

Fetal Risk, Federal Response:
How Fetal Alcohol Syndrome Influenced the
Adoption of Alcohol Health Warning Labels

by

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ABSTRACT

In the fifteen years between the discovery of fetal alcohol syndrome (FAS) in 1973 and the passage of alcohol beverage warning labels in 1988, FAS transformed from a medical diagnosis between practitioner and pregnant women to a broader societal risk imbued with political and cultural meaning. I examine how scientific, social, moral, and political narratives dynamically interacted to construct the risk of drinking during pregnancy and the public health response of health warning labels on alcohol. To situate such phenomena I first observe the closest regulatory precedents, the public health responses to thalidomide and cigarettes, which established a federal response to fetal risk. I then examine the history of how the US defined and responded to the social problem of alcoholism, paying particular attention to the role of women in that process. Those chapters inform my discussion of how the US reengaged with alcohol control at the federal level in the last quarter of the twentieth century. In the 1970s, FAS allowed federal agencies to carve out disciplinary authority, but robust public health measures were tempered by uncertainty surrounding issues of bureaucratic authority over labeling, and the mechanism and extent of alcohol's impact on development. A socially conservative presidency, dramatic budgetary cuts, and increased industry funding reshaped the public health approach to alcoholism in the 1980s. The passage of labeling in 1988 required several conditions: a groundswell of other labeling initiatives that normalized the practice; the classification of other high profile, socially unacceptable alcohol-related behaviors such as drunk driving and youth drinking; and the creation of a dual public health population that faced increased medical, social, and political scrutiny, the pregnant woman and her developing fetus.

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CHAPTER 1

INTRODUCTION

Prior to the early 1970s, a causative relationship between alcohol and poor birth outcomes was largely unknown, and it was not uncommon for a pregnant woman to consume alcohol. That began to change in 1973 when pediatricians at the University of Washington coined fetal alcohol syndrome (FAS) to describe a specific host of birth defects caused by prenatal alcohol exposure. David W. Smith and Kenneth L. Jones observed a group of children born to alcoholic mothers, children who shared similar symptoms: very low birth weights, visible birth defects along the midline of the face, and low IQs that resulted in cognitive and psychological issues.

The newly coined syndrome met with substantial skepticism from physicians to the general public. Initial challenges in defining the syndrome were complicated by questions of a safe-level of alcohol consumption, and whether concomitant causes such as malnutrition or cigarette and illegal drug use were to blame. The spectrum nature of the defects caused by prenatal alcohol exposure also complicated the definition, with a variety of possible defects ranging in severity based on the mother's pattern of drinking and the full blow syndrome representing the most severe expression of a group of potential symptoms.

Despite the scientific ambiguities surrounding FAS, within three years of its initial description government agencies proposed the idea of requiring warning labels on alcohol to alert pregnant women to the risk of birth defects posed by consumption. The discussions represents the government's first foray into public health measures aimed at

educating mothers in order to protect the well-being of the unborn. Private decisions, such as when and how much to drink, were transformed into very public social harms when the population under investigation was pregnant women. FAS is an illustrative example of how public health interventions are conceived of and implemented when pregnant women are the focus of such public health interventions.

In this dissertation, I examine how actors operating amid different institutional traditions constructed the population-level risks and responsibilities surrounding FAS to propose specific policy interventions. As FAS became politicized in the two decades following its discovery, it became imbued with new meaning, making public latent ideals of pregnancy, motherhood, personal freedoms, and reproductive choices. Such values make FAS an excellent case study for constructing how we as a nation prioritize competing scientific, social, and moral evidence for public health policy decision making. The standard of public health policy is sound, evidence-based science, but often the evidence is conflicting, uncertain, and colored by the epistemic investments of the experts. That is especially true in a policy context when empirical research is legitimately shaped as much by moral and political constraints as by data. To such ends, this dissertation investigates the context and process by which scientific, social, moral, and political narratives dynamically interact to give rise to policy, in this case how agents constructed the risk of drinking during pregnancy in order to mandate health warning labels on alcohol.

Surprisingly few robust historical accounts surrounding FAS exist, given the widespread modern understanding that drinking during pregnancy should be avoided. The interplay between social, medical, and regulatory understandings of FAS has been

addressed best by Elizabeth M. Armstrong and Janet Golden. Prior to the book-length research conducted by Armstrong and Golden, historical accounts related to FAS tended to focus on accounts of how drinking impacted pregnancy centuries ago. (Abel 1999) (Warner and Rosett 1975) Even in the literature review for articles published in the last five years, scientists have traced the history back as far as antiquity by appealing to biblical references, edicts in Carthage and Sparta forbidding alcohol use in newlyweds, or Plato and Aristotle's appeals to maternal impression. Those authors that forgo antiquity in examining the history of FAS more than likely still mention classic descriptions of Great Britain's 18th century Gin Epidemic or W.C. Sullivan's observations of birth outcomes among imprisoned pregnant inebriates in the late nineteenth century. (Abel 2001) (Sullivan 1899) Armstrong and Golden introduce these antiquated but popular concepts of FAS's history, before quickly departing to focus on more recent history that examines the social construction of FAS.

In *Conceiving Risk, Bearing Responsibility: Fetal Alcohol Syndrome and the Diagnosis of Moral Disorder*, Armstrong focuses on how the medicalization of FAS and the public response to the risks posed by drinking were shaped by the social contexts in which they occurred. (Armstrong 2003) Armstrong is a sociologist by training and approaches the narrative of how FAS was medicalized in the latter half of the 20th century using historical methods, qualitative surveys, and quantitative analyses of FAS' epidemiology, which included an examination of drinking patterns, socioeconomic factors, and prenatal health care. Armstrong is particularly interested in how physicians' conceptions of FAS and the risk of alcohol consumption during pregnancy have changed over time, and how those views are influenced by the social environment in which they

are embedded (e.g. pediatricians' understanding and willingness to diagnose/discuss FAS differ when compared to family practice physicians). Armstrong's work is aimed at examining how medical understanding became public knowledge, and ultimately how women who drink during pregnancy are publicly perceived as reflecting the social anxieties and moral failings of US culture in the late 20th century.

Historian of medicine, Janet Golden, approaches the history of FAS's emergence and integration into the cultural lexicon in a much different way in her book, *Message in a Bottle: The Making of Fetal Alcohol Syndrome*. Golden makes use of historical resources and interviews to present what she describes as "a biography of a diagnosis." (Golden 2005) Golden describes the emergence of FAS as both a medical entity and a moral disorder that required intervention by the law, government, and general public. The emergence of FAS is contextualized through court decisions surrounding reproduction and a control over a woman's body such as birth control and abortion. She focuses extensively on how FAS and drinking during pregnancy became publically recognized through broadcast and print media, and how women who flouted the emerging medical and public consensus that drinking while pregnant was unacceptable, were not only vilified but charged with child abuse in some instances. Although Golden deals briefly with the narrative of how FAS was regulated in the late 1970s and 1980s, it comprises a single chapter in her much larger book, and she does not rigorously delve into the topic of how FAS came to be constructed as a risk to public health.

In this dissertation I examine how the emergent prenatal risk of FAS became transformed through federal policy interventions, moving from a medical diagnosis between practitioner and pregnant women to a broader societal risk imbued with political

and cultural meaning. Toward that end, the dissertation examines how evidences and values prioritized in those decisions illustrate issues of authority and responsibility central to the process of governing public health risks. And by doing so, better reveal how we as a society engage with complex issues at the intersection of science and society.

To accomplish that goal, I begin by examining how the regulatory responses to thalidomide and cigarettes in the mid-twentieth century set a precedent for later regulatory responses that arose in response to alcohol's risk to development. I then transition into an examination of how the US had previously responded to the social problem of alcohol, from the colonial era through the mid-twentieth century. After engaging with the requisite history to contextualize the topic of my dissertation, I then approach the main historical narrative of my dissertation in three parts. The first part examines how the government approached a federal alcoholism agenda for the first time since Prohibition, and how the emergence of FAS in the early 1970s required the government to engage with a new public health demographic, the female alcoholic and the fetus she carried. The second part of the narrative focuses on the rise of alcohol warning labels as the solution to the public health problems of FAS, as labeling discussions dominated the legislative discussion for five years between the 1977 National Institute on Alcohol Abuse and Alcoholism health warning and the 1981 Surgeon General's warning that alcohol impacts pregnancy. The third part of the narrative examines how social and moral evidences began to be privileged in the 1980s, which expanded the focus of public health problems to include a wide variety of disordered

drinking such as drunken driving, youth drinking, and concomitant interaction with other drugs.

In Chapter Two, “Thalidomide and Cigarettes: How Hazards to Pregnancy Became a Regulatory Concern of the Federal Government,” I examine how those historical precedents situated FAS within existing bureaucratic and legislative frameworks and how emergent fetal risks became public health concerns. Thalidomide, a popular over-the-counter sleep aid that originated in Europe, was used by many pregnant women to counteract morning sickness in the late 1950s and early 1960s. However, if taken during the first trimester of pregnancy, thalidomide causes dramatic limb defects, long-term neurological deficits, and at times fetal death. The United States avoided widespread thalidomide birth defects as a result of medical officers at the FDA who required more robust information regarding thalidomide’s side effects before approving the drug. As a result the FDA gained a legacy as a consumer protector for both pregnant women and fetuses, and the experience helped to expand the FDA’s regulatory power over testing and approving drugs, food, and drink. That legacy is evidenced by the FDA’s integral role as an advocate for alcohol warning labeling as a response to the risk posed by FAS, and Congress’s acknowledgement throughout hearings that the FDA should be charged with regulating alcohol labeling.

The second precedent examined in Chapter Two, the regulatory response to smoking both generally and specific to pregnancy, shares many similarities with the case study of FAS. One such similarity is how industry in both cases “manufactured uncertainty” by funding industry groups that released competing scientific studies in order to introduce a degree of doubt into scientific consensus on a topic. (Brandt 2007)

The tobacco industry created such uncertainty by funding researchers that repudiated claims that smoking caused cancer, while the alcohol industry had a preoccupation with finding as “safe” level of drinking for both pregnant women and recovering alcoholics. Advocacy organization for both substances also engaged in “moral entrepreneurship” as a means of defining and disseminating a social problem. In the case of cigarettes several decades of social response to the problem shifted smoking from an activity that the majority of Americans indulged in to a profoundly unsocial activity limited to specific places so as not to pollute the air of others. Likewise, in the mid-twentieth century it was common for women to drink during pregnancy, but following the identification of FAS, women drinking during pregnancy widely became associated with moral failure.

Following the discussion of historical predecessors to FAS and public health, I then examine the broader historical landscape of alcoholism, in Chapter Three, “A Short History of How the United States has Defined and Responded to the Social Problem of Alcoholism.” In that chapter I trace the history of how the US has responded to issues of habitual heavy drinking from the colonial period through the mid-twentieth century from combined medical, social, and moral perspectives.

I examine early definition of drunkenness from medical professionals, and the temperance advocacy groups that adopted those definitions to navigate early community-level responses to the social issues of habitual drinking. The American Temperance Society, formed in 1826, is one of the first groups to attempt to address such concerns on a large scale, focusing on preventing such transgressions rather than reforming the inebriate. The success of that organization is due in large part to the mobilization of women who used the opportunity to preach the social gospel and engage in a socially

acceptable form of politics that bettered their community. The rise of temperance plays and the social and moral tropes within those tragic cautionary tales helped to proliferate and define such social values, particularly the role of the mother as the pillar of purity and morality within the family. Shortly thereafter, a group of reformed inebriates founded the Washingtonian Temperance Society that focused on shifting the social response to inebriety from prevention to reformation. The group introduced the idea of loss of control as a hallmark of inebriety, lobbied for the creation of asylums to treat the disorder, and sought to remove the religious and moral stigma associated with the disorder.

Following those early temperance responses, the pressure for social reform continued in the post-war Reformation Era with the American Association for the Cure of Inebriety in 1870 and the formation of the Woman's Christian Temperance Union in 1874. Doctors carved out a disciplinary niche with the creation of the American Association for the Cure of Inebriety and the *Journal of Inebriety* in 1876. The organization helped bolster the nascent field of psychology and created a national group to continue the work started by Benjamin Rush and researchers running inebriate asylums. Also, women post-Civil War became much more engaged with organizations like the Woman's Christian Temperance Union, which embraced a broad feminist agenda that extended beyond temperance. Social reform such as temperance impacted many aspects of women's well-being, and they expanded to also petition for women's suffrage, expanded access to education, and labor rights for women and children.

That broad agenda allowed a new organization to hone the national agenda surrounding social control of alcohol, the Anti-Saloon League in 1895 that focused solely on the legal and legislative path to prohibition. By helping to elect politicians and judges

sympathetic to prohibition, the group succeeded in ushering in the passage of the 18th Amendment in 1919 which prohibited the sale, production, and transport of alcohol. Prohibition also gained popularity as medical and psychological attempts at long-term reformation continued to yield poor results, motivating some researchers to shift to examining the possibility of alcoholism being a hereditary trait. Prohibition also had the unintended effect of medicalizing access to alcohol, with doctors profiting from the restrictions by writing prescriptions for alcohol at unprecedented rates.

As support for Prohibition evaporated, Congress reversed course and passed the 21st Amendment at the end of 1933, ushering in an almost 40 year lull in federal alcohol control measures. Rather, the government ceded control to individual states and established a self-policing morality code for the alcohol industry. Social control of alcoholism shifted largely to the individual, and the self-help group Alcoholics Anonymous formed in 1935 to help alcoholics identify their disordered drinking and reform. Women remained an underserved and invisible population of alcoholics, even after Marty Mann introduced an accessible narrative of reform as the first female success story in Alcoholics Anonymous.

Simultaneous with the formation of a support group for those navigating and defining their relationship with problem drinking, scientific research into problem drinking found renewed vigor with the Yale Center of Alcohol Studies. The Center acted as a national research, training, and treatment hub for alcoholism with one of the nation's preeminent alcoholism researchers Elvin Morton Jellinek. He helped to define the alcoholism research agenda and in 1960 published the formative text in the field of alcoholism, *The Disease Process of Alcohol*. He advocated for measures to humanize the

alcoholic, and with the help of Mann formed the National Committee for Education on Alcoholism with the stated mission of educating the public that alcoholism is a disease, it can be treated, and that alcoholics are worthy of that investment.

Chapter Four, “Reengaging with Alcohol at the Federal Level: Alcoholism as a Disease, Fetal Alcohol Syndrome, and Female Alcoholics,” traces how alcoholism once again became part of the federal public health agenda. Alcohol in the mid-twentieth century had taken on a benign character in medicine compared to decades past. Many recommended alcohol to their patients to treat a variety of ailments, along with cigarettes and a variety of pills now deemed narcotic but commonplace in the housewife’s cupboard. (Pullar-Strecker 1952) Physicians routinely smoked and drank at the same rates as their patients, and they most certainly did not ask about patients drinking habits during check-ups. (American Medical Association 1973) That tendency is illustrated by Senator William Hathaway in a 1976 congressional hearing, “It seems ludicrous almost, doctors asking patients whether they are drinking or not.” (U.S. Senate 1976: 33) The public’s perception of alcoholics was skewed by almost 40 years of federal detachment from issues of alcoholism, and advocacy groups filled that gap by seeking to erase the stigma surrounding the disease of alcoholism.

While AA worked at the local level via word of mouth, advocacy groups such as the National Council on Alcoholism opened a branch in Washington, D.C., specifically aimed at bringing alcoholism treatment into the mainstream. President Lyndon B. Johnson was one of the first federal officials to speak of alcoholism as a national problem in the mid-1960s, creating a task force to recommend federal action and signing legislation that created a humble federal research center. Soon after, Congress built on

those initial steps and passed the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act, creating the National Institute on Alcohol Abuse and Alcoholism with research, treatment, and educational outreach at its core.

However, as with much of mid-twentieth century medicine they prioritized men over other affected groups such as women, minorities, the elderly, or youths. That began to change after the discovery of fetal alcohol syndrome (FAS) made visible both the female alcoholic and the fetus she impacted by drinking. The chance that alcohol could cause birth defects rapidly politicized the discussion surrounding appropriate federal and social control of alcoholism. FAS also brought into question other victims of alcohol abuse, including those adversely impacted by drunk driving, youth drinking, and prescription drug interactions.

FAS offered an opportunity for lawmakers and politicians to capitalize on a newly discovered public health concern as a placeholder, upon which they pinned many of the same arguments surrounding federal alcohol control in the US as the teetotalers from the mid-nineteenth century. Broad-reaching public health policy proposed to address the mental, physical, and social harms of alcohol consumption followed a similar trajectory as in decades past with the medical diagnosis taking on social and moral meanings as it moved from a primarily professional concern to the status of a public threat. That re-medicalization of alcoholism as a disease process in the mid-twentieth century attempted to eliminate the stigma of seeking treatment, but within the decade legislation moved the federal agenda from treating and preventing alcoholism, to punishing alcoholics and protecting those harmed by the alcoholic's behavior.

Chapter Five, “Alcohol Warning Labels as a Means of Addressing the Risk of Fetal Alcohol Syndrome” focuses on a five year period between when the government first released a warning regarding FAS in 1977 to when the Surgeon General’s warning against drinking during pregnancy arose in 1981. During that time period alcohol beverage warning labels in response to FAS dominated policy discussions. Between those two government warnings, uncertainty abounded surrounding the bureaucratic authority over labeling, the mechanism and extent of alcohol’s impact on development, and whether labeling could accomplish anything of value or if it simply represented a neo-prohibitionist response to alcohol control.

The chapter begins with a discussion of the complicated bureaucratic jurisdiction over labeling alcohol, which led to decades of infighting between the U.S. Food and Drug Administration (FDA) and the Bureau of Alcohol, Tobacco, and Firearms (BATF). The FDA’s history as a consumer protector, particularly during pregnancy caused many in legislative and administrative contexts to point to that agency as the logical choice to regulate alcohol warning labels. However, the BATF’s long-standing labeling jurisdiction was assured by a federal judge who interpreted previous congressional intent in creating the agency. That placed the BATF firmly in control of labeling, a concern for many as the agency was viewed as too close to industry interests and continually declined to include a health warning label on alcohol.

Labeling arose hand-in-hand with congressional hearings on how to approach the emerging public health problem of FAS, with the first congressional hearing in 1978 titled, “Alcohol Labeling and Fetal Alcohol Syndrome.” (U.S. Senate 1978) Surprisingly, industry and advocacy tended to align in their disapproval of alcohol beverage labeling,

for economic reasons in the case of industry and to prevent increased stigma in the case of advocacy. Although increasingly, the amount of industry support advocacy groups received led some to question how independent their decisions were from their corporate board members. The continued push for alcohol control measures by the NIAAA and FDA, of which labeling was just one initiative, had opponents of such public health measures decrying a neo-prohibitionist agenda.

Industry had remained fairly disengaged from presenting at hearings and lobbying for an anti-labeling agenda, but that changed in 1979 when Senator Strom Thurmond appended a labeling amendment to a larger health bill. Administrative turmoil surrounding the Carter administration's reorganization made any unified executive or bureaucratic front unlikely, making the legislative route to labeling a more successful possibility. When the bill passed in the Senate and advanced to the House of Representatives, a flurry of industry lobbyists crushed the amendment. Thurmond would have to wait almost a decade until 1988 to see labeling come to full fruition.

After the Thurmond amendment failed, labeling suffered another major setback in 1981 with the release of a joint report by the FDA and BATF. In the report the agencies set their disagreement over alcohol labeling jurisdiction aside and collectively agreed on a new platform: not labeling alcohol. Instead, the agencies suggested that the Surgeon General release a warning cautioning pregnant women of the risk associated with alcohol consumption and the agencies vowed to continue the industry-sponsored and NIAAA-sponsored public education efforts already underway. Soon after, FAS retreated as the main public health concern surrounding alcohol and faced competition from driving

drunk and youth drinking. Not until the mid-1980s would labeling and FAS again return as issues of regulatory concern.

Chapter Six, “The Moral Agenda: Federal Alcoholism Policy and the Final Push Toward Labeling,” examines that social shift to incorporate other areas of problem drinking, which arose in step with the election of President Ronald Reagan and the rise of social conservatism. Dramatic budgetary cuts rewrote the purpose of the NIAAA, creating a research agency and eliminating the majority of social research. That coupled with fracture among federal alcoholism advocacy groups weakened the formerly unified federal alcoholism agenda. In that turmoil, the social conservatism that characterized Reagan’s administration and the rise of the New Right wing of the Republican Party became increasingly preoccupied with the morality of the drinker and began to focus more on the victims of the alcoholic’s behavior than the personal agenda of reform and treatment.

Among those issues that became a pressing concern in the mid-1980s, FAS and labeling were not well-represented. Rather, drunk driving, youth drinking, and FAS among indigenous populations emerged as issues that required engagement with social and moral evidence to craft appropriate public health policy. Controversy surrounded whether a safe level of drinking existed, both for recovering alcoholics and for pregnant women. The 1982 hearing that arose in response to that controversy “Effects of Alcohol Consumption during Pregnancy” best represents an example of industry “manufacturing uncertainty.” In this case, whether an unknown safe level of drinking during pregnancy meant that implementing alcohol beverage labeling was impossible.

That 1982 hearing represented the last time Congress engaged in a hearing related to FAS until a final legislative hearing titled simply, “Alcohol Warning Labels” in 1988. To reignite the federal concern with labeling, Strom Thurmond had to create of a bipartisan group of Senators in 1986 to advocate for labeling alcohol, which passed in 1988 following that hearing led by Senator Albert Gore, Jr. The alcohol industry did not even attend that final hearing before labels were enacted, and instead embraced an example set by the cigarette industry, which used its label as a shield against possible legal challenges. By 1988, the alcohol industry preferred to accept the burden of implementing labels to gain a degree of protection from legal challenges.

CHAPTER 2

THALIDOMIDE AND CIGARETTES: HOW HAZARDS TO PREGNANCY BECAME A FEDERAL REGULATORY CONCERN

Inherent to discussions of how to regulate dangerous substances that can cause fetal injury are underlying tensions surrounding issues of authority and expertise, risk and harm reduction, and the nature of government intervention with respect to private choice and social responsibility. These tensions take on heightened meaning when the autonomy of a pregnant woman impacts the potential for life developing within her womb. This chapter will more deeply examine the construction of legislative and regulatory responses under those conditions by examining two historical case studies: how the government responded to the risks thalidomide and cigarettes posed to pregnancy in the mid-twentieth century. The case studies represent the US government's first forays into crafting public health measures to address fetal risk, and set a precedent for the government's later response to the risks of women drinking during pregnancy.

The first case study surrounding the drug thalidomide in the early 1960s introduced the public to the possibility that what a woman imbibes during pregnancy can impact fetal development. In Europe, many doctors and researchers recommended thalidomide as an effective drug to combat the nausea of morning sickness for pregnant women, and considered the drug safe with no known limit of overdose. As such, manufacturers sold thalidomide over-the-counter in countries across Europe until realizing that thalidomide impacted fetal development during pregnancy in the first trimester, leading to infant mortality or life-long cognitive and physical abnormalities.

How the US government responded to the risk posed by thalidomide firmly entrenched the Food and Drug Administration (FDA) as the entity responsible for protecting consumers against risks to fetal development. The proactive reforms strengthened existing regulatory frameworks, and had the effect of establishing the double-blind clinical trial as the hallmark of determining efficacy and safety. However, the swift regulatory response is at odds with the contentious, slow-moving regulatory apparatus surrounding the risk of cigarette smoke to development.

The ongoing public health response to the harm posed by smoking, particularly that of passive (“second-hand”) smoke and smoking during pregnancy, is more comparable to how alcohol warning labels arose in response to women who drink during pregnancy. The fetal effects of prenatal exposure to tobacco are less well-defined than the strong causative relationship between thalidomide exposure and birth defects. That mechanistic and causative uncertainty called for rigorous scientific inquiry into the relationship between poor fetal health outcomes and pregnant women’s consumption of cigarettes. That also had the effect of allowing private industry to “manufacture uncertainty,” a term historian of medicine Allan M. Brandt uses to describe how the tobacco industry funded studies to intentionally obfuscate scientific consensus and blunt regulatory responses that may discourage consumers from engaging in potentially risky behaviors. (Brandt 2007) The regulation of social vices such as cigarettes also led advocacy groups to leverage the power of “moral entrepreneurship” to create and enforce concepts of social deviance that aligned with their mission and impacted the social acceptability of smoking during pregnancy. (Kagan and Nelson 2001) (Tuggle and Holmes 1997) The interaction of science, government, industry, and advocacy

surrounding the regulatory responses to thalidomide and tobacco served as informal best practices for the subsequent response to the risks posed by alcohol consumption during pregnancy.

Thalidomide Establishes the FDA as a Consumer Protector during Pregnancy

The regulatory response to thalidomide serves as an important predecessor to later legislative discussion surrounding the risks of alcohol to the developing fetus, by shaping the standard for regulatory responses to emergent maternal and fetal health risks. The response solidified the federal Food and Drug Agency (FDA) as the government entity charged with examining potential fetal risks that arise from what a pregnant woman imbibes. The regulatory response expanded the powers of the FDA to ensure that new drugs and food were effective and safe, both to the pregnant woman and to prenatal development, and set the precedent for the FDA as an agency that navigates and defines that public risk. The FDA's legacy as a consumer advocate motivated members of congress to continually charge the agency with the authority to implement alcohol labeling in numerous bills proposed. Officials from the FDA also testified in congressional hearings from the beginning of legislative discussions through the culmination of a labeling initiative a decade later. That tradition of looking to the FDA as a consumer protector during pregnancy began when the risk of thalidomide emerged in the early 1960s.

The case study of thalidomide is also important as it dramatically introduced the public to the concept that what a woman consumes during pregnancy breeches the placental boundary to impact the development of the embryo or fetus. Prior to the

thalidomide tragedy of the 1960s, few environmental agents had been substantiated as impacting embryonic or fetal development during pregnancy. In the early 1940s Norman McAllister Gregg, an Australian ophthalmologist, identified rubella as the first infectious agent to act as a teratogen. In mothers who contracted the rubella virus in their first trimester, Gregg observed ocular, auditory, and cardiac birth defects. (Gregg 1941) Soon after in 1945, the unprecedented, massive exposure of ionizing radiation following the bombing of Hiroshima and Nagasaki, Japan, allowed scientists who had been researching the impact of x-rays on development since the early 1900s to expand their understanding. (Kathren 1964) (Yamazaki and Schull 1990) Despite research into those two teratogens, prior to the highly publicized and dramatic birth defects caused by thalidomide, few drugs had emerged as posing a risk to prenatal development. Although scientists recognized that chemicals could cross the placenta from mother to developing fetus decades prior to the case of thalidomide, much of the public operated under the assumption that the placenta provided a barrier to exposure from what a pregnant woman consumed. (Greek et al. 2011)

That popular assumption of the placenta as a barrier to exposure shattered as large-scale birth defects began to emerge in Europe between 1959 and 1963 as a result of women taking thalidomide during pregnancy. Newspapers and broadcast news featured sensational pictures of children born with truncated or missing limbs, a rare birth defect called phocomelia, a Greek term that translates to “seal extremities.” While phocomelia was the most recognizable symptom of thalidomide’s impact on the fetus, unseen birth defects like damage to internal organs and the developing brain also occurred with regularity and often led to infant death. (Mellin and Katzenstein 1962) The teratogen

responsible for those birth defects, thalidomide, was an over-the-counter sedative advertised as an anti-nausea drug, consumed by many pregnant women to counteract morning sickness.

Produced by Chemie-Grünenthal in West Germany in 1957, thalidomide was sold over the counter and hailed as a safe and effective drug. Researchers had not encountered a known overdose level or adverse side effects in the pre-market, laboratory study on mice. And although Chemie-Grünenthal destroyed their records researchers have claimed it was likely those studies also included prenatal exposure in mice. (Greek et al. 2011) As a result, thalidomide was approved for use in over 46 countries by 1960, and the US drug company Richardson-Merrell submitted a new drug application to the FDA in 1960 to approve Kevadon, its brand name for thalidomide in US markets. The application was assigned to three reviewers at the FDA, chemist Lee Geismar, pharmacologist Jiro Oyama, and chemical pharmacologist Frances Oldham Kelsey, a newly hired medical review officer. (Watts 2015) All reviewers found issues with the structure and rigor of the laboratory studies testing safety, and Kelsey, acting as the primary contact with Richardson-Merrell, expressed those views to the company. She specifically required additional studies regarding the potential for prenatal impact and peripheral neuritis, lost feeling or tingling in extremities, which began to be reported in conjunction with thalidomide in medical journals in 1960. (Florence 1960) (Fullerton and Kremer 1961)

Pending additional laboratory tests and clinical trials to establish Kevadon as safe, the FDA refused to approve the drug for US markets. Richardson-Merrell relented and Kelsey recalled that Merrell contacted the FDA's Bureau of Medicine to circumvent her authority as a medical reviewer and approve the drug for American markets. However,

the complaints to both Kelsey and her superiors did not change the status of the drug, which was denied with each new drug application submitted. Kelsey held firm even when Richardson-Merrell threatened to sue her for libel regarding her claims that their testing did not meet the standards for safety. (Daemmrich 2002) At the same time, in part of what they claimed to be an investigational study, Richardson-Merrell distributed over two million samples of Kevadon to doctors across the US, a common practice by drug companies at the time. The company claimed that the drug was under investigation by the FDA and would soon be approved for market, citing its success abroad as a less risky sedative than other options on the market.

That changed with the publication of two independent, concurrent studies toward the end of 1961 that claimed thalidomide caused birth defects in the first trimester of pregnancy. Physician Widukind Lenz from West Germany observed an increased number of birth defects among women taking thalidomide, and delivered his findings at a German Pediatric Society meeting November 18, 1961. He then published the full results on December 29, 1961. (Lenz 1961) (Lenz and Knapp 1962) Simultaneously, in the December issue of the British medical journal *The Lancet*, gynecologist and obstetrician William G. McBride from Australia published a letter detailing birth defects among patients who took thalidomide. (McBride 1961) Several months later, American pediatric cardiologist Helen Taussig traveled through West Germany observing the birth defects caused by thalidomide and returned to the US an advocate for banning thalidomide, later testifying in front Congress on her observations and the need for heightened new drug testing. (Taussig 1962)

Despite the independently corroborated risk of thalidomide's teratogenicity, and the fact that thalidomide began to be withdrawn from the European market as early as December 1961, Richardson-Merrell continued to petition the FDA to approve Kevadon. For an additional three months they kept the new drug application open, until March 1962 when they withdrew Kevadon's appeal in the face of overwhelming evidence of thalidomide's teratogenicity. As a result of the FDA's intervention, only 17 cases of phocomelia were reported in the US from pregnant women receiving the drug abroad or taking part in the investigative trials in the US. Upward of 10,000 children had been born abroad with defects by the time thalidomide had been removed from the worldwide market. (Daemmrich 2002)

Concurrent with the FDA's examination of the drug Kevadon, Estes Kefauver, a Democratic senator from Tennessee and chair of the Senate Subcommittee on Antitrust and Monopoly, recognized the thalidomide crisis as a political opportunity. Kefauver had been holding hearings to investigate price fixing by the pharmaceutical industry, specifically price gouging on the part of companies that held proprietary patents on drugs. (Hunter 1962) He had initiated that series of congressional hearings and legislative investigations beginning in 1959. In response to those early hearings, the FDA wrote and presented a bill, "Factory Inspection and Drug Amendments of 1960," to the Senate for legislative consideration in July of 1960. (McFayden 1973) The amendments recommended changes that bolstered the agency's authoritative power to require more extensive drug testing, to better report side effects, and inspect drug factories. And after the birth defects of thalidomide arose, the FDA revised the language to include efficacy testing in addition to safety regulations.

In April of 1961, prior to the thalidomide controversy, Kefauver presented a drug regulation bill to amend the 1938 Food, Drug, and Cosmetic Act and allow for more competition among drug manufacturers with cross-licensing agreements. (Daemmrich 2004) The bill was met with ambivalence by both President John F. Kennedy's administration and the department of Health, Education and Welfare (HEW), which houses the FDA. Both the Kennedy administration and HEW preferred the FDA-authored amendments. However, following a series of political maneuvers drug lobbyists working in conjunction with other congress members all but stripped the bill of its original provisions by June of 1962.

As the narrative of thalidomide began to unfold in Europe, and Kevadon remained tied up in the new drug approval process, major news organizations began to cover the high number of birth defects recorded in Europe with the first story appearing in April 1962. (Plumb 1962) Even after those initial editorials in publications like *The New York Times*, it was not until July of 1962 that a story emerged linking FDA reviewer Kelsey to the denied Kevadon application in the US. (Associated Press 1962) (New York Times 1962) Kefauver's associates leaked the heroic story of how Kelsey prevented thalidomide from being approved in the US in an effort to breathe life into Kefauver's bill, which had stalled given the wider support for the still stymied, industry-friendly version of the legislation. (Carpenter 2010) As the thalidomide tragedy became sensational news in the United States, President Kennedy pushed Congress to reexamine Kefauver's original bill. Given the anxieties surrounding thalidomide, the bill was rewritten to include much of the safety provisions stripped in previous congressional hearings, and better reflect the FDA's earlier recommendations rather than the appeal to drug companies. Kefauver

attempted to petition for the inclusion of one last amendment to reflect his original patent and pricing aims, but the proposal was subsequently tabled and discarded. (Fontenay 1980) The bill passed unanimously in both the House and Senate, and on October 10, 1962, President Kennedy signed the “Drug Efficacy Amendments” into law.

The amendments transformed the accountability of the FDA to the American people and strengthened their regulatory power to ensure the safety and efficacy of new drugs, particularly related to potential fetal risk. The bill also required a retrospective analysis of previously approved drugs from 1938 onward, which resulted in the removal of about 600 drugs on the basis of unproven effectiveness. (Greene and Podolsky 2012) The passage of the Drug Efficacy Amendments also protected consumers from pressures exerted by the pharmaceutical industry or doctors willing to prescribe sample drugs prior to FDA approval. That practice was relatively common prior to the amendments being passed, a tradition that motivated the American Medical Association to petition the initial efficacy requirements in Kefauver’s amendments, as they argued only rigorous clinical application could adequately demonstrate efficacy. Additionally, the amendments granted the FDA the ability to tour places of drug manufacturing and research, protected generic drugs from being sold under more expensive trade names, and strengthened the reporting of side effects by doctors to the central government.

The amendments also had the effect of lengthening how long it took for new drugs to be approved for sale. One provision of the amendments lengthened the new drug application process from 60 to 180 days to avoid rushing and allow adequate time to review new standards. The requirements also resulted in higher drug development costs because of efficacy regulations and the need to rigorously test safety during prenatal

development. As an unforeseen result, the standards set forth by the FDA led to a reliance on clinical pharmacology and cemented the randomized, double-blind clinical trial as the gold standard for determining efficacy and safety. That burden of proof on drug developers eventually resulted in pharmaceutical companies pushing for extended patent protections to recoup the cost of drug development, an ironic result fundamentally at odds with Kefauver's original intention to limit drug costs.

The FDA's increased political voice in the legislative process is evident in the public health discussions surrounding fetal alcohol syndrome and alcohol beverage warning labels a decade after the FDA amendments passed. (Hilts 2003) The thalidomide incident increased the involvement of FDA officials testifying before Congress, a trend that continues as the FDA routinely presents at congressional hearings as the voice of a consumer protector. (Hutt 2007) That reputation is reflected in how often congressional representatives consistently presented bills to amend the Federal Alcohol Administration Act and grant the FDA authority to establish and monitor alcohol warning labels.

The high profile case of thalidomide also introduced the field of teratology and birth defects research to the public, and prompted broader research funding to investigate possible environmental causes of developmental defects. That rapid growth and legitimization of the field of teratology as a result of the thalidomide scare motivated research into a wide variety of drugs and environmental stimuli. The teratogenicity of both cigarettes and alcohol were soon called into question, followed by legislative hearings surrounding the government's responsibility to warn the public about such teratogens.

Tobacco Regulation, Manufacturing Uncertainty, and Regulating Risk

The history of tobacco regulation serves as an informative precedent for the regulatory discussions surrounding alcohol beverage labeling, an example of how society regulates legal substances with the potential to cause social harm. Both substances are regularly consumed by adults, despite their addictive nature and proven health risks to the user, and both also pose broader risks to health and well-being beyond the primary user. Cigarette smoke causes cancer and other health problems even in second-hand form, from the smoker to those in the surrounding area or to in utero development. Alcohol is responsible for a host of social issues, from motorist deaths due to driving while drunk, to interpersonal violence and fetal alcohol syndrome. Both substances are also legal for adult consumption, raise a substantial amount of tax revenue for their states to fund public and social programs, and are subject to varying degrees of regulation depending on the will of constituents in a particular locality.

The federal regulatory narratives in response to the health risks posed by tobacco and alcohol also share similarities, and include agency and congressional pressure to include warning labels, limits on advertising, and broad public health initiatives. The role of industry is also intrinsic to the proceedings, as they lobbied for minimal federal oversight and manufactured scientific uncertainty surrounding the risk posed by both substances to the health of the user and those impacted by the user's behavior. Grassroots groups mobilized in each case, in response to the social risks with the formation of local branches of advocacy organizations like Action on Smoking and Health (ASH), Groups Against Smoking Pollution (GASP), and Mothers/Students Against Drunk Driving (MADD/SADD). Those organizations acted as moral entrepreneurs and served to

redefine socially acceptable behavior surrounding tobacco and alcohol use, thereby changing the public will for particular legislative measures to address such risks.

However, the legislative trajectory surrounding both tobacco and alcohol are much different in several respects, particularly as the prenatal risks identified with tobacco use were decades separated from the initial push for general health warning labels. Even though federal research into the health risks of tobacco use arose as early as 1956, the concerns surrounding smoking during pregnancy began in earnest in the late 1970s. (Oaks 2001) That inquiry into the risks of cigarette smoke to prenatal development occurred at the same time as congress discussed whether to mandate health warning labels on alcohol to address the risks of FAS.

Additionally, the federal agencies involved in pushing for warning labels and prenatal health warnings were different in each case, with heavy Surgeon General and Federal Trade Commission (FTC) involvement with tobacco legislation. The Surgeon General served as an important figure in the public health campaign against tobacco use, and published thousands of pages on the matter in annual reports on the health risks of smoking, with an entire 1980 report dedicated to the specific risks of women who smoke. (U.S. Department of Health and Human Services 1980) However, reorganizations within the Department for Health, Education, and Welfare conflated and then separated the positions of Surgeon General and Assistant Secretary for Health in the 1970s and 1980s, complicating the authority and scope of the Public Health Service during that time period. Instead, the National Institute on Alcoholism and Alcohol Abuse served as the primary voice of research and legislative advocacy within the government. Also, while the FDA served as the consumer protector in the alcohol case study, the FTC was the first

organization to question tobacco companies' responsibility to their consumers, their truthfulness in advertising, and the need for health warning labels on cigarettes.

The FTC began that work in 1955 when the agency met in several informal meetings with cigarette manufacturers to explain their revised guidelines for advertising that banned unproven health claims about the benefits of smoking, guidelines passed September 15, 1955. Advertisements claiming that cigarettes had a positive impact on respiratory, digestive, and nervous function were banned, along with other unsubstantiated claims regarding nicotine content and the relative health of one brand over another on the market. (U.S. Bureau of Economics 1985) In their annual report, the FTC took an optimistic perspective to meeting directly with cigarette companies, stating those meetings, "probably will result in closer cooperation of the cigarette industry with the Commission and a substantial decrease in the use of questionable advertising claims for cigarettes." (U.S. Federal Trade Commission 1955)

Uncertainty surrounding such health claims were compounded by the work of the Tobacco Industry Research Committee, founded in December 1953 after tobacco corporations began to notice scientific studies claiming that cigarettes caused cancer. In an effort to take control of the scientific narrative and public relations related to the health issues associated with cigarettes, 14 tobacco companies united to form the Tobacco Industry Research Committee. (Brandt 2007) The organization announced their mission in a 1954 "A Frank Statement To Cigarette Smokers," stating that the companies believed their product to be safe for consumers and pledging financial assistance to research the health impacts of tobacco moderated by an "Advisory Board of scientists disinterested in the cigarette industry." (Tobacco Industry Research Committee 1954)

However, that assurance of impartiality never materialized as industry-funded research used the perceived objectivity of the scientific process in order to manufacture controversy and uncertainty surrounding the health risks of cigarettes. Those studies casted doubt on the need for robust public health measures and served to reify the risks each individual assumed when they chose to smoke, rather than addressing corporation's responsibilities to the health of their consumers. (Brandt 2012) The need to establish that individual risk occurred at an opportune time, as the industry faced its first substantive lawsuit over a consumer's death later that same year. The effort allowed the industry to shape the scientific evidence being released about tobacco's health impacts and spin their public identity as an industry concerned with the health of its consumers. (Staros 2008)

The Tobacco Industry Research Committee's motives for founding the organization proved prescient when shortly thereafter the Surgeon General began to research the risk of cancer posed by smoking. The Surgeon General was the first federal official to identify cigarettes as cancer causing, an endeavor that began in June 1956 when Surgeon General Leroy E. Burney formed a coalition to examine the scientific findings on cigarette smoke and cancer. Burney brought together interest groups such as the American Heart Association, the American Cancer Society, the National Cancer Institute, and the National Heart Institute to comb through 16 published health studies across 5 countries to determine if smoking caused cancer. A year later, on June 12, 1957, Burney served as the first federal official to declare that causative link in a statement: "The Public Health Service feels the weight of the evidence is increasingly pointing in one direction: that excessive smoking is one of the causative factors in lung cancer." (U.S. Department of Health, Education, and Welfare 1964) Two years later, a subsequent

publication to the *Journal of the American Medical Association* strengthened that statement and identified smoking as the “principal etiological factor in the increased incidence of lung cancer” with a recommendation to quit smoking, as non-smokers had a much lower risk of developing lung cancer. (Burney 1959)

In 1960 the FTC followed up on their advertising ban on unsubstantiated health claims in tobacco ads, meeting with tobacco companies to discuss a voluntary ban on advertising claims comparing the effectiveness of cigarette filters. Those scientific claims were largely unsubstantiated and used to market one brand of cigarettes as more health conscious than others, contentious claims difficult to scientifically verify. (Brandt 2007) Tobacco executives across multiple companies agreed to a voluntary ban of those claims in advertising, while maintaining that the negative health impacts of tobacco remained unproven. While the FTC and others initially considered that concession to be a success of federal pressure on the tobacco industry, it had the troubling effect of also doing away with the FTC monitoring a public discussion of nicotine, tar, and additives in cigarettes. As companies agreed to halt even peripheral or implied health claims in advertising, they also withheld those metrics regarding ingredients and composition of cigarettes, a successful strategy in the ongoing efforts of the tobacco industry to manufacture scientific uncertainty surrounding its product. (Brandt 2007)

Following the FTC discussion of cigarettes and health, the American Lung Association and the American Heart Association urged President John F. Kennedy to further investigate the scientific evidence for cigarette smoke causing lung cancer. In 1961, Kennedy charged then Surgeon General Luther Terry with the task of expanding upon Surgeon General Burney’s previous inquiries to determine the full health impact of

cigarette smoking. Although most non-industry funded science had already arrived at the conclusion that cigarette smoking caused cancer, industry-funded studies still impeded robust government action on the matter. To bolster those initial claims and insulate the Surgeon General's conclusions and policy recommendations from industry criticism, Terry developed what Brandt calls "procedural science," a robust, objective, and transparent method of inquiry. (Brandt 2007) Terry accomplished that by querying evidence-based medicine in a manner whereby the process of arriving at the final results was done so in a way that could not be construed as being vested in the financial interests of the tobacco corporations. To do so, he chose representatives from across disciplines and institutions not associated with the tobacco industry, and spent years allowing those respective experts to examine the evidence for cigarette's carcinogenicity.

The experts, about half of whom were smokers, examined all epidemiological, laboratory animal models, and histological evidence, and concluded that cigarette smoke caused cancer. While many scholars cite the transparency and thoroughness of the process as a means of acquiring the best scientific evidence for a legislative decision, historian Robert Proctor claims that scientists by and large had already reached the conclusion that cigarettes caused cancer. (Proctor 2011) He argues instead that such procedural science had less of an impact on reaching scientific consensus than it did arriving at an administrative consensus on a politically contentious topic in order to justify federal intervention. The procedural science techniques developed by Terry and the Advisory Committee to the Surgeon General went on to serve as a model for how subsequent government-run scientific endeavors were conducted, both within tobacco

research (over 30 more smoking studies following a similar protocol in its wake) and in other contentious public health arenas.

The result of those exhaustive studies culminated in the 1964 report “Smoking and Health: Report of the Advisory Committee to the Surgeon General of the United States.” The authors determined that seventy percent of smokers died earlier than non-smokers; that smoking increased the risk of bronchitis, emphysema, and heart disease; that there was a causative relationship between lung cancer and smoking; and that smoking during pregnancy was correlated with underweight infants. (U.S. Department of Health, Education, and Welfare 1964) The conclusion of the report recommended that the FTC require warning labels on cigarette advertisements and packages of cigarettes. In March 1964, the FTC held hearings to address the issue of both labeling cigarette packs and requiring cigarette advertising to carry the label: “Caution: Cigarette smoking is dangerous to health and may cause death from cancer and other disease.” After a very short period to solicit public comment on the proposed legislation, the FTC passed the requirement on January 1, 1965. (U.S. Department of Health and Human Services 1989)

Upon hearing of the FTC’s decision to require labeling on both cigarette packs and advertising, the tobacco corporations began courting congressmen in their districts to bring forward legislation that would precede that of the FTC. Brandt describes the move as an, “unprecedented attack on the federal regulatory structure of consumer protection.” (Brandt 2007) Congress mobilized in response to industry pressure and passed the Federal Cigarette Labeling and Advertising Act of 1965 a mere seven months later in July 27, 1965. The act superseded the requirements of the FTC and changed the label

language to express a degree of scientific uncertainty: “Caution: Cigarette smoking *may* be hazardous to your health” (emphasis added).

The congressional act further weakened the FTC’s original proposal by not requiring warning labels be displayed on advertisements, and prohibited government intervention in cigarette advertising for a period of four years until July 1, 1969. The Act also required that the Surgeon General present annual reports on the health issues associated with smoking to Congress beginning in 1967, including any public health recommendations based on the changing research. The Federal Cigarette Labeling and Advertising Act of 1965, went into effect on January 1, 1966, and demonstrated the power of a private interest like the tobacco companies to influence national-scale legislation, going so far as to censure the FTC for its attempts at regulation trends.

At the time, government agencies and industry still advocated for research into cigarettes for the purpose of creating a safer cigarette. The government’s Tobacco Working Group was tasked with that responsibility, researching the components of cigarettes to discover which ingredients were unsafe. (Staros 2008) The group arose as a result of a 1967 task force created by President Lyndon Johnson to investigate lung cancer. The task force created a subcommittee, the Less Hazardous Cigarette Working Group in 1968, later renaming it the Tobacco Working Group. Housed in the National Cancer Institute, the Tobacco Working Group routinely collaborated with industry-funded scientists of the Tobacco Research Institute under the direction of their chairman Gio Batta Gori, Deputy Director of the National Cancer Institute’s Division of Cancer Cause and Prevention. (Gori and Lynch 1978) The group routinely assayed cigarette components with the goal of creating a safer cigarette, which remained a high priority

until 1978 when that group abandoned that research priority, and soon after the Tobacco Working Group disbanded, the chairman forced to resign at the request of his superiors. (Staros 2008)

Smoking rates held steady in the wake of labeling, but cigarette consumption levels began to drop as anti-smoking public service announcements flooded the airwaves in an effort to discourage smoking rather than craft a “safer cigarette.” The man who spurred such action was John Banzhaf, who formed ASH (Action on Smoking and Health) in 1967 a grassroots anti-tobacco association. Banzhaf petitioned the Federal Communication Commission (FCC) to honor the tenets of the Fairness Doctrine with respect to anti-tobacco advertisements, which would run counter to the \$227 million dollars of tobacco advertising appearing on television and the radio. (Bayer and Colgrove 2004) The fairness doctrine required that a plurality of viewpoints be expressed for controversial issues in an honest and equitable manner, and six months following Banzhaf’s application, the FCC granted free time for anti-tobacco advertisements on FCC-licensed radio and television channels in June 1967. The tobacco industry appealed, and in 1968 the case was decided in the District of Columbia US Circuit Court of Appeals, which reinforced the FCC’s jurisdiction to apply the fairness doctrine for anti-tobacco public service announcements. (Banzhaf v. FCC 1968)

Three months following the court ruling, the FCC banned all radio and television advertisements with the passage of the Public Health Cigarette Smoking Act of 1969. Although contentious, the tobacco industry supported such an initiative as it eliminated the free advertising for anti-tobacco public service announcements. The Act also strengthened the language of the health warning label to insert the authority of the

Surgeon General: “Warning: The Surgeon General has determined that cigarette smoking is dangerous to your health.” As ads dropped from radio and air waves, the number of ads in magazines and newspapers increased 400 percent, and the decrease in smoking which resulted from the anti-tobacco PSAs ceased. (Bayer and Colgrove 2004)

In 1969 the Surgeon General published their annual report on the health risks of smoking, and turned to the risks to prenatal development for the first time, with an entire chapter devoted to the current state of the science. Whereas previous Surgeon General’s reports had reported low maternal birth weights or prematurity—if they reported anything at all about smoking and pregnancy—the 1969 report referenced epidemiological and experimental studies. The findings reported a statistically significant increase in spontaneous abortion, stillbirth, and neonatal death among women who smoked during pregnancy. (U.S. Department of Health, Education, and Welfare 1969) While scientists had been examining the correlation for years, the procedural science technique pioneered by the Surgeon General’s office helped to define a causative relationship instead of just correlations in the data.

Beginning in the 1970s, the influence of anti-tobacco activists turned from large-scale federal reform to more local regulation, particularly surrounding smoking bans due to the risk of second-hand cigarette smoke to the non-smoker. In 1971 Surgeon General Jesse L. Steinfeld addressed the Interagency Council on Smoking and Health and began that line of investigation stating that, “Nonsmokers have as much right to clean air and wholesome air as smokers have to their so-called right to smoke, which I would redefine as a ‘right to pollute’.” (U.S. Department of Health and Human Services 2014) That increasingly included smoking by pregnant women and the risk to prenatal development,

and the Surgeon General continued to examine the causative relationship between smoking and poor birth outcomes in the next two annual reports. The reports in 1971 and 1972 mirrored the information presenting in the 1969 report. (U.S. Department of Health, Education, and Welfare 1971) (U.S. Department of Health, Education, and Welfare 1972) However, by the 1973 report, the research expanded from short chapters to a 54-page discussion of cigarette smoke's impact on birth weight, fetal and infant mortality, sex ratio, congenital malformations, lactation, and preeclampsia. (U.S. Department of Health, Education, and Welfare 1973) The chapter was selectively republished in the 1976 report, which served as a reference manual aggregating the best available scientific information. (U.S. Department of Health, Education, and Welfare 1976)

By the late 1970s, the federal government began to focus heavily on the specific risks to women who smoke, instead of generalizing the data collected from men. In the following year, the 1977-1978 report that resulted in the Surgeon General recommending warning labels appear on oral contraception for sale warning of the cardiovascular risks of smoking while taking the drug. (U.S. Department of Health, Education, and Welfare 1979a) The report also makes the first mention of requiring specific public health measures geared toward women who smoke, stating that "A dose-response relationship exists between smoking and the incidence of low birth weight, preterm delivery, perinatal mortality, abruptio placentae, placenta previa, bleeding during pregnancy, and prolonged and premature rupture of the membranes," but that 40 percent of women remained unaware of those risks.

That same year, the Surgeon General, acting with the 12 other agencies of the US Department of Health, Education, and Welfare, published a 15 year anniversary report

following the original 1964 report that aggregated information surrounding public health information missing from the original report. In particular, it addressed concerns specific to a particular demographic, making clear not only that “Women who smoke like men, die like men who smoke,” but also that women who smoke place their pregnancies at risk of increased morbidity and mortality. (U.S. Department of Health, Education, and Welfare 1979b) The chapter dealing with pregnancy used the same procedural science framework as the original 1964 report, citing in excess of 200 medical studies to review the most current scientific understanding of how cigarettes impacted pregnancy and prenatal development. (Oaks 2001)

The public health impacts of women smoking took prominence the next year, in “Health Consequences of Smoking for Women: A Report of the Surgeon General.” Following the 15 year retrospective, the Surgeon General began to focus on one specific public health smoking concern in each subsequent year, beginning with the risks posed to one of the most vulnerable populations, the pregnant woman and her developing fetus. Described in the foreword as “one of the most alarming in the series” of annual reports, the publication described the health risks in indisputable terms: “cigarette smoking is a major threat to the outcome of pregnancy and well-being of the newborn baby.” (U.S. Department of Health and Human Services 1980) The authors reported that smokers birthed infants that weighed 200 grams less on average than comparable non-smokers, a trend that existed in spite of potentially conflicting demographic, economic, and life history differences. The authors also reported the most dramatic growth restrictions in chest and head circumference, suggesting possible long-term cognitive and behavioral impacts based on smaller brain size. Placental size was reported much larger than average

and its function as a fetal support system was reported as compromised, leading to a variety of life-threatening conditions to both the pregnant woman and developing fetus. The authors also reported a higher number of deaths among fetuses, neonates, and infants of women who smoked during pregnancy compared to nonsmokers, with an increase in “sudden infant death syndrome” and long-term morbidity for children. From what they observed across medical studies, those health issues existed in a dose-response relationship, whereby the more a woman smoked during pregnancy, the worse an effect it had on prenatal development. Despite that preponderance of evidence, Surgeon General Julius B. Richmond still took a position of education and individual accountability on the issue, stating that, “Each individual woman must make her own decision about this significant health issue.” (U.S. Department of Health and Human Services 1980)

As the late 1970s ushered in a robust analysis of the risks of cigarette smoking to special populations like the pregnant woman, the government also ended its attempts at advocating for a safer cigarette. The Tobacco Working Group disbanded in 1978 and Gori from the National Cancer Institute published the group’s final report to the *Journal of the American Medical Association*. In the report he claimed that while they had not discovered a safer cigarette, they had identified the level of smoke inhalation for six toxic chemicals below which there were no observable health problems. (Gori and Lynch 1978) The claim that some low tar cigarettes could be considered “tolerable” to health generated political uproar within the Department of Health, Education, and Welfare. Gori soon found himself all but pushed out of his position in the National Cancer Institute, unable to secure funding or administrative approval for his work. He resigned shortly thereafter to serve as a consultant for a research institute funded by tobacco companies,

and later continued the tradition of obfuscating scientific consensus surrounding issues of tobacco's risk by publishing reports against the risks of second hand smoke, including *Passive Smoke: The EPA's Betrayal of Science and Policy*. (Gori and Luik 1999)

That disapproval of Gori's agenda can be traced all the way up to Secretary Joseph Califano, the top administrator within the Department of Health, Education, and Welfare. Califano disapproved of discovering a safer way to smoke a cancer-causing substance, and instead favored efforts to reduce the number of people who smoked. (Staros 2008) Califano sought to increase taxes on cigarettes, ban smoking in airplanes, and increase the research allocations of the public health service from \$1 million to \$6 million to examining techniques to discourage smoking and to treat smoking as a chronic disease. An ex-smoker, Califano called smoking "slow motion suicide," a position echoed by the newly appointed Surgeon General C. Everett Koop, who stated that "there is no benefit; cigarette smoking is all risk." (New York Times 1978) (Fairchild and Colgrove 2004)

Government agencies shifted their public health approaches from educating the individual smoker on risks to actively discouraging their choice to smoke, and Congress followed suit. Democratic Senator Edward Kennedy of Massachusetts presented the first piece of legislation that adhered to that agenda, the Smoking Deterrence Act of 1978. The proposed bill died in committee but attempted to establish smoke-free federal facilities and require non-smoking signs. The bill also provided incentive for industry to develop safer cigarettes or face higher tax rates on their products, with lower tax rates for cigarettes with less tar and other levels of dangerous substances. (Staros 2008)

However, the federal discussion of how to regulate cigarettes tends to run secondary to the more successful grassroots efforts to organize at the local level and pass restrictions on the where individuals could legally smoke. In 1973, Arizona became the first state to enact restrictions on smoking in public places, followed closely by Minnesota's Clean Indoor Air Act of 1975. (Brandt 2007) Those acts were outliers compared to the majority of pre-1980 non-smoking laws, which were established to protect workers and products from issues of flammability or contamination than from the toxic chemical in tobacco smoke. (Fielding 1986) While passionate and well-entrenched local advocacy networks began to organize and experience a degree of success with local and state ordinances addressing the public health risks of cigarette smoke, scientists began to coalesce around how tobacco smoke acts as a risk to non-smokers.

That risk to others was established in the early 1980s with the first reports substantiating respiratory damage in nonsmokers chronically exposed to tobacco smoke. (White 1980) One particularly impactful researcher, Takeshi Hirayama of the Tokyo National Cancer Center Research Institute had been collecting data on the phenomenon since 1965. He examined whether the risk of lung cancer increased among the non-smoking wives of heavy smokers, and published his results in 1981. He discovered a 90 percent increased risk of developing cancer in non-smokers habitually exposed to tobacco smoke. (Hirayama 1981) The robustness of that study spurred federal-level research, and in 1981 the National Research Council also released a report that further bolstered the growing scientific consensus that passive smoke was a health hazard to nonsmokers. (National Research Council 1981) In this same time frame, smoking began to be referred

to as addictive, with the National Institute on Drug Abuse likening tobacco to the same feedback loops and addictive cravings experienced by drug users.

Issues of smoking during pregnancy, the addictive nature of cigarettes, and the risk of cigarette smoke to non-smokers spurred federal agencies and Congress to revise the original warning label language on cigarettes to reflect the new risks. In 1981 Democratic Representative Henry Arnold Waxman of California's 24th District presented a bill to require more federal research into smoking risks and to modify the warning labels on cigarettes. (Brandt 2007) Different iterations of the bill continued to be shuffled between the two chambers of Congress as the object of hearings and continual modification until September 22, 1983, when Senator Waxman introduced Comprehensive Smoking Education Act (H.R. 3979), which was referred to the House Committee on Energy and Commerce. A year later, in September 1984 the bill passed by voice votes in both the House and Senate with minimal amendments and President Ronald Reagan signed the bill into law on October 12, 1984.

Provisions of the act became effective one year from the date of signing, and included increased research into the health risks of smoking and amended cigarette warning label language (Comprehensive Smoking Education Act 1984). The bill called for the creation of an agency to coordinate smoking research and led to the creation of the Interagency Committee on Smoking and Health that publishes reports to Congress on the issue. Additionally, four rotating warning labels were approved, all of which referenced the authority of the Surgeon General as the highest medical official in the country. Two of the labels specifically mentioned the risk to pregnancy, although the language still

included a modicum of doubt with the modifier “may” tempering the severity of the warning:

“SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, and May Complicate Pregnancy.

SURGEON GENERAL'S WARNING: Smoking by Pregnant Women May Result in Fetal Injury, Premature Birth, and Low Birth Weight.

SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.” (Comprehensive Smoking Education Act 1984)

Concurrent with discussions of warning labels, Congress began to discuss the issue of raising excise taxes on cigarettes both to lower the federal budget deficit and possibly lower consumption levels, an increasing public health focus of the Surgeon General and Secretary of Health and Human Services. The 1982 decision to raise the excise tax from 8 to 16 cents a pack was made permanent in 1986. (Bayer and Colgrove 2004) States responded in kind to the federal decision to raise cigarette taxes, and throughout the 1980s nineteen states elected to increase taxes by more than double. (Kagan and Nelson 2001) That trend increased even more in the 1990s with 38 states also choosing to raise taxes substantially on cigarettes, primarily through legislation and ballot initiatives.

The public attitudes regarding cigarettes had changed drastically within the 20 years since Congress’s initial warning label requirements, with smoking prevalence dropping from about fifty percent of the population to only 36 percent. (Kagan and

Nelson 2001) The anti-tobacco advocates had enacted dramatic change from the status quo, and by 1985 the American Medical Association set its goal for a “smoke-free America.” That goal was supported by the American Heart Association, the American Lung Association, and Surgeon General Koop who proposed a total ban on tobacco advertising and promotions. The efforts ultimately proved premature, however, and failed to garner political support. In the subsequent decade, the argument was reframed to target a ban on youth advertising, a measure that proved successful. In 1986, Surgeon General Koop also released a report on second hand smoking that placed the estimated number of deaths of nonsmokers at about 3,000 per year. (U.S. Department of Health and Human Services 1986) That was followed by the National Academies of Science report on children of smokers who were dramatically more likely than those of nonsmoking households to contract pneumonia, bronchitis, and respiratory infections. (National Research Council 1986)

Concurrent with those federal efforts, numerous grassroots activist organizations called GASPs (Groups Against Smoking Pollution) began to form. Those grassroots efforts helped to pressure government primarily at the local level to institute smoking bans, a move that avoided involving the state legislature which was more influenced by tobacco industry funding. By the end of the 1980s, the number of local smoking bans shifted from less than 100 to over 500, and affecting about 70 percent of the nation’s population. (Kagan and Nelson 2001) Additionally, over 41 states had enacted public smoking restrictions by 1986, and as of 1988 Congress had banned smoking on domestic flights less than two hours, a measure extended two years later to all flights less than six hours. (Bayer and Colgrove 2004) The social acceptability of smoking in public

dramatically dropped, and even without ordinances in place, a high level of voluntary compliance began.

In response to the overwhelming scientific evidence about the damage nonsmokers can incur due to exposure, and the social shift in the acceptability of smoking, the tobacco industry founded the Center for Indoor Air Research in 1988. Although the stated goal was to examine the scientific evidence surrounding the negative health outcomes of exposure to tobacco smoke, just like the Tobacco Industry Research Council decades prior, the acting goal appeared to be undermining the preponderance of evidence and framing the debate as one of personal liberties rather than potential threats. (Bayer and Colgrove 2004) Despite Big Tobacco's best efforts, by the end of the 80s, only 28 percent of the population smoked cigarettes, a number that dropped further throughout the years with only 16.8 percent of the population as of 2014. (Jamal et al. 2015) And among pregnant women, between 10 and 12 percent report smoking in the last trimester of pregnancy according to the CDC's Pregnancy Risk Assessment Monitoring System. (Jones et al. 2009) (Ward et al. 2014) Coincidentally, the Centers for Disease Control reports similar numbers of women who drink during pregnancy, a statistic that tends to hold steady at ten percent. (Tan et al. 2015)

Federal regulation of cigarettes served as an informative example for how government agencies, congress, industry, and activists approached the question of whether to require health labels on alcohol in response to fetal risk. However, more than a decade separated the initial passage of cigarette warning labels, and substantial federal inquiry into the impact of cigarette smoke on prenatal development. As such, legislative discussions surrounding cigarette warning labels to address risk to pregnancy occurred

simultaneous with discussions of requiring alcohol health warning labels for the same purposes. In congressional hearings discussing the possibility of requiring health warning labels on alcohol, cigarettes were often cited as the model for how to enact such a measure, with both advocates and cynics citing aspects of the cigarette labeling narrative to support their position.

The alcohol industry learned from the example of cigarettes, particularly with regard to advertising, which was banned in the Public Health Cigarette Smoking Act of 1969 but remained prevalent with alcohol. The alcohol industry communicated with the FTC to create a self-regulating code of ethics in order to avoid congressional and agency interference. In 1985 the FTC received the “Omnibus Petition for Regulation of Unfair and Deceptive Alcoholic Beverage Advertising and Marketing Practices,” submitted by the Center for Science in the Public Interest along with 28 other co-sponsoring organizations. (U.S. Federal Trade Commission 1985) The organizations argued that while alcohol advertisements were not expressly deceptive, like cigarette ads with unproven health claims, the marketing campaigns were inherently deceptive in the manner in which they portrayed alcohol use. By portraying alcohol consumption in such a positive manner the ads sought to increase consumption and the potential for abuse. As such the authors of the petition recommended that the alcohol industry be banned from advertising in venues with young audiences, and required to display warning labels on advertisements and fund public service announcements warning about problem drinking. After reviewing the petition, the FTC denied its standing and dismissed the petition’s claims as not being based in facts, especially regarding the causal relationship marketing and alcohol abuse. Additionally, the FTC cited jurisdictional conflicts with the Bureau of

Alcohol, Tobacco, and Firearms, which had been collaborating with alcohol industry since 1978 on an advertising code of ethics. Compared to the cigarette industry, alcohol has been incredibly successful in navigating FTC requirements in order to avoid official advertising censure.

Industry concern with researching the health of their product is similar in both cases as well, with inquiry into a safer cigarette sharing similarities with researchers seeking to find a “safe level” of drinking. Instead of the National Cancer Institute, the National Institute on Alcohol Abuse and Alcoholism (NIAAA) funded major investigations into safe levels of drinking. Similarly, the role of Gori as the primary official investigating those safe levels in cigarettes through the National Cancer Institute, and his subsequent dismissal and shift to pro-industry consulting parallels the administrative history of Morris Chafetz, first director of the NIAAA. Chafetz served as director from the inception of the NIAAA in 1971 until his resignation in 1975 under allegations that he had unduly influenced the institute’s grant review process. Following his resignation, Chafetz continued to be active in the area of alcohol policy and later advanced the pro-industry position of responsible drinking over abstinence, similar to Gori’s switch to a pro-industry position following his resignation. Chafetz also served on the Presidential Commission on Drunk Driving as chair of the Education and Prevention Committee beginning in 1982 and described the recommendation to raise the minimum drinking age to 21 as “the single most regrettable decision of my entire professional career.” (Chafetz 2009)

That focus on individual accountability is something highlighted in the discussion of cigarettes as well, when expert witnesses like Chafetz cast doubt on the need for

warning labels and efforts. The alcohol industry used that argument to insulate themselves from critics, suggesting that each individual assumed the known risks when they drank. That knowing acceptance of the risks, called contributory negligence in tort lawsuits, is what tobacco corporations argued across hundreds of lawsuits leading up to the Tobacco Master Settlement of 1998. In that settlement, tobacco companies were charged with \$206 billion in the first 25 years for damages caused by their products. Those lawsuits leading up to that massive class action settlement are what motivated the alcohol industry to eventually accept warning label provisions in 1988, as the label clearly outlined the risks of consuming alcohol and helped to protect industry from legal challenges. The Tobacco Master Settlement also prompted the release of thousands of proprietary industry documents that illuminated the cigarette industry's heavy hand in manipulating their products to be more addictive, and to obstruct public health efforts that would hurt sales. Some documents released in that settlement were from Miller Brewing Company, a holding of Phillip Morris which acquired the brewery in 1977. The documents hint that alcohol companies adopted a similar strategy to that of cigarette companies. They groomed underage individuals to become regular consumers and petitioning against warning labels as a stigma to the brand, although without a similar class action lawsuit details on the extent of such actions is impossible to determine. (Bond et al. 2009) (Bond et al. 2010)

The role of activism in shifting the social and moral acceptability of cigarette and alcohol consumption, particularly when it impacts the well-being of others, also served as an important motivating factor in the passage of warning labels for each. Grassroots organizations such as GASPs helped to pass ordinances eliminating smoking in public

places shared with non-smokers, and served to turn smoking into a dramatically antisocial activity. The formation of MADD in 1980, by comparison, and their local chapters also shifted the acceptability of drinking and driving through powerful storytelling and organizing at the local level, which influenced national conversations. In both cases local level activism translated to federal legislation addressing the issues of a constituency that had re-conceptualized social mores surrounding the use of tobacco and alcohol. In the case of alcohol, the Presidential Commission on Drunk Driving and the push toward a federal minimum age for alcohol consumption, combined with increasingly indisputable evidence surrounding the risks of fetal alcohol syndrome created a moral issue surrounding atypical drinking problems. That shift in what was considered socially acceptable in terms of cigarette and alcohol consumption led to the passage of comprehensive warning label legislation in both cases.

CHAPTER 3

A SHORT HISTORY OF HOW THE UNITED STATES HAS DEFINED AND RESPONDED TO THE SOCIAL PROBLEM OF ALCOHOLISM

This chapter will examine the history of social responses that arose as solutions to the problem of excessive drinking in the US, starting with colonial America and progressing through the nineteenth century and into the early twentieth century. One of the first medical figures in the nation to examine the disease of drunkenness, colonial-era physician Benjamin Rush, identified in his writing many of the difficult decisions surrounding alcoholism that the US has grappled with for centuries. Is drunkenness a habitual compulsion, a weakness of will, a progressive disorder? Does all alcohol lead to the same symptoms when consumed in excess, is there a safe level of drinking, and can habitual excessive drinkers ever resume moderate drinking or must they remain abstinent? Can they be reformed through medical intervention alone, or are punitive legal and social measures required? And what responsibility do the community and government have to reform or punish those individuals?

Many of the concerns voiced by Rush were later adopted by temperance organizations with varying social agendas and solutions for the problem of drunkenness, and many of their same concerns are echoed in modern public health discussions on the topic. Should groups focus on prevention or reform, embrace moral or medical solutions, or enact legislation to limit the sale of alcohol? Those questions remain relevant two centuries later as America defines and redefines what constitutes acceptable patterns of social drinking, what deviation from that norm looks like, and how to grapple with those

social transgressions. Because I am examining the changing identity of habitual drinking, the definitions of that behavior changed over time, from drunkenness to inebriety and alcoholism. Within each time period I discuss, I strive to remain current with the medical terminology used.

This chapter traces the ebb and flow of America's response to the risks posed by drinking, examining the medical, social, and moral movements that arose to address the public health risks presented by those who habitually drank to excess. The first part of this chapter, "From Prevention to Reform: Defining Drunkenness and Early Temperance Initiatives," examines the early medical and social responses beginning with the colonial era through the Civil War. The discussion starts with colonial era America and Benjamin Rush's medical contribution to the field, before progressing into an examination of early temperance societies. Those organizations such as the American Temperance Society and Washingtonian Temperance Society had dramatically different solutions for the same problem of drunkenness, whether to preach prevention or provide self-help groups for reform.

The second part of this chapter, "When Reform Fails: Temperance Measures Post-Civil War and the Remedy of Prohibition," examines the time period post-Civil War through Prohibition. From those early reform efforts new medical and social organizations arose with the focus of reforming the alcoholic, including the American Association for the Cure of Inebriety and the Woman's Christian Temperance Union. Those medical and social efforts failed to create long-term, sustained reform among alcoholics, and as the social problems caused by habitual drinkers continued to amass, the issue-specific Anti-Saloon League arose. That group abdicated the arguments over the

morality and reform of alcoholics and instead focused on a legislative solution to inebriety. By helping teetotaling legislators into office, the solution of Prohibition arose as a means of addressing drunkenness in the population.

The third section of this chapter, “Collective Amnesia: Repeal and the “Rediscovery” of Alcoholism as a Disease,” examines the medical and social responses that arose in the wake of Prohibition’s repeal. The federal government limited their involvement with alcohol to primarily trade and taxation, ceding social control of alcohol to the states. In the absence of strong national advocacy organizations with a mission of reform, the self-help group Alcoholics Anonymous arose and allowed its members to collectively define their experience with alcoholism. The Yale Center of Alcohol Studies also gained a following, becoming a national research hub for alcohol-related science and creating a robust discipline of study. Those medical researchers soon branched into the realm of advocacy with the creation of the National Committee for Education on Alcoholism, formed by the preeminent alcoholism researcher in the US and the first female to succeed in the Alcoholics Anonymous treatment program. That alignment of mission between medical and advocacy interests led to the reengagement of the federal government with alcoholism research and treatment in 1970.

Such a robust historical understanding will enrich the chapters which follow and help to illuminate how we continue to repeat well-worn tropes in our response to the social problems that arise from alcoholism. The interplay between community health measures and organized medical interventions ebbed and flowed throughout history with one constant, a frustratingly low long-term success rate for reforming the alcoholic. Additionally, the groups that arose in response to alcohol-related social issues tended to

be well-populated by women exerting a socially acceptable form of political agency to better their communities. Engagement with such groups defined women's relationship with alcohol early in the history of the US, creating an idealized stereotype of the mother and wife as a moral compass for the family and overlooking those who failed to adhere to such standards of temperance and domesticity. Those gender expectations of women generally excluded female alcoholics from early historical consideration, an historical trend that continued well into the twentieth century. That shifted with fetal alcohol syndrome, which increased female-centric research in alcoholism and the mechanism of how alcohol impacted fetal development, in order to craft appropriate public health policy to address the problem of women who drink during pregnancy.

From Prevention to Reform: Defining Drunkenness and Early Temperance Initiatives

While the medical definitions and community health responses have changed over time, the social response to “drunkards” in the US has existed since before its creation as a nation. The increased availability of hard alcohol “spirits” in the eighteenth century led much of that intemperance, rather than fermented beverages with lower alcohol content such as cider, beer, and wine. Early in America's history, community leaders held a position of power in proscribing appropriate social behavior, particularly as early colonies existed in the tradition of religious reformation. Those early social views of how to address overindulgence of alcohol adhered to social class distinctions, and drunkenness was not considered a problem among the landed social class with the means of supporting such a habit. (Levine 1978) For the higher class drunkard, their indulgence was often

viewed as a love of excess to the point of drunkenness, rather than a weakness of will as in those without such economic privilege.

The idea of weak men succumbing to spirits is addressed early in the writings of noted New England theologian, Jonathan Edwards, who uses the example of the drunkard in his 1754 *Freedom of the Will*. Edwards references the plight of the drunkard throughout the work stating that “Nothing is wanting but a will” in the case of why an individual would choose to drink. (Edwards 1754: 27) That example demonstrates the commonplace nature of overindulgence in alcohol prior even to the foundation of the United States as a nation. For habitual drunkards in Edwards’ time, those without the same safety net as their more moneyed counterparts, that decision to drink to excess was viewed as a personal, moral deviance without any biological or psychological impetus.

One of the first Americans to integrate the biological and social aspects of heavy drinking was Benjamin Rush, early American physician, signer of the Declaration of Independence, and collaborator with some of the finest intellects in the newly formed democracy. Rush defined what constituted abnormal alcohol consumption in his 1784 *Effects of Ardent Spirits on the Human Body and Mind*. (Rush 1790) He felt a deep personal drive to educate others of the health effects of alcohol consumption and to push for social control of hard spirits. (Katcher 1993) Rush discussed the effects of “spirits” (hard alcohol) on the physical and emotional constitution of early Americans, including how drinking resulted in a gradual production of symptoms over time, and the social impacts of drinking to excess. In the US, that professional recognition of alcohol as a causal agent, responsible for a variety of physical and social problems began with Rush and helped to inspire the first wave of temperance advocates in the following decades.

Many of Rush's observations of the impact of drunkenness align with later biological descriptions of alcoholism. In the text, Rush lists a series of symptoms and conditions that arise from addiction to spirits that are quite similar to the symptoms observed by modern clinicians. (Rush 1790: 3-4) He cites nausea and tremors that dissipate when the patient resumes drinking in the morning, and makes note of the "small red flecks" across the drunkard's cheeks that suggest the spidery burst capillaries that arise from sustained heavy drinking. Another common malady he elaborates on is dropsy, which he describes as a swelling in the lower limbs that then spreads, and could indicate edema of the limbs caused by cirrhosis of the liver. He also cites "obstruction of the liver" directly, which he references as causing inflammation, jaundice, and "dropsy of the belly," which suggests abdominal distention caused by alcohol-induced pancreatitis. Rush also claims that spirits cause a variety of psychological and neurological conditions, including madness, palsy, apoplexy, and epilepsy, although he does not elaborate much on those conditions in the text.

In transitioning to describing the social impacts, Rush takes the opinion that "spirituous liquors destroy more lives than the sword" and offers social and medical solutions to the problem of individuals losing their ability to moderate drinking habits. In describing the social conditions of drunkards, Rush calls the offspring born to those who indulge in spirits "half clad dirty children, without principles, morals, or manners." (Rush 1790: 4) Such a description mirrors that made by fellows of the British Royal College of Physicians in 1726 describing the behavior of children birthed to women in the throes of gin addiction in the 17th and 18th century, as alcohol was "too often the cause of weak, feeble and distempered children, who must be, instead of an advantage and strength, a

charge to their country.” (Royal College of Physicians 1987) Some scholars have pointed to this as evidence for fetal alcohol syndrome in medical texts, while others argue that such interpretation constitutes revisionist history. (Abel 2001) (Warner and Rosett 1975)

Rush goes on to describe the poor moral faculty of the drunkard’s temper, veracity, and integrity, as “they fill our church yards with premature graves, they fill the Sheriff’s docket with executions, they crowd our jails,” and as such they should be publicly accountable for their actions through “some mark of publick (sic) infamy.” (Rush 1790: 5) To treat drunkenness, Rush suggests sudden and total abstinence from spirits (“taste not, handle not, touch not”), substituting cider, beer, wine, or vinegar with water as more appropriate. While an odd definition of abstinence compared to later teetotaling agendas, such a distinction does accurately reflect the ubiquity of alcohol use at the time and was a position that aligned with some early temperance advocates that focused more on abstaining from spirits.

Rush continued to espouse his views on the cause and reformation of heavy drinkers and the appropriate medical remedies in subsequent treatises. He expanded his initial inquiry into a much longer four volume book, and in that 1805 publication he expands upon the physical and mental symptoms of drunkards, reiterates the progressive nature of the disease (“no man ever suddenly became a drunkard”), and recommends new medical and social interventions. (Rush 1805: 366) His social solutions included limiting the number of taverns in operation, more heavily taxing spirits, securing the property of habitual drunkards in a trust to protect their families, and publicly shaming or revoking the civil rights of unreformed drunkard. Beyond those social recommendations, he invokes a wide variety of physical treatment options to induce sobriety and reformation,

including corporal punishments from dunking inebriates in cold water to literally whipping sense into them.

In one of his final publications before his death, Rush delves into the mental maladies that affect the heavy drinker, and calls for the formation of “sober houses” to help reform inebriates. Throughout Rush’s 1812 *Medical Inquiries and Observations upon the Diseases of the Mind* he advocates for more humane treatment of those with mental illness, including those addicted to alcohol. Within the text he calls for “the establishment of a hospital in every city and town in the United States, for the exclusive reception of hard drinkers,” as that group of individuals can be even more detrimental to society than “deranged patients” of mental institutes. (Rush 1812: 267) Rush firmly establishes the physician as the arbiter of drunkenness as a disease, by proposing the formation of a court consisting of a physician and civil magistrates to determine whether a drunkard should be committed. Physicians and alienists (early psychologists) adopted many of Rush’s suggestions in their creation of early hospitals to treat heavy drinkers, but Rush’s public persona and influence in the medical field also inspired organized responses to the social problem of alcohol abuse at the level of community health.

One such individual, evangelical preacher Reverend Lyman Beecher, helped to establish the American Temperance Society in 1826, which aimed to prevent alcohol abuse rather than reform heavy drinkers. The Society organized at the local and state-level to distribute literature and hold lectures on alcohol control, with Beecher delivering some of the most widely distributed speeches. In particular, his “Six Sermons of Intemperance” helped to establish the tone of community-level health initiatives in subsequent decades, characterizing the drunkard as corrupt in moral, spiritual, and a

physical sense. (Beecher 1827) In those sermons, Beecher outlines a similar set of physical maladies as Rush, echoing some of Rush's well-known proclamations such as "taste not, handle not, touch not" and suggesting such a declaration be included as a warning label on alcohol for sale. (Beecher 1827: 40) Although Beecher agreed to an extent with Rush, his brand of abstinence was much different, relying on total abstinence rather than moderation with a focus on preventing drunkards from arising rather than reforming those already in the throes of addiction.

Beecher's characterization of the drunkard as a sick man, both spiritually and physically, found a sympathetic audience among rapidly industrialized urban population centers and as a result membership swelled for the American Temperance Society. In that setting, maintaining social order was integral to economic and community interests, as sober husbands led a strong working class and held stable families. In that respect, the focus shifted to alcohol as a moral evil leading to "sullen and disrespectful employees, runaway husbands, paupers, Sabbath breakers, brawlers and theatergoers," all demographics that threatened social stability. (Hallberg 1988) To eliminate the social risks of alcohol, community-level health organizers through the American Temperance Society began to recruit members using an abstinence pledge.

To become a member, the organization required individuals to sign a temperance pledge recognizing that intoxicating liquor was "hurtful to the social, civil, and religious interests of men" and that the signee intended to abstain from using or handling intoxicating liquor. Additionally, the pledge included language promoting the proselytizing of such community-health measures, to "discountenance the use of it [alcohol] throughout the community." (American Temperance Society 1836: 12) Such

recruitment measures worked well, and ten years after its formation, more than 6,000 local branches of the American Temperance Society existed with membership ranking over a million strong. (American Temperance Society 1836: 270)

The swelling rosters of the American Temperance Society owed much of their expansion to middle class women in the social sphere, who acted as moral representatives of the community. For both mothers and volunteers in community-reform measures, early temperance work represented a rare opportunity for women to use their stereotypical caregiving and nurturing aptitudes to expand beyond their domestic responsibilities and engage in acts of political importance. (Baker 1984) The women impacted by intemperance are featured almost exclusively in historical literature as pious and loyal spouses of drunkards, to the detriment of recording the narrative of women inebriates at the time. That silence speaks volumes about the ideal role of women in society, as a caregiver whose worth is defined by her value to her family and more broadly to creating and instilling values into the next generation of moral citizens that will comprise a productive society. In that respect, women who violated the sacred covenant of motherhood and domesticity by indulging in alcohol were stigmatized. They were particularly looked down upon by the growing contingent of female alcohol reformation workers who extended compassion toward male inebriates and scorn toward their female counterparts. (Hallberg 1988)

Such a narrative is reflected in the public visibility of temperance ideals as entertainment, with over 100 temperance-related plays written in the nineteenth century expounding on the domestic melodrama of men succumbing to ardent spirits. Those plays ranged from simple morality tales to be performed in an amateur setting to elaborate

stage productions. And while the theatre was often characterized as lurid and frivolous by religious authorities, temperance plays quickly became the exception to the rule, as morality plays presented an allegory that reinforced appropriate social behavior.

(McArthur 1989) Most of the plays capitalized on melodrama situated within the family dynamics of the time period, with wives fulfilling the role of the pious and pure family role model and the innocence of children often leading the male protagonists to embrace abstinence. The standard format of those plays further demonstrates the stereotypical everyman affected by alcohol, and the then prevalent notion that he needed moral and religious reformation—modeled by a pious wife—over medical assistance in order to abstain.

However, the increasing moral focus of many community-level health initiatives did not exclude physicians from continuing to define abnormal alcohol use as a disease and pursue medical solutions to the problem. In 1830, the head of the Connecticut State Medical Society, Eli Todd, released a publication proposing the creation of inebriate asylums to take on the task of reforming and not just preventing or punishing drunks. (Todd et al. 1830) Another author of that paper was Samuel Woodward, the first superintendent of the Worcester State Hospital in Massachusetts. In 1938 Woodward continued to press for the creation of asylums with *Essays on Asylums for Inebriates*, in which he expounding upon the need for special institutions specifically to treat alcohol abuse as a disease of the mind. (Woodward 1838) Later in 1844, Joseph E. Turner continued the argument that inebriety was a disease, and began advocating for inebriate asylums to treat the malady. Two decades later Turner achieved that goal after years of advocacy when he became the superintendent for the New York State Inebriate Asylum

in 1864. (Lender and Martin 1987: 120) The medical focus of those early asylum options to treat drunkenness helped shift temperance groups from a focus purely on prevention to a more reform-driven response to the addressing the social problems of alcohol abuse.

The need for reform soon manifested as the focus of the newly founded Washingtonian Temperance Society in 1840. Founded by six former drunkards sharing their experiences of reformation and recovery in a secular environment, the founders' admission to former inebriety was remarkable. Before then such public declarations were uncommon, but a united and organized group of middle and upper class gentlemen admitting their weakness helped to remove the stigma surrounding inebriety. (Griffin 2000) The Washington Temperance Society also helped to shift the popular temperance agenda from prevention to reform, and personal narratives from reformed drunkards helped to introduced loss of control as a rationale for why a man chose to habitually drink to excess. (Ajzenstadt and Burtch 1990) That mirrored some of the explanations being presented in the medical profession, and led to the formation of the Washingtonian Homes to treat inebriates that in some cases outlasted many branches of the Washingtonian Temperance Society, which dissolved less than a decade after its formation because of a fragmentation in the social advocacy mission and discord among leadership. (White 2001)

The focus on reform instead of prevention motivated even more women to become involved in temperance movements. The roster of volunteers expanded from primarily women of the middle classes to working and lower middle class women more directly impacted by the social strain of inebriety, often the wives and daughters of reformed inebriates. "Martha Washingtonian" auxiliaries, comprised of women, formed

alongside male branches with the goal of providing material support for families impacted by inebriety. The auxiliaries also trained, inspired, and supported mothers to advocate for temperance as the bedrock of their family's salvation. (Alexander 1988)

Initially, joining the Society was as simple as signing a pledge of abstinence, although the material support provided by the group later required members to demonstrate good moral standing in order to be accepted, prioritizing assistance to demographics identified as more socially deserving. (Alexander 1988)

An influential female presence in the temperance crusade, the Martha Washingtonian auxiliaries presented a foil to previous temperance efforts by freeing women from the confines of home life to advocate for a more widespread community-level health. However, all of the Washington Temperance Society groups soon experienced a gradual decline and by 1847 had practically disappeared. Although the ideas driving such a reformation society seeded a new round of temperance movements in the latter half of the 1800s following the Civil War. (Hallberg 1988)

The success and eventual downfall of Washingtonian Era temperance occurred alongside a variety of other optimistic social experiments of the 1830s and 1840s, including abolition of slavery, women's rights, and education reform. (Griffin 2000)

However, with little agreement among professionals as to the best treatment for inebriation, and few asylums to absorb the population physicians had identified as in need of treatment, the ideals of reform and recovery remained out of reach. In the latter half of the twentieth century, that frustration at the community level with enacting lasting change in the behavior of the alcoholic shifted the efforts of temperance groups from medical reform and moral salvation to state-mandated abstinence.

When Reform Fails: Temperance Measures Post-Civil War and the Remedy of Prohibition

In the Reconstruction period following the end of the Civil War, the institutional organization of the temperance movement renewed with vigor. Practitioners focused on the development of treatment and cures as much as theoretical identification of how such a compulsion emerges. Scholars continued to catalog the physiological and psychological symptoms of the disease and hinted at causes, identifying different types of alcohol abuse and appropriate interventions to manage what they viewed as an increasingly chronic condition. Inebriate asylums and reform homes were insufficient compared to the high demand for such services. In response to that demand, physicians and directors of inebriate homes met in 1870 to form the American Association for the Cure of Inebriety, whose name later changed to the American Association for the Study and Cure of Inebriety in 1888. (Weiner and White 2007) The organization published the biannual *Journal of Inebriety* beginning in 1876, under the tagline “the first and only journal devoted to spirit and drug neurosis.”

The journal served as a means of carving out disciplinary space around the study of inebriety in the area of psychiatry, but the professional response to the venture was slow. Lower participation in researching inebriety owed to the moral stigma of the disorder many still believed arose from a lack of will. That led to disagreement about whether to use public funds for inebriate institutions staffed by psychologists, a profession that suffered already low public esteem among the medical professions. (Schneider 1978) Despite reservations, inebriate asylums that had tried and failed to gain traction in the first half of the nineteenth century experienced a boom, with over eleven

not-for-profit inebriate hospitals emerging by 1874 and over fifty in the US by the 1900s. However, treatment models could differ dramatically between institutions with some focusing more on punitive measures than reform.

The mobilization of temperance groups at the community level also surged as many women joined progressive era reform initiatives, continuing their increased responsibilities outside of the home which had been required with husbands away at war. The Woman's Christian Temperance Union is one such group, established in 1874 from earlier efforts in women's anti-saloon crusades from 1873 to 1874 in Oxford, Ohio. (Stevenson 1907) After three months of grassroots mobilization, the group of women had successfully eradicated saloons and the sale of liquor in that community, inspiring women across the nation to followed suit. Housewives mobilized to host pray-ins at local saloons to stop the sale of alcohol, and temporarily succeeded in shutting down many establishments. From there, the Woman's Christian Temperance Union organized to expand that agenda beyond praying outside saloons and petitioning for their shut down.

The reforms advocated by the Woman's Christian Temperance Union focused on their motto "For God and Home and Native Land," and included as much in the way of proselytizing against intemperance as advancing feminist ideals of suffrage, child custody, child labor protections, establishing age of consent, and labor rights for women in sweatshops. (Donovan 1995) The Woman's Christian Temperance Union placed blame on the will of the individual who chose to drink and required moral suasion and support from the female head of house as a model of temperate behavior and morality. Beyond that traditional approach the group extended such moral censure to the saloons and distributors profiting from social vice. The overlap between politics and the saloon

was also notable, as matters of politics were often discussed behind saloon doors and beyond the reach of respectable women, who instead asserted their social and political power by shuttering saloons in their communities.

While the Woman's Christian Temperance Union focused on the widespread decline in morality, they also advanced a feminist agenda as the largest women's organization in the nation. In 1879, under the tenure of then President Frances Willard who was a noted feminist, the group expanded to take on new areas of reform outside of inebriety and vice, with the understanding that social change in one sector crossed over to influence reform in other areas. For instance, the push for temperance was viewed as influencing all sorts of social ills impacting those of low socioeconomic means and by addressing a broader cross-sector of those concerns it improved the family as a whole. (Gusfield 1955) Willard also began to push for more of a political presence in advocating for temperance reform and other progressive agendas. By 1894, the Woman's Christian Temperance Union had almost forty departments and over half of those were dedicated to non-temperance issues. (Stevenson 1907) Temperance ideals still drove a good portion of the group's efforts though, and they increasingly lobbied for Prohibition at the national level.

The Anti-Saloon League, founded nationally in 1895, quickly eclipsed the more established Woman's Christian Temperance Union to become the most influential Prohibition advocates of the early twentieth century. To put their political clout into perspective, the Anti-Saloon League spent millions to lobby for legislative action in 1919 (not adjusted for inflation), and focused their efforts more on courting legislators with

anti-alcohol voting records than embracing a more varied moral agenda such as the Woman's Christian Temperance Union. (Kerr 1985)

As the name suggests, the Anti-Saloon League focused their resources on opposing the commercial sale of alcohol at the level of the drinking establishment, instead of preoccupying themselves with the morality of those who drank. That focus on commercial sales instead of personal choice regarding alcohol consumption allowed the League to find a way around the accusations of their agenda impinging on personal liberties. (Donovan 1995) To that end, they also did not require a pledge of total abstinence from their members. The Anti-Saloon League's near exclusive focus on legislative action at both the state and federal level, using local and national resources, resulted in the election of "dry" politicians who worked to impact a teetotaling agenda. That push toward banning the sale of alcohol through legislative action was supported by many with a temperance-focused agenda because it had the same effect of limiting drinking and achieving their social and moral agenda.

Toward the end of the century, research into the heredity of inebriety also peaked alongside eugenic solutions to the hereditary problem of alcoholism, to keep parental drunkenness from being inherited by the next generation. Medical discussions of eugenics and "germ poisons" entered the public sphere, casting intemperance as a public health concern because of the risk of alcohol-induced germ degeneration tainting the genetic stock of the US. (Courtwright 2005) Those ideas arose as Darwinian ideas infiltrated the social realm, creating hypotheses surrounding how some races were more susceptible to alcoholism than others through generations of breeding. (Pauly 1996) Studies began to proliferate surrounding the inheritance of criminality and vice across

generations of families, and those ideas rapidly shifted discussions surrounding alcohol abuse into the realm of eugenics, with prohibition as a solution for preventing the social disease of alcoholism.

However, those social reactions also tended to focus primarily along a division in class, with higher and middle class individuals being diagnosed with psychological mania, where as a lower class inebriate would be considered “feeble minded” and more subject to eugenic reactions. (Valverde 1997) That divide is particularly notable among women, who at the higher levels of society enlisted in female-only treatment houses that more resembled countryside retreats than madhouses. For those without the same social polish and financial means, such as prostitutes and hereditary degenerates, the asylum experience greater resembled punitive incarceration than a reformatory, restorative retreat.

At the turn of the twentieth century, social support began to erode for medical reformation of the alcoholic because of poor long-term recovery numbers, leading social activists to advocate for prohibition as a means of ensuring abstinence. That critical mass of discontent shifted the discussion from searching for a cure to simply removing alcohol to prevent broader social ills. Frustration with medical and public health attempts to reform alcoholics helped drive such a dramatic shift. (White 2005) The study of alcohol prevention turned from personal reform to examine the broader issues of social reform, with the idea that abnormal alcohol use arises from a combination of poor social conditions and faulty heredity. (Ajzenstadt and Burtch 1990) The confluence of those two effects is evidenced by eugenic programs which surged in popularity following the “rediscovery” of classical Mendelian inheritance at the turn of the twentieth century.

(Henig 2001: 8) Increasingly, alcohol reform groups argued that intemperance and alcoholism were passed down through generations and constituted a form of “heritable idiocy” or “feeble-mindedness” that could be rectified through the use of eugenic principles.

Evidence of such heritable degeneration was examined by psychologist Henry H. Goddard in his 1912 examination of the “Kallikak” family, an infamous case study in which he examined the genealogy and psychological defects of an anonymous family. (Goddard 1912) Some have suggested that the number of alcoholics reported and heavy habitual drinking by the family may be an expression of the executive functioning defects that characterize fetal alcohol syndrome. (Karp et al. 1995) Goddard sought to rectify the inheritance of such undesirable mental traits across generations through compulsory sterilization to cease what he described as a cycle of poverty, criminality, and feeble-mindedness. Also in the same time period, medical professionals began to examine the results of alcohol’s impact on the germ line. Between 1910 and 1930, several researchers examined how alcohol impacted reproduction and development, and came to the conclusion that there was no measurable impact. (Pauly 1996) Their failure to see even a correlation reflects the trouble with turn of the century scientific protocol in designing multigenerational experiments, and also of an inherent gender bias. The researchers focused almost exclusively on how alcohol affected the paternal genetic contribution instead of the pregnant animal.

The turn of the 20th century also represented a demographic shift in America from rural to urban, and the influx of immigrants was causing xenophobic and nationalistic political unrest. The existence of only a few state-sponsored social welfare systems and

financial problems among the urban poor were remedied by institutions like “tied houses,” which gained popularity with the immigrant working class. Owned directly by brewers and distillers, tied house offered perks like a free lunch to those that purchased alcohol, giving rise to the idiom, “there’s no such thing as a free lunch” based on the number of return customers. (Lawson 2008: 59) The number of individuals drinking was exacerbated by cultural affiliation with ethnic groups like the Germans or Irish, for which alcohol use was standard.

In response, Progressive-era moral crusaders like the Woman’s Christian Temperance Union, American Temperance Society, and the Anti-Saloon League, seized on the idea of abstinence as a means of personal and societal betterment. Women leveraged the social acceptability of their involvement in community health work to progress even further into the political sphere, characterizing intemperance as a threat not only to the home, but to nationwide productivity and citizenship. (Hallberg 1988) Temperance proponents drew heavily upon the fields of science, law, and moral authority to justify their solution to the social ills of increased alcohol consumption. Claiming moral authority in a precipitous time, the “dry” movement lobbied for a prohibition on the sale of alcoholic beverages as a means of addressing the nefarious public conduct of inebriates. The ratification of the 18th Amendment on 16 January 1919 prohibited the sale, production, and transport of “intoxicating liquors,” but it was the separate passage of the Volstead Act later that year that contained the specifics of the arrangement.

While Prohibition did not ban the consumption or possession of alcohol, in Great Depression America, the demand for alcohol was such that many entrepreneurs were drawn to the monetary incentives for breaking the newly passed laws. Prohibition’s

unintended effect was the strengthening of organized crime in the US. As alcohol sales ceased, career criminals raced to fill the power vacuum for alcohol control. The well-organized, well-funded criminal organizations monopolized already meager federal resources during the Great Depression. (Jurkiewicz and Painter 2008) A government used to regulating the sale of alcohol instead needed to develop methods of trying to enforce the tenets of Prohibition and the Volstead Act, which proved functionally impossible.

In light of the illegality of alcohol trafficking, bootlegging and speakeasy operations flourished, as organized crime ensured that alcohol deliveries remained constant. To illustrate the relationship between government regulation and private production, in 1921 95,933 illegal distilleries were shut down by the federal government, a number that had almost tripled to 282,122 by 1930. Speakeasies numbered more than 500,000, and federal courts found themselves hopelessly overwhelmed by the burden of enforcing Prohibition. (Jurkiewicz and Painter 2008: 5)

A notable exception to Prohibition was alcohol use for medicinal and religious purposes, which had the odd effect of making physicians alcohol distributors. Use of prescription alcohol was inexpensive, easily accessed, and recommended by medical professionals for a wide variety of ailments. In 1921, doctors wrote \$40 million of whiskey prescriptions, a figure not adjusted for inflation. (Jurkiewicz and Painter 2008: 5) As those numbers suggest, the medical profession was less than single-minded in enforcing temperance as a means of moral and social betterment.

In effect Prohibition represented a failure to fully medicalize atypical drinking patterns, due to a wide variety of factors, among them the role of medicine in carving out addiction as a scientific field of study and treatment. Problems included the nascent

disciplinary authority of public health and medical groups, coupled with the punitive nature of the majority of inebriate asylums, and the confusing often contradictory medical ideas surrounding addiction and the agency of the alcoholic. As such, in the time period prior to WWI, disagreement existed about where to focus resources to best address the social problem of alcoholism. Should doctors focus on a single substance like ardent spirits or demon rum, incorporate drug addiction into the same framework, have different class and gender distinctions to the disease process, or focus more closely on heredity and degeneration? (Valverde 1997) Or were evangelical preachers closer to the truth in characterizing the alcoholic as a sinner capable of reformation only through salvation? In light of the plurality of opinions, the unwavering and familiar morality narrative of being framed by temperance workers gained the most support, shifting the focus from reformation of the alcoholic to the outward social harms inflicted on victims of the alcoholic's behavior.

Collective Amnesia: Repeal and the “Rediscovery” of Alcoholism as a Disease

The Repeal of Prohibition by the 21st Amendment on 5 December 1933 ushered in an era of detachment and exhaustion at the prospects of regulating alcohol. Society seemed to collectively reverse course and disavow their former zealotry by enforcing a code of silence surrounding the social controls of alcohol. In reverting legislative control over alcohol to the states, the federal government washed its hands of a very expensive and unpopular decision, and seemed to regard Prohibition as an episode of madness. Indeed, not until 1970 would legislation regarding alcohol pass congressional muster, creating an almost 40 year vacuum at the federal level. In that time frame, medical and

scientific studies began to emerge that again began to characterize alcoholism as a disease that required medical intervention. Likewise, community health initiatives recalibrated their motivations with some such as the Anti-Saloon League all but disappearing, while others like the Woman's Christian Temperance Union redirected their social efforts toward other endeavors that benefitted their constituents.

Following Repeal, the federal government needed some sort of protocol for ensuring that the transfer of power between federal and state progressed in a smooth manner. Integral to that transition was the publication of *Toward Liquor Control* in 1933, a data-driven and scientific assessment of alcohol use that sought to provide a pragmatic approach to state-regulated alcohol by addressing it as a commodity but trying to limit potential alcohol abuse. (Fosdick and Scott 1933) Written by Raymond Fosdick and Albert Scott, and funded by philanthropist and teetotaler, John D. Rockefeller, the objectives of the report were asserted by Rockefeller to be twofold in nature: the "abolition of lawlessness" with a focus on how the state can continue to promote "self-control and temperance" because "public standards as a basis for law can only be improved as private standards are improved." (Fosdick and Scott 1933: 9)

The publication ushered in an era of laissez faire federal regulation, as politicians and social scientists tried to distance themselves from the divisive "dry" and "wet" perspectives that exemplified contentious pre-Prohibition debates. Rather, the ambivalence regarding alcohol consumption was expressed by the authors of the book-length treatise, which characterized pre-Prohibition debates as relying too heavily on an appeal to emotion. *Toward Liquor Control* sought to examine the goal of alcohol reform from the objective, non-ideological perspectives of science and social statistics. After

interviewing experts across a wide range of fields including judicial, religious, bureaucratic, journalism, industry, and local and federal law enforcement among others, the authors identified a variety of initiatives the majority wanted to pursue. Those included a return to more local control to better reflect the desires of the community, and an end to bootlegging, racketeering, and the poor social influences of tied houses on the community. (Diamond 2008) The report also identified the hope that brewers, vintners, and distillers would adopt a self-policing morality code that did not outright violate established social norms.

The examination recommended that states implement a state-owned and operated monopoly system for hard liquor, and a three-tiered system to control the distribution and sale of alcoholic beverages. (Fosdick and Scott 1933) The three-tiered system was intended to ensure that wholesalers served as an intermediary between distillers and customers to avoid the possible reemergence of tied houses where distillers offered deep discounts on their product to entrench a customer base. Taxation, tariffs, and licensing processes were all discussed at great length in the treatise as well, although it was left to the states to determine how, or even if, states should permit and implement alcohol regulation. In addition to presenting an objective and dispassionate assessment of options related to alcohol regulation, Fosdick and Scott also counseled that it was alcoholism and not moderate alcohol consumption that should be the focus of alcohol research. (Daniels 2008)

The foundation of Alcoholics Anonymous in 1935 exemplified that spirit of apolitical involvement in alcohol-related issues by focusing on individual personal reformation and refusing to take a stance on any legislative or social controls. Such a

focus filled the gap in terms of individuals seeking personal help, destigmatized the title of alcoholic, and legitimized alcoholism as a medical concern. (White 2004) Alcoholics Anonymous and their guide for success in the program, *The Big Book*, represents a throwback to the testimonial-driven efforts of early reform groups like the Washington Temperance Society comprised of reformed drunks seeking to better themselves and teach others how as well. That focus speaks to the personal utility of defining a collective experience by creating the language to describe one's illness as a personal struggle, which allows the alcoholic to define his or her own substance abuse relationship within the context of their own lives.

Alcoholics Anonymous looked to both the future and the past in their approach to treating the disorder, integrating moral and biological frameworks. However, they do not characterize it in those terms, as one of their founding tenets is that "AA has no opinion on outside issues; hence the AA name ought never be drawn into public controversy." (Kurtz 2002) Among the "Twelve Steps" converts must achieve in the program is the idea of repentance or "making amends" and releasing oneself to the guidance of a higher spiritual power. Likewise, the framework of the program emerged from the idea of biological addiction to alcohol, with alcoholics experiencing a loss of willpower over the desire to drink, and their members often describing themselves as afflicted with the disease of alcoholism. While Alcoholics Anonymous did not create or explicitly disseminate such a disease framework, their members were instrumental in spreading the idea of biological addiction and alcoholism as a disease into the public sphere.

However, women who approached Alcoholics Anonymous for help reforming remained largely underserved and overlooked, just as they had throughout history. Those

women who found themselves addicted to alcohol had “failed” at womanhood, extending back to the well-entrenched cultural expectations of women as the nurturing, moral bedrock of the family, and few in Alcoholics Anonymous believed women capable of even completing the program. (Hallberg 1988) Indeed, Lil, the first woman who approached the founder of Alcoholics Anonymous, “Dr. Bob,” to solicit help with her drinking problem was described as unfeminine, coarse, profane, promiscuous, and the reason Dr. Bob was “leery of anything to do with women alcoholics for a long time thereafter.” (Hallberg 1988) Likewise, Florence’s story of recovery, “A Feminine Victory,” was cataloged in the 1938 version of *The Big Book* before being removed when Florence relapsed and died of complications from alcoholism two years later. (Brown and Brown 2005: 114) But when Marty Mann joined Alcoholics Anonymous in 1939, an articulate upper middle class woman of good breeding who had attended finishing school in Florence, Italy, her status and class helped to secure her position as the lauded “first” woman to complete the Alcoholics Anonymous program. Mann published her personal story of reform, “Women Suffer Too,” in the 1939 edition of *The Big Book* and used her position of authority from within the organization to reform how Alcoholics Anonymous served the women who approached the organization looking for help.

That focus on heavy drinkers, or alcoholics, instead of moderate or light imbibers made the research less controversial and motivated a reengagement with alcohol research. During Prohibition, much of the alcohol research had evaporated in the face of a social solution of enforced abstinence as a cure for alcohol-related maladies. Alcoholism as a disease was nothing new, having been coined in 1849 by Magnus Huss, a Swedish physician who used the term to describe individuals in a near chronic state of intoxication

who had psychological and social impacts in addition to physiological damages. (White 2004) Researchers further refined that definition of alcoholism in the subsequent century, and what arose in the mid-twentieth century demonstrates the rhetorical power of the classification of alcoholism. Separating a group of heavy drinkers and singling them out as suffering from a disease that erodes their willpower to not drink provided both the individual and society with an adequate vocabulary to describe the condition in a way that de-stigmatized the heavy drinker as a sick individual in need of treatment instead of a morally unsound reprobate.

Work toward that eventual classification began with the reengagement of scientists in alcohol research, including the foundation of the Research Council on Problems of Alcohol following Repeal. With few federal, state, and philanthropic entities willing to fund alcohol studies post-Repeal, physicians and researchers had difficulty obtaining funds in the field and largely relied on teetotaling friendly philanthropists such as Rockefeller. (Schneider 1978) However, when the Research Council on Problems of Alcohol emerged from an alcohol interest group of the American Association for the Advancement of Science, they became a highly influential organization funding alcohol-related research.

The Council solidified that reputation after providing the funds to help court one of the most influential alcohol researchers in America to enter the field: Elvin Morton Jellinek. (Roizen 2000) They provided a grant to conduct a literature review examining the biological impact of alcohol on humans conducted by Jellinek, and helped to shift his research focus into the emergent, science-driven field of alcohol studies. (Schneider 1978) With the initial monetary support of the Research Council, the nexus of alcohol

science soon shifted from the council's New York City location to the Yale Center of Alcohol Studies in New Haven, Connecticut, where Jellinek worked to define the problem of alcoholism and devise solutions for the disorder.

The Center of Alcohol Studies emerged from the Yale University Laboratory of Applied Physiology and Biodynamics, which was directed by Howard W. Haggard and researched the biological and physiological mechanisms of alcohol addiction. In 1941 Jellinek accepted a position as Associate Professor of Applied Physiology at Yale, where he headed the Section on Alcohol Studies and helped Haggard with the new publication, *Quarterly Journal on Studies of Alcohol*. (Schneider 1978) The journal and the Center both sought to integrate evidence across a variety of fields of study, examining both physiology in addition to psychology and later social science to define how alcohol advanced as a disease and other risk factors of alcohol addiction. (Metlay 2010: 27)

The journal did not shy from publishing content that argued for increased state- and federal-level oversight, however. That included a 1945 piece published that introduced a proposed Massachusetts alcohol warning label that arose from a 1943 committee to investigate the problem of alcoholism and the role of warning labels for the purposes of education. That early proposed alcohol warning label read: "Directions for use: Use moderately and on successive days. Eat well while drinking, and if necessary, supplement food by vitamin tablets while drinking. Warning: if this beverage is indulged inconsistently and immoderately, it may cause intoxications (drunkenness), later neuralgia and paralysis (neuritis) and serious mental derangement such as delirium tremens and other curable and incurable mental diseases, as well as kidney and liver damage." (Haggard 1945)

Under Jellinek's direction, programs for practitioners and patients expanded in the Center to include a Summer Course on Alcohol Studies starting in 1943, and the Yale Plan Clinics in 1944. The summer course offered practitioners and researchers the opportunity to attend lectures and workshops at the Section on Alcohol Studies to learn the most recent information in scientific advancement being studied at the Center. While Yale Plan Clinics arose from a relationship with the Connecticut Prison Association to provide treatment to community members referred by courts or seeking support for a personal problem with alcohol, offering students the opportunity to put into practice the skills they had been learning and community members to access treatment options. (Haggard and Jellinek 1944) Both programs sought to advance the disease model of alcoholism and teach frameworks and skills that attendees could use in the future.

Alongside those institutional courses and clinics, Jellinek joined Mann to found the National Committee for Education on Alcoholism in 1944, initially housed in Jellinek's Section on Alcohol Studies. Charged with expanding the narrative of alcoholism as a disease, the National Committee for Education on Alcoholism crafted a national agenda for expanding public health efforts addressing alcoholism and relied on local branches of volunteers to broadly disseminate such positions. (Roizen 2004) Such a network also served as a means of reaching a broad audience of local supporters to solicit financial and moral support for the work being conducted with Yale's alcohol research program. The organization exemplified the long term reform goals pursued by Mann, who as a reformed alcoholic herself, sought to influence the public's understanding that the alcoholic is sick and deserving of treatment. The formation of that program, which would later become the highly respected alcoholism advocacy group, National Council

on Alcoholism in 1956, helped to cement necessary institutional frameworks for a future public health and legislative response to the problem of alcoholism.

Scientific and institutional support for the disease concept began to gain traction and become the dominant paradigm for explaining heavy, sustained drinking through the mid-twentieth century. While the Public Health Service had alcoholism and alcohol addiction in their manual for coding illness since 1944 proper use of nomenclature moved to humanize the alcoholic. (Keller 1976) In 1956, the American Medical Association's Committee on Alcoholism moved toward that destigmatization by passing a resolution which urged hospitals to accept alcoholics in need of treatment for their inebriety alongside regular patients. (Schneider 1978) Following that, a 1958 joint report was issued by the American Medical Association and the American Bar Association that suggested alcohol be treated as a medical problem of addiction rather than a criminal issue.

Shortly thereafter, Jellinek published his highly influential work *The Disease Process of Alcohol* in 1960, a publication that defined the best practices for research up to that point and firmly established biological and physiological mechanisms as responsible for alcoholism. (Jellinek 1960) In the book, Jellinek begins by examining social factors in a cross-cultural perspective to demonstrate that in spite of differences in drinking patterns and acceptability of alcohol consumption, biological and physiological metrics to gauge the disease process remain consistent. He then moves on to establishing the different physiological and psychological factors required for a drinking problem to be considered alcoholism, establishing different types of alcoholism but only recognizing certain patterns at true alcoholism. In order to be considered alcoholism, Jellinek establishes that

the disease process and symptoms must progress to clear physiological dependence that consists of increased tolerance, changes at the level of cellular metabolism, withdrawal symptoms, insatiable cravings, loss of control, and marked psychological issues and behavioral changes. Those psychological and behavioral issues manifest as anxiety, frustration, inability to cope, intolerance, neurosis, and the rapid alleviation of that host of problems simply by taking a drink.

Jellinek's assessment of alcoholism was a formative publication in the field and ushered in a host of new professional and paraprofessional programs addressing alcoholism as a condition to be treated, and alcoholics as sick men in need of treatment. Women, even with the influence of Mann in an advocacy capacity, continued to be largely overlooked in most treatment and research contexts. Until 1973, when fetal alcohol syndrome introduced the nation to a neglected population and created two distinct classes of patients in need of treatment and protection, women who drink and the fetuses they affect.

CHAPTER 4

REENGAGING WITH ALCOHOL AT THE FEDERAL LEVEL: ALCOHOLISM AS A DISEASE, FETAL ALCOHOL SYNDROME, AND FEMALE ALCOHOLICS

The rise of federal public health efforts to treat alcoholism in the 1960s and 1970s built on the groundwork established in the mid-twentieth century, with medical and advocacy groups converging in their agreement that treatment and rehabilitation be made more accessible to the alcoholic. Branching out from the work being conducted at the Yale Center for Alcohol Studies by Elvin Morton Jellinek and associates, a growing field of professional treatment options emerged as society began to embrace the idea of alcoholism as a disease. Likewise, the prominence of Alcoholics Anonymous and the power of shared experience and personal narrative inspired a new wave of alcoholism advocacy organizations. Lobbyists pressured Congress and the federal government to craft legislation and public health programs that recognized alcoholism as a disease and the alcoholic as a sick individual worthy of treatment. At the federal level, medical and advocacy groups found themselves trying to change the collective consciousness of an America that had largely detached from the previous generation's cultural obsession with social control of alcohol.

However, within a decade of federal involvement the social concern with alcoholism and the victims of the alcoholic's behavior had resulted in legislation addressing numerous problems that arose from the use of alcohol. Fetal alcohol syndrome (FAS) was the first among those social issues identified and addressed, and offered an opportunity for lawmakers and politicians to engage in arguments similar to those of the

teetotalers from the mid-nineteenth century. This chapter will examine how fetal alcohol syndrome motivated broad-reaching public health policies proposed to address the physical, social, and moral harms of alcohol consumption.

The chapter begins with an examination of how alcohol research and advocacy missions aligned to petition the federal government for alcoholism research, training, and treatment support in “Research and Advocacy Align: Re-Establishing Federal Involvement with Alcoholism.” In the mid-1960s the federal government under President Lyndon B. Johnson began to discuss the problem of alcoholism and the appropriate federal response for the first time since Prohibition. As advocacy groups and medical organizations worked to erode the stigma surrounding alcoholism, reformed alcoholic Senator Harold E. Hughes acted as a figurehead for federal intervention and petitioned for the creation of a new organization to address the national problem of alcoholism. The passage of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 accomplished those goals by creating the National Institute on Alcohol Abuse and Alcoholism (NIAAA). That organization marked the federal government’s reengagement with research and treatment surrounding issues of alcoholism, and soon transitioned to address the social harms of alcohol use. However, as those measures arose they prioritized the male experience over other affected groups such as women, minorities, the elderly, or youths.

That began to change after the discovery of FAS made the female alcoholic visible in new ways, and introduced another population impacted by drinking, the fetus she carried. The second part of this chapter, “Fetal Alcohol Syndrome: Establishing a New Public Health Risk,” outlines the history of how physicians identified FAS in 1973

and reacted to the possibility that alcohol acted as a teratogen during development. The chance that alcohol could cause birth defects rapidly politicized the discussion surrounding appropriate federal and social control of alcoholism, with the third publication on the subject going so far as to recommend abortion to pregnant alcoholics. FAS also brought into question other victims of alcohol abuse, including those adversely impacted by drunk driving, youth drinking, and prescription drug interactions.

While researchers were attempting to ascertain how alcohol impacted development and the extent of that damage among the population, the NIAAA was busy carving out disciplinary authority and trying to keep from being dissolved or absorbed by other federal organizations. “The NIAAA Carves Out Disciplinary Authority: Establishing a Federal Alcohol Agenda,” examines the early organizational history of the NIAAA as it fought for funding and navigated federal bureaucracy. Resignations and political turn-over plagued the agency, with a grant funding scandal causing the resignation of the first director Morris E. Chafetz, who promptly shifted to embrace a pro-industry perspective on many alcohol-related policy issues.

The last section of this chapter, “The Pregnant Alcoholic: Expanding the Research Agenda to Include Women and Their Fetuses,” elaborates on how the discovery of FAS and the focus on female alcoholics both complicated and aided the NIAAA in establishing its importance as a federal public health organization. The push for alcohol warning labels to educate about the risk of FAS also began in this time period, and prompted heavy congressional involvement in the form of bills proposed and subsequent hearings to discuss the risks of FAS and the appropriate public health measures. After decades of work to remove the stigma of alcoholism and expand treatment options, FAS

and the pregnant woman who drank redefined what constituted deviant social behavior surrounding alcohol, and reinvigorated the social concern with protecting the victims of the alcoholic's behavior.

Research and Advocacy Align: Re-Establishing Federal Involvement with Alcoholism

Alcohol research and treatment continued to surge in the 1960s, a result of research and advocacy efforts to classify a group of individuals with the compulsion to drink as patients worthy and deserving of treatment. Jellinek's highly influential work at the Yale Center on Alcohol Studies had cultivated and trained a growing number of professionals in the field of alcohol research and treatment. Simultaneously, the voice of the alcoholic also helped to define the need for social services, through advocacy efforts supported by the National Council on Alcoholism and the growing popularity of Alcoholics Anonymous. As the stigma surrounding alcoholism diminished, increasingly prominent public figures began to divulge their own problems with alcoholism, demonstrating that addiction cut across all socioeconomic boundaries and further normalizing the alcoholic. That combination of research and active patient involvement helped to establish alcoholism as a social problem in need of a federal public health solution.

Research and advocacy interests found a sympathetic figure in then President Lyndon B. Johnson, who considered alcoholism a disease and brought federal awareness to the overwhelming need for treatment services. In keeping with those principles, in July of 1963 the Department of Health, Education, and Welfare (HEW) held the first federal-level conference to address the problem of alcoholism since Prohibition. (Schaffer 1965)

The National Conference on Alcoholism brought bureaucrats together with professionals from medical, judicial, correctional, psychiatric, and social welfare backgrounds to discuss the problem of alcoholism. Although no formal recommendations arose from the meeting, the panel agreed that too little was currently being done to address the problem and federal public health measures began to manifest. (Schaffer 1965) The Secretary of HEW, Anthony J. Celebrezze, formed the Committee on Alcoholism within HEW shortly thereafter to advocate for increased federal and state assistance to alcoholism treatment programs. (New York Times 1964) The committee supported several conferences surrounding vocational rehabilitation, drunk in public cases, and the legal issues specific to chronic alcoholics.

Among those HEW-sponsored conferences, “Legal Issues in Alcoholism and Alcohol Usage,” did the most to help erase the social stigma surrounding alcoholism. Suggestions that arose from that meeting included a recommendation that the executive branch increase its involvement, and that the American Bar Association and American Medical Association release a joint missive urging those in medicine and law to act with fairness when dealing with alcoholics, both of which came to fruition. (Chayet 1965) Shortly thereafter President Johnson presented a “Special Message to the Congress on Domestic Health and Education,” in which he announced his intent to establish an alcoholism health advisory committee, a center for alcoholism research within the Public Health Service, and to advocate for increased public education efforts and assistance for local and state treatment options. In the speech he declared that, “The alcoholic suffers from a disease which will yield eventually to scientific research and adequate treatment.” (Johnson 1966: 243) Following that initiative, Johnson established by executive order an

advisory committee on alcoholism to counsel the Secretary of HEW. Political control of alcoholism had once again infiltrated the highest branches of government.

With a firm disease concept and actionable treatment options for alcoholism on the rise, the American Civil Liberties Union began to search for a court case to argue for decriminalization of public drunkenness on the grounds that a person who is sick in public is not breaking the law. (Kurtz 2002) The legal argument was first tested with DeWitt Easter in 1965 and Joe Driver in 1966, both of whom had their convictions for public intoxication reversed upon appeal because both men were found to be involuntarily displaying symptoms of their disease, alcoholism, in public. (*Easter v. District of Columbia* 1966) (*Driver v. Hinnant* 1966) In 1968, the American Civil Liberties Union argued a similar case for Leroy Powell before the US Supreme Court, which in a 5 to 4 decision upheld his conviction because Powell was not homeless and therefore did not need to be drunk in public as a condition of his disease. But in doing so the US Supreme Court established the firm legislative precedent that alcohol was a disease and that the criminal justice system exists to punish acts, but not statuses such as disease states. (*Powell v. Texas* 1968)

The legal decision was followed by the American Medical Association in 1967 passing a resolution that clearly identified alcoholism as a disease and with President Johnson's "Special Message to the Congress on Crime and Law Enforcement" in 1968. In that message, he identified alcoholism as one of the highest medical, legal, and economic priorities in the US. (Johnson 1968: 189) In the speech he called for the expansion of alcoholism research and treatment programs within HEW and advocated for

the creation of an Alcoholism Rehabilitation Act to help states address the need for reform and not just punishment among those afflicted.

On October 15, 1969, President Johnson strengthened federal involvement in alcohol programs with “Alcoholic and Narcotic Addict Rehabilitation Amendments of 1968.” (Public Law 90-574) The legislation called for the foundation of alcoholism treatment facilities in an attempt to reform instead of punish the alcoholic, and included grant money for states to construct and staff specialized facilities to diagnose, treat, and rehabilitate alcoholics within their populations. In addition to construction grants, the legislation called for the creation of the National Center for Prevention and Control of Alcoholism within the National Institute of Mental Health (NIMH), which itself had separated from the National Institutes of Health in 1967. (Institute of Medicine 1991) The National Center for Prevention and Control of Alcoholism served primarily as a federal research institute, and doled out \$6.4 million dollars in grants and fellowships by 1969 for the purposes of research and training. (Stimmel 1983: 16) Although the Center represented the first government foray into funding federal alcohol control studies since Prohibition, the meager funding left much to be desired by advocates for alcoholism treatment programs.

Congress continued to increase the visibility of alcoholism as a social problem, and in May of 1969 the Chairman of the Senate Committee on Labor and Public Welfare, Ralph Yarborough (D-TX), created a Special Subcommittee on Alcoholism and Narcotics with the stipulation that little budget existed for the subcommittee’s operational costs. (Hewitt 1995) Yarborough was convinced to establish the committee at the urging of a very persistent junior senator, Harold E. Hughes (R-IA), who became the head of the

subcommittee and used his connections in the alcoholism advocacy realm to find volunteers willing to help operate the special subcommittee. (Hughes 1979: 278) Hughes, a reformed alcoholic, fervently advocated for expanded access to alcoholism treatment programs and broad educational reforms to destigmatize the condition.

In its first act, the special subcommittee held a series of hearings on the “Examination of the Impact of Alcoholism” in July of 1969 to examine the current state of affairs surrounding alcohol treatment in the US and determine recommendations going forward. (U.S. Senate 1969) Hughes was very forthright about his former alcohol abuse problem, and sought other prominent figures in recovery to share their personal narratives in testimony before the subcommittee. He did encounter difficulty convincing others to go public with their problem as few were willing to chance the potential repercussions that might arise from such an admission. (Olson 2003) In the end, the subcommittee heard from several well-established reformed alcoholics and individuals in Alcoholics Anonymous and Al-Anon, the support group for family members of alcoholics.

Hughes relied so heavily on instances of personal narrative from recovered alcoholics active in advocacy work during the hearings because his first stated goal was to “dramatize to the Congress and the public the magnitude and urgency” of the problem of alcoholism in the US. (U.S. Congress 1969: 2) Among those testifying were “Bill W.,” William Griffith Wilson, co-founder of Alcoholics Anonymous who testified under his AA moniker to honor the anonymity of the organization. Bill W. described Hughes’ work toward widespread federal alcoholism research as the “Big Twelfth Step,” alluding to the final step of AA’s program. (Olson 2003) Also on hand to testify was, Marty Mann, co-founder of the National Committee on the Education of Alcoholism, later re-named the

National Council on Alcoholism. Mann had since abdicated her position in the organization to speak broadly at the federal level about alcoholism advocacy. She outlined her well-established advocacy position: alcoholism is a disease, alcoholics are sick, they can be treated, they are worthy of treatment, and the widespread social nature of the disease requires a widespread public health response.

Hughes also sought to use the hearings as an opportunity to present new approaches to the problem and envision a federal-level response “not previously dreamed of by this government.” (U.S. Congress 1969: 2). To begin examining how to devise such a broad response, Hughes held 14 hearings across the US in the summer of 1969 to speak with individuals from different backgrounds and areas of expertise who agreed on one principle—alcoholism presented a major public health problem and something needed to be done to address it. (Hewitt 1995)

Building on the momentum of those hearings, Hughes worked to draft and introduce the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act, presenting it before the Senate on May 14, 1970. (Hughes 1979) Nicknamed the Hughes Act, the far reaching federal legislation established the foundation of the National Institute on Alcohol Abuse and Alcoholism (NIAAA) to be overseen by the Secretary of HEW, who would be advised by an newly established National Advisory Council on Alcohol Abuse and Alcoholism. The NIAAA would be tasked with organizing an expanding federal agenda surrounding alcohol, and enacting provisions of the Act like broader federal assistance for states through formula grants, project grants, and contracts. The Hughes Act also mandated the creation of a treatment program for alcoholic federal civilian employees (non-civilians were already being

served by a military plan), and required that all hospitals receiving federal funds admit alcoholics “on the basis of medical need” without discrimination (P.L. 91-616: 1852).

The Hughes Act passed the Senate by unanimous assent on August 10, and faced with the year-end deadline for congressional action and a packed House of Representatives docket, slight modifications were made to the legislation and an influential congressman fast-tracked the Act to a vote on December 15, 1970. (Hewitt 1995) The congressionally approved federal alcohol legislation advanced to President Richard Nixon’s desk for approval, where it faced an unknown fate as rumors circulated that President Nixon intended to veto the Act. Nixon reportedly did not want to create the NIAAA, and more broadly was opposed to expanding programs within the National Institute for Mental Health where the nascent NIAAA would be housed. (Hewitt 1995) Despite his opposition, and with the urging of influential business men, President Nixon quietly signed the legislation into law December 31, 1970, without public fanfare or ceremony. Despite the relative quiet surrounding the passage of the act, alcoholism advocacy and research circles were abuzz with the return of broad-reaching federal oversight to public health measures surrounding alcoholism.

Although the act had passed, implementation of the measures proved slow, leaving some wondering whether the Nixon administration planned to slowly smother the act by refusing to enact the requirements of the legislation. (Olson 2003) On March 3, 1971, Senator Hughes held a hearing of the Subcommittee on Alcoholism and Narcotics to inquire into the progress surrounding federal implementation of the act which carried his name. During a heated hearing, Hughes remained “convinced there must be some miscarriage of high executive intent.” (U.S. Senate 1971: 10) Among the Nixon

administration appointees called to testify was Morris E. Chafetz, who ran the then current iteration of federal alcohol grant management within the National Institute for Mental Health which had been established under President Johnson. At points during the testimony Chafetz and Hughes heatedly argued, with Hughes demonstrating open contempt for the administrator and questioning whether Chafetz was devoted to seeing an increase in federal alcohol funding. Years later, Hughes' assistant Nancy Olson revealed that bit of statesmanship to be political theater that Chafetz and Hughes worked out ahead of time to stir the passions of those in attendance. (Olson 2003)

That particular bit of fiction worked out well for Chafetz, as the NIAAA became an operational institute two months later with Chafetz at the helm as director. In one of his first acts as director, Chafetz organized the NIAAA's First Annual Alcoholism Conference that attracted 300 attendees. That same month the government released the 1972 fiscal year budget numbers for the NIAAA at \$84.6 million, more than six times what Chafetz worked with in his first year as Director of the NIAAA, and 13 times what he worked with as former director of the National Center for Prevention and Control of Alcoholism. Alcoholism research, treatment, and prevention had once again achieved a substantial federal presence.

With the establishment of the NIAAA, an institute devoted to coordinating federal funding and research on alcoholism, the problem of alcoholism took on new public prominence, and the social narrative surrounding appropriate alcohol use began to change. The "First Special Report to the US Congress on Alcohol & Health," from the Secretary of Health, Education, and Welfare even garnered its own news conference, and made the front page of the *New York Times* presenting facts from the report, that alcohol

abuse “warps nine million lives” at the cost of 15 billion dollars a year. (Schmeck Jr. 1972) Although it went largely unnoted in the media, the report also found that the demographic of heavy drinkers experiencing the fastest growth was women, particularly women drinking distilled spirits over beer and wine. (U.S. Department of Health, Education, and Welfare 1971: 9, 12) The newly emboldened NIAAA used that press conference to help launch their \$200,000 public service campaign to “encourage more responsible, controlled drinking patterns in healthier social contexts.” (Schmeck Jr. 1972) Concurrently, the NIAAA’s Clearinghouse for Alcohol Information began operation, responding to solicitations for information and disseminating educational materials throughout the country and fulfilling 900,000 requests for information in the first year of operation. (Olson 2003)

Fetal Alcohol Syndrome: Establishing a New Public Health Risk

As alcoholism treatment programs became more established, physicians began to identify a new at risk demographic impacted by alcoholism, the pregnant woman and the fetus she carried. Called fetal alcohol syndrome (FAS), the birth defects that could result when pregnant women consume alcohol ushered in a whole new arena of research and public health response. Publication of possible birth defects arising from prenatal alcohol consumption arose in 1973, but had been hinted at in the literature since the late 1960s with different research groups examining independent aspects of fetal alcohol syndrome such as stunted growth and developmental delays. (Ulleland 1970) (Lemoine 1968) Scientists had also rigorously examined issues of reproductive fitness and alcohol among chicks, rats, and guinea pig litters between 1910 and the mid-1930s with mixed results.

(Pauly 1996) (Pearl 1917) (Stockard 1913, 1922) That line of research ended as the reflective lens of Prohibition gathered all the conflicting results among those scientists, and declared the association unsubstantiated. (Fosdick and Scott 1933) Those studies of the early twentieth century went largely unidentified, buried in history, reliant on dated scientific ideas, and tainted by eugenic justifications.

The duo responsible for piecing together the causative relationship between alcohol and developmental defects, David Weyhe Smith and Kenneth Lyons Jones, practiced pediatrics at the University of Washington and specialized in an emergent field called dysmorphology. Coined by Smith, dysmorphology represented a field of study that focused on the identification and diagnosis of the underlying causes of birth defects and anomalies, bringing together the fields of pediatrics, embryology, and genetics to explain morphological deviations from the norm during development. (Smith 1968) In 1973, Smith and Jones were contacted by a physician at the University's Harborview Medical Center to examine a group of eight children and try to determine the cause of their developmental delays. (Golden 2005) During their initial visit, Smith and Jones observed that four of the eight children shared similar growth deficiencies, abnormally small heads (a condition called microcephaly), and delays in cognitive development.

The case histories of the affected infants cut across racial groups and therefore made a similar genetic anomaly unlikely, and the only environmental commonality was that each infant was born to an alcoholic mother. Two of those mothers were even hospitalized for delirium tremens and one gave birth in an "alcoholic stupor." (Jones et al. 1973) Smith and Jones suspected that alcohol may be the teratogen responsible for the developmental defects, even though medical evidence at the time did not fully support the

idea that alcohol acted directly on development. Instead, researchers tended to blame maternal nutritional defects and poor home environment for the type of “failure to thrive” that Smith and Jones observed in the cohort of children.

In 1973, Smith and Jones consulted with colleagues and presented the collective evidence observed among those eight children in a publication to the British medical journal *The Lancet* titled, “Pattern of Malformation in Offspring of Chronic Alcoholic Mothers.” (Jones et al. 1973) The normal process of peer review and revision were waived or rushed by the journal, and the article was accepted for publication a week after being submitted. (Golden 2005: 4) The authors discussed morphological abnormalities, cognitive defects, and growth deficiencies affecting children whose mothers heavily consumed alcohol during pregnancy, citing a possible partial expression of symptoms in mothers who drank less during pregnancy.

The medical community’s overwhelming response to the possibility of a link between alcohol consumption and pregnancy prompted Jones and Smith to publish a follow-up five months later. “Recognition of the Fetal Alcohol Syndrome in Early Infancy,” represents the first time the name of the syndrome appeared in press, and the article presented three new cases of possible FAS, including the results of one autopsy, and an historical survey of possible cases of birth defects caused by prenatal exposure to alcohol. (Jones and Smith 1973) However, instead of pointing to American ideas of how alcohol impacted reproductive capabilities, the authors focused on historical evidence from Roman and Greek mythology and British reactions to the Gin Epidemic in 18th century England. That appeal to deep history as a means of retrospectively examining potential evidence often appeared in early publications, presumably in an attempt to

figure out how the relationship between alcohol use by a pregnant women and birth defects had gone unclassified if not unnoticed for so long.

Those two articles sparked a firestorm of activity in the medical community, with physicians writing in to medical journals both to present individual case studies of patients they suspected of having fetal alcohol effects, and to criticize the certainty of suggesting a causative relationship. (Ferrier et al. 1973) (Bianchine and Taylor 1974) (Tenbrinck and Buchin 1975) One year after the initial publication, Smith, Jones, and colleagues examined a repository that contained the health outcomes of pregnant women called the Collaborative Perinatal Project, which had previously been used to substantiate the teratogenicity of thalidomide. (Golden 2005: 7) Among the 55,000 women listed in the database, researchers had confirmed maternal alcohol use in the medical charts of only 23 alcoholics, speaking to how infrequently doctors even discussed the topic of alcohol use with their patients in the mid-twentieth century.

Alcohol use was considered a substance benign to pregnancy and was not inquired about in the Collaborative Perinatal Project's questionnaire, with researchers noting maternal alcohol use in the case of severe alcoholics. The authors published their findings in the paper, "Outcome in Offspring of Chronic Alcoholic Women," published in *The Lancet* in 1974. Among those 23 women who drank during pregnancy, a significant correlation was noted between maternal alcohol consumption and perinatal mortality or severe birth defects. The article ended on the suggestion that chronic alcoholics should be counseled by practitioners as to whether the "magnitude of this risk" warranted "serious consideration be given to early termination of pregnancy in severe chronically alcoholic women." (Jones et al. 1974) Such a suggestion echoed similar

themes exposed by proponents of eugenics a century prior, bringing into question the responsibilities of the pregnant woman to create the next generation of productive citizens and firmly situating FAS as a public concern at the intersection of medicine and society.

Research related to prenatal birth defects as a result of exposure to alcohol had also been conducted in France in 1968, several years prior to Smith and Jones' papers. Paul Lemoine examined 127 children from 69 French families with chronic alcoholism noted in at least one parent. The facial abnormalities described in the French study were similar to those noted by other researchers defining FAS, and a similar range of cognitive defects were also included that manifested as low IQ, hyperactivity, and developmental delays in motor coordination and language skills. (Lemoine et al. 1968) Despite its publication five years prior to the observations made by Smith and Jones in their series of three articles, Lemoine's work went largely unrecognized in the US and medical communities abroad, even after the abstract was translated to English.

Both Jones and Lemoine followed their initial cohorts into adulthood in order to ascertain the long-term effects of FAS, and corresponded at length in 1974 after learning of their convergent observations of alcohol-impacted birth defects. (Golden 2005: 6) Among the eleven original children examined by Jones and colleagues, four were severely mentally handicapped, and another four were moderately handicapped. (Streissguth et al. 1985) Of Lemoine's original 127 children, 105 had been institutionalized as a result of psychological issues or mental handicaps. (Golden 2005: 8)

The three articles published by researchers from the University of Washington to *The Lancet*, provided an initial correlation between maternal alcohol exposure and a host

of developmental abnormalities, while Lemoine's independent corroboration of these results helped to substantiate the characteristics of FAS. Despite two dramatically different research groups arriving at the same conclusion, many in the medical community remained skeptical of the association between drinking during pregnancy causing a specific compendium of birth defects.

A new era of alcohol control, that of broad-reaching public health policy to address mental, physical, and social harms of alcohol consumption began to subsume the agenda of medical and addiction treatment. While medical communities were publishing on the risks of drinking during pregnancy, the preoccupation with maternal responsibility toward a healthy pregnancy was latent in the early scientific source materials. Authors used "embryotoxins," "acute fetal poisoning," and "harsh intrauterine environment" to describe the womb, and while technical in nature the language chosen to describe women's bodies passed clear moral judgment on those who drank during pregnancy. (Armstrong 1998) The same habit would be mirrored in the congressional hearings that identified FAS as a public health risk, adopted by various members of Congress and expert witnesses offering testimony on the best means of prevention and treatment for women who drink during pregnancy, and whether alcohol beverage labeling acted as a means of alerting the public to the potential risk.

The NIAAA Carves Out Disciplinary Authority: Establishing a Federal Alcohol Agenda

As scientists and physicians collected case studies and amassed scientific evidence toward establishing the symptoms of FAS, government agencies and Congress were largely just trying to keep the newly formed NIAAA functional. In the early 1970s

the NIAAA faced an increasingly uncertain future in a Nixon administration that preferred to distance the federal government from providing alcoholism treatment services. The administration went so far as to propose the idea of dissolving the Health Services and Mental Health Administration, which housed the NIAAA, by allowing the funding provisions to expire. (Institute of Medicine 1991)

However, Senator Hughes and other alcoholism treatment advocates doubled down on their investment in federal programs and instead increased the fiscal provisions for such services, much to the dismay of newly appointed Secretary of HEW, Caspar W. Weinberger. A lawyer by training, he had no formal experience in the health arena and instead sought to reorganize the department to cut spending, earning him the nickname “Cap the Knife.” (Kovach 1973) Although Congress determined appropriations for the NIAAA, the Nixon administration had essentially impounded the grant money for project grants in 1973, leaving over 115 federally approved project grant proposals unfunded. (Olson 2003)

Several months later in September of 1973, Hughes held a Senate hearing to craft amendments to the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act, using the opportunity to inquire into the executive block on approved congressional appropriations. The amendments passed and had the effect of releasing those \$218 million of impounded funds to the NIAAA for fiscal year 1974, and ensuring continued funds to the program. (Public Law 93-282) Despite substantial administrative opposition, Nixon even held a signing ceremony for the Amendments to the Hughes Act on May 14, 1974.

Concurrent with the uncertainty surrounding continued funding to the NIAAA, were attempts at administrative reorganization to consolidate programs, pushed by Secretary Weinberger. His Assistant Secretary, Charles Edwards, organized the Mental Health Task Force in 1973 to examine the institutional requirements for alcohol, drug, and mental health organizations at the federal level. The task force met with individuals within the existing trifecta of research institutes (National Institute on Alcohol Abuse and Alcoholism, National Institute on Drug Abuse, and National Institute on Mental Health) and branching out to professionals outside of the government in order to determine how best to structure such organizations that balanced research and treatment. (Institute of Medicine 1991) Despite the administrative desire to combine the three institutes, the task force determined that an institutional presence at the federal level served the alcohol and drug institutes in helping to legitimize treatment and research into such conditions and continue to eliminate stigma. (Institute of Medicine 1991)

Among the several restructuring solutions offered by the task force, the administration chose to create the Alcohol Drug Abuse and Mental Health Administration (ADAMHA) that would act as an administrative oversight body to three independent research institutes: the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse, and the National Institute on Mental Health. The controversy surrounding tenure of Secretary Weinberger continued after the formation of the ADAMHA, predictably related to issues with adequate funding. In an article published to *The New York Times*, prospective director of the new administration, Daniel Freedman, elaborated on his reasons for turning down the opportunity. He did not mince words in explaining his decision to decline the position, citing “cut-backs in health funds,

made with no understanding of the long-range effects of such cuts” that he saw as “producing ‘chaos’ in mental health research, training and services.” (Hicks 1974) Instead, James D. Isbister accepted the position as director of the ADAMHA, the former deputy director of the NIMH and acting administrator of the ADAMHA had no formal scientific training but extensive managerial experience and was formally appointed September 1974. (Lewis 1976b) The NIAAA had arrived on the federal stage as a wholly independent institute, but its future remained uncertain.

Despite institutional uncertainty surrounding the NIAAA and organizational attempts to limit its operation, the agency continued to establish a federal research agenda. In June of 1974, the NIAAA released the *Second Special Report to the US Congress on Alcohol & Health*, which generated substantial public interest. The report was released in a press conference and the results were heavily covered by health and science journalists, with NIAAA officials and Director Chafetz traveling the country for about 100 days giving talks and holding press conferences to popularize the problem of alcoholism and the federal response. (Olson 2003) The publication also represents the first time a government agency addressed the fetal risk posed by maternal use of alcohol during pregnancy.

In their section of the report addressing the problem of “Alcoholism: Heredity and Congenital Effects,” the authors also briefly discussed newly discovered fetal alcohol effects. In that section, they discussed whether alcoholism could be passed down through generations, at times sounding much like their temperance era predecessors concerned with the repercussions of demon rum on germ plasm. The authors cite as far back in history as Benjamin Rush, eighteenth century physician and the first to work toward a

medical understanding of alcoholism, noting that Rush observed the process of alcoholism as a condition that “resembles certain hereditary, family, and contagious diseases.” (U.S. Department of Health, Education, and Welfare 1974: 49). The authors also addressed the recent observations by physicians in the United States and Great Britain of alcoholic women birthing “maldeveloped or malformed infants,” although the authors remained uncertain as to whether the observed effects were caused by alcohol or a result of more traditionally understood causes such as “poor intrauterine environment” combined with malnutrition and poor prenatal care. (US. Department of Health, Education, and Welfare 1974: 49) The authors concluded with the recommendation that more work be conducted to discern the impact of maternal drinking on fetal development, and that working more closely with pregnant women could be a beneficial investment of resources for the NIAAA.

As those sorts of widespread research and education initiatives continued to be enacted by the NIAAA, a series of resignations changed the shape of the organization. The administrative pressure on the NIAAA abated somewhat as President Nixon resigned on August 9, 1974, and Gerald Ford, Jr., was sworn in as the new Commander in Chief. Ford accepted Secretary Weinberger’s resignation shortly thereafter. (Ford 1975) Weinberger’s successor, F. David Matthews, was reported by administrative staff to be “far more open to suggestion and more interested in discussing options than his predecessor.” (Hicks 1975) That was followed in the spring of 1975 by the resignation of the NIAAA’s first director, Chafetz, in a move many viewed as a means of avoiding censure for improperly using federal tax dollars and demonstrating favoritism in the grant review process. (Anderson 1974) Three NIAAA officials including Chafetz had charged

the government for a trip to Palm Springs in order to visit an NIAAA contractor, Grey-North Advertising. However, the contractor had already paid for the costs of the trip, and soon after received a multi-million dollar extension of their contract. Administrator of the ADAMHA, Jim Isbister, appointed John Deering as Acting Director of the NIAAA until Ernest P. Noble was chosen as the new head of the NIAAA in February of 1976. Noble faced the prospects of dramatically decreased funding through the Ford administration, at “a time of great flux—a point in the road where a wrong direction might signal the eclipse of a national effort just beginning to prove itself.” (Lewis 1976c)

At the same time as that organizational turmoil, alcoholism advocacy lost their staunchest congressional supporter when Senator Hughes decided to step down from Congress to enter the seminary. (Hughes 1979) Senator William Hathaway (D-ME) replaced Hughes as the chair of the Senate Subcommittee on Alcoholism and Narcotics fourteen months after Hughes’ resignation, and his appointment seemed odd to some advocates for federal alcoholism treatment programs. (Olson 2003) He initially failed to introduce the reauthorization bill to fund the Hughes Act, and early in his capacity as chair, he questioned the classification of alcoholism as a disease in public speeches, despite the NIAAA’s firm assertion to the contrary. (Lewis 1976a) However, while Hathaway faced a rocky start, he ended up defending the NIAAA from severe budget cuts proposed by the Ford administration, and expanded the topics addressed in subcommittee hearings to explore new realms of alcohol-related issues, including regulations on alcohol advertisements, the particular problems facing women alcoholics, and whether the risks of FAS required the adoption of alcohol beverage warning labels.

Those advocating for health warning labels to alert the public to the risk of FAS found a staunch ally in Senator Strom Thurmond (R-SC). Thurmond was a lifelong teetotaler and long-standing advocate of health warning labels to educate the public to the dangers of alcohol. (Bass and Thompson 2006: 151) He first introduced warning label legislation in a bill before the Senate in 1969, and had continued to present independent labeling bills or amendments appended to virtually every health-related act that passed through the Senate, until the Alcohol Beverage Labeling Act of 1988 finally delivered on almost twenty years of dogged effort.

In the early 1970s, Thurmond's warning label bills focused primarily on the broad assessment that alcohol caused health problems, and he pushed primarily for labeling distilled spirits and other alcohol with greater than 24% alcohol by volume. The early label read, "Caution: Consumption of alcoholic beverages may be hazardous to your health and may be habit forming" (S.895, S. 356). He had not yet adopted the specific focus of warning pregnant women in his labeling initiatives, but that soon changed as the Senate began to discuss the experience of an historically overlooked group of alcoholics, women, and by proxy the fetal effects of alcohol consumption during pregnancy.

The Pregnant Alcoholic: Expanding the Research Agenda to Include Women and the Fetuses They Endanger

Five years after the passage of the Hughes Act, with alcoholism firmly established as a medical concern with expanding treatment options, research and advocacy began to depart from the standard white male alcoholic to make room for other life histories and demographics affected by alcoholism, such as the elderly, women, minorities, and youth

drinkers. By the mid-1970s, even with the increase in treatment options proliferating at the state level, very little was known about how many women were classified as alcoholics and whether they sought treatment at a level equivalent to that of men. The NIAAA did know that women were the fastest growing demographic of alcohol users, with 61% of women drinking by 1974 and an increase in alcohol-associated death rates increasing yearly. (U.S. Senate 1976: 3) That coincided with a push for women's rights and equality in the 1970s, as equality surrounding alcoholism treatment and research became a topic pursued by advocacy organizations and congressional hearings.

The series of female-centric programs arising at the federal-level in Washington, D.C., included the 1975 formation of an alcoholism recovery group called Women for Sobriety. The group, created by Jean Kirkpatrick, presented a secular, gender-specific, individualized approach to maintaining sobriety. As a sociologist who had tried and failed in other male-dominated self-help settings such as AA, Kirkpatrick sought to create a cognitive therapy-based program that addressed what she considered to be the primary cause underpinning women's problems with alcohol, their low self-esteem. (Fenner and Gifford 2012) Women for Sobriety expanded in the US and internationally through the end of the twentieth century, and while it never reached near the prominence of AA, the group functioned as a smaller, more intimate alternative that could be pursued as an alternate in addition to other treatment options. Indeed, some women with drinking problems arising from more gender-specific issues such as a history of male aggression and violence, found better success pursuing sobriety in an all-female environment. (Kaskutas 1994) The creation of a recovery group specifically for women is reflective of

a larger push toward female-centric research and support initiatives pursued in the mid-1970s.

The advocacy-driven group National Council on Alcoholism also made the female experience a point of examination in March of 1976, creating an Office of Women and hiring Jan DuPlain to be the Program Director. That was a wise move considering the vast number of initiatives she accomplished in her first seven months on the job. DuPlain had previously worked at the NIAAA's National Clearinghouse for Alcohol Information and in her new position was responsible for developing and enacting objectives with the organization's National Steering Committee on Women and Alcoholism. (Olson 2003) In one of her first initiatives, DuPlain created a two-day track specifically focused on the topic of women and alcohol during the annual May conference of the National Council on Alcoholism in Washington, D.C. In addition to a women's forum, the conference also served as the inaugural meeting of the National Congress of State Task Forces on Women and Alcoholism, which organized advocates from across the country to push for the integration of women's issues into more local treatment and research schema. (U.S. Senate 1976: 10)

Later that summer, DuPlain also helped to organize the annual Summer School on Alcohol Studies at Rutgers University that focused on issues related to female alcoholics for the first time in its 34 year existence. With little preexisting research on the topic, the course served as an opportunity to both aggregate and conduct original research in the area. (U.S. Senate 1976: 10) In the wake of her success advocating for the integration of women into alcoholism treatment and research programs, DuPlain called on her previous connections at the NIAAA to urge Senator Hathaway to hold a congressional hearing in

the Subcommittee on Alcoholism and Narcotics devoted to issues facing female alcoholics. (Olson 2003)

Hathaway acted on that suggestion and in September of 1976 the Senate Subcommittee on Alcoholism and Narcotics of the Committee on Labor and Public Welfare met to hear testimony specific to women, “Alcohol Abuse among Women: Special Problems and Unmet Needs.” The hearing represented the first time the Subcommittee addressed the specific concerns facing female alcoholics, including the first inquiries into FAS. Testimony consisted of representatives from the NIAAA, the National Council on Alcoholism, and a variety of practitioners and professionals engaged with alcoholism treatment programs. Senator Hathaway began the testimony by articulating the purpose of the hearing, to “end the male dominance of substance abuse treatment, prevention, and rehabilitation” and to alleviate the stigma of seeking treatment. (U.S. Senate 1976: 2)

The first witness, Ernest Noble, director of the NIAAA, testified on many health and social issues related to alcoholism in women, and briefly addressed FAS. He outlined the work being conducted by the NIAAA which included eleven research studies devoted to women since 1972, but only four of those studies he listed were behavioral, with the remaining seven studies focused more on fetal alcohol effects, demonstrating a research agenda skewed in favor of examining how alcohol impacted the mere potential for life over how it directly impacted the life of the female alcoholic. He also outlined the scope of the problem, explaining that some studies place the number of female alcoholics in the same proportion to their representation in society, but that women comprised only 17% of the NIAAA’s clients in alcoholism treatment programs. (U.S. Senate 1976: 5) Noble

stressed that while the symptoms associated with FAS may be caused by alcohol, significant uncertainty still remained as to whether other factors such as poor maternal nutrition were responsible for the symptoms observed. To that end, he promised NIAAA resources to examine alcohol-related effects in pregnant animal models to see if the teratogenic effects reported across medical journals were indeed alcohol-dependent. (U.S. Senate 1976: 4) Noble also reminded the subcommittee of the language which had changed in the most recent amendments to the Hughes Act which had passed in 1976 and allocated preference to grants examining women's issues. (Public Law 94-371)

The advocacy contingent, headed by Antonia D'Angelo of the National Council on Alcoholism, followed Noble's testimony and pointed out the shortcomings of the NIAAA in addressing the problem of female alcoholism. She characterized the organization's research agenda of 574 programs with only 14 grants dedicated to women's issues as reflective of the predominant assumption that, "what is discovered about male alcoholics will also be true for female alcoholics." (U.S. Senate 1976: 12) She followed up that assessment with a series of suggestions for improvement, ranging from hiring a full-time staff position in the NIAAA devoted to women and alcoholism, to expanding the type of treatment accommodations for mothers, and calling for educational materials that "stress the nonsexual aspects of alcoholism." (U.S. Senate 1976: 13) That requirement is no doubt in response to the long-standing stigma that accompanies female alcoholics, who for generations have been characterized as impure, promiscuous, and by extension, less worthy of treatment. Those stereotypes not only existed in the social realm, but saturated scientific studies as well, as demonstrated by a publication to the

Public Health Reports of the Centers for Disease Control that describes women who use alcohol as self-medicating for problems with sexuality. (Roman 1988)

The 1976 hearing also represents the first time Henry L. Rosett, a professor of psychiatry at Boston University School of Medicine, testified before Congress on FAS, although he would return on numerous occasions to address the syndrome. In his first appearance Rosett discussed the preliminary results of Boston City Hospital's long term study on the impact of alcohol on prenatal development. In the hearings, Rosett explained that about 9% of the women in the study qualified as heavy drinkers and were responsible for the majority of congenital abnormalities observed in infants born, including a significant reduction in the length, weight, and circumference of the head in those infants. (U.S. Senate 1976: 21) The hospital warned all women of the risks drinking may pose to pregnancy and offered the women counseling and prenatal vitamins with their routine check-ups, noting that among those women who abstained or dramatically reduced their intake of alcohol, their infants were born with much fewer birth defects. Rosett also cited confounding maternal factors that may obscure the clear relationship of alcohol as a teratogen, including maternal smoking, malnutrition, nutrient absorption, and metabolism. In disclosing the United States Brewers as one of the funders at the end of his testimony, Rosett also foreshadowed the later controversy he would become embroiled in with accusations of industry funding impinging upon his scientific integrity.

Following the special topic testimony of Rosett, Edward J. Khantzian, assistant professor of psychiatry at Harvard University Medical School, spoke to another special topic affecting female alcoholics—adverse drug interactions between tranquilizers and alcohol. Khantzian describes a common situation in which a woman reluctant to disclose

her alcohol problems to the doctor, instead complains of nerves or some other related malady and is in turn prescribed mood altering drugs. Those drugs when combined with the alcohol use present an increasing public health problem, and Khantzian recommended that physicians needed to improve their means of screening for alcohol problems among their patients, training that could begin in medical school. The response of the Subcommittee chairman, Hathaway, clearly illustrates how different the conversations surrounding substance abuse were compared to now, stating that “It seems ludicrous almost, doctors asking patients whether they are drinking or not.” (U.S. Senate 1976: 33) A marked departure from the near mandatory inquiry now asked by general practitioners.

The final panel drew on their collective experience running treatment programs for alcoholics and witnessing first-hand the underserved population of female alcoholics. The panel of practitioners consisted of LeClair Bissell, medical director of the Smithers Center treating alcoholism in New York City's Roosevelt Hospital; Martha Ganis, a paraprofessional in the Akron Health Department; and Cecilia A. Graham, assistant director of a rehabilitation center. The three women expanded upon their personal experiences administering treatment programs to female alcoholics, arguing for the need to break down gender boundaries and stigma surrounding female alcoholics.

Shortly after the introduction of FAS to congressional testimony, Noble followed up on the goal of examining the science of FAS. The NIAAA held a workshop attended by doctors and alcohol researchers with the goal of determining what evidence existed for FAS, and if the strength of that evidence warranted action. On June 1, 1977, the NIAAA released the first government warning of alcohol's effect on birth outcomes that cautioned against drinking during pregnancy. (U.S. Department of Health and Human

Services 2010) The warning established the risk of FAS as substantiated in women who consume between three and six drinks per day, and that while no safe level of consumption had yet been determined, those consuming between one and three drinks per day should exercise caution. Oddly enough at that news release Noble later recalled that he did not think recommending a warning label regarding FAS would “impact too much” on the national discussion. (Lewis 1980a) Noble, head of the NIAAA, then forwarded a copy of the notice to every medical school chair and state medical association. (U.S. Senate 1978) Two days later the Center for Disease Control and Prevention published a similar version of the caution in the *Morbidity and Mortality Weekly Report*. (U.S. Department of Health, Education, and Welfare 1977)

CHAPTER 5

ALCOHOL WARNING LABELS AS A MEANS OF ADDRESSING THE PUBLIC HEALTH RISKS OF FETAL ALCOHOL SYNDROME

In the years between the passage of the Hughes Act in 1970 and the government's first warning on fetal alcohol syndrome (FAS) issued by the National Institute on Alcohol Abuse and Alcoholism (NIAAA) in 1977, the focus on problems specific to female alcoholics had taken a prominent role in public health discussions. In particular, the risks posed by drinking during pregnancy and FAS had helped the NIAAA carve out disciplinary authority to enact a robust federal public health agenda on the scale not seen since Prohibition. Among those public health responses, health warning labels on alcohol became a heavily contested topic that dominated congressional engagement with issues of alcoholism, as proponents and detractors engaged in heated conversations about social control of alcohol.

This chapter will examine how alcohol beverage warning labels arose in response to FAS, and dominated policy discussions in the five years following the NIAAA's 1977 warning that women should limit their consumption of alcohol during pregnancy. At the end of those five years in 1981, the Surgeon General released a warning that abstaining from alcohol during pregnancy was the safest course of action. Between those two government warnings, uncertainty about surrounding the bureaucratic authority over labeling, the mechanism and extent of alcohol's impact on development, and whether labeling could accomplish anything of value or if it simply represented a neo-prohibitionist response to alcohol control.

The chapter begins with bureaucratic bickering over which agency had the authority to regulate alcohol labeling in, “Consumer Protection or Industry Burden: Alcohol Labeling and the Jurisdictional History of the FDA and BATF.” Alcohol is an odd exception to the U.S. Food and Drug Administration’s (FDA) oversight, instead falling under the purview of the Bureau of Alcohol, Tobacco, and Firearms (BATF). As consumer advocacy organizations and the FDA petitioned for the inclusion of alcohol ingredient labels in the 1970s, the conversation soon morphed to include alcohol health warning labels in response to the public health risks posed by FAS. When that occurred, the BATF took the opinion that labeling in response to such a complex syndrome would create burden on the industry and increase the stigma of alcoholism. The FDA had a long-standing reputation for protecting the public from emergent fetal risks posed by pharmaceuticals and food, but alcohol warning labels were a much different political beast than reviewing a new drug application or regulating ingredients.

The need for labeling was also questioned by both industry and advocacy organizations in the 1978 congressional hearings that addressed the risk of fetal alcohol syndrome and what an appropriate public health response should entail. The second section of this chapter, “‘Alcohol Labeling and Fetal Alcohol Syndrome’: Congress Engages with the Problem,” examines the arguments elaborated upon in that hearing. Convened in response to Senator Strom Thurmond’s re-introduction of a bill to require alcohol health warning labels, the hearing entrenched the FDA and NIAAA as pro-labeling and the BATF, industry, and patient advocacy organizations as anti-labeling. Those positions remained fairly intractable into the early 1980s, until the election of Ronald Reagan, which refocused the national agenda surrounding alcohol policy.

In the wake of those 1978 hearings, administrative turmoil plagued the NIAAA and Senator Thurmond responded by taking a different approach to labeling. Instead of submitting a bill during the congressional session, he proposed a labeling amendment as a rider to a larger health bill. It surprised everyone when the amendment passed by voice vote in the Senate. As the bill advanced to the House of Representatives for consideration, the alcohol industry mobilized significant opposition to kill the labeling amendment in the bill. Following that, the chair of the Subcommittee on Alcoholism and Drug Abuse promised more hearings on the possibility of labeling. A second congressional hearing was held specifically to address health warning labels, the topic discussed in “‘Labeling of Alcoholic Beverages’: Congressional Action as a Remedy to Administrative Turmoil.”

As those hearings drew to a close, Congress ordered the BATF and FDA to collaborate on a joint report expounding on the current state of science regarding FAS and the pros and cons of labeling in response to that risk. What arose from that report is discussed in “Surgeon General Warning: Pregnant Women and the Risks of Drinking During Pregnancy.” Even as the Surgeon General released a warning cautioning against drinking during pregnancy in response to incontrovertible evidence of alcohol’s teratogenicity, federal concern with alcohol soon shifted to incorporate a broader number of disordered drinking habits. As federal responses to driving drunk, youth drinking, and FAS converged in the mid-1980s, it led to a broader base of social support for labeling as a means to both educate and codify such behaviors as socially unacceptable.

Consumer Protection or Industry Burden: Alcohol Labeling and the Jurisdictional History of the FDA and BATF

Following the 1976 congressional hearing on the special risks faced by female alcoholics, certain members of the Senate began to coalesce around the need to warn the public of the risks associated with fetal alcohol syndrome. Strongest among those supporters was Senator Thurmond (R-SC), who continually introduced bills to require health warning labels on alcohol, starting as generalized health warnings that focused on distilled spirits. That focus on hard alcohol as the culprit of alcoholism harkens back to the temperance era, when proponents made the distinction between ardent spirits and less dangerous forms of alcohol such as beer and wine. But as FAS emerged as a substantial threat to development, the language in such bills narrowed to focus on specific populations, and broadened to include all alcohol as a potential risk. The warnings focused on pregnant women and the risk of drinking during pregnancy, but later expanded to incorporate drunk driving as warning label legislation moved into the 1980s.

Overwhelmingly, the language of such bills proposed in the Senate identified the FDA as the regulatory body that should have jurisdiction over labeling. That distinction is important, as the FDA previously had no formal regulatory jurisdiction over alcohol, but Congress perceived that agency as most appropriate to implement health warning labels. That decision highlights how well the agency had established their reputation as a consumer protector of adverse drug effects on fetal development, which emerged as a result of the thalidomide epidemic a decade earlier in the mid-1960s. Many European women who took the over-the-counter drug thalidomide during pregnancy gave birth to tens of thousands of children with dramatic birth defects. The US avoided such an

epidemic of thalidomide-induced birth defects because of stringent requirements instituted by FDA officials charged with reviewing the drug for approval to US markets. That decision set a precedent for the agency as a consumer protector, both of pregnant women and fetal development, and represents the first regulatory expansion into the womb of pregnant women surrounding the safety of food and drugs.

Alcohol was a rare exception to the FDA's food and drug jurisdiction, as the Federal Alcohol Administration Act of 1940 had established a joint relationship with the Treasury Department's Bureau of Alcohol, Tobacco, and Firearms (BATF) regarding regulatory oversight. In 1972, the Center for Science and the Public Interest, a non-profit consumer rights agency, approached the BATF with an appeal to include ingredient labels on alcohol, which they suggested be overseen by the FDA. (Cooper 1979) The two agencies worked toward developing ingredient regulations and signed a memorandum of understanding to establish jurisdictional boundaries in an attempt to keep from overlapping work between agencies. The memorandum stated that the FDA "will defer to the Bureau of Alcohol, Tobacco and Firearms for primary regulation of the labeling of alcoholic beverages," with the stipulation that the BATF would adhere to the standards for ingredient disclosure already established by the FDA. (U.S. Department of Treasury 1974, 39 Fed.Reg. 36127)

Despite continuing pressure from industry groups, the BATF spent more than a year approaching how to formulate ingredient labeling requirements before declaring the process too burdensome. The agency published notice of proposed rulemaking in the *Federal Register* on February 11, 1975, which solicited public engagement and reactions to the proposal, and after reviewing the evidence the BATF rejected ingredient labeling

nine months later. (40 Fed.Reg. 6349-6360) In their published explanation, the BATF described weak public support for the measure, and made the argument that adulteration of alcohol was already heavily regulated. They also stated that labels could impact trade and may be misleading to the consumer, who gained very little compared to the cost of enacting such a measure. (40 Fed.Reg. 52513) Not surprisingly, the BATF later used those same arguments in congressional hearings surrounding health warning labels on alcohol.

Viewing the BATF as breaching their previous agreement, the FDA revoked their memorandum of understanding with the BATF and declared their intent to put a health warning on alcohol. In response to the FDA's assertion, by March of 1976 eight distillers and one winery, accompanied by three trade organizations (Distilled Spirits Council of the United States, National Association of Alcoholic Beverage Importers, and the Wine Institute), filed *Brown-Forman Distillers Corp. v. Mathews* against Forrest David Mathews, the Secretary of the Department of Health, Education and Welfare (HEW) under which the FDA resides. The primary objective of industry interests was to set a legal precedent that the FDA had no jurisdiction regarding alcohol labeling.

Three months later, Judge James F. Gordon of the US District Court in Western Kentucky heard *Brown-Forman Distillers Corp. v. Mathews* (1976), and ruled in favor of industry interests, granting exclusive control of labeling to the BATF. In the ruling, US District Court judge James F. Gordon in the Western District of Kentucky examined the legislative materials that enumerated the duties of the FDA. Those included the 1906 Pure Food and Drug Act that established the FDA and the 1938 Food, Drug, and Cosmetic Act that built upon and strengthened regulatory responsibility beyond the

primary goal of preventing product adulteration. The Federal Alcohol Administration Act passed in 1935 in the wake of Prohibition had established beer as a food product, but not whiskey, wine, or cordials. In a 1940 provision the FDA had stated that, "...we expect to continue our policy of not duplicating the work of the Federal Alcohol Administration with respect to the labeling of such products." (*Brown-Forman Distillers Corp. v. Mathews* 1976)

Taking into account that missive, in addition to numerous other institutional documents and congressional appropriations, Justice Gordon ruled that a conflict existed between the 1935 Federal Alcohol Administration Act and the 1938 Food, Drug, and Cosmetic Act. While alcohol was defined as a food in terms of those acts, and the FDA was responsible for addressing issues of adulteration of alcohol, their jurisdiction stopped short of any form of alcohol beverage labeling. Later examination of the ruling called it a "'sweetheart' decision rendered 'in the heart of Bourbon Country [by] a Kentucky judge...'" but for the purposes of ingredient labeling, and subsequent alcohol warning labeling, that "sweetheart decision" effectively revoked the FDA's jurisdictional authority over the issue. (Abel 2012: 220)

Although the FDA decided not to appeal Judge Gordon's decision, an unpublished excerpt from a discarded draft to petition the decision highlighted the institutional tensions between the FDA and the BATF, particularly as the BATF was perceived as taking the side of the alcohol industry. "The courts are not at liberty to pick and choose between congressional enactments, and when two statutes are capable of coexistence, it is the duty of the courts absent a clearly expressed congressional intention to the contrary, to regard each as effective." (U.S. Senate 1979: 92) Rapidly running out

of options to enact ingredient labeling, FDA Commissioner Donald Kennedy appealed to the Executive Office of the President through the Office of Management and Budget in July of 1977, which ordered the BATF to work with the FDA toward labeling (U.S. Senate 1979: 82). Following such a circumvention of the District Court ruling, the alcohol industry interests from the *Brown-Forman Distillers Corp. v. Mathews* ruling attempted to sue Kennedy for contempt of court, but the challenge failed and the BATF again began to address labeling jointly with the FDA.

The adversarial relationship between the two agencies continued through the late 1970s as the FDA kept pressure on the BATF regarding ingredient labeling, and soon expanded ingredient labeling to incorporate health warnings regarding the risk of FAS. Following the June 1977 FAS warning released by the NIAAA, which advised pregnant women to exercise caution in how much they drank during pregnancy, FDA Commissioner Kennedy contacted the Director of the BATF, Rex D. Davis. In a letter dated 15 November 1977, Kennedy alerted Davis to the fetal risks posed by alcohol consumption during pregnancy, and urged the BATF to “initiate immediately whatever procedures are necessary to require the placement on the labeling of alcoholic beverages of a warning against consumption of excessive amounts of alcohol by pregnant women...I hope that BATF, which now has exclusive responsibility for such labeling, will move promptly to address this serious health risk.” (U.S. Senate 1978)

As the agency charged with jurisdiction over labeling, BATF director Davis responded to the FDA’s call for labeling with an open bulletin published to the *Federal Register* on 16 January 1978 titled “Warning Labels on Containers of Alcoholic Beverages, Proposed Rulemaking.” The published bulletin solicited opinions from public

agencies and private parties regarding aspects of alcohol warning labeling. The missive asked for pragmatic considerations such as the appearance and wording of prospective health labels, in addition to more difficult questions such as consumer impact of the labels. Those concerns focused specifically on whether such a warning would even be helpful in deterring pregnant women from drinking, and whether alternative public health initiatives should be undertaken to better educate the public to the risk of FAS. The BATF also solicited basic research information regarding FAS, evidence that supported the causative relationship between alcohol and birth defects, and more importantly contradictory evidence “refuting the existence of fetal alcohol syndrome.” (U.S. Department of Treasury 1978) Concurrent with that call for comment, Congress held the first hearings devoted specifically to the issue of alcohol labeling in response to the risks of FAS, but it would not be the last.

“Alcohol Labeling and Fetal Alcohol Syndrome”: Congress Engages with the Problem

As the BATF dragged its feet on agreeing to alcohol warning labels, and government agencies were releasing initial warnings to educate pregnant women to the risk of FAS, Strom Thurmond reliably introduced his traditional alcohol health warning bill following the assembly of the 95th Congress on January 24, 1977. The bill (S.414) sought to revise the Federal Alcohol Administration Act in order to require a warning label on the health hazards and habit forming nature of alcohol that was more than 48 proof. That bill was the same he had previously introduced twice only to have it die in committee without a vote. Thurmond also declared his intent to append a warning label amendment to the Health Planning Act of 1977, but was persuaded to withdraw his

amendment when William Hathaway, chair of the Subcommittee on Alcoholism and Drug Abuse, promised to hold hearings on the subject in the following congressional session. (U.S. Senate 1978)

Senator Hathaway was on the record as being weary of the BATF's opposition to warning labels, stating in an interview that there was a "disturbing tendency of a regulatory agency to develop what amounts to an advocacy position for the industries they regulate." (Lewis 1977) The committee had changed its name and reorganized to just three members from the original eleven at the beginning of the 95th Congress, when new rules on how many committees and subcommittees a congressman could serve went into effect. (Lewis 1977) Despite the cut to membership and staff resources, fifteen days after the BATF published their solicitation in the *Federal Register* regarding alcohol warning labels, the Senate Subcommittee on Alcoholism and Drug Abuse convened in a session devoted to "Alcohol Labeling and Fetal Alcohol Syndrome" on January 31, 1978. The specific goal of the hearing was to examine the scientific evidence for FAS and weigh whether alcohol labeling should be adopted to alert the public to the risk of drinking during pregnancy, with representatives from the FDA, NIAAA, BATF, and a variety of researchers and practitioners in attendance.

Senator Thurmond's 1978 bill (S.1464) was the first that he modified to include reference to the risk posed by drinking during pregnancy. The proposed warning read: "Caution: Consumption of alcoholic beverages may be hazardous to your health, may be habit forming, and may cause serious birth defects when consumed during pregnancy" (U.S. Senate 1978). During the hearing Thurmond proposed extending the regulation to all alcohol rather than just hard liquor, and also to include the warning on alcohol

advertising. While he described his belief that “government cannot dictate the personal habits of the citizens of this country,” Thurmond viewed labeling as an educational tool to help citizens come to their own decisions about whether to drink. (U.S. Senate 1978: 5)

The hearing also included information on the most recent research agenda of the NIAAA regarding FAS, presented by the Administrator of the ADAMHA, Gerald Klerman. He described the numerous scientific studies being conducted, with 11 FAS-specific projects totaling almost a million dollars funded in 1978. Those studies included epidemiological prospective studies at three teaching hospitals (Loma Linda University, University of Washington in Seattle, and Boston University’s City Hospital), as well as animal studies to determine the specifics of alcohol’s teratogenicity. Further, Klerman introduced the intention of the ADAMHA to double the funding for fetal research to \$2.2 million in order to determine how often FAS occurred, whether there was a safe level of drinking, what sort of drinking patterns produced FAS, specific public health programs for women, and “proper methods of intervention to safeguard the fetus.” (U.S. Senate 1978: 16)

Klerman also introduced the first evidence of a spectrum effect of alcohol on development, recognizing that symptoms arose in infants exposed to alcohol that lacked the full expression of FAS. Elaborating on that public health concern, he noted that “it is reasonable to suspect that some adverse outcome less severe than the full syndrome may arise in other children of alcoholic women.” (U.S. Senate 1978: 13) Ernest Noble, then director of the NIAAA, was also at the hearing but presented very minimal commentary, speaking briefly on the NIAAA and presenting research that as little as one ounce of alcohol daily lowered fetal birth weights. For the most part, Noble deferred to his

superior, Klerman, to present the research and funding agenda of the NIAAA. Klerman assured senators and critics that the FDA, NIAAA, and ADAMHA were “in agreement that evidence is conclusive that alcohol has a deleterious effect on the fetus and there is a full-blown syndrome.” (U.S. Senate 1978: 97)

In light of that proclamation, the FDA Commissioner Donald Kennedy described his experience pressing the BATF to adopt labelling, outlining the complicated legal landscape between the BATF and the FDA regarding who had jurisdiction on the subject. Required to defer to the BATF, the FDA was currently asking for both ingredient labeling to warn of potential allergens and a health warning label to warn of the risks of FAS. Kennedy then continued to outline the most recent scientific knowledge regarding alcohol’s teratogenicity and took a position characteristic of the FDA: “Wherever there is a special population at risk, as pregnant women, it seems to me that the government has an obligation to inform the population of their special risk, and that obligation exists independently of what sort of prior efficacy judgment one makes about the warning.” (U.S. Senate 1978: 84) That statement illustrates both the FDA’s role as a consumer protector, especially as it applies to issues of fetal risk, while casting aspersion on the BATF’s public proclamation in the *Federal Register* that called into question the scientific veracity of FAS.

Also in attendance were BATF officials who took an opposing opinion from those agents in HEW that characterized FAS as a well-established risk. Director of the BATF, Rex Davis, was joined by Richard Davis, the Assistant Secretary for the Treasury Department that oversees all activities within the BATF. Both men took the opinion also supported by the Distilled Spirits Council of the United States (DISCUS) and the United

States Brewers Association that the scientific evidence for FAS was not conclusive and that warning labels were the wrong approach to the problem of women drinking during pregnancy. In a statement submitted to the hearing, DISCUS characterized labels as an overly simplistic solution to the complex problem of women who drink during pregnancy and outlined opinions of health professionals who disagreed with labeling. That included Morris Chafetz, former Director of the NIAAA, who characterized health warning labels as a “magic bullet” and a “cop-out,” suggesting that in excess even “water, oxygen or aspirin can cause death.” (U.S. Senate 1978: 257-258) Chafetz, a long-time advocate for responsible drinking over abstinence had since his resignation from directorship of the NIAAA become increasingly critical of the institute and a vocal opponent to warning labels, making claims like “paternalism is even more destructive than alcoholism.”

(Olson 2003)

Richard Davis began the BATF’s testimony, reiterating the Department of the Treasury’s jurisdictional authority over alcohol beverage labeling, and describing the notice of proposed rulemaking regarding labels to address FAS. The BATF had submitted that notice to the *Federal Register* fifteen days prior to the hearing on January 16, 1978, and required a 60-day comment period in order to ascertain the “maximum amount of information in the most efficient manner so that the best judgment can be made as to the appropriate course of action.” (U.S. Senate 1978: 110) While text of the proposal published in the *Federal Register* called for evidence refuting the existence of FAS and alternatives to labeling as a means of educating the public to the risks of FAS, in the testimony Secretary Davis remained agnostic on the matter. He assured the Subcommittee that the BATF’s call for alternatives to labeling did not exclude labeling.

Senator Hathaway pressed Secretary Davis to better define when the BATF would decide on such a measure several times, but received nothing more than vague platitudes for his efforts.

Rex Davis, Director of the BATF, then testified and followed his superior's lead on alcohol warning labels, summarizing his prepared remarks and reiterating much of what Secretary Davis emphasized. Director Davis outlined how the BATF approved labels on all alcohol for sale, emphasizing the scale of their work with 74,500 applications filed in 1977, of which 63,900 were approved. (U.S. Senate 1978: 127) He described the BATF's previous decision to forgo labeling as a result of the Education Commission of the States Task Force that "no evidence was found that such warning statements would prevent alcohol-related problems." (U.S. Senate 1978: 132) Senator Hathaway grilled Director Davis on labeling and alcohol advertising, questioning why a tax-collecting agency should be charged with health warning labels instead of the FDA.

Also on the witness panel were five medical professionals who testified on the most current science surrounding FAS and the need for public health responses to the problem. Two of the individuals, Henry L. Rosett and Robert J. Sokol both headed long-term, longitudinal studies to track the prevalence and symptomatology of FAS. Rosett, the first to testify, was an associate professor of psychiatry at Boston University's School of Medicine, which was chosen as one of the three NIAAA-funded hospitals to conduct epidemiological studies to examine FAS. Rosett described a study conducted at the hospital, in which heavy drinkers who persisted in their drinking habits throughout pregnancy gave birth to children with anomalies at almost twice the rate of nondrinkers. (Rosett et al. 1978)

He described obstetricians' general objection to asking pregnant women about their drinking habits, and described the need for rigorous, standardized means of screening for alcohol through an anecdote. He elaborated that, "...when one lady reported that she drank one glass of gin, a day, I asked, 'how large a glass?' She had been using a water tumbler." (U.S. Senate 1978: 142) He also held a less restrictive version of warning labels that emphasized heavy drinking, what he defined as more than six drinks per day, because "it would be a mistake to make every woman who ever had a drink during pregnancy feel guilty that this might have caused the damage that her child is having." (U.S. Senate 1978: 181)

Sokol, the assistant professor of obstetrics and gynecology at Case Western Reserve University, then testified about the longitudinal study conducted at Cleveland Metropolitan General Hospital over the course of three years. Across 8,000 pregnant women and infants born at the hospital, 114 were noted with alcohol problems with five FAS-affected infants, but the study also confirmed a spectrum of effects outside of the strict definition of FAS. However, Sokol also cautioned against rushing to interpret his limited results as, "The whole story is not in." (U.S. Senate 1978: 152) In terms of reducing FAS, Sokol suggested diagnostic education for practitioners and a public education campaign geared toward women most at risk of giving birth to a child with FAS.

Following the presentation of those longitudinal studies, three medical professionals presented information on comparable animal models that induced FAS, neurological symptoms indicative of prenatal alcohol damage, and maternal nutrition. (U.S. Senate 1978) Carrie L. Randall, assistant professor at the University of South

Carolina, presented a series of visuals in a slideshow demonstrating the alcohol-based abnormalities observed both in children diagnosed with FAS and in animal models such as mice and dogs. Bennett A. Shaywitz, associate professor of pediatrics and neurology at Yale University, then followed and explained the compendium of neurological symptoms being identified from alcohol-effects, including hyperactivity, inability to adapt, poor cognitive performance, concentration, impulse control, and attention span. The last witness, registered nurse Barbara Luke, a clinical specialist in maternal nutrition at the Sloan Hospital for Women at the Columbia Presbyterian Medical Center, reiterated that FAS was a distinct entity beyond any maternal effect. Luke recommended a series of initiatives to address the problem, including congressionally approved health warning labels, better training for physicians, a more robust federal public health campaign, and potential warning labels on advertisements as well.

The 1978 hearings concluded with the decision that as the BATF was the government agency with the authority to institute labeling, the subcommittee would reconvene after the 60 day call for comments on proposed labeling, with adequate time for the BATF to interpret the commentary and make recommendations on proposed alcohol beverage labeling. At the conclusion of the comment period, the BATF compiled and addressed labeling concerns in a publication titled “The Fetal Alcohol Syndrome Public Awareness Campaign: Progress Report Concerning the Advance Notice of Proposed Rulemaking on Warning Labels on Containers of Alcoholic Beverages, and Addendum,” released in February of 1979. (U.S. Department of Treasury 1979)

The report contained transcripts from the parties who submitted information, the analysis of which concluded that while a public awareness campaign regarding the risks

of FAS was needed, “because of the nature of the evidence now available as to the possible dangers, it is not yet clear that warning labels on alcoholic beverage containers would be the best tool to educate the public.” (U.S. Department of Treasury 1979) Shortly thereafter, DISCUS formed the Licensed Beverage Information Council, along with nine other industry entities with the stated intent to implement the sort of public education programs for FAS in lieu of labeling. The FDA had been unsuccessful in urging the BATF to implement alcohol beverage warning labels cautioning against drinking during pregnancy, and the alcohol industry seized the opportunity to influence the narrative with their industry-funded education initiatives.

“Labeling of Alcoholic Beverages”: Congressional Action as a Remedy to Administrative Turmoil

The NIAAA had a notorious reputation for being an unstable agency constantly on guard from budget cuts and administrative efforts to dissolve or transfer the duties of the NIAAA to other agencies. Federal alcoholism reporter Jay Lewis described the bureaucratic situation as follows, “...if the NIAAA alcoholism programs have not always worked well, it might be because the previous administrations did not want them to work at all” (Lewis 1979a). As such, pushing for labeling tended to garner less agency support than efforts to keep current research and treatment efforts solvent.

To illustrate that tension, following the 1978 hearings on alcohol warning labels and fetal alcohol syndrome, the Secretary of Health, Education, and Welfare, Joseph A. Califano, initiated a sweeping review of the ADAMHA under the direction of Gerald Klerman. Given that directive, Klerman identified grant review as an area ripe for

streamlining and argued that the combination of independent grant review processes across all three institutes in the ADAMHA would save time (those institutes being the National Institute on Alcohol Abuse and Alcoholism [NIAAA], National Institute on Drug Abuse [NIDA], and the National Institute on Mental Health [NIMH]). A memo regarding the plan leaked and spread like wildfire across the institutes. (Olson 2003) For institutes like the NIAAA that had spent their entire existence trying to assert independence in the face of budgetary cuts and attempts to appropriate it within other agencies, such suggestions were met with open hostility. Employees later characterized the process as ignorant to how Washington functioned, and as such the “brutally frank suggestions about how to manipulate the issue in order to circumvent resistance” failed before gaining any traction. (Smith 1978b)

That did not keep Klerman and Califano from shaking things up, though. Within five months of being appointed to the position of ADAMHA director, Klerman had fired all three Institute directors who reported to him: Bertram Brown from NIHM, Robert DuPont from NIDA, and Ernest Noble from NIAAA. Earlier that December, following his confirmation as Director of the ADAMHA, Klerman had fired Bertram Brown in what Califano claimed was an attempt “to invigorate the agency with new blood,” a move that earned the two the nickname vampires among the press. (Smith 1978b) (Olson 2003) In March of 1978 Noble discussed the NIAAA with federal alcoholism reporter Jay Lewis, and signaled his intent to stay on as director for an additional two years—one month later Klerman had fired him. (Lewis 1979b)

Many in the department viewed the firing as retribution for Noble’s opposition to Klerman’s attempt to centralize grant review, while others cited industry pressure

because Noble had shifted the NIAAA's agenda into industry-unfriendly territory. (Smith 1978b) (Olson 2003) Prior to resigning, Chafetz, the previous director of the NIAAA had funded a study to examine "responsible decisions regarding the use or misuse of alcohol" habits through the Task Force on Responsible Decisions About Alcohol on the Education Committee of the States through a \$1,626,674 NIAAA grant. (Lewis 1980a) The results of that study were published April 1977, a year after Noble had accepted the directorship. Instead of adopting those recommendations that echoed Chafetz's previous agenda on "responsible drinking," Noble shifted the NIAAA toward prevention. And the way he characterized prevention caused discord among both industry groups and alcoholism advocacy organizations. He advocated for measures such as alcohol beverage labeling and defined the measure of successful alcoholism programming as a reduction in overall per capita drinking, leading both industry and advocacy groups to unite in characterizing such measures as "neo-prohibitionism." (Lewis 1980a)

Alcoholism advocacy groups and industry were unlikely partners, but they shared a goal of not wanting to backslide into abstinence only prohibitionist arguments, for economic reasons in the case of industry, and for social reasons in the case of advocacy. The two entities had historically intermingled as well, with industry sitting on the board of directors for many alcoholism advocacy groups and infusing the organizations with money. Alcoholism advocacy journalist, Jay Lewis described the relationship as never being "seriously questioned until the warning label and related issues cropped up at the national level." (Lewis 1980a) Many advocacy organizations adopted an agnostic or openly hostile position toward labeling, arguing that labels would increase stigma and shame among a vulnerable population that they had worked so hard to normalize as

patients afflicted with a disease. Initially, far from using a warning label to indemnify themselves from legal challenge as the alcohol industry later learned from the example of cigarettes, industry groups opposed labeling on the grounds of its cost to implement and low perceived efficacy. Any decrease in sales arising from a health warning label likely also motivated such a position.

Industry and advocacy again combined forces to criticize Califano's release of the "Third Special Report to the U.S. Congress on Alcohol and Health," dated June 1978 but in fact released on October 17, 1978. Unlike previous reports in which the NIAAA had hosted press conferences and traveled around the country to publicize the findings, Califano had quietly released the report without alerting the media, and two days after Congress had adjourned in anticipation of congressional elections. (Olson 2003) That appears to be a calculated move considering how strongly industry and advocacy groups criticized the report. Sam Chilcote, Jr., President of DISCUS, perhaps best describes industry's general response, characterizing the report as a "blueprint of the neo-prohibitionists...a litany of gloom reminiscent of the darkest propaganda about demon rum." (Lewis 1980a) Likewise, the National Council on Alcoholism, the National Coalition for Adequate Alcoholism Programs, and the Alcohol and Drug Problems Association all criticized the report, taking umbrage at the suggestion that alcoholics cost the US \$43 billion annually as a result of their disease and limiting availability of alcohol was the solution over medical intervention. (Lewis 1980a)

As the 96th Congress convened in January of 1979, new leadership shifted the status quo in alcohol labeling legislation. After Senator Hathaway suffered defeat in reelection, Donald W. Riegle, Jr. Under his energized leadership, the Subcommittee

within a single month introduced the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act Amendments of 1979 (S.440) to approve continued funding for the NIAAA. (Olson 2003) That was much different than the first month of Hathaway's tenure several years earlier, when he had allowed the appropriations bill to lapse upon his assignment as subcommittee chair. Around the same time, Senator Thurmond again introduced his traditional health warning label on 48 proof and higher alcohol (S.427) on February 2, 1979. As usual, the bill was referred to committee where it died without garnering a hearing or a vote.

Senator Thurmond then approached labeling from another perspective, by proposing an amendment to Senator Riegle's NIAAA reauthorization bill during hearings. (U.S. Senate 1979a) After Thurmond had read his statement in support of Amendment No. 125, which was co-sponsored by Senator Orrin Hatch, Senator Riegle surprised those in attendance by accepting the amendment. (Wall Street Journal 1979) Instead of deferring the amendment until a hearing on the matter could be conducted, as was the expected response to such a proposal, he considered the 1978 subcommittee hearings on FAS and alcohol beverage labeling to serve in that capacity. Senator Riegle seemed particularly disturbed that the alcohol industry had not accepted the invitation to attend those hearings, as "sending a statement is not the same as being there in person to testify," and promised hearings within the next congressional session on the subject regardless of the outcome of the amendment. (Olson 2003)

Following the assurance that more hearings regarding alcohol beverage labeling were imminent, Thurmond's amendment survived a motion to table with 68 senators in favor of allowing the amendment to stand and 31 voting to scrap the proposal. The

amendment then advanced to the House of Representatives, and the Subcommittee on Alcoholism and Drug Abuse published a comprehensive report that gathered scientific evidence and opinions on labeling to serve as a resource for the House. (U.S. Senate 1979c) However, labeling proved to be a symbolic victory that was soon discarded in the House as industry representatives had more time to lobby for its removal than they had during the Senate hearings. Alcohol beverage labeling legislation had “passed” after a decade of work on Thurmond’s part, but the victory was short lived and soon congress returned to hearings on the matter.

Also emerging from the NIAAA reauthorization hearings was an appointment of a new director of the NIAAA, following Senator Riegle’s questioning of Klerman during testimony. (U.S. Senate 1979a: 36) After almost a year of acting director Loran Archer, on April 15, 1979, John A. DeLuca became the new Director of the NIAAA. DeLuca, a young 35-year-old without a medical or scientific degree, was the former acting director of the New York State Division of Alcoholism and Alcohol Abuse. He had previously encountered controversy in that position surrounding grant review, with some accusing him of favoritism and using “fear tactics” regarding funding for alcoholism rehabilitation programs. (Rule 1978) In an interview shortly after his appointment, DeLuca elaborated on the shift in policy at the NIAAA and distanced himself from Noble’s previous ambitious agenda to limit alcohol stating that, “The public health model approach should not be defined in any way as a neo-prohibitionist approach.” (Lewis 1979c)

With HEW still feeling the pushback from alcoholism advocacy groups and industry following their publication of the third special report on alcohol to Congress, shifting away from accusations of neo-prohibitionism by appointing DeLuca was a

politically expedient position. However, that measure came too little too late for Califano, who was asked to resign shortly thereafter, along with the Secretary of the Treasury, W. Michael Blumenthal. The Carter administration had initially stressed “the independence of Cabinet secretaries, many of whom had almost total freedom in choosing their top assistants.” Yet, for senior White House aides, that approach was viewed as “a costly mistake that left the White House impotent to implement presidential decisions.” (Walsh 1979) That mistake the Carter administration hoped to rectify by orchestrating the resignation of more than just those two secretary positions, with multiple other individuals resigning because as one White House source noted, “nothing short of a wholesale revamping of his administration would salvage his Presidency.” (Smith 1979)

The general attitude surrounding both the firing of Califano and the reorganization of the Carter administration was one of anxiety and worry among individuals and organizations recommending alcohol policy at the federal level. (Olson 2003) Califano had angered not only the powerful alcohol industry but the tobacco interests as well, prompting Senator Silvio Conte (R-MA) to described Califano as having “the temerity to place the health of our citizens above the financial interests of the people, the States and the political power brokers who stand to gain from the continued production and consumption of tobacco and alcohol.” (Olson 2003) In short order, Patricia Roberts Harris, former Secretary of Housing and Urban Development was announced as Califano’s replacement.

In spite of administrative turmoil, the Subcommittee on Alcoholism and Drug Abuse soon followed through with its promise of hearings devoted to alcohol warning labels and on September 14, 1979 held “Labeling of Alcoholic Beverages.” (U.S. Senate

1979a) Because Senator Thurmond's alcohol warning bill had technically passed as an amendment to NIAAA reauthorization, Senator Henry L. Bellmon (R-OK) introduced S.1574, "A bill to amend the Federal Food, Drug and Cosmetic Act, the Federal Alcohol Administration Act, to provide for Health Warning Labels on alcoholic beverages," to serve as the pending bill under question in the hearings. The hearings represented a more labeling-centric discussion, with several industry interests on hand to discuss the prospects of labeling. While the risks of drinking during pregnancy were still addressed at length, unlike with previous hearings they did not comprise the sole motivation for labeling. In fact, as the hearings demonstrated, the deviant form of drinking that required public health intervention in the form of labels expanded to include youth drinking and drunk driving in addition to FAS.

Senators on the Subcommittee demonstrated the pro- and anti-labeling arguments well in their opening statements. Senator Howard M. Mezenbaum (D-OH) highlighted the \$43 billion national cost of alcoholism, stating that "no dollar figure can reflect the human suffering that the abuse of alcohol has brought to millions of Americans" and that "if a label persuades one pregnant mother not to drink—if it prevents the birth of one retarded child—then I think that such a requirement is worthwhile." (U.S. Senate 1979c: 5) While Senator Gordon Humphrey (R-NH) facetiously suggested the label read: "Warning: The US Senate has determined that alcohol may be hazardous to your health" (U.S. Senate 1979c: 3). And Senator Orrin Hatch (R-UT), characterized labels as "a quick fix and legislative cop out" that "portends unnecessary over-government regulation at a time when the government needs to back off from its stranglehold on business and its paternalistic attitude toward consumers." (U.S. Senate 1979c: 4)

Following those introductions, newly appointed director of the NIAAA, John R. DeLuca, testified in his first appearance in the position. He presented the opinion of the NIAAA that after rigorous study of how alcohol impacted animal models and long-term epidemiological studies, the NIAAA had concluded that FAS existed. The only ambiguity that remained was whether there was a safe level of consumption during pregnancy, as there were difficulties determining how dosage and timing, or maternal and environmental effects of consumption impacted pregnancy. As there was no way to figure out a safe level of consumption or how much was too much, the NIAAA cautioned against consumption during pregnancy. From that perspective, he advocated for labeling as a result of the evidence, stating that “we require warnings on many drugs and other products with less dramatic effects and less potential for harm than alcohol.” (U.S. Senate 1979c: 21) DeLuca was also quick to stress the cooperative attitude of industry interests who were launching education initiatives regarding youth drinking, drunk driving, and the risks of drinking during pregnancy.

The chief counsel for the FDA, the ironically named Donald Beers, was also in attendance to offer a legal opinion on the jurisdictional authority of the two regulatory agencies that had been deadlocked over implementing alcohol beverage labeling. Beers adopted the formal position of the FDA, that alcohol warning labels were needed, and that it was the responsibility of the BATF to implement that warning either voluntarily or as a result of congressional requirement. Beers viewed the BATF, an agency whose primary goal is tax collection, as incapable of addressing the debate over alcohol warning labels because they did not have a strong stake in the protection of health like the FDA. Both departments had just lost their secretaries under the Carter administration

reorganization, and despite Beers' testimony to the contrary, the differences between the two departments on the goal of labeling would soon dissipate in a 1981 joint report.

In addition to the regulatory agency representatives, the medical experts advocating for warning labels included Dan Beauchamp, professor of public health at the University of North Carolina medical school, Sheild Blume, director of New York State's Division of Alcoholism and Alcohol Abuse, and J. Takamine, an internist from Lost Angeles presenting the American Medical Association's recommendations. Beauchamp highlighted the fact that he could not recall a "single case where the claim that the public has a right to know is seen as a paternalistic interference with the public's individual liberty," and recalled his own family's struggle with a child born disabled and the self-blaming questions that arose under those circumstances. (U.S. Senate 1979c: 141) Blume railed against the prevailing theme of the hearings, which characterizes government paternalism in a much different light, that women are fragile, guilt-ridden sex who "must be protected from reality." (U.S. Senate 1979c: 308) While Takamine characterized the need for alcohol warning labels as paramount, "not in terms of dollars and cents, but in terms of human lives." (U.S. Senate 1979c: 325)

Also notable in the 1979 hearings were the number of expert witnesses with medical backgrounds testifying against alcohol warning labels. That included Chafetz, former Director of the NIAAA, who since his resignation had founded the Health Education Foundation, a non-profit that examined issues related to alcohol and health, funded in part by the alcohol industry. (Grimes 2011) Chafetz took the same position on responsible drinking that he had advocated as director, characterizing the concern over

limiting and regulating alcohol as a “hysteria,” stating that “alcohol abuse and alcoholism is a people problem, not a substance problem.” (U.S. Senate 1979c: 78)

That concern with a product and placing limitations on alcohol adhered to the same argument that many of the private industry interests also advocated: alcohol can be beneficial in moderation, treatment and recovery are personal and individual, and warning labels exacerbate stigma and do not work. Chafetz was joined in his dissent by David Pittman, professor of sociology at Washington University, and Jack Mendelson, professor of psychiatry at Harvard Medical School. They were both against adopting warning labels to alert pregnant women to the risks of FAS, citing the need to treat alcoholism as a disease and not a moral failing on the part of the alcoholic woman to control her drinking. Although, the theme of consulting with an individual’s physician suggests that there was also an unspoken fear that authority and knowledge surrounding alcohol-related issues were being usurped at the federal level instead of dealt with on an individual basis in the confines of a doctors’ office.

Among the industry representatives present and several Congressmen arguing against the need for labeling, the theme of government paternalism and infringement on personal liberties was prevalent. Representatives from the U.S. Brewers Association and the Wine Institute echoed concerns presented by Sam Chilcote, President of the Distilled Spirits Counsel of the United States (DISCUS), who characterized the issue as such: “Will our nation’s fight against alcoholism be focused on helping people or labeling products?” (U.S. Senate 1979c: 159) He then went on to describe the 20 years of research, 372 projects, and 150 research centers who received funding from DISCUS’s

scientific advisory council, and the 7 million dollars spent last year on public service announcements.

Although the argument was one that was characterized as having a positive impact, the parallels between private industry's "manufacturing consent" and "manufacturing controversy," as viewed in the previous decade with tobacco, is unmistakable. The comparison is notable as Chilcote also served as the chairman of the Beverage Alcohol Information Council, formerly the Licensed Beverage Information Council, which represented ten alcohol-related interests and served as the primary means of funding and disseminating more industry-friendly education campaigns.

At the end of the highly contentious, industry-driven 1979 subcommittee hearings, Congress required the FDA and the BATF, the two agencies who had been dueling on the subject of alcohol labeling, to collaborate on a joint research venture. (Public Law 96-180, 45 Fed.Reg. 12557). Both the Secretary of the Treasury and the Secretary of Health, Education, and Welfare were directed by Congress to report on "(1) The extent and nature of birth defects associated with alcohol consumption by pregnant women; (2) The extent and nature of other health hazards associated with alcoholic beverages; and (3) The actions which should be taken by the Federal government." (45 Fed.Reg. 12557) That required the FDA and BATF to collaborate on a report to definitively establish which agency was responsible for alcohol labeling. It also required the two agencies to aggregate the current state of science related to all health impacts of alcohol, not just FAS research, and to devise adequate public health solutions.

Surgeon General Warning: Pregnant Women and the Risks of Drinking During Pregnancy

In the years following the identification of FAS, scientists continued to refine the definition of the syndrome and its broader public health implications. Researchers accomplished this by publishing case studies to aggregate a more robust symptomatology, and address comorbid or rival causes for symptoms observed. They also reported on recent political developments in editorials, argued for public health and policy proclamations, and published review articles that aggregated the rapidly shifting state of science to reflect the most current research available. In the years following the initial diagnosis, longitudinal epidemiological studies funded largely by the NIAAA definitively confirm that alcohol acted as a teratogen during development and researchers began to examine data from experiments on animal models to help determine aspects of mechanism, timing, and severity of alcohol's effect in utero. That certainty would be reported in the 1981 joint report between the Secretary of the Treasury and the Secretary of Health, Education, and Welfare, leading to a Surgeon General warning on the topic in 1981.

In the years directly following the initial publications on FAS, researchers published case studies in an attempt to substantiate or repudiate the existence of the syndrome. (Bianchine and Taylor 1974) (Ferrier et al. 1973) (Tenbrinck and Buchin 1975) However, starting in 1976 few articles focused on the existence of the disorder, as researchers came to a consensus that alcohol caused a specific set of birth defects in children exposed in utero. Instead, dissent flourished over the particulars regarding the mechanism of alcohol's effects on prenatal damage and how aspects of maternal biology

and environment may overlap with or impact the expression of symptoms. Disagreement over the prevalence of FAS and whether fetal alcohol effects could be observed in children born to moderate and light drinkers also increased. That healthy caution and fact-checking, while essential to producing robust and trustworthy scientific findings, complicated the potential for an early scientific consensus surrounding whether policy and public health measures should be aimed solely at female alcoholics or whether health warning labels were appropriate to reach a broader public audience. Rightfully so, as in the early 1970s scientists had not figured out what impact drinking had on pregnancy with respect to dosage, duration, frequency, or timing related to different stages of development, or differences between and across women.

Even as Noble, Director of the NIAAA, offered testimony regarding FAS in a 1976 congressional hearing specific to problems faced by female alcoholics, researchers were already shifting toward identifying overlooked symptoms of the syndrome. Many of those early articles published to medical journals in the mid-1970s later became incorporated into larger areas of alcohol-related research such as alcohol-related brain wave activity, defects of the liver, ophthalmic impacts, and urogenital abnormalities. In 1976, *The Lancet* published an article on the EEG patterns displayed in FAS-affected infants with abnormal brain waves, closer to epileptic patterns than normal rest patterns. (Havlicek and Childaeva 1976) Researchers working in that area later used EEGs as a tool for examining what areas of the brain were functional in FAS-affected versus non-affected infants and children, noting similar disrupted rest patterns in the brain. (Mattson et al. 1992) A variety of alcohol-related birth defects were also reported around the same

time related to the liver, eyes, urinary tract, and genitals. (Hornstein et al. 1977) (Habbick et al. 1979) (Khan et al. 1979) (Gonzales 1981) (McGivern 1984)

For every publication presenting a potentially new characteristic of the syndrome in major medical journals, there were studies scrutinizing the diagnosis and suggesting alternate possible explanations for certain symptoms observed. (Qazi and Masakawa 1976) (Hurst 1982) (Qazi and Milman 1983) Issues of malnutrition and marijuana were two such concerns that later appeared in congressional testimony, along with a contentious article on a reported case of FAS in a child whose parents had stopped drinking. (Scheiner et al. 1979) That article presented the possibility that alcohol may impact sperm and ova in the long-term, persisting even after parents ceased drinking. The case study involved two former alcoholic parents active in AA who claimed to have given up drinking a year and a half prior to the birth of a child with FAS. Those scientists embraced a similar line of reasoning as researchers of the early twentieth century who used animal models to classify how alcohol caused feeble-mindedness over generations. While the authors speculated on the veracity of the mother's claims of abstinence, they also suggested that perhaps alcohol affected the germ plasm, causing hereditary damage in the absence of uterine exposure to alcohol.

The purported case of FAS in a child born to former alcoholics set off a flurry of activity in the letters to the editor section, with letters questioning both the honesty of the woman reporting abstinence and the competence of the researchers classifying FAS. One letter addressing the study was published by physicians John M. Graham, Jr., and David W. Smith, who was one of the two physicians that originally defined FAS. (Smith and Graham 1979) In the article they recalled hearing the authors present the same work at

the National Foundation Conference on Birth Defects a month earlier in Chicago, where they also took issue with the diagnosis and conclusion. In the letter they explained their disappointment at the publication of such half-truths: “We consider it most unfortunate that single cases of this type are published when the clinical diagnosis is insecure but which may lead to a conclusion that the risk of fetal alcohol syndrome can persist beyond the alcoholic status of the mother and/or that the alcoholic status of the father may cause the fetal alcohol syndrome.” (Smith and Graham 1979) While the possibility was rigorously refuted in counter letters, that did not stop expert witnesses testifying during congressional hearings from latching on to the implications of a child being born with FAS in the absence of alcohol. Such a case study was later used by industry representatives in congressional hearings to help manufacture uncertainty surrounding the robustness of FAS as a diagnosis and the need for alcohol warning labels as a public health solution.

Review articles began to appear in medical journals as early as 1978, aggregating the current state of FAS-related science for a broad body of practitioners (Clarren and Smith 1978) (Streissguth et al. 1980) (Eckard 1981) (Kalter and Warkany 1983) One rebuttal to a 1978 review article suggested that there was still too much uncertainty to be circulating such a diagnosis as fact, referring to FAS as “polydrug-abuse-nutritional-deficit-stress-induced fetal syndrome” to which the authors of the article asserted that the “fundamental fact should no longer be doubted in the medical or lay community.” (Mendelson 1978) (Clarren and Smith 1978) That growing certainty surrounding the existence of FAS as a standalone entity irrespective of other maternal or environmental

effects continued to grow as testing in animal models duplicated much of what physicians observed in the clinic.

The teratogenic effects noted in laboratory models of animals tested increased through the late 1970s and early 1980s, with the first review article on those studies published in 1980 which illustrated a dose-response curve of fetal alcohol effects. It showed that the more alcohol introduced, the more severe the expression of FAS-related symptoms. (Streissguth et al. 1980) Scientists had demonstrated the toxicity of alcohol both in vitro and in vivo, and by 1981 researchers had published the first mouse model illustrating how alcohol impacted embryogenesis. (Brown 1979) (Diaz and Samson 1980) (Sulik et al. 1981) (West et al. 1981) (Mukherjee and Hodgen 1982) In that publication, the researchers noted fetal alcohol effects in mice in the developmental stage equivalent to three weeks in humans, noting that many women may not even know they are pregnant at that stage. (Sulik et al. 1981) They also noted that based on their patterns of alcohol distribution among developing mice, binge or social drinking patterns may prove as detrimental to fetal development as heavy, sustained drinking.

The certainty surrounding FAS as a diagnosis was further substantiated by the release of numerous epidemiological studies being conducted at the same time period as those animal models, which confirmed a higher number of birth defects in children born to heavy drinking mothers. Three initial longitudinal studies were funded by the NIAAA at Loma Linda University in California, the University of Washington in Seattle, and Boston University's City Hospital in Massachusetts, and those were joined by studies in Cleveland. (U.S. Senate 1978) (Sokol et al. 1980) Results of those studies indicated that FAS occurred in from 0.6 to 3.1 infants per 1,000 born, while alcohol-related birth

defects and neurodevelopmental disorders bumped that number as high as 5.9 births per 1,000. (Hanson et al. 1978) (Hingson et al. 1982) (Ouellette et al. 1977) (Sokol et al. 1980) (Sokol et al. 1986). The American Medical Association published a notice in 1977 that even moderate drinking could impact fetal development, but by the mid-1980s research had confirmed that even one to two drinks a day led to a substantial increase in an infant being diagnosed with symptoms of FAS. (American Medical Association 1977) (Mills et al. 1984) Those measures called into question the idea of a “safe level” of drinking that industry interests had been using as an argument against future research into alcohol’s effect on the fetus and adequate policy recommendations.

In 1982, the American Medical Association’s Council of Scientific Affairs urged physicians to do a better job of screening women for alcohol problems and referring appropriate treatment when necessary, as a means of decreasing the incidence of FAS. (Council on Scientific Affairs 1983) The AMA cited their open letter from 1979 where they joined with the American Congress of Obstetricians and Gynecologists in endorsing the NIAAA’s physician-based education treatment. The AMA offered the advice that doctors should “encourage them [pregnant women] to decide about drinking in light of the evidence and their own situations,” while also being “explicit in reinforcing the concept that, with several aspects of the issue still in doubt, the safest course is abstinence.” (Council on Scientific Affairs 1983) The report ended with the call for more long-term longitudinal studies, educational campaigns, and increased physician involvement in educating the public.

Indeed, while screening remained the best way of identifying an at risk population and prenatal counseling for heavy drinkers had proved successful at reducing their intake,

physicians continued to express reserve about asking patients about their alcohol consumption habits and referring them to appropriate treatment centers. (Rosett et al. 1983) (Weiner et al. 1983) In 1984, then director of the NIAAA, Robert Niven, published a piece in the *Journal of the American Medical Association* urging physicians to create a more robust means of identifying and treating women at risk of giving birth to a child with FAS. (Niven 1984) Niven pressed physicians to increase their screening, make connections among treatment programs to refer women in need, encourage alcoholics to join AA and Al-Anon, and even to screen for drinking problems in teenagers given the risk of unplanned pregnancy. Also, Niven advised physicians to avoid telling pregnant women that abstinence is the only course of treatment, as even a reduction in drinking for those addicted was beneficial to no action. He admonished physicians who “prescribed” alcohol as a therapeutic aide, and those who even in the face of increasing evidence, still did not inform their pregnant patients about the risks of FAS.

Among the many journals reporting on FAS at the time, *Science* holds the distinction of also running articles written by science journalists that addressed health warning advisories surrounding FAS. (Smith 1978a) (Smith 1978b) (Smith 1979) (Kolata 1981) As the voice of the American Association for the Advancement of Science, the largest and broadest scientific society, *Science* represents a prestigious and exclusive publication. That they would use their limited print space to update their general membership on the status of alcohol beverage label warnings multiple times speaks to their perception on the importance of the topic.

In 1978, the journal criticized the BATF in “Agency Drags Its Feet on Warning to Pregnant Women,” reiterating a point many in the FDA and Congress had made earlier

that an agency charged with taxation is at odds with regulating a health warning label as well. Shortly thereafter, the journal turned its ire to the Department of Health and Human Services in “Political Fracas over Peer Review Is Factor in Firing of NIAAA Director,” in which it described the “bitter” political fight between Carter administration appointees, such as Califano and Klerman, and directors of substance abuse research institutes, like Noble of the NIAAA. Looking for an “infusion of new blood” the pair became known as “vampires,” after firing the directors of the NIAAA, NIDA, and NIHM in retribution for opposition to centralized peer review of all agencies under the Alcohol, Drug Abuse, and Mental Health Administration.

Following those early proclamations, the journal reported on the repeated failure of agencies and congress to label alcohol. In 1979, the journal described the BATF’s decision to forgo labeling but engage in an educational campaign to “indemnify themselves against lawsuits.” (Smith 1979) Two years later, the journal expounded upon the “slippery slope” reasoning many used when discussing the Surgeon General’s 1981 warning that pregnant women abstain from drinking. (Kolata 1981)

Much of that scientific information and history about labeling was included in the 1980 joint report released by the Department of Health and Human Services and the Department of the Treasury. The report represented a rare moment of unity between the two departments whose agencies had debated for years on the need for alcohol ingredient and warning labels. Instead of continuing their adversarial position on the matter, the two agencies found common ground: not labeling. “Given these considerations it appears that the risks may be too complex to communicate on a label.” (U.S. Department of the Treasury and U.S. Department of Health and Human Services 1980: 40) The Carter

administration had succeeded in reorganizing their administration to eliminate discord, but failed in moving the agencies toward a better reflection of the administration's platform. The Carter administration prefaced the joint report with a disclaimer that the policy recommendations did not reflect the position of the administration, which considered labeling to be "a useful and cost-effective means of informing the public about health hazards in appropriate situations." (U.S. Department of Treasury and U.S. Department of Health and Human Services 1980)

To reach their final decision against labeling, the departments consulted with experts across various topics from medicine to communications and industry to advocacy, to hear from a variety of viewpoints and areas of expertise. (U.S. Department of Treasury and U.S. Department of Health and Human Services 1980) Those meetings helped to aggregate the current state of science, with irrefutable evidence of FAS with lesser alcohol effects emerging from even moderate drinking. The report highlighted the need for more study on the dose-response relationship, the effects of different patterns of drinking, specific periods of increased vulnerability during prenatal development, and any genetic or maternal influences on symptoms. The report also elaborated on a variety of other alcohol-induced health hazards such as cancer, cirrhosis, pancreatitis, depression, malnutrition, hormonal issues, cognitive impairment, drug interactions, and traffic deaths, while also making note of a lowered instances of heart disease in moderate imbibers.

Among the series of recommendations that arose to address those health issues, both departments agreed to improve their public education campaigns, through the NIAAA's Clearinghouse for Alcohol Information and the BATF working in conjunction with the Beverage Alcohol Information Council's Fetal Alcohol Awareness Campaign.

(U.S. Department of Treasury and U.S. Department of Health and Human Services 1980)

The Department of Health and Human Services also agreed to combine forces with their newly separated partner, the Department of Education, to devise curricular materials on problem drinking. Also, the Department of the Treasury would pressure industry to revise their voluntary code of conduct for advertising, relying on compliance instead of suggesting regulation. And both would work with the National Highway Traffic Safety Administration in the Department of Transportation, to address the problems of drunk driving, a problem that would soon see the formation of a Presidential Commission on Drunk Driving in 1982 to “fight against the epidemic of drunk driving on the Nation's roads.” (Reagan 1982)

The Department of Health and Human Services also reinforced their commitment to ensuring that those public health campaigns reach medical professionals in a more focused manner. (U.S. Department of Treasury and U.S. Department of Health and Human Services 1980) To accomplish that they agreed to develop alcohol-related health curricula for continuing education, create standards for certification, and evaluate screening methods to detect alcoholism and potentially intervene. Further, the FDA would shift their focus on alcohol warning labels to address adverse interactions from prescription and over-the-counter drugs. In terms of policy, the authors recommended that Congress pass a bill to amend the Federal Alcohol Administration Act and require clearer labeling for the percent alcohol by volume. They also suggested that the Surgeon General issue an advisory if necessary based on the health problems enumerated in the report. (U.S. Department of Treasury and U.S. Department of Health and Human Services 1980)

Conspicuously absent from the final recommendations was anything related to health warning labels on alcohol for sale, as the authors took the opinion that a concise, clear, specific recommendation was impossible given the complexity of FAS and alcohol-induced health issues. And that creating labels would be costly and increase guilt and stigma among drinkers. Shortly following that report, the Office of the Surgeon General released the warning cautioning pregnant women to abstain from drinking: “According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects.” (U.S. Department of Health and Human Services 1981) The highest medical official in the nation had announced that FAS existed, and that women should abstain from drinking to avoid giving birth to a child with defects. However, it would take an additional seven years for labels with a similar warning to appear on alcohol for sale in the US.

CHAPTER 6

THE MORAL AGENDA: FEDERAL ALCOHOLISM POLICY AND THE FINAL PUSH TOWARD LABELING

As the Reagan administration replaced the Carter administration in the early 1980s, the character of the federal alcoholism agenda morphed to incorporate a new preoccupation with the morality of the drinker. A new presidential agenda had always brought change to the federal landscape, and federal alcoholism programs were no stranger to budget cuts from fiscal conservatives. But the brand of social conservatism that characterized President Reagan's platform created an environment ripe for federal expansion into alcohol-related areas that focused more on the victims of the alcoholic's behavior than the personal reformation of the alcoholic.

Prioritizing small government through aggressive cuts to social programs, and focusing on the deregulation of industry also had complicated the implementation of health warning labels on alcohol. Health warning labels were a paradox in the Reagan administration, both rebelling against de-regulation tenets of fiscal conservatism, while adhering to socially conservative impulses to legislate morality. Labeling representing a paternalistic intrusion into an individual's autonomy, but served to codifying socially unacceptable drinking behaviors.

The chapter begins by examining the historical lead up to that phenomenon, in "The Rise of Reagan: The New Right and the Focus on Alcohol as a Social Vice." For much of the 1980s, alcohol health warning labels as a public health response did not garner broad support. Severe budget cuts, disinterest at the subcommittee level, and

fracture among advocacy organizations all impacted the previous decade's agenda to treat and destigmatize alcoholism. The power vacuum created in the absence of a strong national agenda for dealing with issues of alcoholism allowed the New Right to look beyond FAS to identify and react to other types of problematic drinking. Among those issues, driving drunk, youth drinking, and FAS among indigenous populations joined FAS as issues that required engagement with social and moral evidence to craft appropriate public health policy.

The early to mid-1980s also saw controversy arise over levels of drinking, both whether alcoholics required complete abstinence from alcohol to recover, and whether pregnant women had to completely abstain from drinking or if a threshold existed below which there was no measurable developmental defects. The second part of this chapter, "Controlled Drinking and a 'Safe Level' of Drinking During Pregnancy" examines those controversies, particularly as such issues arose during the last FAS-specific congressional hearing in 1982, "Effects of Alcohol Consumption During Pregnancy." That hearing best demonstrates the "manufacturing controversy" that characterized industry-obfuscated cigarette research in the mid-twentieth century. Among industry objections to health warning labels, they claimed that the uncertainty was simply too complex to convey in a label, and would lead to confusion and anxiety among pregnant women.

That 1982 hearing represented the last time Congress engaged with warning labels or FAS until a final legislative hearing titled simply, "Alcohol Warning Labels" in 1988. The final section of this chapter, "To Educate and Protect: How Industry Ceded the War on Labeling to Buffer against Legal Challenges," examines how industry interests accepted labeling as a means of insulating itself against legal redress. The concerns

addressed in the proposed five rotating alcohol warning labels expanded public health concerns to include FAS, driving while drunk, drug interactions with alcohol, youth drinking, and general health concerns such as cancer and cirrhosis of the liver. Despite the erosion of industry opposition, successful labeling required a non-partisan group of four senators consistently petitioning from 1986 onward. Among those legislators was Senator Strom Thurmond, whose twenty year petition for health warning labels on alcohol finally came to full fruition in 1988.

The Rise of Reagan: The New Right and the Focus on Alcohol as Social Vice

President Ronald Reagan won election over a second Carter term, and the broad dissatisfaction with the Carter administration also had the effect of ushering in a wave of socially conservative Republican congressmen. Following 26 years of democratic leadership, the Senate flipped to Republican control in January of 1981. That rise of the “New Right” within the Republican Party, focused on social issues along with economic conservatism, is exemplified by President Reagan’s agenda as he engaged with issues surrounding drug and alcohol abuse.

That also meant the Subcommittee on Alcoholism and Drug Abuse welcomed the appointment of a new chair, Republican Senator Gordon Humphrey of New Hampshire, longtime opponent of health warning labels on alcohol. Senator Humphrey, chair of the Subcommittee on Alcoholism and Drug Abuse, cited his motivation for entering politics from a career as a former pilot to be “disillusionment with the Great Society and all the programs it had spawned” that had led to more “government intrusions into our lives right down to the family.” (Kaiser 1979) Because federal alcohol control arose following

President Johnson's Great Society initiatives, Senator Humphrey represented an odd choice for the position. As the only member of the Subcommittee on Alcoholism and Drug Abuse to vocally oppose requiring health warning labels on alcohol, Senator Humphrey predictably focused the Subcommittee in different directions throughout his tenure as chair.

One of the first subcommittee hearings Senator Humphrey held in 1981 examined federal drug and alcohol programs and exemplified his "New Right" skepticism of government. Motivated by his commitment to be the "toughest skinflint in the Senate" and "bring under control spending and inflation," Humphrey held an oversight hearing that focused on both the NIAAA and NIDA. (Kaiser 1979) Held July of 1981, the hearing examined the agencies' financial and programing commitments, and followed in the wake of the Surgeon General's FAS advisory released earlier that month.

Related to the risks of FAS identified by the Surgeon General, Senator Humphrey conceded that, "research can be important in the formulation of new policies and in the creation of new prevention and treatment approaches." (U.S. Senate 1981: 2) Senator Humphrey took the opinion that the "federal government does not have a monopoly on the wisdom needed to address major national problems" and looked to the states, universities, and industry to supplement or replace NIAAA initiatives. (U.S. Senate 1981: 3) That push toward diverting authority from the federal government to the states dramatically affected the NIAAA and the push toward labeling.

Loran Archer, filling in as the Acting Director of the NIAAA, justified the programs funded by the NIAAA at the administrative oversight hearing under pressure of looming budget cuts. Former NIAAA director John DeLuca had resigned after President

Reagan's win, citing his lack of scientific or medical credentials as the reason for his resignation. He claimed that his background was incompatible with Reagan's vision for the NIAAA, which shifted away from alcoholism treatment programs and research surrounding social issues and toward more biomedical research. (Olson 2003) At the hearings Archer discussed the NIAAA's programs to target women and educate them to the risks of drinking during pregnancy, a strategy he hoped to be able to modify in order to address other high priority alcohol issues such as youth drinking, driving drunk, and alcohol's interaction with other drugs.

Among the approaches to combatting those high priority alcohol issues, health warning labels had lost political traction following the 1980 joint report to the President and Congress by the Department of the Treasury and the Department of Health and Human Services. (U.S. Department of the Treasury and U.S. Department of Health and Human Services 1980) The agencies authoring the report agreed that FAS presented a substantial public health risk, but that health professionals should be the population targeted for education rather than the general public. The agencies did suggest that the amount of alcohol by volume be reflected on labels as a percentage, and that instead of including a FAS warning on alcohol, the Surgeon General should release a warning about drinking during pregnancy. The agencies' joint recommendations proved contentious enough that the Carter administration included a preface to the report explaining that such opinions did not represent the administration's stance, though that soon changed with the incoming Reagan administration.

The Reagan administration not only took the opinion that labeling was an unnecessary regulatory oversight that should generally be avoided, but that the agency

responsible for alcohol labeling, the BATF, should be abolished. The administration cited budgetary restrictions and attempted to dissolve the agency, shifting its law enforcement responsibilities to the Customs Office and Secret Service, and requiring states to assume full regulatory oversight of alcohol. (U.S. House of Representatives 1981) (U.S. Senate 1982) However, that motion was blocked by Congress as unfeasible after a series of hearings and the administration dropped their vendetta. Instead of shrinking the budget, by 1985 the BATF had grown to an agency with a \$179 million dollar budget, up from \$150 million in 1981. (Maitland 1985) Other proposed budget cuts to federal agencies did not fare as well, particularly in the sector related to social research.

Among those budget cuts to programs that it decreed “social research,” were numerous initiatives funded by the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA). Initially the Reagan administration conceived of all ADAMHA research activities as social, but after negotiating with the new Department of Health and Human Services Secretary, Richard Schweiker, they settled at 15 percent of the agency’s budget. The eliminated programs focused in areas of alcoholism treatment, including training personnel and funding prevention programs. (Reinhold 1981a) The decision forced the NIAAA to adapt to new budgetary constraints and revised the agency’s mission, creating more of a research institute that funded biomedical, physiological, and epidemiological research. As a result the NIAAA began to resemble a research institute rather than the combined research and service agency, and by 1992 the NIAAA had become a research institute within the National Institutes of Health (NIH), along with the National Institute on Drug Abuse (NIDA) and the National Institute for Mental Health (NIMH). (DuPont 2010)

The role of hatchet man at the HSS was forced upon Secretary Schweiker throughout his three year tenure as President Reagan's first Secretary of Health and Human Services. As a career politician and moderate conservative Secretary Schweiker tempered the dramatic budget cuts the Reagan administration called for in the area of government-funded social programs. Secretary Schweiker reduced federal funding for welfare, food stamps, Medicare, and Medicaid to the states, while simultaneously defending Social Security and research funds for health and medicine to the NIH and Public Health Service. (McFadden 2015) (Pear 1982) Senator Robert Kennedy later described the mixed legacy of Schweiker, "The country may never know how much greater the damage to social programs would have been without Dick Schweiker as secretary." (McFadden 2015)

In addition to budget cuts, controversy plagued the Department of Health and Human Services surrounding its social agenda and those appointed to enact such policy. Secretary Schweiker faced public criticism for pushing legislation surrounding reproductive health. He defied former Secretary Harris's assertion that the "country faced a disaster" without adequate sex and contraceptive education, stating that the family and not the government was responsible for such measures. (Rosenbaum 1981) He also supported legislation to require clinics receiving federal funds to notify parents of a minor's desire to obtain birth control, described by Senator Henry A. Waxman as "Big Brother getting into the bedrooms of people," and took the opinion that "the fetus has the same rights as the mother." (United Press International 1981a) (United Press International 1982) That apparently contradictory view was broadly supported by the Reagan

administration; that the government should stay out of issues of reproductive health while simultaneously enacting intrusive legislation into such private decisions.

Controversy followed more than just Secretary Schweiker, with the first chosen Assistant Secretary of Health resigning from the nomination process, and the choice of Surgeon General arousing widespread unease. Secretary Schweiker had previously been named a prospective Vice President candidate in Reagan's unsuccessful primary bid in 1976 against Gerald Ford, although George W. Bush replaced him as Vice President in the successful 1981 election. As a career politician, Secretary Schweiker's political positions were well known. However, other nominees in the Department faced more scrutiny, including Warren Richardson, Schweiker's first nomination for Assistant Secretary of Health. (United Press International 1981b) In April of 1981, after a protracted congressional approval process, Richardson removed himself from the process after accusations of anti-Semitism arose. Richardson had served as the primary lobbyist for the Liberty Lobby from 1969 to 1973, an organization with a long history of racist and anti-Semitic views.

In the midst of that controversy and against Schweiker's desires, the Reagan administration pushed for the confirmation of C. Everett Koop as Surgeon General, who had previously been serving as Deputy Assistant Secretary of Health. Koop represented a choice that many regarded as a political appointee to satisfy conservative and anti-abortion groups supporting the president, because Koop had previously published such opinions in his 1976 book *Right to Live, Right to Die*. (Koop 1976) During Koop's congressional hearings, Schweiker revealed that he did not support the choice but agreed with the administration on the condition that he could choose a higher ranking physician

as Koop's overseer in the newly reopened position of Assistant Secretary of Health. (Reinhold 1981b) That position was awarded to Edward Brandt, Jr., who both the American Medical Association and Association of American Medical Colleges supported for the position. Brandt was appointed in May of 1981, and served as acting Surgeon General until Koop was sworn in January of 1982.

The early 1980s represented a time of change among alcohol advocacy organizations as well, with mass resignations occurring in the wake of advocacy groups so opening aligning with industry interests. The National Council on Alcoholism in particular had numerous individuals walk out of an April 1980 meeting, leading to the resignation of the National Association of Alcoholism Counselors from the organization because of how the National Council on Alcoholism chose to handle warning labels. (Olson 2003) Likewise, the National Coalition for Adequate Alcoholism Programs lost the National Association of State Alcohol and Drug Abuse Directors for their opposition to labeling as well. Both the larger federal alcoholism agencies, the National Council on Alcoholism and the National Coalition for Adequate Alcoholism Programs, had industry board members and received substantial industry funding. Such a relationship was increasingly becoming more of an issue among general members of the organizations as the extent of the industry ties continued to be revealed in congressional hearings and reports, but critics of the closeness between the two would have to wait another couple years for the breakup.

Controversy among alcoholism advocacy organizations continued following the publication of the Fourth Special Report to the U.S. Congress on Alcohol and Health as well, released January 19, 1981, the day before President Reagan was sworn into office.

(U.S. Department of Health and Human Services 1981) The third report on the same subject was controversial among alcoholism advocacy groups, with the American Council on Alcoholism, the National Council on Alcoholism, the Alcohol and Drug Problems Association of North America, the North Conway Institute, and the Salvation Army expressing offense at the report's findings that alcoholics cost the nation \$43 billion a year and that restricting alcohol would lead to less alcoholism. The National Coalition for Adequate Alcoholism Programs went so far as to vote in favor of drafting a letter to then Secretary Califano expressing their outrage over the report, at the recommendation of board members from the alcohol industry Wine Institute. (Olson 2003)

In response to many of the concerns with the third report, the NIAAA sent the fourth report out for review among several advocacy actors prior to publication. In a clear political move, the NIAAA chose individuals from groups that had previously voted to leave the National Council on Alcoholism after industry support influenced an anti-warning label stance. That led to still more accusations that the report was not properly vetted in the field among alcoholism interests. Namely among two of the most powerful and industry-friendly groups, the National Council on Alcoholism and the National Coalition for Adequate Alcoholism Programs, each of which received industry funds and had members from the alcohol industry in positions of administrative power. (Olson 2003)

In reporting on the current state of science surrounding FAS, the authors of the fourth report discussed a more expansive definition of alcohol-related birth defects than in the past. They made note of the clear spectrum of effects that “may range from mild

physical and behavioral deficits to the fetal alcohol syndrome (FAS)” and described how even women who drank moderately put their developing fetus at risk of symptoms on the lower end of that spectrum. (U.S. Department of Health and Human Services 1981: 5)

The authors also presented the epidemiological studies that had by then definitely confirmed the existence of such a syndrome, and discussed how scientists were continuing to refine the mechanism and impact of alcohol on development through animal models. What had not changed in the report were the areas for further research regarding FAS. The authors cited the need for more studies on variation among individuals, how different patterns of drinking impacted development, when during development the fetus was most vulnerable, and what sort of maternal effects existed. (U.S. Department of Health and Human Services 1981: 5)

As scientific consensus surrounding FAS began strongly to coalesce, fracture at the level of alcoholism advocacy groups and severe budget cuts impeded a robust federal alcoholism agenda. The combination led federal alcoholism reporter Jay Lewis to characterize 1981 as the year that “saw the severe contraction of the federal effort as it was constructed during the 1970s.” (Lewis 1980a) What the NIAAA could achieve as an institute was dramatically slashed, with the full elimination of all state-level formula and project grants that had been funneling \$120 million to local programs focused on treatment, rehabilitation, and prevention. (Lewis 1980a) Those grants were diverted to a broader program of block grants shared among NIDA and NIMH, which decreased the amount of federal money for those causes and increased the competition for such resources. In the course of a year the staff was reduced by almost 40 percent, and their budget stagnated at \$21.7 million instead of the Institute of Medicine’s recommendation

of \$50 million. The NIAAA had essentially become a research institute, with difficulty even keeping the public-facing National Clearinghouse for Alcohol Information running.

In the absence of a strong institution to set a federal alcohol policy agenda, a federal alcohol advocacy constituency that had also begun to implode, and a Subcommittee on Alcohol and Drug Abuse more interested in oversight than a “paternalistic” regulatory agenda, public health problems surrounding alcohol were reshuffled and reprioritized. Treatment programs for alcoholics went under- or unfunded, and in the case of federal employees the programs were quietly revoked by the Office of Personnel Management after years of negotiation on the part of alcoholism advocacy groups, the NIAAA, and congressmen like Senator Orrin Hatch (R-UT) to get inpatient treatment covered by private insurers. (Olson 2003) Prevention efforts relied more on private industry like the Beverage Alcohol Information Council, the industry-funded education initiative that had recently welcomed on as chairman the former Secretary of the Department of Treasury, Rex D. Davis.

The scaling back of those activities previously core to the NIAAA and alcoholism advocacy groups created a power vacuum in the area of federal alcohol policy, one ripe for vocal special interests to emerge that embodied the social and moral decline which so worried the “New Right.” Chief among those concerns was President Reagan’s desire to curb traffic fatalities associated with drunk driving, guided by the Presidential Commission on Drunk Driving in 1982 and addressed through congressional hearings by the Subcommittee on Alcoholism and Drug Abuse. Also important among the emerging areas of social concern were special populations of drinkers, including minors engaging in dangerous drinking habits that led to the National Minimum Drinking Age Act of

1984, the surge in alcoholism and FAS among indigenous residents addressed mainly by the Indian Health Bureau, and women who drink during pregnancy and endanger their fetuses.

Controlled Drinking and a “Safe Level” of Drinking During Pregnancy

Federal discussion surrounding alcohol beverage warning labels had stymied in the early 1980s. However, concern surrounding FAS remained high following the 1981 Surgeon General’s warning. The highest medical official in the land asserted that FAS presented a risk to pregnancy and that abstinence was recommended in light of some uncertain scientific issues surrounding the risks of drinking during pregnancy. The controversy surrounding a safe level of drinking was carried into prenatal education initiatives enacted by both the government and industry, through the NIAAA and Beverage Alcohol Information Council, respectively.

That controversy was accompanied by new evidence being collected in the field of alcoholism studies that called into question the need for a far-reaching health warning label. That evidence included studies indicating that moderate alcohol consumption had health benefits, and may be more successful at rehabilitating alcoholics than abstinence. The health benefits of alcohol in moderation had existed for years and continued to be cited as a reason against a general health warning. (Baum-Baicker 1985) The controlled drinking controversy was more recent though, and had gained popularity as an alternate to abstinence. (Davies 1962) The topic gained prominence in the research community after a government-funded report presented the alternative in 1976. (Armor et al. 1976) (Roizen 1987)

Conducted by the Rand Corporation in 1976, the report “Alcoholism and Treatment” examined the progress of patients from across 44 NIAAA-funded treatment centers 18 months following their treatment. The authors of the report suggested that moderate drinking rather than abstinence may present a more successful model for alcoholism rehabilitation than sustained non-drinking. (Armor et al. 1976) However, soon after the 1981 hearings on FAS, *Science* magazine substantially rebutted such notions of controlled drinking as beneficial, demonstrating that “normal” drinking patterns appeared unattainable in a ten-year follow-up of patients. (Pendery et al. 1982) The moderate drinking controversy had persisted in opposition to traditionally funded government treatment programs that prioritized abstinence from drinking, and the 1982 publication in *Science* rebutting the original analyses and experimental data only entrenched positions and furthered the controversy. (Roizen 1987)

In light of recent publications describing the benefits of moderate alcohol consumption, the Subcommittee for Alcoholism and Drug Abuse met to discuss FAS and the risks posed by such a suggestion. Senator Humphrey, chair of the Subcommittee, organized hearings on the “Effects of Alcohol Consumption during Pregnancy.” (U.S. Senate 1982) In the opening remarks, Senator Humphrey described the goal of holding such hearings to “clarify the results of recent research so a clear message can be sent to women on the specific nature of the risks of alcohol consumption during pregnancy.” (U.S. Senate 1982) And to “present a clear picture of the nature of the effects of maternal alcohol use and abuse during pregnancy, and provide for us an understanding of the measures needed to achieve a more complete public awareness of the risks involved.” (U.S. Senate 1982)

At the hearings, subcommittee member Senator Orrin Hatch (R-UT) spoke to the importance of the Surgeon General's 1981 warning, highlighting the dependence of the fetus on the pregnant woman for nutrition. He emphasized that when a mother got drunk, so too did her fetus through the exchange of alcohol in the blood stream and across the placenta. He even pointed to a particularly vulnerable time of development that had been identified by the use of animal models, the first trimester, when the body plan and major organs are being decided. (U.S. Senate 1982) He also made mention of a newer statistic, that FAS-related expenses cost the federal government upward of \$1.5 billion a year, but highlighted the "emotional drain" of FAS as immeasurable.

The first panel to present at the hearing consisted of government officials who described the research currently being conducted surrounding FAS. They included Edward N. Brandt, Jr., the Assistant Secretary for Health of the Department of Health and Human Services, and William Mayer, the newly appointed Director of the Alcohol, Drug, and Mental Health Administration (ADAMHA). Brandt, serving in his capacity as acting Surgeon General, had released the 1981 report that called for pregnant women to abstain from alcohol. (U.S. Department of Health and Human Services 1981) He stated a conservative estimate of yearly FAS-affected births between 1,800 and 2,400, with over 360,000 births with some sort of alcohol-related impact on development, or 1 in 100 births in the US. (U.S. Senate 1982) That expansive number was also accompanied by a revised level of safe drinking that was dramatically lower than in the decade past, as little as two drinks a day to cause problems related to birthweight and spontaneous abortion. Mayer echoed the chronic nature of the disorder and the cognitive handicaps which were beginning to be more fully understood.

Among the varied members of the panel of medical experts who presented, few took the position that there was not enough evidence to warrant action on even moderate levels of drinking during pregnancy. The one exception was Serio E. Fabro a professor of gynecology who presented the position of the American College of Obstetricians and Gynecologists that, “At present time, there is not sufficient evidence to substantiate or refute that moderate intake of alcohol is harmful to the fetus.” (U.S. Senate 1982) Fabro went on to discuss the controversy surrounding a safe level of drinking and increasing evidence for a threshold effect instead of a linear dose-response curve, where the fetus needed to be introduced to a certain amount of alcohol before birth defects manifested.

Also notable were the women testifying who objected to the notion that had been broached in previous hearings, that labeling should not be adopted because it would increase the feelings of guilt and shame among women who drank during pregnancy. LeClair Bissell testified as a representative of the American Medical Association, and railed against the archaic attitude that women are nervous and “cannot be trusted with the truth and make their own decisions based on fact.” (U.S. Senate 1982) She also emphasized that the evidence of FAS was concrete and that doctors should recommend pregnant women abstain from alcohol rather than the more ambivalent positions of encouraging women to decide how much to drink based in light of evidence and their own situation. Sheila Blume, member of the advocacy organization National Council on Alcoholism and past president of the American Medical Society on Alcoholism, also supported labeling. In particular, she advocated for labeling, because while public and professional education campaigns faced funding and time limits, labels were an ongoing measure that helped to increase general knowledge about the risks of FAS.

The following panel exemplified the sort of manufacturing uncertainty that characterized labeling discussions about cigarettes decades prior, primarily consisting of industry-funded organizations. Following the previous discussions of how women deserved to be treated like fully actualized humans in the medical process, Arthur J. Salisbury of the March of Dimes stated that “at the risk of being called a male chauvinist pig by the women who just preceded me” the March of Dimes’ advice that women abstain from drinking during pregnancy caused “anxiety, guilt, and disbelief,” and that labeling may have a similar impact. (U.S. Senate 1982) Former Secretary of the Treasury and current Chairman of the Licensed Beverage Information Council, charged with industry-funded public education initiatives, offered the caution that “warning label legislation would denigrate this successful, cooperative program” and that “effective education and not simplistic scare tactics” would work much better than a label on alcohol. (U.S. Senate 1982) Among those “effective education” projects that the BATF pursued, were Rex Morgan comics on the topic of FAS and a video public service announcement titled “Two Tummies,” while the Licensed Beverage Information Council focused more on catch phrases to brand educational materials: “Friends don’t let friends drive drunk,” “Know when to say when,” and the classic, “Enjoy in moderation.” (U.S. Senate 1988)

Surprisingly, Henry L. Rosett, one of the original researchers who had conducted the prospective epidemiological study establishing the syndrome among patients at Boston Hospital, also testified in the anti-labeling panel. Rosett argued that because there was no measurable effect on development with small amounts of alcohol, physicians did a better job explaining the complexity of FAS than a public education campaigns or

warning labels. He also further elaborated on a running theme of the hearings, that women are anxious and fearful, and required special treatment to avoid feelings of guilt that arise from drinking during pregnancy. He went so far as to state that “scare tactics” surrounding information about FAS were “detrimental to mother-child relationship and marital relationship.” (U.S. Senate 1982)

While some experts characterized the scientific findings surrounding FAS as substantial and worthy of a broad scale public health campaign to educate the population, like health warning labels on alcohol. Others found the degree of uncertainty surrounding a “safe level” of drinking to be too complex and contentious to be captured on the side of a bottle of alcohol. In the wake of the 1982 hearing on the “Effects of Alcohol Consumption during Pregnancy” the only certainty was that neither federal agencies nor Congress was adopting labels in the near future.

The societal risks posed by women who drink during pregnancy did not cease to influence alcohol policy discussions, however. Instead, the risk figured prominently in other legislative discussions surrounding other types of problem drinking. FAS appeared in reports of the Presidential Commission Against Drunk Driving, appointed in April 1982, which conducted well over 100 hours of hearings across 8 cities. FAS also emerged during the October 1983 hearings for the 1984 National Minimum Drinking Age Act, which replaced the patchwork of state regulations with an age of twenty-one. Bills addressing alcohol regulation shifted instead to the issue of advertising in alcohol, with a series of hearings in the mid-1980s that scrutinized the idea of the industry defined self-policing morality code. While bills and hearings addressing special populations affected

by alcohol shifted to the Indian Health Service, as indigenous populations experienced the highest rates of FAS in the nation.

To Educate and Protect: How Industry Ceded the War on Labeling to Buffer against Legal Challenges

After years of inaction on alcohol beverage warning labels, Senator Strom Thurmond organized a non-partisan coalition of senators consisting of himself, Orrin G. Hatch (R-UT), Ted Kennedy (D-MA), and Christopher Dodd (D-CT) who banded together in order to petition for legislative hearings regarding alcohol warning labels and to propose amendments to health bills. On May 20, 1986 they succeeded by attaching an amendment to a reauthorization bill for the NIAAA, but the bill languished on the docket and died at the end of the congressional session. The bill required a series of rotating labels on all alcohol for sale, with information about not just FAS, but the risk of drinking and driving, mixing alcohol with drugs, and specific health problems, similar to warnings on later bills (U.S. Senate 1988).

The group continued to petition for warning labels, and in the next health bill that appeared they recorded a resolution asking the Public Health Service to conduct a study on the efficacy of warning labels. The group appended their “Sense of the Senate” resolution to the Anti-Drug Abuse Act of 1986 (S.2878), which was introduced on September 25, 1986. While not a legislative law with the legal power to compel an organization to action, the Sense of the Senate resolution instead acted as formal record of the group’s mission recorded in the legislative record (U.S. Senate 1988). The National Institute on Alcohol Abuse and Alcoholism, headed by newly appointed director Enoch

Gordis, accepted the request and began to compile a comprehensive literature review on the subject.

As a government agency assembled evidence that would be used in alcohol warning label discussions, the typical pro- and anti-labeling positions were clearly outlined in a 1986 article in the *New York Times* that pitted Senator Thurmond against then President of the Distilled Spirits Council of the United States (DISCUS), Frederick A. Meister. In the “60-Second Debate” Thurmond presented statistics highlighting three afflicted groups that had come to represent the most commonly grouped trifecta of victims afflicted by the harm of alcohol, those impacted by drunken driving, FAS, and youth drinking. Thurmond cited statistics in the debate which included that 53 percent of traffic fatalities were caused by alcohol, that damages from FAS comprised the third most common birth defect, and that 3.3 million underage drinkers were on the path toward alcohol dependence in the US in 1986. (Thurmond and Meister 1986) His industry counterpart, Meister, rebutted by citing the joint report by the Department of Treasury and the Department of Health, Education, and Welfare back in 1980 that decided against warning labels, and emphasizing that industry already spent \$10 million annually on public education programs in lieu of labeling. (Thurmond and Meister 1986)

The year 1986 also marked one of the first lawsuits brought forth by a customer against the alcohol industry, alleging that industry was liable for the plaintiff’s alcoholism because no warning label existed to alert to the dangers of alcohol. (Lewin 1986) Wayne Hoover, a 24-year-old alcoholic for the past seven years, sued the G. Heileman Brewing Company and the Brown-Forman Distillers in an attempt to seek compensation for his disease, and to require that alcohol warning labels be added to

alcohol to warn others of the addictive nature of the product. Although the challenge failed, the spirit of the lawsuit was continued by the advocacy organization Council for Law and Education on Alcohol Risks, who stated that their mission was adapting “product-liability law and using it on alcohol-related problems.” (Lewin 1986) The liquor industry had continually stifled legislation requiring alcohol warning labels, but that position began to shift as corporations realized that left them open lawsuits.

When the 100th Congress convened on January 3, 1987, Senator Strom Thurmond once again introduced labeling with five rotating labels and some of the strongest language yet, going further than just suggesting that alcohol is addictive and referring to it as a the “most abused drug in America.” (S.2047) Thurmond’s bill would serve as the legislation around which the 1988 hearing, “Alcohol Warning Labels” revolved. Later that year, the NIAAA acting on the direction of the Office of the Assistant Secretary for Health, published *A Review of the Research Literature on the Effects of Health Warning Labels* on August 3, 1987. (U.S. Department of Health and Human Services 1987) The report concluded that health warning labels did have a positive effect on impacting consumer behavior, and provided the most up to date challenge to anti-labeling proponents that no measurable change in behavior could be observed from warning labels.

A couple months later, plaintiffs in Seattle, Washington, filed the first lawsuits against a distiller for failing to disclose that alcohol could cause birth defects. While courts had previously ruled that warning labels on cigarettes protected the companies from being sued for harm that arose from the use of their product, no such label existed for alcohol. (Associated Press 1987) Among the three lawsuits filed on November 5,

1987, only one, filed by Candace and Harold Thorp on behalf of their then two-year-old son Michael Thorp progressed to trial. (Golden 1999) In *Michael Thorp v. James B. Beam Distilling Company* (1989), Michael's mother Candace argued that because labels did not exist on the whiskey she consumed while pregnant, she did not know about the risks of FAS. The James B. Beam Distilling Corporation countered with a series of argument casting aspersion on the full extent of alcohol's effect on pregnancy, and launched a campaign to assassinate the character of Candace Thorp as a competent and caring mother. Candace may not have been on trial, but a jury would be hard pressed to tell the difference.

Public opinion on labeling had begun to shift and with it so too did the industry's willingness to concede labeling as a means of protecting themselves from legal challenge. The inevitability of labeling made the final congressional hearing on the matter "Alcohol Warning Labels" in August of 1988 more of a piece of political theatre than an actual inquiry into the feasibility of warning labels. (U.S. Senate 1988) No industry interests even showed up to the hearings, and those that did take an anti-labeling position were skewered by Senator Albert Gore, Jr., (D-TN) the Chairman of the Subcommittee on the Consumer, who seemed to delight in verbally sparring with his opposition and picking apart the logic of their arguments.

The bill under examination in the hearings, "S. 2047 To Require a Health Warning on the Labels of All Alcoholic Beverage Containers" was previously introduced by Senator Thurmond and cited a laundry list of rationale for its creation: decreased productivity, traffic fatalities, FAS, accidental deaths, suicides, homicides, crime, teen drinking, youth drug abuse, and more. To address that litany of social harms the bill

required an amendment to the Public Health Service Act to include five rotating warning labels.

One of the first witnesses to testify, Senator Thurmond elaborated on how he had been introducing labels for almost twenty years, citing the “strong power of the liquor interests” as the reason why such legislation repeatedly failed to gain traction (U.S. Senate 1988). Senator Wendell H. Ford (D-KY) explained his “somewhat mixed emotions” on the bill as “one part bourbon and two parts water.” Among several senators testifying, Senator Ernest F. Hollings (D-SC) elaborated on what seemed to explain the prevailing attitudes about labeling: “The argument ensues that labeling does not help. But I have not seen that it will hurt.” (U.S. Senate 1988)

Deputy Director of the BATF, William T. Drake, testified at length about why his agency had not adopted labeling much earlier. He cited the joint report between the BATF and FDA that had decided against labeling as setting a precedent, and cautioned against the newly compiled evidence by the Department of Health and Human Services that stated warning labels were effective. Drake ended on an appeal that labeling wait until a BATF study on consumer attitudes to labeling finished, prompting ire from Senator Gore who mocked the BATF’s “bloomin’ polls” even in the face of overwhelming evidence that alcohol is a danger to health, “you want to go out just generally and start taking a political poll?” (U.S. Senate 1988)

Gore’s exasperation was gentle compared to that of William Jerry McCord, from the South Carolina Commission on Alcohol and Drug Abuse who followed Drake’s testimony with a scathing indictment: “In ten years of inaction—and please do not take this personally, but the waffling, wimpish, leadership stance we have had from the federal

regulatory agencies is significant testimony that they are under the influence themselves of the regulated industry.” (U.S. Senate 1988)

Representing the American Academy of Pediatrics, Kenneth L. Jones, presented the current state of science surrounding alcohol’s impact on development. As one of the first physicians to identify FAS, Jones was uniquely qualified to speak to how the field had changed over time. He characterized how harmful alcohol is to development by listing street drugs, “cocaine, heroin, methadone, PCP, marijuana,” and assuring those in attendance that “none of them holds a candle to alcohol and to its effects on the unborn baby.” (U.S. Senate 1988) Physicians Sheila Blume and LeClair Bissell also offered testimony in favor of labeling, reprising their roles following the 1982 hearings where they rebelled against the notion that women could not handle the truth about FAS.

A representative for the National Council on Alcoholism (NCA), Christine Lubinski, was also present at the hearing and described the strong pro-labeling stance of the oldest alcoholism advocacy organization. When pressed by Senator Gore for details, she explained that it was not until the NCA rejected industry money and removed those board members that the organization could come out in support of regulating alcohol. She also presented a long list of other substances already being labeled, such as cigarettes, aspirin, and saccharin, highlighting that only in one agency does a warning label elicit “cries of Prohibition from industry.” (U.S. Senate 1988)

There were industry interests represented at the hearing, and the three industry-recommended witnesses faced substantial criticism from Senator Gore. Kip Viscusi a Duke University economist presented a semantic argument that warning labels did not meet the qualifications he enumerated for a successful hazard warning program. Senator

Gore cross-examined his argument and picked apart the reasoning at length. Another industry-recommended witness, Robert Lloyd, Vice Chairman of the American Council on Alcoholism, cited his volunteer work with the council and his background as a retired school teacher in opposing warning labels which he did not believe to be educational. Further, he described individuals who supported labeling as a reversion back to the era of Prohibition, inciting the ire of Gore who responded: “I think it is ridiculous, with all due respect. I just think that is ridiculous to have a spokesman for a group funded by the industry come in here and make a statement like this. I mean, you talk about insulting the intelligence of people with warning labels. A warning that we are headed down the slippery slope back to Prohibition is something that fits into that category as far as I am concerned. You are welcome to respond if you want to.” Lloyd offered no counter argument. (U.S. Senate 1988)

The last witness suggested by industry interests, August Hewlett, President of the Alcohol Policy Council, touted his 30 years of experience in alcoholism policy leadership. He elaborated on the standard anti-labeling arguments that alcohol may have some measurable health benefits and that labels may cause fear and guilt among alcoholics. When Senator Gore queried his relationship with the industry and what funding he received, Hewlett reassured Gore that he operated totally independent of industry money. “I am the only person in the Alcohol Policy Council headquarters. It is my home.” (U.S. Senate 1988) Industry interests had essentially ceded their opposition to alcohol health warning labels.

Following the hearings the bill was revised and added to a larger omnibus drug bill, the Anti-Drug Abuse Act of 1988. The Act passed on November 18, 1988 with a

proud Senator Thurmond at the signing ceremony. The final language issued by the BATF in February 1990 asserted the authority of the Surgeon General in the language and focused on both the harms to pregnancy, motorists, and general health: “Government warning: (1) According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects. (2) Consumption of alcoholic beverages impairs your ability to drive a car or operate heavy machinery, and may cause health problems.” (Public Law 100–690, 102 Stat. 4181) On November 14, 1990 warning labels were required by law, seventeen years after physicians first identified that alcohol impacted the normal course of fetal development.

CHAPTER 7

CONCLUSION

In the early 1970s, fetal alcohol syndrome (FAS) emerged as a public health concern and identified alcohol as a teratogen capable of causing birth defects. Alcohol was previously thought to be largely benign to pregnancy, but the concern surrounding the risk of birth defects among women who drank during pregnancy redefined America's relationship with alcohol in medical, political, and social contexts. The most visible among regulatory responses to the risks posed by FAS, alcohol beverage labeling, took fifteen years to implement and forced discussions that transformed FAS from a medical disorder between practitioners and pregnant women, to a broader social and moral disorder that some characterized as resulting from women who willfully chose to endanger the development of their fetuses. FAS and alcohol warning labels became political objects around which discussions of the paternalistic state, individual agency, and scientific authority were occurring, and upon which social anxieties and shifting national priorities were pinned.

That tension between the paternalistic state and the autonomous individual reflects the American cultural tradition of pitting individual agency and responsibility against government intervention and social welfare. (Conly 2012) By drawing a distinction between the good of the individual versus the collective good of society, the degree of government interference into daily decision making often drives oppositional camps of thought. There are opponents who may characterize the legislative response as patronizing, paternalistic, or the result of "big brother" intervening unnecessarily on the

private lives of citizens, instead of allowing those citizens to exercise free will and make an informed and educated decision. While supporters may see the intrusion as a necessity to ensuring the protection and well-being of society's most vulnerable citizens, while compelling more privileged actors to comply with decisions that prioritize the good of the whole over individual or group interests.

Such an intersection is at the heart of the moral entrepreneurship movements that construct social deviance and usually lead to social policing, casting private behaviors in an increasingly public light. (Becker 1963) Successful moral entrepreneurship seeks to publicize policy prescriptions for their particular definition of a social problem. As maternal and fetal health risks became characterized on the national scale through moral entrepreneurship movements and political engagement, fetal alcohol syndrome took on a moral and political identity in addition to its diagnostic, medical identity. (Gusfield 1984) (Glazer 1994) Consider youth smoking or drinking, driving while drinking, smoking indoors, or smoking and drinking during pregnancy, all of which were commonplace at points in the twentieth century but are now widely considered moral failings on the part of the individual who engages in such behavior.

Defining that moral failing surrounding what pregnant women imbibe and its impacts on the fetus happens more frequently in the absence of a well-defined, acute medical understanding of how a teratogen impacts pregnancy. (Armstrong 2003) When the teratogenic potential of a substance is unknown but clear, as was the case with thalidomide, pregnant women were socially absolved of guilt and moral failing as they did not knowingly impact the normal course of fetal development. However, when a pregnant woman willfully engages in behavior that experts have identified as potentially

dangerous to fetal development, such as smoking or drinking during pregnancy, the mother may be perceived as acting immorally. (Gomez 1997) When the causative relationship between the proposed teratogen and the observed risk is under scrutiny, that uncertainty makes it difficult to craft appropriate public health policy.

However, that uncertainty arises from more than just a deficit in scientific knowledge, as those regulatory tensions reflect the inherently gendered nature of policy crafted to address fetal risk during pregnancy. The social expectations and responsibilities of the pregnant woman, her fitness as a mother, and her moral responsibility to raise the next generation of productive citizens are latent and inextricable from decision making. Failure on the part of the pregnant woman to adhere to well-established social norms transforms the medical risks and diagnosis into a social disease with a moral component.

When women knowingly endanger the development of their fetus, some decision makers view it as a personal moral failing, and craft legislation that motivates legislation in response to that perceived culpability. Those concerns at times lead legislators to favor punitive measures that punish the pregnant woman for transgressing society's rules instead of more long-term public health initiatives to educate, prevent, and reform. However, if the goal of such legislation is risk reduction and increased quality of life, punitive measures fail to accomplish either. (Campbell 2000) Particularly as public health measures are currently executed there has been little change in the number of women who drink during pregnancy from the 1980s to present, which has held steady at ten percent of pregnant women.

As the fifteen year history of this narrative progressed, the public health response to FAS forced regulation to shift from restricting the substance, alcohol, to targeting more

discrete populations and behaviors. In regulating the substance, government actors pressed for labeling as part of a public health agenda to decrease overall drinking and reduce associated health risks. That move in the late 1970s led industry actors to decry neo-prohibitionism and patient advocacy organizations to worry about an increase in stigma among alcoholics, a population that they had long sought to normalize as patients. In targeting populations, government actors aimed their public health interventions at traditionally underrepresented groups, including the first meaningful interaction at serving female alcoholics. Public health efforts targeted indigenous populations, the elderly, minors, prescription and street drug abusers, and most importantly, the dual public health population of the pregnant woman and her developing fetus. In targeting specific behaviors, government actors purported to target women who drink during pregnancy but the dramatic budgetary cuts to social research in the 1980s all but eliminated potential research to examine the factors surrounding why women engage in such risky behavior. Instead, legislative discussions substituted all women of reproductive age who drink as a proxy for reaching that population.

In order for alcohol beverage labeling to pass in 1988, several conditions were met that created a favorable environment in which to enact legislation that had toiled on the congressional docket for almost fifteen years. Other labeling initiatives normalized the practice of warning consumers about health risks, including cigarettes, saccharine, and numerous over-the-counter drugs. Industry also increasingly saw labeling as a means of adequately alerting the consumer to the risks of such a product and requirement, to protect against legal challenges that arose from adverse health effects. The case study of cigarettes was integral to this shift, particularly surrounding issues of fetal risk posed by

women who smoke during pregnancy, as labeling to convey the risk to fetal development occurred simultaneous in the 1980s with discussions of alcohol health warning labels.

The federal alcoholism treatment agenda also shifted in identifying and responding to high profile, socially unacceptable behavior in the fifteen years from FAS's emergence to the passage of alcohol warning labels. While it began by identifying alcoholism as a disease, the political agenda surrounding issues of alcoholism rapidly shifted in the 1980s to incorporate other types of drinking that also became abnormal and subject to social censure. Those included drinking during pregnancy, driving while drunk, and youth drinking. The infusion of industry money complicated the formerly unified patient advocacy branch as well, which had for years focused on garnering acceptance for alcoholism as a disease and the alcoholic as a patient in need of treatment. As they achieved that goal, organizations such as the National Council on Alcoholism began accepting substantial amounts of money from the alcohol industry, and detached through the early 1980s as a strong voice of action on matters of federal alcoholism policy. After revoking those industry board seats, the push toward labeling renewed with vigor in the advocacy sector.

Labeling also required the creation of a new group in need of public health intervention, women who choose to drink during pregnancy and their fetuses who are harmed. In the history of FAS, the perception of that group changed over the 15 years between FAS's medical emergence and the passage of alcohol beverage warning labels. Initial political discussions were concerned with instituting alcohol warning labels as a means of abating the ignorance of well-meaning mothers, who if they only knew of the risks, would abstain from drinking during pregnancy. Those discussions morphed over

time, and the group identity shifted from naïve future mothers to women who willingly disregarded prevailing medical and public opinion to subject their fetuses to harm. In that shift, alcohol warning labels were imbued with a social and political purpose, as they changed from an informative public health response to a public censure of aberrant behavior. By the time warning labels passed in 1988 they were a symbolic victory for those who had petitioned for their passage for so many years. Fetal alcohol syndrome and the women who chose to drink during pregnancy were already far more noticeable in the public sphere than a small warning label on a bottle of beer.

Administrative consensus and congressional action also needed to be achieved, without open antagonism from the executive branch. While the Bureau of Alcohol, Tobacco, and Firearms and the Food and Drug Administration were initially at odds, they later united against alcohol warning labels, forcing the labeling discussion into congress. It took the 1987 NIAAA paper examining the efficacy of labeling, combined with further congressional hearings in the late 1980s to swing the parent bureaus of the BATF and FDA into collaborative action toward realizing labels. The Reagan administration's support for regulations surrounding drunk driving, youth drinking, and eventually alcohol warning labels demonstrates an odd proclivity of New Right Republicans in the 1980s. Although they took the general political position that government should deregulate industry and not intrude in citizens' personal lives, the group still used their political clout to prescribe legislation that adhered to a socially conservative agenda, and were integral in characterizing women who drink during pregnancy as immoral.

This dissertation presented an historical case study of how the federal government envisioned and executed its responsibility to engage in risk abatement measures and

educational campaigns in response to FAS, an emergent, population-level health risk. But as this narrative demonstrates, those discussions are rarely simple and require the integration of evidences across sectors of scientific and social research, executive and legislative branches of government, private industry, patient advocacy, and public concern. And that regulatory complexity was only heightened by the population at risk, pregnant women and the fetuses they place at risk by drinking.

REFERENCES

- Abel, Ernest L. "Was the Fetal Alcohol Syndrome Recognized by the Greeks and Romans?" *Alcohol and Alcoholism* 34, no. 6 (1999): 868–872.
- Abel, Ernest L. "The Gin Epidemic: Much Ado about What?" *Alcohol and Alcoholism* 36, no. 5 (2001): 401–405.
- Abel, Ernest L. "Gin Lane: Did Hogarth Know about Fetal Alcohol Syndrome?" *Alcohol and Alcoholism* 36, no. 2 (2001): 131–134.
- Abel, Ernest L. *Fetal Alcohol Syndrome and Fetal Alcohol Effects*. New York City: Springer Science & Business Media, 2012.
- Ajzenstadt, Mimi, and Brian E. Burtch. "Medicalization and Regulation of Alcohol and Alcoholism: The Professions and Disciplinary Measures." *International Journal of Law and Psychiatry* 13, no. 1-2 (1990): 127–147.
- Alexander, Ruth M. "'We Are Engaged as a Band of Sisters': Class and Domesticity in the Washingtonian Temperance Movement, 1840-1850." *Journal of American History* 75, no. 3 (1988): 763–785.
- American Medical Association. "The Sick Physician. Impairment by Psychiatric Disorders, Including Alcoholism and Drug Dependence." *Journal of the American Medical Association* 223, no. 6 (1973): 684–687.
- American Medical Association. "Even Moderate Drinking May be Hazardous to Maturing Fetus." *Journal of the American Medical Association* 237, no. 24 (1977): 2585–2587.
- American Temperance Society. *The Temperance Manual of the American Temperance Society for the Young Men of the United States*. Boston: Seth Bliss, 5 Cornhill, and Perkins and Marvin, 1836.
- An Act to Amend the Public Health Service Act so As to Extend and Improve the Provisions Relating to Regional Medical Programs, to Extend the Authorization*

of Grants for Health of Migratory Agricultural Workers, to Provide for Specialized Facilities for Alcoholics and Narcotic Addicts, and for Other Purposes. Public Law 90-574. *U.S. Statutes at Large* 82 (1968): 1005–1013.

An Act to Provide a Comprehensive Federal Program for the Prevention and Treatment of Alcohol Abuse and Alcoholism. Public Law 91-616. *U.S. Statutes at Large* 84 (1970): 1848–1855.

An Act to Extend through Fiscal Year 1974 Certain Expiring Appropriations Authorizations in the Public Health Service Act, the Community Mental Health Centers Act, and the Developmental Disabilities Services and Facilities Construction Act, and for Other Purposes. Public Law 93-282. *U.S. Statutes at Large* 88 (1974): 125–139.

An Act to Establish a National Program to Increase the Availability of Information on the Health Consequences of Smoking, to Amend the Federal Cigarette Labeling and Advertising Act to Change the Label Requirements for Cigarettes, and for Other Purposes. Public Law 98-474. *U.S. Statutes at Large* 98 (1984): 2000–2205.

Anderson, Jack. “The Washington Merry-Go-Round.” *United Feature Syndicate* October 30, 1974.

Armor, David J., J. Michael Polich, and Harriet B. Braiker. *Alcoholism and Treatment*. Vol. 232. Santa Monica: RAND Corporation, 1976. Accessed July 25, 2016. <http://www.rand.org/pubs/reports/R1739.html>.

Armstrong, Elizabeth M. “Diagnosing Moral Disorder: The Discovery and Evolution of Fetal Alcohol Syndrome.” *Social Science & Medicine* 47, no. 12 (1998): 2025–2042.

Armstrong, Elizabeth M. *Conceiving Risk, Bearing Responsibility: Fetal Alcohol Syndrome and the Diagnosis of Moral Disorder*. Baltimore: Johns Hopkins University Press, 2003.

Associated Press. “U.S. Considering Regulations to Reduce Peril of New Drugs; Move by Food and Drug Administration Spurred by Thalidomide Birth Defects—Controls Are Limited at Present.” *New York Times*, July 29, 1962.

Associated Press. "Distillers and Breweries Face Suit on Birth Defects." *New York Times* December 6, 1987. Accessed July 25, 2016.
<http://www.nytimes.com/1987/12/06/us/distillers-and-breweries-face-suits-on-birth-defects.html>

Baker, Paula. "The Domestication of Politics: Women and American Political Society, 1780-1920." *American Historical Review* 89, no. 3 (1984): 620–647.

Banzhaf v. FCC. 405 F. 2d 1082 (D.C. Cir., 1968).

Bass, Jack, and Marilyn Thompson. *Strom: The Complicated Personal and Political Life of Strom Thurmond*. New York City: PublicAffairs, 2006.

Baum-Baicker, Cynthia. "The Health Benefits of Moderate Alcohol Consumption: A Review of the Literature." *Drug and Alcohol Dependence* 15, no. 3 (1985): 207–227.

Bayer, Ronald, and James Colgrove. "Children and Bystanders First: The Ethics and Politics of Tobacco Control in the United States." In *Unfiltered: Conflicts over Tobacco Policy and Public Health*, edited by Eric A. Feldman and Ronald Bayer, 8–37. Cambridge: Harvard University Press, 2004.

Becker, Howard S. *Outsiders: Studies in the Sociology of Deviance*. New York City: The Free Press, 1963.

Beecher, Lyman. *Six Sermons on the Nature, Occassions, Signs, Evils, and Remedy of Intemperance*. New York City: American Tract Society, 1827.

Bianchine, Josette W., and Bruce D. Taylor. "Noonan Syndrome and Fetal Alcohol Syndrome." *The Lancet* 303, no. 7863 (1974): 933.

Bond, Laura, Mike Daube, and Tanya Chikritzhs. "Access to Confidential Alcohol Industry Documents: From "Big Tobacco" to "Big Booze"." *Australasian Medical Journal* 1, no. 3 (2009): 1–26.

Bond, Laura, Mike Daube, and Tanya Chikritzhs. "Selling Addictions: Similarities in Approaches between Big Tobacco and Big Booze." *Australasian Medical Journal* 3, no. 6 (2010): 325–332.

Brandt, Allan M. *The Cigarette Century: The Rise, Fall, and Deadly Persistence of the Product That Defined America*. New York City: Basic Books, 2007.

Brandt, Allan M. "Inventing Conflicts of Interest: A History of Tobacco Industry Tactics." *American Journal of Public Health* 102, no. 1 (2012): 63–71.

Brown, Nigel A. "Ethanol Embryotoxicity: Direct Effects on Mammalian Embryos in vitro." *Science* 206, no. 4418 (1979): 573–575.

Brown, Sally, and David R. Brown. *A Biography of Mrs. Marty Mann: The First Lady of Alcoholics Anonymous*. Center City: Hazelden Publishing, 2005.

Brown-Forman Distillers Corp. v. Mathews, 435 F. Supp. 5 (W.D. Ky. 1976).

Burney, Leroy E. "Smoking and Lung Cancer: A Statement of the Public Health Service." *Journal of the American Medical Association* 171, no. 13 (1959): 1829–1837.

Campbell, Nancy. *Using Women: Gender, Drug Policy, and Social Justice*. New York City: Routledge, 2000.

Carpenter, Daniel P. *Reputation and Power: Organizational Image and Pharmaceutical Regulation at the FDA*. Princeton: Princeton University Press, 2010.

Chafetz, Morris E. "The 21-Year-Old Drinking Age: I Voted for It; It Doesn't Work." *Huffington Post*, September 18, 2009. Accessed July 25, 2016. www.huffingtonpost.com/morris-e-chafetz/the-21-year-old-drinking_b_262264.html

Chayet, Neil L. "The Legal Issues in Alcoholism." *New England Journal of Medicine* 273, no. 10 (1965): 547–548.

Clarren, Sterling K., and David W. Smith. "The Fetal Alcohol Syndrome." *New England Journal of Medicine* 298, no. 19 (1978): 1063–1067.

Conly, Sarah. *Against Autonomy: Justifying Coercive Paternalism*. Cambridge: Cambridge University Press, 2012.

Cooper, Iver P. "FDA, the BATF, and Liquor Labeling: A Case Study of Interagency Jurisdictional Conflict." *Food Drug and Cosmetics Law Journal* 34 (1979): 370–390.

Council on Scientific Affairs. "Fetal Effects of Maternal Alcohol Use." *Journal of the American Medical Association* 249, no. 18 (1983): 2517–2521.

Courtwright, David T. "Mr. ATOD's Wild Ride: What Do Alcohol, Tobacco, and Other Drugs Have in Common?" *Social History of Alcohol and Drugs* 20 (2005): 105–140.

Daemmrich, Arthur A. "A Tale of Two Experts: Thalidomide and Political Engagement in the United States and West Germany." *Social History of Medicine* 15, no. 1 (2002): 137–158.

Daemmrich, Arthur A. *Pharmacopolitics: Drug Regulation in the United States and Germany*. Chapel Hill: The University of North Carolina Press, 2004.

Daniels, Mark R. "Toward Liquor Control: A Retrospective." In *Social and Economic Control of Alcohol: The 21st Amendment in the 21st Century*, edited by Carole L. Jurkiewicz and Murphy J. Painter, 217–232. Boca Raton: CRC Press, 2008.

Davies, David Lewis. "Normal Drinking in Recovered Addicts." *Quarterly Journal of Studies on Alcohol* 23 (1962): 94–104.

Diamond, Stephen. "The Repeal Program." In *Social and Economic Control of Alcohol: The 21st Amendment in the 21st Century*, edited by Carole L. Jurkiewicz and Murphy J. Painter, 97–116. Boca Raton: CRC Press, 2008.

Diaz, Jaime, and Herman H. Samson. "Impaired Brain Growth in Neonatal Rats Exposed to Alcohol." *Science* 208, no. 4445 (1980): 751–753.

Donovan, Brian L. "Framing and Strategy: Explaining Differential Longevity in the Woman's Christian Temperance Union and the Anti-Saloon League." *Sociological Inquiry* 65, no. 2 (1995): 143-154.

Driver v. Hinnant. 356 F. 2d 761 (4th Cir., 1966).

DuPont, Robert L. "National Institute on Drug Abuse at Its First 35 Years." *Drug and Alcohol Dependence* 107, no. 1 (2010): 80–81.

Easter v. District of Columbia. 361 F. 2d 50 (D.C. Circ., 1966).

Eckardt, Michael J., Thomas C. Harford, Charles T. Kaelber, Elizabeth S. Parker, Laura S. Rosenthal, Ralph S. Ryback, Gian C. Salmoiraghi, Ernestine Vanderveen, and Kenneth R. Warren. "Health Hazards Associated with Alcohol Consumption." *Journal of the American Medical Association* 246, no. 6 (1981): 648–666.

Edwards, Jonathan. *Careful and Strict Enquiry into the Modern Prevailing Notions of That Freedom of Will, Which is Supposed to Be Essential to Moral Agency, Virtue and Vice, Reward and Punishment, Praise and Blame*. Boston: S. Kneeland, 1754.

Fairchild, Amy, and James Colgrove. "Out of the Ashes: The Life, Death, and Rebirth of the "Safer" Cigarette in the United States." *American Journal of Public Health* 94, no. 2 (2004): 192–204.

Fenner, Rebecca M., and Mary H. Gifford. "Women for Sobriety: Thirty-five Years of Challenges, Changes and Continuity." *Journal of Groups in Addiction & Recovery* 7, no. 2-4 (2012): 142–170.

Ferrier, Pierre E., I. Nicod, and Simone A. Ferrier. "Letter: Fetal Alcohol Syndrome." *The Lancet* 302, no. 7844 (1973): 1496.

Fielding, Johnathan E. "Banning Worksite Smoking." *American Journal of Public Health* 76, no. 8 (1986): 957–959.

Florence, A. Leslie. "Is Thalidomide to Blame?" *British Medical Journal* 2, no. 5217 (1960): 1954.

Fontenay, Charles L. *Estes Kefauver: A Biography*. Knoxville: University of Tennessee Press, 1980.

Ford, Gerald R. "Letter Accepting the Resignation of Caspar W. Weinberger, Secretary of Health, Education, and Welfare." June 26, 1975. American Presidency Project, edited by Gerhard Peters and John T. Woolley. Accessed July 25, 2016. <http://www.presidency.ucsb.edu/ws/?pid=5028>

Fosdick, Raymond B., and Albert L. Scott. *Toward Liquor Control*. New York City: Rockefeller Foundation, 1933.

Fullerton, Pamela M., and Michael Kremer. "Neuropathy after Intake of Thalidomide (Distaval)." *British Medical Journal* 2, no. 5256 (1961): 855.

Glazer, Nathan. "How Social Problems are Born." *The Public Interest* 115 (1994): 31–44.

Goddard, Henry Herbert. *The Kallikak Family: A Study in the Heredity of Feeble-Mindedness*. New York City: Macmillan Company, 1912.

Golden, Janet. "'An Argument that Goes Back to the Womb:' The Demedicalization of Fetal Alcohol Syndrome, 1973–1992." *Journal of Social History* 33, no. 2 (1999): 269–298.

Golden, Janet. *Message in a Bottle: The Making of Fetal Alcohol Syndrome*. Cambridge: Harvard University Press, 2005.

Gomez, Laura E. *Misconceiving Mothers: Legislators, Prosecutors, and the Politics of Prenatal Drug Exposure*. Philadelphia: Temple University Press, 1997.

- Gonzales, Elizabeth Rasche. "New Ophthalmic Findings in Fetal Alcohol Syndrome." *Journal of the American Medical Association* 245, no. 2 (1981): 108.
- Gori, Gio Batta, and John C. Luik. *Passive Smoke: The EPA's Betrayal of Science and Policy*. Calgary: Fraser Institute, 1999.
- Gori, Gio Batta, and Cornelius J. Lynch. "Toward Less Hazardous Cigarettes." *Journal of the American Medical Association* 240, no. 12 (1978): 1258–1259.
- Greek, Ray, Niall Shanks, and Mark J. Rice. "The History and Implications of Testing Thalidomide on Animals." *Journal of Philosophy, Science & Law* 11, no. 3 (2011): 1–32.
- Greene, Jeremy A., and Scott H. Podolsky. "Reform, Regulation, and Pharmaceuticals: The Kefauver-Harris Amendments at 50." *New England Journal of Medicine* 367, no. 16 (2012): 1481–1483.
- Gregg, Norman McAllister. "Congenital Cataracts Following German Measles in the Mother." *Transactions of the Ophthalmological Society of Australia* 3 (1941): 35–46.
- Griffin, Charles. "The "Washingtonian Revival": Narrative and the Moral Transformation of Temperance Reform in Antebellum America." *Southern Journal of Communications* 66, no. 1 (2000): 67–78.
- Grimes, William. "Morris Chafetz, 87, Dies; Altered View of Alcoholism." *New York Times*, October 21, 2011. Accessed July 25, 2016.
www.nytimes.com/2011/10/21/US/morris-chafetz-87-dies-altered-view-of-alcoholism.html
- Gusfield, Joseph R. "Social Structure and Moral Reform: A Study of the Woman's Christian Temperance Union." *American Journal of Sociology* 61, no. 3 (1955): 221–232.
- Gusfield, Joseph R. *The Culture of Public Problems: Drinking-Driving and the Symbolic Order*. Chicago: University of Chicago Press, 1984.

- Habbick, Brian F., Witold A. Zaleski, Robin Casey, and Frank Murphy. "Liver Abnormalities in Three Patients with Fetal Alcohol Syndrome." *The Lancet* 313, no. 8116 (1979): 580–581.
- Haggard, Howard W. "The Proposed Massachusetts "Label" and Its Place in Education against Inebriety." *Quarterly Journal of Studies on Alcohol* 6 (1945): 1–3.
- Haggard, Howard W., and Elvin Morton Jellinek. "Two Yale Savants Stress Alcoholism as True Disease." *AA Grapevine* 1 (1944): 1.
- Hallberg, Lillian Mae. *Rhetorical Dimensions of Institutional Language: A Case Study of Women Alcoholics*. PhD thesis, University of Iowa, 1988.
- Hanson, James W., Ann P. Streissguth, and David W. Smith. "The Effects of Moderate Alcohol Consumption during Pregnancy on Fetal Growth and Morphogenesis." *Journal of Pediatrics* 92, no. 3 (1978): 457–460.
- Havlicek, Viktor, and Rima Childiaeva. "E.E.G. Component of Fetal Alcohol Syndrome" *The Lancet* 308, no. 7983 (1976): 477.
- Henig, Robin Marantz. *The Monk in the Garden: The Lost and Found Genius of Gregor Mendel, the Father of Genetics*. Boston: Houghton Mifflin Harcourt, 2001.
- Hewitt, Brenda G. "The Creation of the National Institute on Alcohol Abuse and Alcoholism: Responding to America's Alcohol Problem." *Alcohol Research and Health* 19, no. 1 (1995): 12–16.
- Hicks, Nancy. "Doctor Rejects Top Mental Post, He Cites Cutbacks in Health Funds at U.S. Agency." *New York Times*, February 23, 1974.
- Hicks, Nancy. "H.E.W. Secretary Says His Main Concern Is Not Details of His Agency, but Impact of Government on People." *New York Times*, September 23, 1975.
- Hilts, Philip J. *Protecting America's Health: The FDA, Business, and One Hundred Years of Regulation*. Chapel Hill: University of North Carolina Press, 2003.

- Hingson, Ralph, Joel J. Alpert, Nancy Day, Elizabeth Dooling, Herbert Kayne, Suzette Morelock, Edgar Oppenheimer, and Barry Zukerman. "Effects of Maternal Drinking and Marijuana Use on Fetal Growth and Development." *Pediatrics* 70, no. 4 (1982): 539–546.
- Hirayama, Takeshi. "Non-smoking Wives of Heavy Smokers Have a Higher Risk of Lung Cancer: A Study from Japan." *Bulletin of the World Health Organization* 78, no. 7 (1981): 940–942.
- Hornstein, Lusia, Carol Crowe, and Ralph Gruppo. "Adrenal Carcinoma in Child with History of Fetal Alcohol Syndrome." *The Lancet* 17, no. 2 (1977): 1292–1293.
- Hughes, Harold E., and Dick Schneider. *The Man from Ida Grove: A Senator's Personal Story*. Waco: Word Books, 1979.
- Hunter, Marjorie. "Drug Curbs, Scoffed At in '60, Are Now Being Sped in Congress." *New York Times*, August 12, 1962.
- Hurst, Daniel L. "Infant Malnutrition and Mental Retardation." *New England Journal of Medicine* 306, no. 9 (1982): 545–546.
- Hutt, Peter Barton. "Turning Points in FDA History." In *Perspectives on Risk and Regulation: The FDA at 100*, edited by Arthur A. Daemmrich and Joanna Radin, 14–28. Philadelphia: Chemical Heritage Foundation, 2007.
- Institute of Medicine. *A Brief History of ADAMHA and Previous Studies of its Organization*. Institute of Medicine, Committee on Co-Administration of Service and Research Programs of the National Institutes of Health, the Alcohol, Drug Abuse, and Mental Health Administration, and Related Agencies. Washington, D.C.: National Academy Press, 1991.
- Jamal, Ahmed, David M. Homa, Erin O'Connor, Stephen D. Babb, Ralph S. Caraballo, Tushar Singh, S. Sean Hu, and Brian A. King. "Current Cigarette Smoking Among Adults—United States, 2005–2014." *Morbidity and Mortality Weekly Report* 64, no. 44 (2015): 1233–1240.

- Jellinek, Elvin Morton. *The Disease Concept of Alcoholism*. New Haven: Hillhouse Press, 1960.
- Johnson, Lyndon B. "Special Message to the Congress on Domestic Health and Education." March 1, 1966. American Presidency Project, edited by Gerhard Peters and John T. Woolley. Accessed July 25, 2016.
<http://www.presidency.ucsb.edu/ws/?pid=28111>
- Jones, Kenneth L., and David W. Smith. "Recognition of the Fetal Alcohol Syndrome in Early Infancy." *The Lancet* 302, no. 7836 (1973): 999–1001.
- Jones, Kenneth L., David W. Smith, Ann P. Streissguth, and Ntinios C. Myriantopoulos. "Outcome in Offspring of Chronic Alcoholic Women." *The Lancet* 304, no. 7876 (1974): 1076–1078.
- Jones, Kenneth L., David W. Smith, Christy N. Ulleland, and Ann P. Streissguth. "Pattern of Malformations in Offspring of Alcoholic Mothers." *The Lancet* 301, no. 7815 (1973): 1267–1271.
- Jurkiewicz, Carole L., and Murphy J. Painter. "Why We Control Alcohol the Way We Do." In *Social and Economic Control of Alcohol: The 21st Amendment in the 21st Century*, 1-18. Boca Raton: CRC Press, 2008.
- Kagan, Robert A., and William P. Nelson. "The Politics of Tobacco Regulation in the United States." In *Regulating Tobacco*, edited by Robert L. Rabin and Stephen D. Sugarman, 11-38. New York City: Oxford University Press, 2001.
- Kaiser, Robert G. "New Hampshire Ex-Democrat Turned Right Into Senate." *Washington Post*, March 3, 1979.
- Kalter, Harold, and Josef Warkany. "Congenital Malformations (Second of Two Parts)." *New England Journal of Medicine* 308, no. 9 (1983): 491–497.
- Karp, Robert J., Qutub H. Qazi, Karen A. Moller, Wendy A. Angelo, and Jeffrey M. Davis. "Fetal Alcohol Syndrome at the Turn of the 20th Century: An Unexpected

- Explanation of the Kallikak Family.” *Archives of Pediatrics & Adolescent Medicine* 149, no. 1 (1995): 45–48.
- Kaskutas, Lee Ann. “What Do Women Get out of Self-help? Their Reasons for Attending Women for Sobriety and Alcoholics Anonymous.” *Journal of Substance Abuse Treatment* 11, no. 3 (1994): 185–195.
- Katcher, Brian S. “Benjamin Rush’s Educational Campaign against Hard Drinking.” *American Journal of Public Health* 83, no. 2 (1993): 273–281.
- Kathren, Ronald L. “William H. Rollins (1852-1929): X-ray Protection Pioneer.” *Journal of the History of Medicine and Allied Sciences* 19, no. 3 (1964): 287–294.
- Keller, Mark. “The Disease Concept of Alcoholism Revisited.” *Journal of Studies on Alcohol* 37, no. 11 (1976): 1694–1717.
- Kerr, K. Austin. *Organized for Prohibition*. New Haven: Yale University Press, 1985.
- Khan, Atiya, Judith L. Bader, Gregory R. Hoy, and Lucius R. Sinks. “Hepatoblastoma in Child with Fetal Alcohol Syndrome.” *The Lancet* 30, no. 1 (1979): 1403–1404.
- Kolata, Gina Bari. “Fetal Alcohol Advisory Debated.” *Science* 214, no. 4521 (1981): 642–644.
- Koop, C. Everett. *The Right to Live: The Right to Die*. Fort Collins: Life Cycle Books, 1976.
- Kovach, Bill. “Cap the Knife Goes to Work.” *New York Times*, July 8, 1973.
- Kurtz, Ernest. “Alcoholics Anonymous and the Disease Concept of Alcoholism.” *Alcoholism Treatment Quarterly* 20, no. 3-4 (2002): 5–39.
- Lawson, Evan T. “The Future of the Three-Tiered System as a Control of Marketing Alcoholic Beverages.” In *Social and Economic Control of Alcohol: The 21st*

Amendment in the 21st Century, edited by Carole L. Jurkiewicz and Murphy J. Painter, 31–56. Boca Raton: CRC Press, 2008.

Lemoine, P., H. Harousseau, J. P. Borteyru, and J. C. Menuet. “Children of Alcoholic Parents—Observed Anomalies: Discussion of 127 Cases.” *Therapeutic Drug Monitoring* 25, no. 2 (2003): 132–136. Originally published, “Les Enfants de Parents Alcooliques: Anomalies Observées, a Propos de 127 Cas.” *Outest Medical* 21 (1968): 476–482.

Lender, Mark Edward, and James Kirby Martin. *Drinking in America: A History*. New York City: The Free Press, 1987.

Lenz, Widukind. “Kindliche Missbildungen nach Medikament während der Gravidität.” *Deutsche Medizinische Wochenschrift* 86, no. 52 (1961): 2555–2556.

Lenz, Widukind, and Klaus Knapp. “Die Thalidomid-Embryopathie.” *Deutsche Medizinische Wochenschrift* 87, no. 24 (1962): 1232–1242.

Levine, Harry Gene. “The Discovery of Addiction: Changing Conceptions of Habitual Drunkenness in America.” *Journal of Studies on Alcohol* 39, no. 1 (1978): 143–174.

Lewin, Tamar. “Business and the Law; A Liquor Issue: Warning Label.” *New York Times*, September 30, 1986. Accessed July 25, 2016.
<http://www.nytimes.com/1986/09/30/business/business-and-the-law-a-liquor-issue-warning-label.html>

Lewis, Jay. “Washington Report.” *Journal of Studies on Alcohol* 37, no. 3 (1976a): 409–414.

Lewis, Jay. “Washington Report.” *Journal of Studies on Alcohol* 37, no. 5 (1976b): 698–704.

Lewis, Jay. “Washington Report.” *Journal of Studies on Alcohol* 37, no. 9 (1976c): 1383–1392.

Lewis, Jay. "Washington Report." *Journal of Studies on Alcohol* 38, no. 9 (1977): 1845–1850.

Lewis, Jay. "Washington Report." *Journal of Studies on Alcohol* 38, no. 3 (1979a): 638–643.

Lewis, Jay. "Washington Report." *Journal of Studies on Alcohol* 38, no. 5 (1979b): 1041–1048.

Lewis, Jay. "Washington Report." *Journal of Studies on Alcohol* 40, no. 7 (1979c): 757–769.

Lewis, Jay. "Washington Report." *Journal of Studies on Alcohol* 41, no. 5 (1980a): 587–596.

Lewis, Jay. "Washington Report." *Journal of Studies on Alcohol* 41, no. 9 (1980b): 1001–1006.

Maitland Werner, Leslie. "An Agency Steps Out of Obscurity." *New York Times*, January 27, 1985. Accessed July 25, 2016.
<http://www.nytimes.com/1985/01/27/weekinreview/an-agency-steps-out-of-obscurity.html>

Mattson, Sarah N., Edward P. Riley, Terry L. Jernigan, Cindy L. Ehlers, Dean C. Delis, Kenneth L. Jones, Catherine Stern, Kathleen A. Johnson, John R. Hesselink, and Ursula Bellugi. "Fetal Alcohol Syndrome: A Case Report of Neuropsychological, MRI, and EEG Assessment of Two Children." *Alcoholism: Clinical and Experimental Research* 16, no. 5 (1992): 1001–1003.

McArthur, Judith N. "Demon Rum on the Boards: Temperance Melodrama and the Tradition of Antebellum Reform." *Journal of the Early Republic* 9, no. 4 (1989): 517–540.

McBride, William Griffith. "Thalidomide and Congenital Abnormalities." *The Lancet* 278, no. 7216 (1961): 1358.

- McFadden, Robert D. "Richard S. Schweiker, Former Senator and Reagan Confidant, Dies at 89." *New York Times*, August 3, 2015. Accessed July 25, 2016. <http://www.nytimes.com/2015/08/04/us/richard-s-schweiker-reagan-confidant-dies-at-89.html>
- McFayden, Richard Edward. "Estes Kefauver and the Drug Industry." PhD diss., Emory University, 1973.
- McGivern, Robert. "Prenatal Alcohol Exposure Alters Adult Expression of Sexually Dimorphic Behavior in the Rat." *Science* 224, no.4651 (1984): 896–898.
- Mellin, Gilbert W., and Michael Katzenstein. "The Saga of Thalidomide: Neuropathy to Embryopathy, with Case Reports of Congenital Anomalies." *New England Journal of Medicine* 267, no. 24 (1962): 1238–1244.
- Mendelson, Jack H. "The Fetal Alcohol Syndrome." *New England Journal of Medicine* 299, no. 10 (1978): 556.
- Metlay, Grischa Jeremy. *Learning from Drunk Monkeys: Expert Approaches to Alcohol and Drug Problems in Modern America*. PhD diss., Harvard University, 2010.
- Mills, James L., Barry I. Graubard, Ernest E. Harley, George G. Rhoads, and Heinz W. Berendes. "Maternal Alcohol Consumption and Birth Weight: How Much Drinking During Pregnancy is Safe?" *Journal of the American Medical Association* 282, no. 14 (1984): 1875–1879.
- Mukherjee, Anil B., and Gary D. Hodgen. "Maternal Ethanol Exposure Induces Transient Impairment of Umbilical Circulation and Fetal Hypoxia in Monkeys." *Science* 218, no. 4573 (1982): 700–702.
- National Center for Health Statistics. *Early Release of Selected Estimates Based on Data from the 2014 National Health Interview Survey*, by Brian W. Ward, Tainya C. Clarke, Gulnur Freeman, and Jeannine S. Schiller. Washington, D.C.: U.S. Government Printing Office, 2014.
- National Research Council. *Indoor Pollutants*. Washington, D.C.: The National Academies Press, 1981.

- National Research Council. *Environmental Tobacco Smoke: Measuring Exposures and Assessing Health Effects*. Washington, D.C.: National Academies Press, 1986.
- New York Times. “Drug Market Guardian Frances Oldham Kelsey.” *New York Times*, August 2, 1962.
- New York Times. “Celebrezze Sets Up Coordinating Panel In Alcoholism Drive.” *New York Times*, April 11, 1964.
- New York Times. “Califano in Drive to End Smoking; Calls Habit ‘Slow Motion Suicide’.” *New York Times*, January 12, 1978.
- Niven, Robert G. “Alcoholism A Problem in Perspective.” *Journal of the American Medical Association* 252, no. 14 (1984): 1912–1914.
- Oaks, Laury. *Smoking and Pregnancy: The Politics of Fetal Protection*. New Brunswick: Rutgers University Press, 2001.
- Olson, Nancy. *With a Lot of Help from Our Friends: The Politics of Alcoholism*. Bloomington: iUniverse, 2003.
- Ouellette, Eileen M., Henry L. Rosett, N. Paul Rosman, and Lyn Weiner. “Adverse Effects on Offspring of Maternal Alcohol Abuse during Pregnancy.” *New England Journal of Medicine* 297, no. 10 (1977): 528–530.
- Pauly, Philip J. “How Did the Effects of Alcohol on Reproduction Become Scientifically Uninteresting?” *Journal of the History of Biology* 29, no. 1 (1996): 1–28.
- Pear, Robert. “Schweiker Assails Curb on Medicare.” *New York Times*, September 21, 1982. Accessed July 25, 2016.
<http://www.nytimes.com/1982/09/21/us/schweiker-assails-curb-on-medicare.html>
- Pear, Robert. “Budget Office Urging Sharp Cuts in Scope of Public Health Service.” *New York Times*, December 1, 1982. Accessed July 25, 2016.

- www.nytimes.com/1982/12/01/us/budget-office-urging-sharp-cuts-in-scope-of-public-health-service.html
- Pearl, Raymond. "The Experimental Modification of Germ Cells." *Journal of Experimental Zoology* 22 (1917): 125–185.
- Pendery, Mary L., Irving M. Maltzman, and L. Jolyon West. "Controlled Drinking by Alcoholics? New Findings and a Reevaluation of a Major Affirmative Study." *Science* 217, no. 4555 (1982): 169–175.
- Plumb, Robert K. "Deformed Babies Traced to a Drug." *New York Times*, April 12, 1962.
- Powell v. Texas*. 392 U.S. 514, 88 S. Ct. 2145, 20 L. Ed. 2d 1254 (1968).
- Proctor, Robert N. *Golden Holocaust: Origins of the Cigarette Catastrophe and the Case for Abolition*. Berkeley: University of California Press, 2011.
- Pullar-Strecker, Herbert. "The Problem of Alcoholism and Its Treatment as it Concerns or Should Concern the Medical Profession." *British Journal of Addiction to Alcohol & Other Drugs* 49, no. 1-2 (1952): 21–32.
- Qazi, Qutub H., and Akiko Masakawa. "Altered Sex Ratio in Fetal Alcohol Syndrome" *The Lancet* 308, no. 7975 (1976): 42.
- Qazi, Qutub H., and Doris H. Milman. "Letter: Nontherapeutic Use of Psychoactive Drugs." *New England Journal of Medicine* 309, no. 13 (1983): 797–794.
- Reagan, Ronald. "Executive Order 12358 - Presidential Commission on Drunk Driving," April 14, 1982. American Presidency Project, edited by Gerhard Peters and John T. Woolley. Accessed July 25, 2016.
<http://www.presidency.ucsb.edu/ws/?pid=42395>
- Reinhold, Robert. "U.S. States to Withdraw All Support for Social Research." *New York Times* April 21, 1981a. Accessed July 25, 2016.
<http://www.nytimes.com/1981/04/21/science/us-states-to-withdraw-all-support-for-social-research.html>

Reinhold, Robert. "The Surgeon General's Pragmatic Boss." *New York Times* May 19, 1981b. Accessed July 25, 2016. <http://www.nytimes.com/1981/05/19/science/the-surgeon-general-s-pragmatic-boss.html>

Roizen, Ron. "The Great Controlled Drinking Controversy." In *Recent Developments in Alcoholism*, 245–279. New York City: Springer, 1987.

Roizen, Ron. "E.M. Jellinek and All That! A Brief Look Back at the Origins of Post-Repeal Alcohol Science in the United States." *H. Thomas Austern Lecture for the annual meeting of the Alcohol Beverage Medical Research Foundation*. San Francisco, CA, October 20-26, 2000.

Roizen, Ron. "How Does the Nation's "Alcohol Problem" Change from Era to Era? Stalking the Social Logic of Problem-Definition Transformations since Repeal." In *Altering American Consciousness: The History of Alcohol and Drug Use in the United States 1800-2000*, edited by Sarah W. Tracy and Caroline Jean Acker, 61–87. Amherst: University of Massachusetts Press, 2004.

Roman, Paul M. "Biological Features of Women's Alcohol Use: A Review." *Public Health Reports* 103, no. 6 (1988): 628–637.

Rosenbaum, David E. "Schweiker is Critical of Programs on Sex Counsel and Contraception." *New York Times* January 30, 1981. Accessed July 25, 2016. <http://www.nytimes.com/1981/01/30/us/schweiker-is-critical-of-programs-on-sex-counsel-and-contraception.html>

Rosett, Henry, Eileen M. Ouellette, Lyn Weiner, and Elizabeth Owen. "Therapy of Heavy Drinking During Pregnancy." *Obstetrics & Gynecology* 51, no. 1 (1978): 41–46.

Royal College of Physicians. *A Great and Growing Evil: The Medical Consequences of Alcohol Abuse*. London: Tavistock, 1987.

Rule, Sheila. "Favoritism Denied on Alcoholism Aid by Acting Director." *New York Times* May 01, 1978.

- Rush, Benjamin. *An Inquiry into the Effects of Ardent Spirits on the Human Body and Mind, with an Account of the Means of Preventing, and of the Remedies for Curing Them*. Boston: Thomas and Andrews, 1790.
- Rush, Benjamin. *Medical Inquiries and Observations. Volume 1*. Philadelphia: J. Conrad & Co., 1805.
- Rush, Benjamin. *Medical Inquiries and Observations, Upon the Diseases of the Mind*. Philadelphia: Kimber & Richardson, 1812.
- Schaffer, Helen B. "Treatment of Alcoholism." In *Editorial Research Reports, 1965*, Vol. II, 839–858. Washington, D.C.: CQ Press, 1965.
- Scheiner, Albert P, Carol M Donovan, and Louis E Bartoshesky. "Fetal Alcohol Syndrome in Child Whose Parents Had Stopped Drinking." *The Lancet* 313, no. 8125 (1979): 1077–1078.
- Schmeck, Jr., Harold M. "U.S. Report Says Top Drug Problem is Alcohol Abuse." *New York Times*, February 18, 1972.
- Schneider, Joseph W. "Drinking as Disease: Alcoholism as a Social Accomplishment." *Social Problems* 25, no. 4 (1978): 361–372.
- Smith, David W. "Dysmorphology (Teratology)." *Medical Progress* 69 (1968): 1150–1169.
- Smith, David W, and John M. Graham. "Fetal Alcohol Syndrome in Child Whose Parents Had Stopped Drinking." *The Lancet* 314, no. 8141 (1979): 527.
- Smith, Jeffrey R. "Agency Drags Its Feet on Warning to Pregnant Women." *Science* 199, no. 4330 (1978a): 748–749.
- Smith, Jeffrey R. "Political Fracas over Peer Review Is Factor in Firing of NIAAA Director." *Science* 200, no. 4346 (1978b): 1131–1132.

- Smith, Jeffrey R. "BATF Decides Against Liquor Warning Label." *Science* 203, no. 4383 (1979): 858–859.
- Smith, Terence. "Carter Replaces Bell, Blumenthal, Califano; Miller Goes to Treasury; Adams Given Option Shifts, Seen as Enhancing Power of Chief of Staff, Get Sharp Criticism." *New York Times*, July 20, 1979.
- Sokol, Robert J., Joel Ager, Susan Martier, Sara Debanne, Claire Ernhart, Jan Kuzma, and Sheldon I. Miller. "Significant Determinants of Susceptibility to Alcohol Teratogenicity." *Annals of the New York Academy of Sciences* 477, no. 1 (1986): 87–102.
- Sokol, Robert J., Sheldon I. Miller, and George Reed. "Alcohol Abuse during Pregnancy: An Epidemiological Study." *Alcoholism: Clinical and Experimental Research* 4, no. 2 (1980): 135–145.
- Staros, James D. "The Making of Public Morality: Politics, Social Engineering and the Development of a Safer Cigarette." PhD diss., Southern Illinois University, 2008.
- Stevenson, Katharine Lent. *A Brief History of the Woman's Christian Temperance Union*. Evanston: The Union Signal, 1907.
- Stimmel, Barry. *Federal Priorities in Funding Alcohol and Drug Abuse Programs*. New York: The Haworth Press, 1983.
- Stockard, Charles R. "The Effect on the Offspring of Intoxicating the Male Parent and the Transmission of the Defects to Subsequent Generation." *American Naturalist* 47 (1913): 641–682.
- Stockard, Charles R. "Alcohol as a Selective Agent in the Improvement of Racial Stock." *British Medical Journal* 2, no. 325 (1922): 255–260.
- Streissguth, Ann P., Sterling Keith Clarren, and Kenneth Lyons Jones. "Natural History of the Fetal Alcohol Syndrome: A 10-Year Follow-Up of Eleven Patients." *The Lancet* 326, no. 8446 (1985): 85–91.

- Streissguth, Ann P., Sharon Landesman-Dwyer, Joan C. Martin, and David W. Smith. "Teratogenic Effects of Alcohol in Humans and Laboratory Animals." *Science* 209, no. 4454 (1980): 353–361.
- Sulik, Kathleen K., Malcolm C. Johnston, and Mary A. Webb. "Fetal Alcohol Syndrome: Embryogenesis in a Mouse Model." *Science* 214, no. 4523 (1981): 936–938.
- Sullivan, W. C. "A Note on the Influence of Maternal Inebriety on the Offspring." *British Journal of Psychiatry* 45, no. 190 (1899): 489–503.
- Tan, Cheryl H., Clark H. Denny, Nancy E. Cheal, Joseph E. Sniezek, and Dafna Kanny. "Alcohol Use and Binge Drinking among Women of Childbearing Age, United States, 2011–2013." *Morbidity and Mortality Weekly Report* 64, no. 37 (2015): 1042–1046.
- Taussig, Helen B. "A Study of the German Outbreak of Phocomelia." *Obstetrical & Gynecological Survey* 17, no. 6 (1962): 840–844.
- Tenbrinck, Margaret S., and Sandra Y. Buchin. "Fetal Alcohol Syndrome: Report of a Case." *Journal of the American Medical Association* 232, no. 11 (1975): 1144–1147.
- Thurmond, Strom, and Frederick A. Meister. "60-Second Debate; Should Congress Pass Legislation to Require Warning Labels on Alcoholic Beverages?" *New York Times* July 9, 1986. Accessed July 25, 2016.
<http://www.nytimes.com/1986/07/09/us/60-second-debate-should-congress-pass-legislation-require-warning-labels.html>
- Tobacco Industry Research Committee. "A Frank Statement to Cigarette Smokers." Ness Motley Law Firm, 1954. Tobacco Documents Library. Accessed July 25, 2016.
<http://www.industrydocumentslibrary.ucsf.edu/tobacco>
- Todd, Eli, Mason F. Cogswell, Samuel B. Woodward, George Sumner, and Horatio Gridley. *Report of a Committee of the Connecticut Medical Society Respecting an Asylum for Inebriates: With the Resolutions of the Society, Adopted at Their Annual Meeting, May 1830*. New Haven: Hezekiah Howe, 1830.

- Tuggle, Justin L., and Malcom D. Holmes. "Blowing Smoke: Status Politics and the Smoking Ban." *Deviant Behavior* 18 (1997): 77–93.
- Ulleland, Christy, Richard P. Wennberg, Robert P. Igo, and Nathan J. Smith. "The Offspring of Alcoholic Mothers." *Pediatric Research* 4, no. 5 (1970): 474.
- United Press International. "Abortion Debate Evokes Heated Schweiker Reply." *New York Times*, May 25, 1981a. Accessed July 25, 2016.
<http://www.nytimes.com/1981/05/25/us/abortion-debate-evokes-heated-schweiker-reply.html>
- United Press International. "Nominee for Health Job Ends Bid Under Pressure." *New York Times*, April 25, 1981b. Accessed July 25, 2016.
<http://www.nytimes.com/1981/04/25/us/nominee-for-health-job-ends-bid-under-pressure.html>
- United Press International. "Schweiker Defends Proposal for Teen-Age Chastity Rule." *New York Times*, February 10, 1982. Accessed July 25, 2016.
<http://www.nytimes.com/1982/02/10/us/schweiker-defends-proposal-for-teen-age-chastity-rule.html>
- U.S. Bureau of Economics. Federal Trade Commission. *Cigarette Advertising, Health Information and Regulation before 1970*, by John E. Calfee. Working Paper No. 134. Washington, D.C.: U.S. Government Printing Office, 1985.
- U.S. Congress. Senate. Committee on Labor and Public Welfare. *The Impact of Alcoholism*. 91st Cong., 1st Sess., July 23, 24, and 25, 1969.
- U.S. Congress. Senate. Committee on Labor and Public Welfare. *Inquiry into the Plans for the Implementation of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (Public Law 91-616), and Related Issues*. 92nd Cong., 1st Sess., March 18, 1971.
- U.S. Congress. Senate. Committee on Labor and Public Welfare. *Alcohol Abuse among Women: Special Issues and Unmet Needs*. 94th Cong., 2 Sess., September 29, 1976.

- U.S. Congress. Senate. Committee on Human Resources. *Alcohol Labeling and Fetal Alcohol Syndrome, 1978*. 95th Cong., 2nd Sess., January 31, 1978.
- U.S. Congress. Senate. Committee on Labor and Human Resources. *Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act Amendments of 1979*. 96th Cong., 1st Sess., February 22 and 26, 1979a.
- U.S. Congress. Senate. Committee on Labor and Human Resources. *Report on Consumer Health Warnings for Alcoholic Beverages and Related Issues*. 96th Cong., 1st Sess., September 1979b. S. Doc. 50-436.
- U.S. Congress. Senate. Committee on Labor and Human Resources. *Labeling of Alcoholic Beverages*. 96th Cong., 1st Sess., September 14, 1979c.
- U.S. Congress. Senate. Committee on Labor and Human Resources. *Oversight on Research Activities of the National Institute on Alcohol Abuse and Alcoholism and the National Institute on Drug Abuse, 1981*. 97th Cong., 1st Sess., July 27, 1981.
- U.S. Congress. House of Representatives. Committee on the Judiciary. *Administration's Proposal to Abolish the Bureau of Alcohol, Tobacco and Firearms*. 97th Cong., 1st Sess., October 1, 1981.
- U.S. Congress. Senate. Committee on Appropriations. *Proposed Dissolution of Bureau of Alcohol, Tobacco, and Firearms*. 97th Cong., 2nd Sess., February 22 and 23, 1982; March 8 and 25, 1982.
- U.S. Congress. Senate. Committee on Labor and Human Resources. *Effects of Alcohol Consumption during Pregnancy*. 97th Cong., 2nd sess., September 21, 1982.
- U.S. Congress. Senate. Committee on Commerce, Science, and Transportation. *Alcohol Warning Labels*. 100th Cong., 2nd Sess., August 10, 1988.
- U.S. Department of Health, Education, and Welfare. Public Health Service. *Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service*. Washington, D.C.: U.S. Government Printing Office, 1964.

- U.S. Department of Health, Education, and Welfare. Public Health Service. Office of the Surgeon General. *The Health Consequences of Smoking: 1969 Supplement to the 1967 Public Health Service Review*. Washington, D.C.: U.S. Government Printing Office, 1969.
- U.S. Department of Health, Education, and Welfare. Public Health Service. *The Health Consequences of Smoking, a Report of the Surgeon General: 1971*. Washington, D.C.: U.S. Government Printing Office, 1971.
- U.S. Department of Health, Education, and Welfare. Public Health Service. *The Health Consequences of Smoking, A Report of the Surgeon General: 1972*. Washington, D.C.: U.S. Government Printing Office, 1972.
- U.S. Department of Health, Education, and Welfare. Public Health Service. *The Health Consequences of Smoking, January 1973*. Washington, D.C.: U.S. Government Printing Office, 1973.
- U.S. Department of Health, Education and Welfare. National Institute on Alcohol Abuse and Alcoholism. *Second Special Report to the US Congress on Alcohol & Health, from the Secretary of Health, Education, and Welfare*. Washington, D.C.: U.S. Government Printing Office, 1974.
- U.S. Department of Health, Education, and Welfare. Public Health Service. Center for Disease Control. *The Health Consequences of Smoking: A Reference Edition*. Washington, D.C.: U.S. Government Printing Office, 1976.
- U.S. Department of Health, Education, and Welfare. Public Health Service. Center for Disease Control. "Fetal Alcohol Syndrome." *Morbidity and Mortality Weekly Report* 26 (1977): 178.
- U.S. Department of Health, Education, and Welfare. Public Health Service. *The Health Consequences of Smoking 1977-1978*. Washington, D.C.: U.S. Government Printing Office, 1979a.
- U.S. Department of Health, Education, and Welfare. Public Health Service. *Smoking and Health, A Report of the Surgeon General*. Washington, D.C.: U.S. Government Printing Office, 1979b.

- U.S. Department of Health and Human Services. Public Health Service. *The Health Consequences of Smoking for Women: A Report of the Surgeon General*. Washington, D.C.: U.S. Government Printing Office, 1980.
- U.S. Department of Health and Human Services. *Fourth Special Report to the U.S. Congress on Alcohol and Health from the Secretary of Health and Human Services*. Washington, D.C.: U.S. Government Printing Press, 1981.
- U.S. Department of Health and Human Services. Food and Drug Administration. “Surgeon General’s Advisory on Alcohol and Pregnancy.” *Food and Drug Administration Drug Bulletin* 11 (1981): 9–10.
- U.S. Department of Health and Human Services. Public Health Service. Centers for Disease Control. *The Health Consequences of Involuntary Smoking: A Report of the Surgeon General*. Washington, D.C.: U.S. Government Printing Office, 1986.
- U.S. Department of Health and Human Services. National Institute on Alcohol Abuse and Alcoholism. *Review of the Research Literature on the Effects of Health Warning Labels: A Report to the United States Congress*, by Office of the Assistant Secretary for Health and Philip Richardson. Silver Springs: Marco Systems, Inc. 1987.
- U.S. Department of Health and Human Services. Public Health Service. Centers for Disease Control. *Reducing the Health Consequences of Smoking: 25 Years of Progress. A Report of the Surgeon General*. Washington, D.C.: U.S. Government Printing Office, 1989.
- U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. *Trends in Smoking Before, During, and After Pregnancy: Pregnancy Risk Assessment Monitoring System (PRAMS), United States, 31 Sites, 2000-2005*, by Jamie R. Jones, Patricia M. Dietz, Denise D’Angelo, and Jennifer M. Bombard. Washington, D.C.: U.S. Government Printing Office, 2009.
- U.S. Department of Health and Human Services. National Institutes of Health. “NIAAA: 40 Years of Research Leadership.” *Alcohol Alert* 79 (2010): 1–5. Accessed July 25, 2016. <http://pubs.niaaa.nih.gov/publications/AA79/AA79.html>

- U.S. Department of Health and Human Services. Centers for Disease Control and Prevention. *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General*. Washington, D.C.: U.S. Government Printing Office, 2014.
- U.S. Department of Treasury. Bureau of Alcohol, Tobacco, and Firearms. “Memorandum of Understanding between the Bureau of Alcohol, Tobacco and Firearms and the Food and Drug Administration Regarding the Promulgation and Enforcement of the Labeling Regulations Promulgated under the Federal Alcohol Administration Act,” by Rex D. Davis, and Alexander M. Schmidt. October 8, 1974. Accessed July 25, 2016. www.ttb.gov/pdf/atf-fda-mou-1974.pdf
- U.S. Department of Treasury. Bureau of Alcohol, Tobacco, and Firearms. “Warning Labels on Containers of Alcoholic Beverages, Proposed Rulemaking.” *Federal Register* 43 (1978): 2186–2187.
- U.S. Department of Treasury. Bureau of Alcohol, Tobacco, and Firearms. “The Fetal Alcohol Syndrome Public Awareness Campaign, 1979: Progress Report Concerning the Advance Notice of Proposed Rulemaking on Warning Labels on Containers of Alcoholic Beverages and Addendum.” Washington, D.C.: U.S. Government Printing Office, 1979.
- U.S. Department of the Treasury and U.S. Department of Health and Human Services. *Report to the President and Congress on Health Hazards Associated with Alcohol and Methods to Inform the General Public of These Hazards*. Washington, D.C.: Government Printing Office, 1980.
- U.S. Federal Trade Commission. *Annual Report of the Federal Trade Commission for the Fiscal Year Ended June 30, 1955*. Washington, D.C.: U.S. Government Printing Office, 1955.
- U.S. Federal Trade Commission. *Omnibus Petition for Regulation of Unfair and Deceptive Alcoholic Beverage Advertising and Marketing Practices: Recommendations of the Staff of the Federal Trade Commission*. Washington, D.C.: U.S. Government Printing Office, 1985.
- Valverde, Mariana. “‘Slavery from within’: The Invention of Alcoholism and the Question of Free Will.” *Social History* 22, no. 3 (1997): 251–268.

- Wall Street Journal. "Liquor Bottle Warnings Are Approved by Senate." *Wall Street Journal*, May 8, 1979.
- Walsh, Edward. "Califano, Blumenthal are Fired from Cabinet." *Washington Post*, July 20, 1979.
- Warner, Rebecca H., and Henry L. Rosett. "The Effects of Drinking on Offspring: An Historical Survey of the American and British Literature." *Journal of Studies on Alcohol* 36, no. 11 (1975): 1395–1420.
- Watts, Geoff. "Frances Oldham Kelsey." *The Lancet* 386, no. 10001 (2015): 1334.
- Weiner, Barbara, and William White. "The Journal of Inebriety (1876-1914): History, Topical Analysis, and Photographic Images." *Addiction* 102, no. 1 (2007): 15–23.
- Weiner, Lyn, Henry L. Rosett, Kenneth C. Edelin, Joel J. Alpert, and Barry Zuckerman. "Alcohol Consumption by Pregnant Women." *Obstetrics & Gynecology* 61, no. 1 (1983): 6–12.
- West, James R., Cheryl A. Hodges, and Asa C. Black, Jr. "Prenatal Exposure to Ethanol Alters the Organization of Hippocampal Mossy Fibers in Rats." *Science* 211, no. 4485 (1981): 957–959.
- White, James R. "Small-Airways Dysfunction in Nonsmokers Chronically Exposed to Tobacco Smoke." *New England Journal of Medicine* 302, no. 13 (1980): 720–723.
- White, William L. "Pre-AA Alcoholic Mutual Aid Societies." *Alcoholism Treatment Quarterly* 19, no. 2 (2001): 1–21.
- White, William L. "The Lessons of Language: Historical Perspectives on the Rhetoric of Addiction." In *Altering American Consciousness: The History of Alcohol and Drug Use in the United States 1800-2000*, edited by Sarah W. Tracy and Caroline Jean Acker, 33–60. Amherst: University of Massachusetts Press, 2004.

White, William L. "Recovery: Its History and Renaissance as an Organizing Construct Concerning Alcohol and Other Drug Problems." *Alcoholism Treatment* 23, no. 1 (2005): 3–15.

Woodward, Samuel Baynard. *Essays on Asylums for Inebriates*. N.p., 1838.

Yamazaki, James N., and William J. Schull. "Perinatal Loss and Neurological Abnormalities among Children of the Atomic Bomb: Nagasaki and Hiroshima Revisited, 1949 to 1989." *Journal of the American Medical Association* 264, no. 5 (1990): 605–609.