealthy Relationship Between the Pharmaceutical Industry and Depression* and Elizabeth Wurtzel’s *Prozac Nation: Young and Depressed in America*, pharmaceutical firms were able to capitalize on this new understanding of depression. By 2002, over 1,800,000 Americans were introduced to the drug and given a prescription. In 1988, by contrast, that figure was just under 900,000. This constituted, for a broad set of scholars across multiple disciplines, a perfectly executed plan to sell a certain sickness.<sup>31</sup>

A second example is Eli Lilly’s Sarafem. In this case, severe premenstrual pain has been redesignated “premenstrual dysphoric disorder” (PMDD). According to the American Academy of Family Physicians, premenstrual symptoms may be treated by a number of alternative therapies besides Sarafem, including diet alterations, massage therapy, aerobic exercise, diuretics, increased vitamin and mineral intake, and non-steroidal anti-inflammatories like aspirin or ibuprofen. In short, a number of suitable therapies can mitigate symptoms and take the place of Sarafem.<sup>32</sup> Yet according to Marcia Angell, the former editor of the *New England Journal of Medicine*, Sarafem has been portrayed in television advertisements as the most effective solution, despite a dearth of evidence. In commercials, satisfied, self-confident, and beautiful women of all ages testify to their contentment and lack of pain – however, Sarafem was by far the most expensive of all the PMDD therapies

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biomechanical mechanisms also interact with a person’s daily life. Its symptoms include pessimism or hopelessness, periodic disturbed sleep or frequent insomnia, among many others.

<sup>31</sup> See John Abramson, *Overdosed America* (New York: HarperCollins, 2004) and Graham Aldred, *An Analysis of the Use of Prozac, Paxil, and Zoloft in USA, 1988-2002*. Alliance for Human Research Protection Document, 2004: consulted at <http://www.ahrp.org/risks/usSSRIuse0604.pdf>.

<sup>32</sup> Consult the American Academy of Family Physicians website at <http://www.aafp.org/afp>.

mentioned above. Furthermore, writes Angell, “some women feel duped” when they discover that Sarafem is none other than Prozac, an SSRI.<sup>33</sup>

Francis Fukuyama, we may recall, questioned how the U.S. pharmaceutical industry was changing human nature and democracy. He suggested that drug companies have sought to reshape and modify human behaviour. Of course, this effort goes beyond Prozac and Sarafem, depression and PMDD; the important point to underscore is that the American public faces a number of dangers when determining which drugs to buy and, in fact, whether they need to buy them at all.<sup>34</sup>

Unsurprisingly, drug companies have a vested interest in expanding diagnostic boundaries and selling as much product as possible. This is imperative to vitiate the risks in developing a drug and overcoming any pipeline problems. The average ten-year process of discovery of a new chemical entity (NCE), the preliminary and advanced clinical testing of that entity, and then the final approval of that entity in the form of a drug is risky and expensive. The price and risk have gone up since the watershed years. It costs, by some estimates, upwards of \$800 million to develop a novel drug. In 1987, however, the price was estimated at \$231 million.<sup>35</sup>

Results of this pipeline problem have taken two perceptible forms. One has been the growth in the introduction of “me-too” or “look-alike” drugs to the market. These are drugs targeted at the same medical condition – whether a cold and sinus problem, or high blood pressure, or generalized anxiety disorder – and often these drugs have similar chemical

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<sup>33</sup> See Angell, *The Truth About Drug Companies*, 88. When Prozac lost its all-important patent, Eli Lilly repackaged the drug, found a new application for it, changed the color, and marketed Sarafem at three and half times the price of over-the-counter Prozac

<sup>34</sup> Heartburn has in recent years been designated as the much more ominous acid reflux disease or gastroesophageal reflux disease (GERD) and portrayed in commercials as the beginning of the serious condition, esophageal disease. Technical studies indicate that this connection, despite what direct-to-consumer advertisements pronounce, is tenuous. Yet, this does not stop AstraZeneca, makers of Nexium, a me-too version of its earlier Prilosec from capitalizing on the acceptance of GERD as a disease. Prilosec is available over-the-counter, of course, but consumers are manipulated into believing it is less effective

<sup>35</sup> Merrill Goozner, *The \$800 Million Pill: The Truth Behind New Drug Costs* (Berkeley: University of California Press, 2004). See also Committee on Government Operations, *FDA Proposals to Ease Restrictions on the Use and Sale of Experimental Drugs*, 100<sup>th</sup> Congress, 1<sup>st</sup> Session, 29 April 1987, 89-90.

profiles and side effects. A second way in which drug companies seek to offset the pipeline problems is with acquisitions and mergers.<sup>36</sup>

First, the purpose of marketing a me-too drug – a variation of a drug already available – is to seize a percentage of a pre-established, lucrative market. Companies even sometimes sell lower-cost versions of their own drugs, as in the case of AstraZeneca’s prescription heartburn medicine Prilosec OTC and its follow-up, the more expensive Nexium.<sup>37</sup> Schering Plough’s allergy medicine Clarinex, for example, also replaced its over-the-counter Claritin in 2002. In both cases, the “new” drugs were marketed for the same purposes as the old ones, and the successive versions had virtually identical chemical properties.<sup>38</sup> New technologies, in short, were not really new at all. One needs to look no further than the FDA approval process, for example. In 2002, of the seventy-eight drugs approved by the FDA in that year, only seventeen contained new active ingredients, and only seven of these were classified as improvements over older drugs. The other seventy-one drugs were duplicates, or me-too drugs.<sup>39</sup>

Second, since 1980 the American pharmaceutical industry has forged ahead with increases in mergers and acquisitions. If a pharmaceutical firm’s R&D pipeline had clogged up, if the flow of innovative products has slowed to a trickle, then the Chief Executive Officer’s solution was to acquire another firm, and thus another pipeline. The trend began in the 1980s, progressed throughout the 1990s, and continues unabated. Biotech-biotech merger and acquisition transactions rose from 70 in 2002 to 128 in 2003. Pfizer acquired Warner-Lambert in 1999 and then Pharmacia in 2002, making it the world’s largest drug

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<sup>36</sup> Rosanne Spector, “Me-too Drugs: Sometimes they’re just the same old, same old,” *Stanford Medicine Magazine*, Summer, 2005; consulted online at <http://stanmed.stanford.edu/2005summer/drugs-metoo.html>

<sup>37</sup> Ibid.

<sup>38</sup> Alex Berenson, “Where Has the Prilosec Gone?” *New York Times*, 2 March 2005. Consulted online at: <http://query.nytimes.com/gst/fullpage.html?res=9D04E0DE133DF931A35750C0A9639C8B63&sec=health&spn=&pagewanted=3>.

<sup>39</sup> *FDA Orange Book – Approved Drug Products with Therapeutic Equivalence Evaluations*. Department of Health and Human Services. Washington, D.C.: Government Printing Office, 2008.

manufacturer.<sup>40</sup> In 2009, as the financial and economic crisis gripped the United States, mergers proliferated. Roche agreed to buy Genentech for \$46.8 billion, Merck bought Schering-Plough for \$41.1 billion, and Pfizer paid \$68 billion for Wyeth.<sup>41</sup>

According to some industry analysts, however, the size of a company does not necessarily mean more products will be sold. Rather, the advantages of size are often trumped by dis-economies of scale: inertia, bureaucracy, risk aversion, clock-watching, office politics. Companies the size of Merck have fantastic scientists running tests and laying the groundwork for new wonder drugs, but they also have middle and upper layers of managers who waste space and clog the company's R & D pipeline. Such managers are detrimental to the development of new drugs; they stifle innovation, hoard resources, and look to insulate themselves and protect their company from risk. Thus, growing bigger may be an antiquated business strategy.<sup>42</sup>

If this is indeed the case, why do pharmaceutical mergers and acquisitions continue to thrive? How does the medication nation benefit? Big companies surely benefit from the acquisition of leaner research-oriented companies. A given pharmaceutical juggernaut benefits precisely because it can focus on what it does best, marketing and distribution, on utilizing the supply chain.<sup>43</sup> In turn, the juggernaut enables the smaller, more cutting-edge and efficient entity to do what it does best: focus on intensive, targeted R&D. Eli Lilly, for example, has partnered with ICOS to sell Cialis in the United States. Britain's GlaxoSmithKline devolved design to small Centers of Excellence for Drug Discovery. The idea was to provide each center with a greater degree of autonomy as a means to surmount

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<sup>40</sup> Susan Warner, "The Urge to Merge: Weak Pipelines Prompt Partners to Eye Each Other with Interest," *The Scientist*, September 2004 (18): 39-41.

<sup>41</sup> Andrew Pollack, "Roche Agrees to Buy Genentech for \$46.8 Billion," *New York Times*, 13 March, B6 and Natasha Singer, "Merck to Buy Schering-Plough for \$41.1 Billion," *New York Times*, 10 March, B1.

<sup>42</sup> Susan Warner, "Pipeline Anxiety: Scientists Pumped into New Roles," *The Scientist* (17): 46.

<sup>43</sup> To draw a parallel what happened in the tech business in the 1970s with I.B.M. and Digital is now playing out among the giants in the pharmaceutical business. In the 1970s, the centre of innovation shifted from the offices of the major manufacturers and distributors to the smaller, more narrowly focused offices of Silicon Valley. Though these are two different sectors of the economy, today, the language of the 1970s is being reused.

bureaucratic barriers. Bigger is better, then, when a measure of devolution characterizes the relationship between partners.

### **Public Perception, Prices, and the Pharmaceutical Industry**

The American pharmaceutical industry is, like the oil, gas, or defense industries, not only evocative but also highly politicized. “Big tobacco, big oil, the big polluters, the pharmaceutical companies, the HMOs, sometimes you have to be willing to stand up and say no, so families can have a better life,” proclaimed Al Gore in 2000.<sup>44</sup> Then a presidential candidate, Gore articulated what many progressive and independent Americans felt about the titans of business – that interests often conflict in the United States and “special interests” frequently triumph during this encounter.

In recent years, public opinion polls point toward Americans’ growing disquiet with the pharmaceutical industry (though this disenchantment has not affected consumption rates). For instance, one poll has found that the public image of pharmaceutical companies decreased perceptibly in a five year period. In 1997, seventy-nine percent of respondents thought that drug companies did a good job of serving their consumers; by 2002, only fifty-nine percent did.<sup>45</sup> A second poll, conducted in 2003, indicated that 23 percent of all those surveyed felt that their doctors were unduly influenced by pharmaceutical companies and thirty percent felt that such companies were too aggressive with doctors.<sup>46</sup>

Anxiety about the drug culture and the mounting supremacy of the U.S. drug industry is also reflected on the big and small screens and in books. Such television series and major motion pictures as *ER*, *House*, *The West Wing*, *The Fugitive*, *X-Men III: The Last Stand*, *V for*

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<sup>44</sup> Al Gore, “Gore’s Acceptance Speech at the Democratic National Convention,” 17 August 2000: consulted at [www.washingtonpost.com/wpsrv/onpolitics/elections/gorettext081700.htm](http://www.washingtonpost.com/wpsrv/onpolitics/elections/gorettext081700.htm).

<sup>45</sup> Harris Poll, Americans Have Few Concerns About How Pharmaceutical Companies Market to Doctors,” consulted at [www.harrisinteractive.com/news/newsletters](http://www.harrisinteractive.com/news/newsletters). According to Humphrey Taylor, chairman of Harris Poll, “The public does not believe that their doctors are manipulated by the pharmaceutical industry marketing.”

<sup>46</sup> Ibid. However, see also Harris Poll, “Oil, Pharmaceutical, Health Insurance, Managed Care, Utilities, Tobacco,” consulted at [www.harrisinteravtive.com/harris\\_poll/index.aspPID=825](http://www.harrisinteravtive.com/harris_poll/index.aspPID=825)

*Vendetta*, *Sicko*, and *The Constant Gardener* have featured enthralling narratives about drugs products, their use and regulation, and the decidedly scheming, greedy nature of the industry. Plotlines have focused on the influencing of doctors to prescribe certain drugs, inordinate research and development costs, and the falsification of drug trial data. Brazilian Fernando Meirelles, director of *City of God* and *The Constant Gardener*, commented, “I did want to expose the pharmaceutical industry a bit...I think the film helps people see it in a different way, not through its press releases.”<sup>47</sup> Novels have also addressed the potency of major pharmaceutical companies. Arthur Hailey’s *Strong Medicine*, George Mannis’s *The Third Patient* and Thomas Locke’s *The Delta Factor*, while certainly popular fiction, are nevertheless successful at weaving together coherent, engaging stories that include drug company representatives and pharmaceuticals lawyers, FDA drug reviewers and medical consultants, family doctors and injured patients, as well as politicians conducting congressional oversight activities.

The increasingly negative perception of the drug industry, as well as the belief that pharmaceutical companies are pitted against every day Americans, has roots in the rising price of drugs. West Virginia governor Bob Wise maintained in 2002 that pharmaceutical prices are “outrageous,” while Congressman Bernie Sanders (I-VT) noted that seniors bore the brunt of the unfair pricing policies and, as a result, “many are suffering and even dying.”<sup>48</sup> For all of the condemnation of the pharmaceutical industry’s pricing structure and its impact on American consumers, however, there have been startlingly few attempts to legislate on the matter. Senator Estes Kefauver (D-TN) first investigated this politically prickly subject in the late 1950s and early 1960s (and subsequent efforts have been made since), but the thalidomide panic in 1962 prompted new efficacy regulations and increased

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<sup>47</sup> Fernando Meirelles Interview. Consulted online (October 13, 2009) at MovieTome.com. See: <http://www.movietome.com/people/370024/fernando-meirelles/trivia.html>

<sup>48</sup> Bob Wise, “Wise Blasts Big Brand Name Drug Companies for Scaring State Citizens,” West Virginia Press Release, September 5, consulted on government website: [www.wygov.org/News.asp](http://www.wygov.org/News.asp); Bernie Sanders, “Let’s Demand Lower Drug Prices,” *Rutland Daily Herald*, 25 July, A11.



authority for the Food and Drug Administration, not pricing legislation.<sup>49</sup> In other words, rhetoric, rather than legislative initiative, has typified the congressional effort since.

As the federal government has allowed prices to be set by the marketplace – and it is the only OECD country to do so – the pharmaceutical industry’s profiteering has advanced a negative perception of the industry.<sup>50</sup> To be sure, thousands of people are employed by an industry that provides valuable medicines that relieve pain, save lives, and cure patients, yet the 5% average annual increase in patented drug prices between 1996-2001 often outweighs these other considerations. This is especially so when other countries’ prices, including Canada, Germany, Sweden, and Switzerland, rise by less than 1% annually, and sometimes even decrease. As drug prices swell in the U.S., however, research and development expenditures fail to grow in an equivalent fashion. In fact, according to commentators, the price of developing a new drug is not nearly as expensive as pharmaceutical companies purport. In some cases, even the taxpayers front the bill for basic R&D, thereafter drug companies establish prices based on that research which are regularly 40-100 times the cost of manufacturing.<sup>51</sup>

The industry’s role in the political and academic arena has further engendered a negative perception of the pharmaceutical industry. A recent report indicated that one industry lobbyist hits the U.S. capital for every member of Congress – many of them former members – while at the same time huge amounts of money flow into the campaign coffers of elected representatives. For example, during the 2001-2002 election cycle the pharmaceutical industry gave a total of \$22 million in individual, soft money, and political action committee (PAC) contributions to Republican candidates. The Pharmaceutical

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<sup>49</sup> For an account of the FDA in the modern era see: Lucas Richert, “Pills, Policy Making, and Perceptions: Inside the FDA during the ‘Reagan Revolution’, 1981-1982,” *Canadian Review of American Studies* 39 (1): 41-63 and “FDA Reform and the European Medicines Evaluation Agency,” *Harvard Law Review* 108 (8) (1995): 2009-2026.

<sup>50</sup> Amanda McCloskey, “Cost Overdose: Grow in Drug Spending for the Elderly, 1992-2010,” Washington, D.C, Families USA (2000): 1-35.

<sup>51</sup> Donald W. Light, Paper for Affordable Medicines Task Force, “The Pharmaceutical Industry and Bush Administration are Locking in High Drug Prices for Americans,” 2004. Consulted at: <http://www.upenn.edu/faculty/index.php?profile=13>.

Research and Manufacturers of America (PhRMA) spent \$3.4 million on Republicans and \$161,300 on Democratic candidates. Then, following the 2002 election, pharmaceutical industry leaders used a full court press to push for market-based solutions to rising drug costs. According to industry critics, the objective was to shield profits with government legislation – and the result of such lobbying was the 2003 Medicare Modernization Act.<sup>52</sup> The new drug entitlement was costly and, in some cases, produced white hot anger on the part of both liberals and conservatives. Senator Ben Nelson (D-FL) proclaimed, “the government pays higher prices for drugs, and the pharmaceutical industry got a windfall.”<sup>53</sup> “The Medicare drug bill,” wrote conservative Bruce Bartlett, “may well be the worst piece of legislation ever enacted.” In his estimation, the Medicare Modernization Act of 2003 was hugely expensive, would lead to tax increases, and represented how Bush betrayed conservatives.<sup>54</sup> The betrayal, of course, if one can accurately call it that, was contingent on the lobbying power of the pharmaceutical industry.

Besides politicians, health care practitioners and academics have also in recent years increased their ties to the drug business. Recent disclosures revealed that many top officials at the National Institutes of Health (NIH) have enjoyed lucrative consulting contracts with the industry and with companies seeking grant funding from NIH. In 2003, the Association of American Medical Colleges, the Association of American Universities, the Department of Health and Human Services, and the NIH leadership itself were all calling upon academic institutions across the country to avoid financial relationships that posed even the perception of a conflict of interest. According to Greg Koski, “the NIH could have led the way –

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<sup>52</sup> See Public Citizen Congress Watch, “Drug Industry Profits: Hefty Pharmaceutical Company Margins Dwarf Other Industries,” June 2003 ([http://www.citizen.org/documents/Pharma\\_Report.pdf](http://www.citizen.org/documents/Pharma_Report.pdf)) and Public Citizen, “The Other Drug War: Big Pharma's 625 Washington Lobbyists” [http://www.citizen.org/congress/campaign/special\\_interest/articles.cfm?ID=6537](http://www.citizen.org/congress/campaign/special_interest/articles.cfm?ID=6537).

<sup>53</sup> Robert Pear and Jackie Calmes, “Senate Panel Rejects Bid to Add Drug Discount,” *New York Times*, 25 September 2009, A18.

<sup>54</sup> Bruce Bartlett, *Imposter: How George W. Bush Bankrupted America and Betrayed the Reagan Legacy* (New York: Doubleday, 2006), 80. See also Lucas Richert, “Radical in the White House?” *AmeriQuests* 7 (1) 2010.

indeed, it should have led the way.”<sup>55</sup> Moreover, the FDA, the nation’s all-important pharmaceutical regulator – the gatekeeper – is in desperate need of reform. A study conducted by *USA Today* revealed that financial relationships between industry and expert members of FDA drug advisory panels are so widespread that finding well-qualified members without such financial interests has become difficult. Worse still, in September 2006, a blue-ribbon panel of experts concluded that the federal system for approving and regulating drugs was in serious disrepair. A host of dramatic changes were needed to fix the problem, proclaimed the 15-member panel. The report, released on 22 September 2006, represented a defining moment after nearly two years of high profile controversy over the safety and side effects of such widely used drugs as pain relievers and antidepressants. It was recommended that the FDA implement a number of initiatives, ranging from restrictions on consumer advertising, to increasing the authority of the FDA, to eliminating squabbling within the agency.<sup>56</sup> By 2009, the negative news reports had not abated. The *Washington Post*, *New York Times*, and *Boston Globe* ran articles in which the FDA featured as a weakened arm of a government that was unable to meet the demands of the twenty-first century biopharmaceutical industry. Public health and industry growth were both at risk.<sup>57</sup>

## Conclusions and the Future

The *New York Times* recently reported that drug companies fared well in 2009, but “concerns over sustainable revenue continued to worry investors.”<sup>58</sup> The future, in short, is murky. What will happen to the medication nation in forthcoming years? Health care reform, instigated by the Obama administration and the Democratic-controlled Congress,

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<sup>55</sup> Greg Koski, “FDA and the Life-Sciences Industry: Business as Usual?” *Hastings Center Report* 34 (5) 2004: 26.

<sup>56</sup> Shankar Vedantam, “FDA Told U.S. Drug System is Broken,” *Washington Post*, 23 September 2006, A01.

<sup>57</sup> Rob Stein, “Ailing FDA May Need a Major Overhaul, Officials and Groups Say,” *Washington Post*, November 26, 2008, A02 and “The FDA in Crisis: It Needs More Money and Talent,” *New York Times*, 3 February 2008: found online at <http://www.strengthenfda.org>.

<sup>58</sup> “Drug Makers Post Strong Profits, but Future is Murky,” *New York Times*, 22 October 2009, B2.

will undoubtedly impact the drug industry – and Americans’ ability and enthusiasm to purchase new drugs. However, neither the immediate nor long-term implications of the reform effort are easily discernible.

Looking backward is just as vital as looking forward. In 2002, Francis Fukuyama raised significant questions about the U.S. pharmaceutical industry’s relationship with Americans. He thought it time for introspection and reassessment. This paper was designed to offer a broad, interdisciplinary overview of the conditions, settings, and actors that empowered the U.S. pharmaceutical industry. A host of historical events – economic turmoil in the late-1970s, specifically stagflation; the rise of deregulation as an answer to the wretched economy; the election of the sunny Ronald Reagan in 1980; passage of crucial new legislation to bring new drugs to market – actuated the medication nation. And these triggers were, of course, married to the paradigm shift in R&D in the 1980s.

Since the watershed years of the early 1980s, the American pharmaceutical industry has developed astoundingly complex and highly beneficial technologies. It has “done much good for mankind,” according to Greg Koski, but at the same time the industry has generated “an environment in which suspicion about ulterior motives now fosters public mistrust and skepticism.”<sup>59</sup> An authoritative assessment of the American pharmaceutical industry during the Clinton and George W. Bush administrations remains to be written and there is certainly space for expansion in the future. Business, medical, political, social, and economic history would all profit from an investigation of the drug industry. Avenues of research might include the FDA’s regulation of Chinese pharmaceuticals and the approval of sophisticated new security technologies to safeguard the U.S. drug supply and identify counterfeits. It would be constructive, moreover, to contemplate the role of pharmaceutical advertising in professional sports and interesting to deconstruct the types of pharmaceutical narratives in fiction and film. Maybe it is best to focus on a particular class of drug in a

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<sup>59</sup> Koski, “FDA and the Life-Sciences Industry,” 27.

specific geographic context like Andrea Tone has recently done with tranquilizers in *The Age of Anxiety*? Perhaps historians might branch out and adopt a transnational or cross-cultural approach and interrogate various intersecting medication nations? Whatever the angle adopted by historians in the future, because the literature remains so radically variable and under-researched, it is safe to speculate that the debate over America's pharmaceutical culture and commercial empires will be marked not by lassitude but verve.

American Indians, African Americans, Hispanics and Latinos, and Japanese Americans all continued to battle discrimination in hopes of a future free of prejudice. In 1980 however, in the Supreme Court case *United States v. Sioux Nation of Indians*, it was ruled that their land was illegally seized and the government owed them over half a billion dollars in repairs (Woodger). This was one of the first times the government recognized their wrongdoings and mistreatment towards American Indians. America is adrift. Our country moves agonizingly, aimlessly, almost helplessly into one of the most dangerous and disorderly periods in history. They are rising up in 1980 to say that this confusion must end; this drift must end; we must pull ourselves together as a people before we slide irretrievably into the abyss. It doesn't have to be this way; it doesn't have to stay this way. We, the Republican Party, hold ourselves forth as the Party best able to arrest and reverse the decline. In the early 1980s, the American economy was suffering through a deep recession. Business bankruptcies rose sharply compared to previous years. Farmers also suffered due to a decline in agricultural exports, falling crop prices, and rising interest rates. Cutting taxes was only one part of Reagan's national agenda of slashing government spending. Reagan believed the federal government had become too large and interfering. During his presidency, he cut social programs and worked to reduce or eliminate government regulations that affected the consumer, workplace, and environment. But he did spend on the military. In the wake of the disastrous Vietnam War, Reagan successfully pushed for big budget increases for defense spending by arguing that the U.S. had neglected its military. first elected president in 1980 and elected again in 1984. He ran on a campaign based on the common man and "populist" ideas. He served as governor of California from 1966-1974, and he participated in the McCarthy Communist scare. Iran released hostages on his Inauguration Day in 1980. While president, he developed Reagannomics, the trickle down effect of government incentives. He cut out many welfare and public works programs. He used the Strategic Defense Initiative to avoid conflict. His meetings with Gorbachev were the first steps to ending the Cold War. He was also responsible f America's superpower status may well be tempered by its own domestic problems and China's economic boom, he argues, but its military, economic and soft power capabilities will continue to outstrip those of its closest rivals for decades to come. My own prediction for America and the American Century? I can only hope and pray for a long and slow decline.