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"No One Can Serve Two Masters": A Separation of Powers Solution for Conflicts of Interest Within the Department of Health and Human Services

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"NO ONE CAN SERVE TWO MASTERS"[1]: A SEPARATION OF POWERS SOLUTION FOR CONFLICTS OF INTEREST WITHIN THE DEPARTMENT OF HEALTH AND HUMAN SERVICES†

1. *Matthew* 6:24 (Revised Standard Version). This phrase was cited by the Supreme Court in reference to a conflict of interests that involved a government official. United States v. Miss. Valley Generating Co., 364 U.S. 520, 549 (1961).

> The obvious purpose of the statute is to insure honesty in the Government's business dealings by preventing federal agents who have interests adverse to those of the Government from advancing their own interests at the expense of the public welfare. The moral principle upon which the statute is based has its foundation in the Biblical admonition that no man may serve two masters, Matt. 6:24, a maxim which is especially pertinent if one of the masters happens to be economic self-interest. Consonant with this salutary moral purpose, Congress has drafted a statute which speaks in very comprehensive terms. Section 434 is not limited in its application to those in the highest echelons of government service, or to those government agents who have only a direct financial interest in the business entities with which they negotiate on behalf of the Government, or to a narrow class of business transactions. Nor is the statute's scope restricted by numerous provisos and exceptions, as is true of many penal statutes. Rather, it applies, without exception, to 'whoever' is 'directly or indirectly interested in the pecuniary profits or contracts' of a business entity with which he transacts any business 'as an officer or agent of the United States.'

Id. at 549–50. The above quote refers to 18 U.S.C. § 434 which has been repealed and replaced with 18 U.S.C. § 208 encompassing equally comprehensive terms. 18 U.S.C. § 208 (2000).

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I. INTRODUCTION

Increasingly, employees of the constituent agencies of the United States Department of Health and Human Services (DHHS) are also paid consultants for the pharmaceutical industry.[2] The DHHS is the Cabinet-level department of the Federal executive branch that is the most concerned with our nation's public health issues.[3] The DHHS is composed of eleven individual health agencies, including such well-known agencies as the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the National Institutes of Health (NIH).[4] Recently, hundreds of private consulting arrangements were revealed between pharmaceutical companies and DHHS employees.[5] The existence and effect of these relationships between private industry and public employees call into question the independence and trustworthiness of these federal health agencies and undermine the administrative agencies' effectiveness in protecting the public health.[6] In essence, the DHHS has been infected, not by a virus, but by a disease known as greed. In addition to the public

2. David Willman, *Stealth Merger: Drug Companies and Government Medical Research* L.A. TIMES, Dec. 7, 2003, at A1 [hereinafter *Stealth Merger*].

3. OFFICE OF THE FED. REGISTER, NAT'L ARCHIVES & RECORDS ADMIN., THE UNITED STATES GOVERNMENT MANUAL 2005/2006, at 217–27 (rev. 2005) [hereinafter U.S. GOV'T MANUAL].

4. *Id.* The FDA is charged with ensuring our food is pure, safe, and wholesome; our medications are safe and effective; and our products emitting radiation are safe. *Id.* The CDC is charged with protecting the public health of the nation by providing leadership and direction in the prevention of and control of diseases and other preventable conditions. *Id.* The NIH supports biomedical and behavioral research domestically and abroad, conducts research in its laboratories and clinics, trains promising young researchers and promotes acquisition and distribution of medical knowledge. *Id.* The other eight agencies within the DHHS organization are responsible for a variety of public health areas from child issues, to the health concerns of the elderly, to the control of toxic substances, and etc. *Id.*

5. *NIH Ethics Concerns: Consulting Arrangements and Outside Awards: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. On Energy and Commerce*, 108th Cong. 488 (2004) *microformed on* CIS No. 2004-H361-48 (Cong. Info. Serv.) [hereinafter *NIH Ethics Hearings*].

6. *See Stealth Merger*, *supra* note 2, at A1 (quoting Dr. Arnold S. Relman and others in the field).

health issue, there may be a Constitutional issue involved as well that may point to a potential solution.

When private industry relationships affect the decisions of a public agency, it creates concerns regarding the constitutional standing of the government agency in its function as a rule making body.[7] The unconstitutional delegation of Congressional legislative power, known as the non-delegation doctrine, can be classed in two forms: (1) those that lack any appreciable standard, and (2) those that allow the promulgation of rules after the involvement of private groups in the legislative process.[8] The "permissive culture" of financial conflicts of interest between employees of the DHHS and biomedical firms, combined with the net effect of approving bad drugs, and the source of funds for drug regulation appears to create substantial private influence and involvement of private interests within the agency.[9] This Comment submits that extensive conflicts of interests can effectively privatize a public agency, and thereby violating the nondelegation doctrine and undermining the constitutionality of an executive branch agency.

The issue of privatization reveals an endemic problem of constitutionality of all federal government agencies under their current formulation that needs to be addressed by the Legislature, Executive, and Judiciary.[10] The current structure of the federal government agencies inherently conflicts with the separation of powers doctrine by providing within one organization or branch of the government all three legislative, executive, and judicial powers.[11] This issue underlies the development of the conflict of interests and allows undue private in-

7. *See* Carter v. Carter Coal Co., 298 U.S. 238, 311 (1936) ("This is legislative delegation in its most obnoxious form; for it is not even delegation to an official or an official body, presumptively disinterested, but to private persons . . . ."); A.L.A. Schechter Poultry Corp. v. United States, 95 U.S. 495, 537 (1935) ("Could trade or industrial associations or groups be constituted legislative bodies for that purpose because such associations or groups are familiar with the problems of their enterprises? . . . Such a delegation of legislative power is unknown to our law and is utterly inconsistent with the constitutional prerogatives and duties of Congress.").

8. E. H. Schopler, Annotation, *Delegation of Legislative Power to Nongovernmental Agencies as Regards Prices, Wages, and Hours*, 3 A.L.R.2d 188 § 3 (1949).

9. *See generally* David Willman, *The Nation*, L.A. Times, Aug. 6, 2004, at A1 [hereinafter *The Nation*] (stating that the NIH is beset with a permissive culture); *NIH Ethics Hearing*, *supra* note 5 (testimony of Dr. Elias A. Zerhouni indicating there had been about 1,500 agreements involving 500 employees over 5 years); *see also* U.S. HOUSE OF REPRESENTATIVES, COMM. ON GOV'T REFORM, 106TH CONG., MAJORITY STAFF REPORT: CONFLICTS OF INTEREST IN VACCINE POLICY MAKING 34–35, 37–38 (2000), *microformed on* CIS No. 2000-H402-4 (Cong. Info. Serv.) [hereinafter MAJORITY STAFF REPORT ON VACCINE POLICY MAKING] (finding that the policy making advisory committees were infected with undue influence by private interests); *United States Senator Charles E. Grassley (R-IA) Holds Hearing on FDA, Merck and Vioxx: Putting Patient Safety First, Part 1: Hearing Before the S. Finance Comm.*, 108th Cong. (2004) [hereinafter *Vioxx Hearing*].

10. *See generally* STEPHEN G. BREYER et al., ADMINISTRATIVE LAW AND REGULATORY POLICY 37–38 (5th ed. 2002).

11. *See Id.*

fluence. Additionally, the executive branch currently exercises the power that allows or denies conflicts of interest to exist, with self-restraint and self-regulation being the only barriers.[12] The structure of Executive Branch agencies do not provide the checks and balance protections that should deter, if not prevent, the development of a permissive culture within one branch of the government.[13] The long term solution must include a return to the framers' intent[14] by requiring the structure of the government to conform to the separation of powers structure defined by the Constitution. As long as the Executive Branch exercises all three powers, any change can be reversed upon its own accord.

This Comment examines the financial conflicts of interests within the DHHS that results in private influence, the consequential impact of the private influence on the agency's constitutionality under the nondelegation and separation of powers doctrines, and offers a solution that better conforms to the principles and structure of the United States Constitution. Part II examines the penetration of conflicts of interests within the DHHS and impact on drug safety and human lives. Part III discusses the separation of powers doctrine and the development of the nondelegation doctrine with respect to delegations to private groups. Part IV analyzes the constitutionality of administrative agencies under the influence of private interests. Part V analyzes the constitutionality of administrative agencies with respect to the separation of powers doctrine. Part VI proposes a solution to the problems of private interests with administrative agencies. This Comment concludes in advocating a long term solution of repairing the structural flaws that violate the separation of powers by advocating the reformation of Executive Branch agencies into constituent legislative, executive and adjudicatory functions and altering their reporting structure to corresponding branches. In practical terms, the agencies must be disassembled and rebuilt to separate the powers.

II. BACKGROUND: THE PRICE IN HUMAN LIVES

Private interest has invaded the DHHS.[15] The invasion began more than twenty years ago and continues to this day.[16] When the private interests affect the safety of drugs, it becomes a life and death issue.[17]

A. *The Price of Rezulin*

Is one death enough? On May 17, 1998, Audrey LaRue Jones, a fifty-five-year-old high school teacher, died of sudden liver failure; she

12. *See* 18 U.S.C. § 208 (2000).
13. *See generally* BREYER, *supra* note 10, at 37–38.
14. *See id.*
15. *Stealth Merger*, *supra* note 2, at A1.
16. *Id.*
17. *See id.*

had taken a drug called Rezulin as part of an NIH study to treat diabetes.[18] There had been early reports of liver failure related deaths that began to show up in fall of 1997.[19] In response, British distributors, in consultation with the British Government's Medicines and Healthcare Regulatory Agency, voluntarily removed the drug from the market citing safety concerns.[20] Although the British withdrawal was announced in December of 1997, it would not be until June 2, 1998, sixteen days after Mrs. Jones died, that officials of the NIH voted, over the objections of the researchers, to remove the drug from the diabetes study.[21] The actions of the researchers involved in the study raised serious ethical questions regarding financial conflicts of interest.[22]

During the Rezulin study in which Mrs. Jones died, the manufacturer of the drug provided either research funding or compensation to at least twelve of the twenty-two scientists operating the nationwide diabetes study.[23] In mid-1996 the drug was selected by NIH researchers as one of two drugs for a $150 million nationwide study.[24] *The L.A. Times* reported that Dr. Eastman received $78,000 from the manufacturer while overseeing the selection of Rezulin for the NIH study in which Mrs. Jones had participated.[25] Another study leader, Dr. Olefsky, advocated the selection while serving as co-founding chairman of a group established to encourage doctors to prescribe Rezulin.[26] The group was financed by the manufacturer. Dr. Olefsky was also listed on three of the drug's patents.[27] Additionally, as an undisclosed matter, Dr. Olefsky co-founded a privately held firm which accepted a diabetes grant from the manufacturer of Rezulin that could total in excess of $50 million.[28] The death of Audrey Jones and the

18. David Willman, *Scientists Who Judged Pill Safety Received Fees,* L.A. TIMES, Oct. 29, 1999, at A22 [hereinafter *Scientists Received Fees*].

19. *Id.*

20. Posting of Syed Rizwanuddin Ahmad to E-Drug, http://www.essentialdrugs.org/edrug/archive/199712/msg00009.php (Dec. 5, 1997, 15:38:16 EST) (on file at Texas Wesleyan Law Review).

21. *Scientists Received Fees, supra* note 18, at A22.

22. *Id.*

23. *Id.*

24. *Id.*

25. *Id.*

26. *Id.*

27. *Id.*

28. *Id.* The grant took the form of upfront license fees and equity investments as well as milestone payments for reaching research objectives. *What They're Talking About Around the Water Cooler*, DIABETES HEALTH, July 2000, *available at* http://www.diabeteshealth.com/read,4000,1939.html (announcing the collaboration of Warner-Lambert and Metabolix). In exchange, Parke-Davis, the pharmaceutical research division of Warner-Lambert, would receive exclusive worldwide commercialization rights to products resulting from the research. *Id.* The funding and compensation represent a conflict of interest for the employees selecting and operating the study.

withdrawal of Rezulin from the study were warning signs for a larger problem because the drug was in circulation in the market.[29]

Are 556 deaths enough? There were warning signs that the drug may have safety issues.[30] Using his official capacity, Dr. Eastman advocated the use of Rezulin both within the NIH and to doctors involved in studies despite having signed a federal recusal disqualifying himself from all official matters involving Rezulin.[31] Even after Britain's Medicines Control Agency concluded Rezulin was unsafe, Dr. Eastman continued advocating the drug and characterized the British market withdrawal as a marketing decision.[32] The decision to withdraw the drug within the United Kingdom was made because of safety concerns, as indicated by GlaxoWellcome's and Sankyo Pharma's effort to warn doctors and pharmacists about reactions to the medication that included severe hepatocellular damage, hepatic necrosis and hepatic failure.[33] The Inspector General, whose mission "is to protect the integrity of Department of Health and Human Services (HHS) programs, as well as the health and welfare of the beneficiaries of those programs,"[34] eventually cleared Dr. Eastman concluding "that unspecified administrative errors . . . contributed to the appearance of a conflict of interests."[35] Officials at the NIH, not the researchers, eventually removed the drug from the study.[36] But it would not be until the year 2000, that the manufacturer Warner-Lambert finally withdrew the drug from the market.[37] This delay would prove critical.[38]

In terms of human life, by the time the drug was withdrawn it was linked to 556 deaths, including sixty-eight that resulted from liver fail-

29. *Scientists Received Fees*, *supra* note 18, at A22.

30. *See* Meds. & Health Prods. Control Agency, *Troglitazone (Romozin) Withdrawn*, 23 CURRENT PROBLEMS IN PHARMACOVIGILANCE 13 (1997), *available at* http://www.mhra.gov.uk/home/groups/pl-p/documents/publication/con007478.htm.

31. *Scientists Received Fees*, *supra* note 18, at A22.

32. *Id.*; *See* Meds. & Health Prods. Control Agency, *Troglitazone (Romozin) Withdrawn*, 23 CURRENT PROBLEMS IN PHARMACOVIGILANCE 13 (1997), *available at* http://www.mhra.gov.uk/home/groups/pl-p/documents/publication/con007478.htm.

33. Posting of Syed Rizwanuddin Ahmad to E-Drug, http://www.essentialdrugs.org/edrug/archive/199712/msg00009.php (Dec. 5, 1997, 15:38:16 EST) (on file at Texas Wesleyan Law Review).

34. Office of the Inspector General, Dep't of Health & Human Servs., OIG Mission, http://www.oig.hhs.gov/organization/oigmission.html (last visited January 25, 2006). The mission statement as it appears in the Federal Registry states that the "OIG was established by law as an independent and objective oversight unit of the Department to carry out the mission of protecting economy, efficiency and effectiveness through the elimination of waste, abuse and fraud." Dep't of Health and Human Services, 69 Fed. Reg. 40,386 (July 2, 2004).

35. *Stealth Merger*, *supra* note 2, at A1 (ellipsis in original) (internal quotations omitted).

36. *Id.*

37. *Id.*

38. *Scientists Received Fees*, *supra* note 18, at A22.

ure. But lives would not be the only critical measure.[39] By October of 1999, drug sales would exceed 1.6 billion dollars ($1,600,000,000).[40] Not unexpectedly, with drug sales of $137 million in just three months of 1997,[41] the resulting delay involved hundreds of millions, if not billions, of dollars in pharmaceutical sales. In the case of Rezulin, there were warning signs, financial conflicts of interests, enormous sales figures, and ultimately action that occurred too late to save lives. This tragic theme would play over and over again.[42]

B. *The Price of Vioxx and Other COX-2 Inhibitor Drugs*

Are 55,000 deaths enough? On November 18, 2004, the Senate Finance Committee heard testimony from Dr. David Graham, an Associate Director of Science at the FDA, regarding the safety of the drug Vioxx.[43] Vioxx is a nonsteroidal anti-inflammatory drug (NSAID), of the COX-2 inhibitor class, which relieves pain and inflammation, and typically used to treat arthritis, acute pain, acute migraine attacks, and menstrual pain.[44] Dr. Graham released a widely publicized review of insurance data that found that Vioxx may have been associated with more than 27,000 heart attacks and strokes.[45] During testimony before the Senate Finance Committee, Dr. Graham estimated that between 88,000 and 139,000 American lives were permanently affected by Vioxx, and also estimated 30% to 40% (26,400 to 55,600) of these patients probably died.[46] Like Rezulin, there were early warnings of problems with the drug.[47]

Internal Merck documents indicated that the company was aware of the problems with Vioxx as early as 1997.[48] Dr. Graham testified that Merck knew of warning signs as of April 1998, prior to the drugs approval in May of 1999.[49] One external committee that monitored Vioxx's safety during clinical trials "had early data suggesting the users could be at increased risk of certain heart problems after as little as

39. *Id.*

40. *Id.*

41. The Diabetes Monitor, *Troglitazone (Rezulin)*, http://www.diabetesmonitor.com/rezulin.htm (last visited January 25, 2006).

42. *See id.*

43. *Vioxx Hearing*, *supra* note 9.

44. *Id.*; U.S. Food & Drug Admin., Vioxx (rofecoxib) Questions and Answers, http://www.fda.gov/cder/drug/infopage/vioxx/vioxxqa.htm.

45. *Id.*

46. *Id.*

47. Press Release, Am. Trial Lawyers Assoc., Facts Merck Can't Make Disappear, Even With the New Jersey Verdict (Nov. 3 2005), http://www.atla.org/pressroom/vioxx/evidence_newjersey.aspx.

48. *Id.*

49. *Vioxx Hearings*, *supra* note 9.

four months."[50] Once again, the familiar issue of conflicts of interest was involved within the process.[51]

The FDA assembled a five person safety advisory committee to monitor Vioxx's safety during clinical trials in 2000.[52] The five person committee included one Merck employee and two scientists that had consulted for Merck.[53] One of the scientists had already authored a paper defending Vioxx's safety by attacking a study that raised concerns about Vioxx.[54] Despite these early warnings, the company did not withdraw the drug until September 30, 2004, after Dr. Graham submitted his findings to the FDA.[55]

Other drugs of the same COX-2 class have also had early safety problems and the conflicts of interest problem pervades the studies of these drugs as well.[56] On December 17, 2004, the NIH announced the suspension of clinical trials involving Celebrex, a drug similar to Vioxx, due to safety issues.[57] *The New York Times* reports that Pfizer "acknowledged that a 1999 clinical trial found that elderly patients taking the drug were far more likely to suffer heart problems than patients taking a placebo."[58] As a result, these drugs have either been withdrawn from the market or have new safety warnings.[59]

Despite the withdrawal, Merck and Pfizer recently argued to reinstate Vioxx, Celebrex, and Bextra, but the review committee once again was composed of voting members with conflicts of interest.[60] The committee voted to keep all three of the drugs on the market.[61] Of the thirty-two person committee, ten voting members that had direct conflicts of interests with one of the three manufacturers and sev-

50. Barbara Martinez, *Merck Documents Shed Light on Vioxx Legal Battles: Records Show Safety Panel Had Early Data Indicating Higher Heart-Problems Risk*, WALL ST. J., Feb. 7, 2005 at A1.

51. *See id.*

52. *Id.*

53. *Id.*

54. *Id.*

55. *Vioxx Hearing, supra* note 9; Cal. HealthCare Found., *FDA Officials Delayed, Discounted Study on Safety Risks of Vioxx, Agency Researcher Says*, CAL. HEALTHLINE, Nov. 4, 2004, http://www.californiahealthline.org/index.cfm?Action=dspItem&itemID=107385&ClassCD=CL116.

56. *See* Alex Berenson & Gardiner Harris, *Pfizer Says 1999 Trials Revealed Risks With Celebrex*, N.Y. TIMESFeb. 1, 2005, at C1.

57. Pres Release, Health Scis. Auth., Updated HAS Advisory for Healthcare Professionals: Celecoxib (Celebrex®) and Related Drugs (Dec. 27, 2004), http://www.hsa.gov.sg/docs/safetyalert_celecoxib_27Dec04.pdf.

58. Berenson & Harris, *supra* note 56, at C1.

59. Press Release, Food & Drug Admin., FDA Alert for Practitioners Celecoxib (marketed as Celebrex), (April 7, 2005), http://www.fda.gov/cder/drug/infopage/celebrex/celebrex-hcp.htm; Press Release, Food & Drug Admin., FDA Alert for Healthcare Professionals, Valdecoxib (marketed as Bextra), (April 7, 2005), http://www.fda.gov/cder/drug/infosheets/hcp/valdecoxibhcp.pdf.

60. Press Release, Ctr. For Sci. in the Pub. Interest, Conflicts of Interest on COX-2 Panel, (Feb. 25, 2005), http://www.cspinet.org/integrity/press/200502251.html.

61. *Id.*

enteen voting members that had more distant connections (of which three were considered so distant as to be non-conflicting).[62] The vote passed by a narrow margin in some matters and a wide margin in others, but if the conflicted members were not allowed to vote, the results would be very different—it would have voted against the reintroduction of Vioxx and Bextra.[63] When Dr. Graham testified that the FDA, as currently configured, is incapable of protecting America against *another* Vioxx, he indicated that "we are virtually defenseless."[64] It took less than six months to prove him right, but even his statements barely covered the reality that America could not be protected from the *same* Vioxx.[65]

The problem of conflicts of interest within the area of medicine development and safety reach far beyond problem drugs.[66] A well-publicized example is the case of Dr. Trey Sunderland who received $508,050 in fees and related income from Pfizer, Inc. while collaborating with Pfizer in studies as part of his governmental function.[67] His actions included endorsing the use of an Alzhiemer's drug made by Pfizer during a nationally televised presentation at the NIH in 2003 without ever disclosing his financial affiliation.[68] Over the last two years, it became public knowledge that the financial conflicts of interest within the DHHS had become a pervasive problem.[69]

C. *Conflicts of Interest within the NIH*

Traditionally, federal government agencies were not closely involved with private industry.[70] In fact, the involvement of private industry in the creation of rule making authority of government agencies has been one of the great taboos since the beginning of the administrative age of the 1930s.[71] Even as recently as twenty years ago, the NIH was so distinct from industry that Margaret Heckler, Secretary of Health and Human Services, called it "an island of objective and pristine research, untainted by influences of commercialization."[72] But, that has all changed as the story of the NIH clearly demonstrates![73]

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62. *Id.*
63. *Id.*
64. *Vioxx Hearing*, *supra* note 9.
65. *Id.*; *see* Press Release, Ctr. For Sci. in the Pub. Interest, *supra* note 60.
66. *See The Nation*, *supra* note 9, at A1.
67. David Willman, *The Nat'l Inst. of Health: Public Servant or Private Markerter?*, L.A. TIMES, Dec. 22, 2004, at A1 [hereinafter *Public Servant*].
68. *Id.*
69. *See generally The Nation*, *supra* note 9, at A1.
70. *See Stealth Merger*, *supra* note 2, at A1.
71. *See generally* Carter v. Carter Coal Co., 298 U.S. 238 (1936); A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495 (1935); Pan. Ref. Co. v. Ryan, 293 U.S. 388, 405–33 (1935).
72. *Stealth Merger*, *supra* note 2, at A1.
73. *See id.*

As early as 1980, consulting arrangements began to grow within the agencies.[74] By 1995, then NIH director Harold E. Varmus removed the ban of consulting fee arrangements by a non-published internal memo to bring NIH standards more in line with new, less stringent Executive Branch standards.[75] Not only was the memo kept secret, so was much of the consulting income and, by 1998, officials of the NIH allowed "94% of the agency's top-paid employees to keep their consulting incomes confidential."[76] Top NIH scientists are among the highest paid employees in the federal government, many are paid more than the Vice-President per year, but it appears the high pay is not enough for some.[77] Increasingly, top scientists working for the NIH are collecting paychecks and stock options from biomedical companies and, in some cases, even being named on patents.[78] Some scientists have collected between $300,000 and $1.4 million ($1,400,000) over the last decade, while simultaneously accepting a government salary.[79] While waiting for the NIH to respond to a request regarding the extent of the consulting activities, House leaders were able to uncover roughly one-hundred consulting deals that were not properly reviewed or reported to the NIH.[80]

An independent panel, commissioned by the NIH, recommended barring all senior NIH officials from accepting income from drug companies.[81] And according to the panel recommendation, it was the problem of approximately 120 of the 17,526 employees in the NIH.[82] In response to the *L.A. Times* investigative articles and based on the recommendations of the independent panel, the NIH Director Dr. Zerhouni announced sweeping changes before a Congressional subcommittee, blaming the problem on the actions of a few.[83] The *L.A. Times* discovered that "at least 530 government scientists at the NIH . . . have taken fees, stock or stock options from biomedical companies in the last five years."[84] When taken into consideration that the NIH

74. *Id.*

75. David Willman, *NIH to Curb Its Scientists' Deals With Drug Firms*, L.A. TIMES, June 23, 2004, at A1 [hereinafter *NIH to Curb Its Scientists' Deals*].

76. *Stealth Merger*, *supra* note 2, at A1.

77. *See id.* "For instance, two prominent NIH laboratory leaders, [Jeffery] Schlom and [Dr. Ronald N.] Germain, make $180,400 and $179,900, respectively. . . . [Dr. Stephen I.] Katz, 62, is paid $200,000 a year. . . ." *Id.*

78. *Id.*

79. *Id.*

80. *NIH to Curb Its Scientists' Deals*, *supra* note 75, at A1.

81. BLUE RIBBON PANEL ON CONFLICT OF INTEREST POLICIES, NAT'L INST. OF HEALTH, REPORT OF THE NAT'L INSTS. OF HEALTH BLUE RIBBON PANEL ON CONFLICT OF INTEREST POLICIES 2–3 (2004) *available at* http://www.nih.gov/about/ethics_COI_panelreport.pdf.

82. *Id.* at 2.

83. *NIH Ethics Hearing*, *supra* note 5.

84. *Public Servant*, *supra* note 67, at A1.

only employed 2025 individuals with Ph.D. or M.D. degrees in 2004,[85] the prevalence is not as inconsequential as indicated by Dr. Zerhouni.

Although the changes were warmly greeted, there were holes in the new proposal, such as allowing laboratory chiefs and study scientists to have consulting agreements.[86] In response to the proposal, the Office of Government Ethics (OGE) issued a report stating that the NIH is beset with a "permissive culture" and that current agencies proposals would not be sufficient.[87] The OGE stated that strict "across-the-board restrictions were needed to restore public confidence in the nation's preeminent medical-research agency."[88] With "at least 530 government scientists at the NIH . . . haven taken fees, stock or stock options from biomedical companies in the last five years,"[89] drug safety is clearly in question.[90] And as Dr. Graham remarks, there are five other drugs that require investigation as ticking time bombs.[91] This may be the proverbial tip of the iceberg, as indicated by conflicts of interest affecting vaccine safety.[92]

D. *Conflicts of Interest in Vaccine Safety within the FDA and CDC*

Are we too late? Vaccinations are considered a hallmark of 20th and 21st century medicine, credited with controlling and even eliminating dangerous diseases.[93] Although vaccines are acknowledged to have risks, the benefit to society usually outweighs those risks.[94] In some cases, the benefit-risk balance may have been ignored.[95] For example, the rotavirus vaccine RotaShield® approval, however, was granted despite known serious risks such as intussusceptions (0.05%),[96] growth retardation (0.7%), and failure to thrive (0.5%).[97] One-half of one percent may not seem significant until it is translated into 1 out of 200 children or 19,000 children of the 3.8 million children affected during trials. For intussusceptions alone, the mortality rate with all treatments is 1% to 2%[98] (nineteen to thirty-eight children per 3.8 million children). The vaccine, estimated to save less than

85. Nat'l Inst. Of Health, NIH Alamanac 2005–2006, at 578 (2005), *available at* http://www.nih.gov/about/almanac/NIHAlmanac2005.pdf.

86. *The Nation*, *supra* note 9, at A1.

87. *Id.*

88. *Id.*

89. *Public Servant*, *supra* note 67, at A1.

90. *See id.*

91. *Vioxx Hearings*, *supra* note 9.

92. *See* Michael E. Horwin, Comment, *Ensuring Safe, Effective and Necessary Vaccines for Children*, 37 CAL. W. L. REV. 321, 327 (2001).

93. *See id.*

94. *See id.* at 334–36.

95. *See id.*

96. *Id.* at 339.

97. *Id.* at 339 n.129.

98. Shaun C. Spalding & Bruce Evans, *Intussusception*, 36(11) EMERGENCY MED. 12, 19 (2004). This figure can be as high as 20% in rural areas of underdeveloped nations. N. Tjarda van Heek, et al., *Intussusception in a Tropical Country: Compari-*

twenty children per year, had a cost that eclipsed its benefit.[99] A similar story is told regarding Prevnar and other vaccines.[100] Several of these vaccines are for conditions that take between twenty and fifty lives per year.[101] Again, the presence of conflicts of interest in the approval of these vaccines creates considerable doubt that many vaccines are worth the risk, especially in light of the history of Prevnar and RotaShield®.[102]

Two committees play key roles in U. S. vaccine policymaking—the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) and the CDC's Advisory Committee on Immunization Practices (ACIP).[103] Federal regulatory and administrative agencies are often referred to as the fourth branch of government.[104] Federal advisory committees that advise these agencies have grown sufficiently influential as to be called a fifth branch of government.[105] The House of Representatives Government Reform Committee investigated these committees for conflicts of interest and produced a Majority Staff Report on August 21, 2000.[106] The report determined that the overwhelming majority of members of VRBPAC, both voting members and consultants, have substantial ties to the pharmaceutical industry.[107] The members were given blanket waivers for conflicts of interest.[108] A similar story is told of the ACIP.

Some ACIP members did not fully disclose their conflicts of interest.[109] Contrary to established rules, some members sit on both committees.[110] A ten member "rotavirus working committee" wrote the RotaShield® recommendation during private meetings.[111] Seven of the working committee members had financial conflicts of interest.[112] The investigation also revealed that the ACIP committee advising the CDC had recommended the RotaShield® for universal use before the vaccine was even approved by the FDA.[113] Not only did most members have financial ties to vaccine manufacturers, but the financial ties

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son Among Patient Populations in Jakarta, Jogyakarta, and Amsterdam, 29(4) J. PEDIATRIC GASTROENTEROLOGY & NUTRITION, 402, 402 (1999).

99. Horwin, *supra* note 92, at 333–34, 338–39.
100. *See id.* at 342–46.
101. *See id.* at 365–66.
102. *See id.* at 338–46, 366.
103. *See* MAJORITY STAFF REPORT ON VACCINE POLICY MAKING, *supra* note 9, at 1.
104. BREYER, *supra* note 10, at 37–38.
105. MAJORITY STAFF REPORT ON VACCINE POLICY MAKING, *supra* note 9, at 3.
106. *Id.* at 1.
107. *Id.* at 20.
108. *Id.* at 28.
109. *Id.* at 27.
110. *Id.* at 20.
111. *Id.* at 33.
112. *Id.*
113. *Id.* at 38.

included patent ownership on a similar rotavirus vaccine.[114] The report concludes that the actions of these committees *allowed private special interest groups to unduly influence* the government.[115]

It appears the message within the Majority Staff Report fell on deaf ears. Five years after the Majority Staff Report was released,[116] the NIH and Vioxx conflicts of interest scandals were revealed.[117] It is clear that the Majority Report recommendations of the Government Reform Committee have not satisfactorily addressed the problem. Despite the efforts of Congress, the situation has not appeared to have changed for the better as the conflicts of interest in the 2005 FDA advisory panel on COX-2 (Vioxx, Celebrex, and Bextra) safety soundly demonstrate.[118] Perhaps the Vioxx disaster could have been avoided if the recommendations had been broadly applied, and it is possible that the situation is worse than it appears.

Has the problem quietly reached horrific proportions? Many independent scientists have found evidence linking childhood vaccines to an increase in neurodevelopment delays (NDD) in children.[119] The CDC estimates almost 400,000 children are affected by Autism Spectrum Disorders (ASDs).[120] The expected costs of caring for these children will exceed one trillion dollars.[121] Although ASDs used to occur 1 in 10,000 children, over the last thirty years the figure has grown to 1 in 166 children, which translates into 113,000 disabled children *every* four years.[122] The ASD figure does not include most Neu-

114. *Id.* at 16.

115. *See id.* at 35–36.

116. *Id.* at 1.

117. *Vioxx Hearing*, *supra* note 9.

118. Press Release, Ctr. For Sci. in the Pub. Interest, *supra* note 60.

119. *See* David A. Geier & Mark R. Geier, *Neurodevelopmental Disorders Following Thimerosal-Containing Childhood Immunizations: A Follow-Up Analysis*, 23 INT'L J. TOXICOLOGY 369, 369–75 (2004); Amy S. Holmes et al., *Reduced Levels of Mercury in First Baby Haircuts of Autistic Children*, 22 INT. J. TOXICOLOGY 277, 277–84 (2003); David S. Baskin et al., *Thimerosal Induces DNA Breaks, Caspase-3 Activation, Membrane Damage, and Cell Death in Cultured Human Neurons and Fibroblasts*, 74 TOXICOLOGY SCI. 361, 367–68 (2003); M. Waly et al., *Activation of Methionine Synthaseby by Insulin-Like Growth Factor-1 and Dopamine: A Target for Neurodevelopmental Toxins and Thimerosal*, 9 MOLECULAR PSYCHIATRY 358, 365, 367–68 (2004). These NDDs include Autism Spectrum Disorders (ASDs) such as Autism, Asperger's Syndrome and Pervasive Delay Disorder (PDD), as well as Attention Deficit Disorder (ADD), Attention Deficit Hyperactivity Disorder (ADHD), Speech Delays and Mental Retardation.

120. *Vaccines and the Autism Epidemic: Reviewing the Federal Government's Track Record and Charting a Course for the Future: Hearing Before the H. Comm. on Gov't Reform*, 107th Cong. (2002) [hereinafter *2002 Autism Hearings*] (statement of U.S. Rep. Dennis J. Kucinich (D-OH)).

121. *Id.*

122. *Id.*; Mark Blaxill, *What's Going On? The Question of Time Trends in Autism.* 119 Public Health Reports 536–51 (2004); AM. ACAD. OF PEDIATRICS, AUTISM A.L.A.R.M. 1 (2004), *available at* http://www.medicalhomeinfo.org/health/Autism%20downloads/AutismAlarm.pdf.

rological Delay Disorders and Behavior Problems[123] which are now reported to affect one in every six children, which based on the 2000 population census reports represents 639,000 children *every* year.[124]

Conflicts of interest arise in even a wider context than just the government agencies of the DHHS, the very scientific literature they rely on suffers from systematic conflicts of interest problems.[125] The only studies showing an actual negative relationship between Thimerosal and Autism were conducted in Europe and the authors of those studies all have financial conflicts of interest.[126] Most importantly, the authors of these studies represent a single network of authors that are all tied, either indirectly or as employees, to a for-profit vaccine manufacturer that makes 80% of its profits from vaccines.[127] The four key authors of the network all hold key leadership positions with the vaccine manufacturer.[128] Additionally, the studies may not be informative for the United States, because Europe uses only one-third the amount of Thimerosal in its vaccine products as compared to the United States, and the studies also suffer from other protocol and statistical difficulties.[129] All three of the conflicted Danish studies were cited by the Institute of Medicine (sponsored by the CDC) in concluding there was no link between Autism and Thimerosal.[130]

The link between Autism and Thimerosal has been consistently denied by the CDC.[131] A simple MEDLINE[132] search, however, reveals

123. *See generally* Ctr. for Disease Control & Prevention, About Autism, http://www.cdc.gov/ncbddd/dd/aic/about/default.htm (last visited Feb. 20, 2005).

124. AM. ACAD. OF PEDIATRICS, *supra* note 122, at 1. A recent report published in the Washington Post indicates that some experts now estimate that it is not uncommon for one in three children "to be diagnosed with a learning disability, developmental delay or behavioral disorder." Cathy Trost, *Enter the Therapy Zone*, WASH. POST, Nov. 30, 2004, at F1. *See also* U.S. CENSUS BUREAU, CENSUS 2000 PHC-T-9. POPULATION BY AGE, SEX, RACE, AND HISPANIC OR LATINO ORIGIN FOR THE UNITED STATES: 2000, *available at* http://www.census.gov/population/cen2000/phc-t9/tab01.pdf.

125. *See generally* Joel Lexchin et al., *Pharmaceutical Industry Sponsorship and Research Outcome and Quality: Systematic Review*, 326 BMJ 1167–1170 (2003), *available at* http://bmj.bmjjournals.com (search "Author" for "Lexchin"; then follow "Full Text" hyperlink) (discussing funding of drug studies by the pharmaceutical industry).

126. *See* Anders Hviid et al., *Association Between Thimerosal-Containing Vaccines and Autism*, 290 JAMA, 1763, 1763–66 (2003); Kreesten M. Madsen et al., *Thimerosal and the Occurrence of Autism: Negative Ecological Evidence from Danish Population-Based Data*, 112 PEDIATRICS 604, 604–05 (2003).

127. Safe Minds, Something is Rotten in Denmark (May 2004) http://www.safeminds.org/pressroom/press_releases/20040518_AutismAuthorsNetwork.pdf.

128. *Id.*

129. Geier & Geier, *supra* note 119, at 374.

130. 150 CONG. REC. H4564, 4566–67 (daily ed. June 18, 2004) (statement of Rep. Weldon).

131. *See* Nat'l Immunization Program, Ctrs. For Disease Control & Prevention, Vaccines and Autism: An Institute of Medicine (IOM) Report (May 2004), http://www.cdc.gov/nip/news/iom-thim5-18-04.htm; Nat'l Immunization Program, Ctrs. For Disease Control & Prevention, Thimerosal & Vaccines: An Institute of Medicine (IOM) Report (Apr. 2001), http://www.cdc.gov/nip/news/iom-thim10-1-01.htm; *cf.*

hundreds of medical peer reviewed articles that document the toxicity of Thimerosal, including severe morbidity and mortality from high level exposure.[133] Further, vaccine policymaking appears to be limited to a small group of individuals who have conflicts of interest.[134] Hence, it would seem natural that such a defined group would be reluctant to disclose that there is the possibility that tainted policy contributed to disabling 400,000 children to date and possibly harming an estimated 639,000 children every year.

Notwithstanding the CDC's denials, the possibility that some elements related to vaccines may have caused the Autism problem is not an unreasonable proposition, albeit a frightening one. The incidence of ASDs in children is very similar to the incidents of side-effects from the RotaShield® vaccine mentioned above. The 1 out of 168 prevalence of ASD's in children is only 0.59%, which is between the 0.7% growth retardation and 0.5% failure to thrive reports related to the RotaShield® vaccine. Clearly this percentage of affect has occurred before. In this case, the problem itself may have remained relatively unnoticed until its growth rate became alarming,[135] and the cause may be buried under private financial influence.

In addition to the private financial influence resulting from the consulting arrangements and the undue influence exerted by private interests in the advisory committees, there may be one more major factor for considering the privatized nature of the DHHS.[136] U.S. Representative Maurice D. Hinchey (D-NY) reported to the House Appropriations Committee that the FDA receives nearly 50% of its funding for drug regulation from the drug companies,[137] and this percentage is increasing.[138] Congressman Hinchey recognizes there are problems with regard to the relationship the FDA has with the entities

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CTR. FOR BIOLOGICS EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., THIMEROSAL IN VACCINES (2004), http://www.fda.gov/cber/vaccine/thimerosal.htm (reporting the FDA's conclusion that Thimerosal poses no threat).

132. MEDLINE is an online bibliographic database produced by the U.S. National Library of Medicine covering worldwide biomedical literature. About MEDLINE, http://medline.cos.com/docs/abmedl.shtml (last visited Feb. 1, 2006).

133. *Truth Revealed: New Scientific Discoveries Regarding Mercury in Medicine and Autism: Hearing Before the H. Subcomm. on Human Rights and Wellness of the Comm. On Gov't Reform*, 108th Cong. 102 (2004) *microformed on* CIS No. 2005-H401-61 (Cong. Info. Serv.) [hereinafter *Nov. 2004 Autism Hearings*] (statement by Lyn Redwood, RN, MSN, President of Coalition for Safeminds).

134. *See* MAJORITY STAFF REPORT ON VACCINE POLICY MAKING, *supra* note 9.

135. *See generally* Mark F. Blaxill, *What's Going On? The Question of Time Trends in Autism*, 119 Pub. Health Rep. 536–50 (2004) (discussing the increasing trend of autism in the United States and the United Kingdom).

136. U.S. Representative Henry Bonilla (R-TX) Holds Hearing on Food and Drug Administration Before the House Appropriations Committee, 108th Cong. (Jul. 26, 2005) [hereinafter *FDA Hearings*].

137. *Id.*

138. *Id.*

that they are regulating under existing law.[139] The pervasive conflicts of interest and privatization of the DHHS calls into question just how the agency fits within our constitutional legal system both in terms of the separation of powers and the nondelegation doctrines.

III. Separation of Powers in the Constitution

Under the separation of powers doctrine, the prohibitions against encroachment and the nondelegation represent two sides of the same sword: one prohibits taking too much power,[140] while the other prohibits giving away too much power.[141] Both variations cut against the accumulation of too much power in any one branch of government.[142] As such, to say that nondelegation is dead is the equivalent of saying that separation of powers cannot exist.

A. *Separations of Powers*

Separation of powers is a foundational concept of our constitutional legal system originating from the three independent branches of powers found in the Constitution itself.[143] The basic concepts of separation of powers can be seen as far back as the works of Aristotle where he describes methods of setting up constitutions in relation to three powers: deliberative, executive, and judicial.[144] Modern approaches followed the philosophies of Montesquieu, built upon and refined by Madison and Jefferson.[145] Madison, a Federalist, wrote that "[t]he accumulation of all powers, legislative, executive, and judiciary, in the same hands, whether of one, a few, or many, and whether hereditary, self-appointed, or elective, may justly be pronounced the very definition of tyranny."[146] These views were echoed by Thomas Jefferson, an anti-Federalist, who called the concentration of the three powers, "the definition of despotic government."[147] Framers had obvious concerns

139. *Id.*

140. *See generally* Clinton v. New York, 524 U.S. 417, 436–47 (1998); INS v. Chadha, 462 U.S. 919, 944–52 (1983); Youngstown Sheet & Tube Co. v. Sawyer, 343 U.S. 579, 587–589 (1952).

141. *See* A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495, 537 (1935); Pan. Ref. Co. v. Ryan, 293 U.S. 388, 420–30 (1935).

142. *See Clinton*, 524 U.S. at 436–47. In his concurrence, Justice Kennedy states: "Liberty is always at stake when one or more of the branches seek to transgress the separation of powers. Separation of powers was designed to implement a fundamental insight: concentration of power in the hands of a single branch is a threat to liberty." *Id.* at 450.

143. U.S. Const. art. I–III.

144. The Politics of Aristotle 188–203 (Ernest Barker trans., Oxford University Press, 1962) (1858) (noting the Greek understanding of the three branches was significantly different than modern functions).

145. Breyer, *supra* note 10, at 37.

146. The Federalist No. 47, at 139 (James Madison) (Roy P. Fairfield ed., 1981).

147. Thomas Jefferson, Notes on the State of Virginia (William Peden ed., Univ. of N.C. Press 1982) (1781).

for avoiding the creation of a tyranny by the accumulation of too much power within one branch of the government.[148]

Separation of powers is not considered a pure separation, meaning, the three branches are not so isolated as to prevent exertion of control on one another.[149] Madison made this intent clear by noting that the "magistrate in whom the whole executive power resides cannot of himself make a law . . . nor administer justice in person, though has the appointment of those who do administer it."[150]

The system of checks and balances is a prime example of the Framers' intent to allow interaction between the branches, especially for the purpose of control of the branches.[151] The President's power to veto legislation and the Congress's power to override a veto demonstrate that some interaction is intended not to violate the separation of powers but there is a distinction of wielding the power and exercising control over the power.[152] These powers do not imply that the President can exercise legislative power or that the Congress can exercise executive power, because as a fundamental restriction,[153] the President does not enact legislation[154] and the Congress may not execute the law.[155]

The formalist and the functionalist theories represent two modern approaches for discussing issues surrounding separation of powers.[156] The formalist approach requires that the three functions of legislative, executive, and judicial must be strictly relegated to respective

148. *See* THE FEDERALIST NO. 47 (James Madison), *supra* note 146, at 139.

149. *See id.* at 140

150. *Id.* (Madison also provides analogous limitations for the Judicial and Legislative branches.).

151. *See* THE FEDERALIST NO. 47 (James Madison).

152. *See id.*

153. *See id.*

154. *See* Youngstown Sheet & Tube Co. v. Sawyer, 343 U.S. 579, 587 (1952) (holding that the President's duty to faithfully execute the laws "refutes the idea that he is to be a lawmaker"); *cf.* Dames & Moore v. Regan, 453 U.S. 654, 686 (1981) (holding that the President was acting in pursuance of Congress's implicit approval). However, approval by Congressional acquiescence is questionable as it prevents the system of checks and balances to operate because Presidential veto becomes meaningless and implies Presidential power whenever Congress has not explicitly forbid it. JESSE H. CHOPER ET AL., CONSTITUTIONAL LAW 154 (9th ed. West Group 2001). The Supreme Court expressed a similar concern in *Clinton v. New York,* 523 U.S. 417, 439 (1998), where it argued that although the Constitution provides a role for the President in enacting laws, it is silent concerning unilateral action that repeals or amends a duly enacted statute implying that enacting or repealing of statutes must follow the same process. 524 U.S. 417, 439 (1998).

155. *See* Bowsher v. Synar, 478 U.S. 714, 732–34 (1986) (holding unconstitutional the Comptroller General's authorization to review the executive deficit estimates and require the President to cut the budget of the federal government). The Comptroller General was considered a legislative officer, and as such, was prohibited from exercising executive power, therefore the Supreme Court held the procedure was unconstitutional. *Id.*

156. Rebecca L. Brown, *Separated Powers and Ordered Liberty,* 139 U. PA. L. REV. 1513, 1522–24 (1991).

branches of the government.[157] The functionalist approach only requires that the respective branches retain exclusive jurisdiction over "core" functions that cannot be usurped, but allows for ebb and flow of power between the branches.[158] Under the formalist model, there can be no inter-branch interference not expressly authorized by the Constitution and separation of powers disputes are to be resolved predominantly by classification of function.[159] Functionalism contrasts with formalism by allowing inter-branch blending, and dispute resolution is analyzed by reference to characteristic functions of separation of powers such as maintaining a system of checks and balances, preventing excessive concentrations of powers, and protecting individual liberty.[160] Nonetheless, they all agree as a minimum that the separation of the core powers, a system of checks and balances, and the prohibition against excessive concentrations of power in a single branch is fundamental to our constitutional government.[161]

This Author submits that, with the exception of a Constitutional amendment, it should be irrelevant on how the excessive power arrives at the concentration point. The existence of an excessive concentration of power violates a foundational principle of the Constitution.[162] Madison's concern regarding the commingling of any two primary powers within the same hands is very clear.[163] This is evident in the very structure of the Constitution when it states: "All legislative Powers herein granted shall be vested in a Congress . . . ," "[t]he executive Power shall be vested in a President . . . ," and "[t]he judicial Power of the United States, shall be vested in one supreme Court, and in such inferior Courts as the Congress may from time to time ordain and establish."[164] The Constitution does not appear to say all legislative Powers herein granted shall be vested in a Congress and sometimes in a President.[165] Therefore, to the extent that the power of the three distinct powers accumulates within the providence of a single branch of government, there exists tension, if not outright violation, with the separation of powers doctrine and the structure of the Constitution of the United States.[166]

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157. *Id.*

158. *Id.* at 1528–31.

159. *See* CHOPER, *supra* note 154, at 155–56.

160. *Id.* According to Rebecca L. Brown, as a good reference, these two views generally encapsulate the dichotomy presented by various constitutional interpretive methodologies: originalist v. non-originalist; neo-classical v. pragmatic; de-evolutionary v. evolutionary; judicial literalism v. judicial interpretation, although each group holds a violation based on different criteria. Brown, *supra* note 156, at 1522–32.

161. CHOPER, *supra* note 154, at 155–56.

162. *See* THE FEDERALIST NO. 47 (James Madison).

163. *See id.*

164. U.S. CONST. art I, §1, art. II, §1, & art. III, §1.

165. *See* U.S. CONST. art. I, §1.

166. *See* U.S. CONST. art. I, §1, art. II, §1, & art. III, §1; THE FEDERALIST NO. 48 (James Madison).

Madison was very concerned with providing an *effective* system of checks and balances to restrain encroachment by one department of the government into another department's area of power.[167] It is clear that Madison, following the philosophy of Montesquieu, was very concerned that the exercise of two distinct powers by one department of government would lead to tyranny.[168]

> When the legislative and executive powers are united in the same person or body . . . there can be no liberty, because apprehensions may arise lest *the same* monarch or senate should *enact* tyrannical laws to *execute* them in a tyrannical manner . . . [w]ere the power of judging joined with the legislative, the life and liberty of the subject would be exposed to arbitrary control, for *the judge* would then be *the legislator*. Were it joined to the executive power, *the judge* might behave with all the violence of *an oppressor*.[169]

But compare the Madison-Montesquieu view to commentator Harold J. Krent: "Thus, if Congress fashions policy itself or delegates authority to the executive branch, the ultimate policy adopted is the product of at least two branches of government and is subject to the continuing check of at least one other coordinate branch."[170] Although it is clear that Madison would not agree with Krent, because Madison considers the combination of any two branches of government as a flirtation with tyranny, even Krent is sensitive to a lack of checks and balances.[171] Consequently, when effective checks and balances do not exist, then separation of powers becomes tenuous because power has an encroaching nature and there would be nothing to limit a single branch from adopting all three different powers of government.[172] In essence, one cannot have a system of checks and balances in a unitary power system no matter how limited the combination.[173]

Separation of powers, although actively invoked by name to prevent encroachment by one branch of the government into the power reserved to another,[174] is usually called by another name when invalidating unsupportable grants of power from one branch to another: the nondelegation doctrine.[175] In terms of legislative grants of power to the Executive Branch, the nondelegation doctrine, by its very nature, (in one of its aspects) is a particular manifestation of the parent sepa-

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167. *See* THE FEDERALIST NO. 48 (James Madison), *supra* note 146, at 149.

168. *See* THE FEDERALIST NO. 47 (James Madison), *supra* note 146, at 140.

169. *Id.* at 141.

170. Harold J. Krent, *Fragmenting the Unitary Executive: Congressional Delegations of Administrative Authority Outside the Federal Government*, 85 NW. U. L. REV. 62, 75–76 (1991).

171. *Id.*; *see* THE FEDERALIST NO. 48 (James Madison).

172. *See generally* THE FEDERALIST NOS. 47, 48 (James Madison).

173. *See generally id.*; Krent, *supra* note 170, at 75–76.

174. *See generally* Clinton v. New York, 524 U.S. 417 (1998); INS v. Chadha, 462 U.S. 919, 944–46 (1983); Youngstown Sheet & Tube Co. v. Sawyer, 343 U.S. 579 (1952).

175. *See* Mistretta v. United States, 488 U.S. 361, 371 (1989).

ration of powers doctrine—the legislature cannot delegate its power to another branch.[176]

B. *The Nondelegation Doctrine*

The nondelegation doctrine has it roots in the separation of powers doctrine that underlies the tripartite system of government established by the Constitution.[177] The nondelegation doctrine prohibits the delegation of the legislative power granted under Article I, Section 1 of the United States Constitution which states that "[a]ll legislative Powers herein granted shall be vested in a Congress of the Unites States, which shall consist of a Senate and House of Representatives."[178] The Supreme Court has, for more than a century, interpreted this vesting clause as prohibiting Congress from delegating, either by abdicating or transferring, its legislative powers to another branch or entity.[179] The principle "that Congress cannot delegate legislative power . . . is a principle universally recognized as vital to the integrity and maintenance of the system of government ordained by the Constitution."[180] These restraints against delegation, however, are not absolute.[181]

Conflicting with the prohibition on delegation, the Constitution in Article I, Section I, empowers Congress "[t]o make all Laws which shall be necessary and proper for carrying into Execution" its general powers.[182] As a competing provision of legislative vesting, the necessary and proper clause provides a premise to delegate subordinate rule making as long as the legislative power itself is not delegated.[183] However, in considering this clause in terms of legislative delegations, the Supreme Court has repeatedly recognized the necessity of adapting legislation to manage the host of details with which a national Legislature cannot deal directly.[184] It is also recognized that the Constitution has never been regarded as denying Congress the flexibility and practicality that allows them to lay down policies and establish standards, while leaving the details to selected agents.[185]

The power of necessity and practicality is not limited to delegations to the Executive Branch.[186] The Supreme Court in *Panama Refining Co. v. Ryan* stated that it could "find nothing in the Constitution

176. *Id.* at 371–72.
177. *Id.* at 371.
178. U.S. CONST. art. I, § 1.
179. *See* Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 472 (2001); Loving v. United States, 517 U.S. 748, 758 (1996); *Mistretta*, 488 U.S. at 371–72; A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495, 529 (1935); Pan. Ref. Co. v. Ryan, 293 U.S. 388, 421 (1935); Field v. Clark, 143 U.S. 649, 692 (1892).
180. *Field*, 143 U.S. at 692.
181. *Mistretta*, 488 U.S. at 372.
182. U.S. CONST. art. I, § 8.
183. *See Schechter*, 295 U.S. at 529; *Pan. Ref. Co.*, 293 U.S. at 421.
184. *See Pan. Ref. Co.*, 293 U.S. at 421.
185. *See id.*
186. *See id.*

which restricts the Congress to the selection of the President as grantee," and that "[t]he Congress may vest the power in the officer of its choice or in a board or commission" as it creates or deems necessary.[187] It was not long before the Supreme Court found an agent that was constitutionally unavailable for delegation: private interest.[188] Clearly contained within the clause is the power that enables Congress to create laws providing for the discretion of the Executive Branch in the execution of laws.[189] But when does discretion become rule making power?

Necessity changed dramatically during the latter part of the 19th century and early 20th century due to the Great Depression.[190] Prior to 1935, permissible Congressional delegation took three forms: the factual determination (the contingency theory), filling up the details and the validity of rule making, and the intelligible principle that eventually allowed broad delegations based on equally broad policy statements.[191]

1. Factual Determination by the Delegate

One early form of allowable discretion was the contingency theory.[192] The contingency theory allowed Congress to delegate to an executive official the determination of a factual contingency to an executive official that would implement the statute.[193] An example of this is found in *Field v. Clark*, where the Supreme Court upheld a provision of the Tariff Act of 1890, which authorized the President to suspend favorable tariff treatments for nations that imposed duties on American products which he found to be unequal or unreasonable.[194] The essential difference is a distinction adopted in *Field* between the "delegation of power to make the law, which necessarily involves discretion as to what it shall be, and conferring authority or discretion as to its execution, to be exercised under and in pursuance of the law."[195] This is the most innocuous form of delegation, where implicitly no power was actually conferred to the Executive Branch, just the ability to execute the law with discretion that is limited to fact-finding activities.[196]

187. 293 U.S. at 420.

188. *See Schechter*, 295 U.S. at 537.

189. *See* J.W. Hampton, Jr., & Co. v. United States, 276 U.S. 394 (1928).

190. *See* BREYER, *supra* note 10, at 45. The impact of the Great Depression propelled the need to create administrative agencies to regulate the economy. *Id.*

191. *See J.W. Hampton*, 276 U.S. at 394; United States v. Grimaud, 220 U.S. 506 (1911); Field v. Clark, 143 U.S. 649 (1892).

192. *See Field*, 143 U.S. at 683.

193. *See id.* at 692–93; Lisa Schultz Bressman, *Schechter Poultry at the Millennium: A Delegation Doctrine for the Administrative State*, 109 YALE L.J. 1399, 1403 (2000).

194. *Field*, 143 U.S. at 692.

195. *Id.* at 693–94.

196. *See id.* at 692.

The discretion delegated based on factual contingency resembles the fact-finding and discretionary implementation that occurs in any executive action, that is, the initial application of a rule or law to a factual situation.[197] Therefore, the contingency theory of delegation only recognizes an already existing executive power to be exercised under and in pursuance of the law.[198]

2. Filling Up the Details

The necessity for delegation outgrew factual contingency implementations to allow the grantee the "power to fill up the details."[199] The Supreme Court in *United States v. Grimaud*,[200] upheld a statute that gave the Secretary of Agriculture broad authority in protecting the public forests and reservations including the authority to make rules to regulate the occupancy and use, and to protect the forests from destruction.[201] The Supreme Court reasoned that it was impractical for Congress to provide general regulations for detailed management and authorizing the Secretary of Agriculture to meet the local conditions was a simple delegation of administrative functions.[202]

> Congress was merely conferring administrative functions upon an agent, and not delegating to him legislative power. The authority actually given was much less than what has been granted to municipalities by virtue of which they make by-laws, ordinances and regulations for the government of towns and cities. Such ordinances do not declare general rules with reference to rights of persons and property, nor do they create or regulate obligations and liabilities, nor declare what shall be crimes nor fix penalties therefor.[203]

The *Grimaud* Court went further to explain that because the functions "are not of a legislative character in the highest sense of the term," it was permissible for Congress to delegate to the local legislature the authority to determine minor matters.[204]

3. The Intelligible Principle Requirement

The final form of the delegation requirement involves the requirement that the statute must provide an intelligible principle.[205] The delegation authorized in *J.W. Hampton, Jr. & Co. v. United States*,[206] where the Supreme Court upheld a statute giving the President, at his discretion, the power to revise tariff duties already specified in the

197. *See id.* at 693.
198. *See id.* at 693–94.
199. United States v. Grimaud, 220 U.S. 506, 517 (1911).
200. 220 U.S. 506 (1911).
201. *Id.*
202. *Id.* at 516.
203. *Id.*
204. *Id.*
205. *See* J.W. Hampton, Jr., & Co. v. United States, 276 U.S. 394 (1928).
206. *Id.*

statute whenever necessary to equalize local productions costs with those of competing countries.[207] The Court held that the delegation was not prohibited as long as Congress legislates "an intelligible principle to which the person or body authorized to [act] is directed to conform."[208] In its analysis, the Court found the statute to be perfectly intelligible—that Congress had described "with clearness" its policy and plan that authorized a member of the Executive Branch to make factual determinations regarding changing conditions, and then implement necessary rate adjustments to conform to the standards contained within the policy and plan.[209] As the needs of administrative regulation grew, so did the flexibility allowed by the Supreme Court in terms of broad delegation, initially from a determination of criteria under the rule, to merely an intelligible principal guiding the actions of the Executive.[210] The latter gives way to the broad general directives.

4. Broad General Directives

The Supreme Court, "driven by a practical understanding that in our increasingly complex society," has consistently held that "Congress simply cannot do its job absent an ability to delegate power under broad general directives."[211] "Without capacity to give authorizations of that sort we should have the anomaly of a legislative power which in many circumstances calling for its exertion would be but a futility."[212] In essence, given the complexity of our society, Congress could not be successful if it were required to legislate every detail.[213] As a result, the Supreme Court has deemed it "constitutionally sufficient if Congress clearly delineates the general policy, the public agency which is to apply it, and the boundaries of this delegated authority."[214]

From the founding of the Federal government, Congress has conferred to executive officers the power to make regulations, but only

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207. *Id.*

208. *Id.* at 409.

209. *Id.* at 405.

210. *See generally* Pan. Ref. Co. v. Ryan, 293 U.S. 388, 421 (1935); *J.W. Hampton*, 276 U.S. at 394; Field v. Clark, 143 U.S. 649, 692 (1892).

211. Mistretta v. United States, 488 U.S. 361, 371 (1989); *see also* Loving v. United States, 517 U.S. 748, 758 (1996); A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495, 530 (1935); *Pan. Ref. Co.*, 293 U.S. at 421; *Field*, 143 U.S. at 692–94.

212. *Pan. Ref. Co.*, 293 U.S. at 421.

213. *See id.*

214. *Mistretta*, 488 U.S. at 372–73. This is remarkably similar to the requirement of legislative action in *Panama Refining* that states "[a]ccordingly we look to the statute to see whether the Congress has declared a policy with respect to that subject; whether the Congress has set up a standard for the President's action; whether the Congress has required any finding by the President in the exercise of the authority to enact the prohibition." *Pan. Ref. Co.*, 293 U.S. at 415.

for the purpose of administering the laws.[215] Although the regulations are binding rules of conduct, "they are valid only as *subordinate rules,*" and only when they do not exceed the Legislature's "*sufficiently defined*" policy framework.[216] The Supreme Court in *Panama Refining*, speaking about the delegation in *Grimaud*, distinguished between rules and laws, which results in a crucial distinction.[217] More recent cases accept rule making as distinct from Congressional law making authority while concentrating on determining if there exists an "intelligible principle" in the contested legislation.[218]

However, Justice Stevens and Justice Souter of the current Supreme Court would do away with the distinction and concentrate on acknowledging that it is "*legislative power.*"[219] This does not necessarily mean the delegation was unconstitutional as indicated in the *Mistretta* analysis, which relied more on the system of checks and balances to provide the necessary protection against tyranny.[220] Further, the distinction between a "law" and a "rule" provides a loophole for constitutional delegation of the legislative power by distinguishing between a law that prescribes the policy and limits of rule-making authority and a rule that is made within limits prescribed by a law.[221] Legislation conferring subordinate rule-making authority does not transfer any meaningful legislative power because it does not confer the power to make policy, and therefore, does not violate the nondelegation requirement.[222] In essence, only laws may make policy and rules do not—the rule must only provide for conduct in furtherance of the policy and standards set by the law.[223] Accordingly, the Court in *Mistretta* notes that it is "constitutionally sufficient if Congress clearly delineates the general policy, the public agent which is to apply it, and the boundaries of this delegated authority."[224]

Justice Stevens and Justice Souter are not alone in their concern for the current formulation of law-rule distinction using and intelligible principle standard, as seen in Justice Thomas's concurrence in *Whitman*:

> I am not convinced that the intelligible principle doctrine serves to prevent all cessions of legislative power. I believe that there are

215. *See Pan. Ref. Co.*, 293 U.S. at 421.
216. *Id.* at 428–29 (emphasis added).
217. *Id.*
218. *See* A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495, 530 (1935); *Pan. Ref. Co., 293 U.S.* at 429–30; *but see* Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 472–74 (2001); *Mistretta*, 488 U.S. at 371–74.
219. *Whitman*, 531 U.S. at 488 (Stevens, J., and Souter, J., concurring in part and concurring in the judgment) (emphasis added).
220. *See Mistretta*, 488 U.S. at 380–81.
221. *See Pan. Ref. Co.*, 293 U.S. at 428–29.
222. *Id.*
223. *See Mistretta*, 488 U.S. at 371–74; *Schechter*, 295 U.S. at 530; *Pan. Ref. Co.*, 293 U.S. at 421; J.W. Hampton, Jr., & Co. v. United States, 276 U.S. 394 (1928).
224. *See Mistretta*, 488 U.S. at 372–73.

> cases in which the principle is intelligible and yet the significance of the delegated decision is simply too great for the decision to be called anything other than "legislative."
>
> As it is, none of the parties to these cases has examined the text of the Constitution or asked us to reconsider our precedents on cessions of legislative power. On a future day, however, I would be willing to address the question whether our delegation jurisprudence has strayed too far from our Founders' understanding of separation of powers.[225]

Either in terms of the recognizing the legislative power or the law-rule distinction the concern is the same—delegations may enable the Executive branch to wield legislative powers contrary to the principles of separation of powers as set out by Madison.[226] In addition, the Court in *Carter v. Carter Coal Co.* held a delegation unconstitutional despite the expression of an intelligible principle, so there must be something more to constraining delegation than an intelligible principle.[227]

On the other hand, the logic of delegation under the rule-law distinction represents a neat package—there is no delegation because Congress has enacted a law, set the policy, standards and boundaries, and the delegation is merely subordinate rule making authority.[228] As demonstrated in both the "filling up the details" and the "intelligible principle" tests, necessity has pushed the applicable effect of nondelegation far away from mere executive discretion and administrative rule-making to delegations under the broad general directives.[229] If the sole requirement is that broad general directives and some intelligible boundaries are sufficient to delegate legislative authority, then logically, only the most boundless or unintelligible legislative delegations could possibly be considered an unconstitutional delegation, which has clearly been the result.[230]

C. *Nondelegatable Legislation*

Often criticized as only having "one good year,"[231] critics of the nondelegation doctrine decry it dead on arrival, claiming it has only been used twice to invalidate statutes and would rename the nondelegation doctrine as the delegation doctrine due to the courts' tendency to uphold delegations of legislative power.[232] It would appear that reports of its demise have been greatly exaggerated, because, not only

225. Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 487 (2001).
226. THE FEDERALIST NO. 47 (James Madison).
227. Carter v. Carter Coal Co., 298 U.S. 238, 311 (1936).
228. *See Pan. Ref. Co.*, 293 U.S. at 421.
229. *See Mistretta*, 488 U.S at 372–73.
230. *See Whitman*, 531 U.S. at 474–75 (2001).
231. BREYER, *supra* note 10, at 44.
232. *See* Marci A. Hamilton, *Representation and Nondelegation: Back to Basics*, 20 CARDOZO L. REV. 807, 807 (1999).

are there additional cases involving nondelegation,[233] the nondelegation doctrine has shown up in different forms.[234] It is clear that both prior to and after the traditional nondelegation doctrine's "one good year," statutes have not been struck down for lacking an intelligible principle.[235] But, limiting the statement to "statutes" and "lacking an intelligible principle" does not paint the entire picture for the nondelegation doctrine.[236] *Panama Refining* and *Schechter* are not the only times that legislation, including ordinances, have been struck down under principles expressed by the nondelegation doctrine, especially in the area of delegations to private parties.[237] The nondelegation doctrine takes on many forms and some of these forms are well disguised.[238]

1. Traditional Nondelegation

In 1935, the nondelegation doctrine found its voice when the Supreme Court used the nondelegation doctrine to strike down legislation in two cases: *Panama Refining Co. v. Ryan*[239] and *A.L.A. Schechter Poultry Corp. v. United States*.[240] These two cases establish, respectively, that the unconstitutional delegation of Congressional rule making authority can be classed in two forms: (1) those that lack any appreciable standard, and (2) those that allow the promulgation of rules after the involvement of private groups in the legislative process.[241] "In both *Schechter* and *Panama Refining*, the Court concluded that Congress had failed to articulate any policy or standard that would serve to confine the discretion of the authorities to whom Congress had delegated power."[242]

2. Boundless verses Broad Delegations

The Supreme Court in *Panama Refining* stated that although delegation has been given wide range, it still cannot be "allowed to ob-

233. *See generally* AT&T Corp. v. Iowa Util. Bd., 525 U.S. 366 (1999); Carter v. Carter Coal Co., 298 U.S. 238 (1936); Washington ex. rel. Seattle Title Trust Co. v. Roberge, 278 U.S. 116 (1928); Eubank v. City of Richmond, 226 U.S. 137 (1912).

234. Cass R. Sunstein, *Nondelegation Canons*, 67 U. CHI. L. REV. 315, 336 (2000) (arguing that nondelegation has changed into a set of nondelegation canons forbidding extraterritorial application of national law, intrusions on state sovereignty, decisions harmful to Native Americans, and absolutist approaches to health and safety).

235. Mistretta v. United States, 488 U.S 361, 373 (1989).

236. *See generally AT&T Corp.*, 525 U.S. at 366; *Carter*, 298 U.S. at 238; *Roberge*, 278 U.S. at 116; *Eubank*, 226 U.S. at 137.

237. *See AT&T Corp.*, 525 U.S. at 366; *Carter*, 298 U.S. at 238 (1936); *Roberge*, 278 U.S. at 116; *Eubank*, 226 U.S. at 137.

238. *See* Sunstein, *supra* note 171, at 329–37.

239. 293 U.S. 388 (1935).

240. 295 U.S. 495 (1935).

241. E. H. Schopler, Annotation, *Delegation of Legislative Power to Nongovernmental Agencies as Regards Prices, Wages, and Hours*, 3 A.L.R.2d 188 § 3 (1949).

242. Mistretta v. United States, 488 U.S. 361, 372 n.7 (1989).

scure the limitations of authority to delegate, if our constitutional system is to be maintained."[243] In pursuing these limitations, *Panama Refining* struck down § 9(c) of the National Industry Recovery Act (NIRA),[244] which provided for Presidential authority to prohibit the transportation of the amount of petroleum or petroleum products produced in excess of the state's permission.[245] The Court in *Panama Refining* looked for three elements: (1) whether Congress had declared a policy with respect to the subject; (2) whether Congress had established a standard for the President's action; and (3) whether Congress had required the agent to make any findings in the exercise of the authority to enact the prohibition.[246] In its analysis, the Court determined that the statute gave the President unlimited power to determine policy and to declare prohibitory law.[247] Throwing off arguments of Presidential good will, the Court established that potential benefits, deleterious consequences, and the President's good will toward self-limitation would not affect the decision—the issue was a matter of law, not motives.[248] More generally, the Court found that the statute did not establish policy or present standards and it failed to provide guidance for the exercise of the delegated authority, and, therefore, it was an unconstitutional delegation.[249]

In every case where the constitutionality of delegation had been raised prior to *Panama Refining*, the Court has recognized that there are limits to delegation which there is no constitutional authority to transcend.[250] The Court in *Panama Refining* held that § 9(c) went beyond those limits and, if upheld, it would be "idle to pretend that anything would be left of limitations upon the power of the Congress to delegate its law-making function."[251] Upholding § 9(c) would render the constitutional prohibition in Article I meaningless.[252]

The *Schechter* case represents either form of unconstitutional delegation because it both lacked appreciable standards and involved private parties within the legislative process.[253] *Schechter* challenged a different section of the NIRA. Section 3(d) shockingly allowed the President:

> [u]pon *his own motion* . . . [and] after such public notice and hearing *as he shall specify*, may prescribe and approve a code of fair compe-

243. *Pan. Ref. Co.*, 293 U.S. at 421.
244. National Industrial Recovery Act of 1933, ch. 90, 48 Stat. 195 (15 U.S.C. § 709(c)), *invalidated by Schecther*, 295 U.S. 495.
245. *Pan. Ref. Co.*, 293 U.S. at 415.
246. *Id.*
247. *Id.*
248. *Id.* at 420. "The point is not one of motives but of constitutional authority, for which the best of motives is not a substitute." *Id.*
249. *Id.* at 430.
250. *Id.*
251. *Id.*
252. *Id.*
253. A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495 (1935).

> tition for such trade or industry or subdivision thereof, which shall have the same effect as a code of fair competition approved by the President under subsection (a) of this section.[254]

In terms of boundless delegations, the Court analyzed § 3 and concluded that it provided no standards.[255] "Instead of prescribing rules of conduct, it authorize[d] the making of codes to prescribe them.[256] Due to the broad declarations coupled with few restrictions, the President's discretion was unfettered.[257]

Broad delegations have been upheld on multiple occasions.[258] A recent decision described the contested statute in *Schechter* as "confer[ing] authority to regulate the entire economy on the basis of no more precise a standard than stimulating the economy by assuring fair competition."[259] The distinction may not be obvious when contrasting the limiting criteria of this decision with other broad delegations based on general restrictions. A good example is the authorization of the Securities and Exchange Commission (SEC) "to modify the structure of holding company systems so as to ensure they are not unduly or unnecessarily complicate[d] and do not unfairly or inequitably distribute voting power among security holders."[260] The distinction, in *Schecter*, is in the sweeping powers invested in the President himself and not to the Executive Branch.[261] The power delegated was to create law "on his own motion," without limitation, resulting in an economy run by the President alone, reminiscent of rule by decree.[262] Despite holding up broad delegations, it is clear that when no policy, standards, and guidance are provided by the Legislature during the delegation of legislative power to the Executive Branch, the law results in a violation of the nondelegation doctrine and the separation of powers.[263]

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254. *Id.* at 522, n.4 (emphasis added).

255. *Id.* at 541.

256. *Id.* "It supplies no standards for any trade, industry or activity. It does not undertake to prescribe rules of conduct to be applied to particular states of fact determined by appropriate administrative procedure. Instead of prescribing rules of conduct, it authorizes the making of codes to prescribe them." *Id.*

257. *Id.* at 541–42. "In view of the scope of that broad declaration, and of the nature of the few restrictions that are imposed, the discretion of the President in approving or prescribing codes, and thus enacting laws for the government of trade and industry throughout the country, is virtually unfettered." *Id.*

258. Mistretta v. United States, 488 U.S. 361, 373–74 (1989).

259. Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 474 (2001).

260. *Id.* at 474.

261. *Schechter*, 295 U.S. at 538–39.

262. *Id.* at 539; *see* BREYER, *supra* note 10, at 37.

263. *See Schechter*, 295 U.S. at 538–42.

3. Delegations to Private Parties

The Court in *Schechter* also attacked delegations to private parties.[264] In fact, at least six Supreme Court cases deal with the delegation of rule making functions to private parties between the years 1912 and 1939.[265] The government in *Schechter* argued that the codes to regulate competition created under NIRA would consist of rules and regulations deemed fair by representatives of affected industry—by those most vitally concerned and familiar with the problems.[266] The Court held that Congress could not delegate its "legislative authority to trade or industrial associations or groups"—that is, privately interested parties—and that these private groups could not "be constituted legislative bodies . . . [just] because such associations or groups are familiar with the problems" at hand.[267] The Court soundly rejected these claims by stating that "[s]uch a delegation of legislative power is unknown to our law and is utterly inconsistent with the constitutional prerogatives and duties of Congress."[268] Hence, the legislative vesting clause not only applies to when the power is delegated to another branch, but when the legislature abdicates power.

This was not the first time, nor the last, that the Supreme Court would invalidate delegations to private parties.[269] In an earlier case, *Eubank v. City of Richmond*, the Supreme Court struck down an ordinance that allowed two-thirds of voters on any one street to effectively set their preferred building line.[270] According to the ordinance, the public committee was bound by the petition of the voters, which left no discretion to the committee and effectively delegated law making functions to private parties.[271] Again, in 1928, the Supreme Court in *State of Washington ex rel. Seattle Title Trust Co. v. Roberge*,[272] struck down an ordinance that required approval by two-thirds of voters who owned property within 400 feet of a site designated to provide a philanthropic home for children or old people.[273] The ordinance effectively gave owners of less than one-half of surrounding land the power to make the decision "uncontrolled by any standard or rule prescribed by legislative action."[274] And just like in *Eubank*, the public official—

264. *Id.* at 537.

265. *See* United States v. Rock Royal Co-op, Inc., 307 U.S. 533 (1939); Currin v. Wallace, 306 U.S. 1 (1939); Carter v. Carter Coal Co., 298 U.S. 238 (1936); *Schechter*, 295 U.S. 495 (1935); State of Washington ex. rel. Seattle Title Trust Co. v. Roberge, 278 U.S. 116 (1928); Eubank v. City of Richmond, 226 U.S. 137 (1912).

266. *Schechter*, 295 U.S. at 537.

267. *Id.*

268. *Id.*

269. *See Carter*, 298 U.S. at 238; *Roberge*, 278 U.S. at 116; *Eubank*, 226 U.S. at 137.

270. *Eubank*, 226 U.S. at 144.

271. *Id.* at 143.

272. Washington ex. rel. Seattle Title Trust Co. v. Roberge, 278 U.S. 116 (1928).

273. *Id.* at 118.

274. *Id.* at 121–22.

the superintendent in this case—was again bound by the decision of the property owners.[275]

Following *Eubank* and *Roberge* and the establishment of the traditional nondelegation doctrine, the Supreme Court in *Carter v. Carter Coal Co.* invalidated a statute that delegated the power to fix maximum hours and minimum wages to the producers of two-thirds of annual tonnage of coal, and the majority of workers.[276] The effect was to subject the dissentient minority to compulsory acceptance at the decision of the majority.[277] Hence, once again an example of an adversely interested private party being given control of a third party's private interests.[278] As the Court noted: "This is legislative delegation in its most obnoxious form; for it is not even delegation to an official or an official body, presumptively disinterested, but to private persons whose interests may be and often are adverse to the interests of others in the same business."[279] Fundamental to the holding is that "*one person may not be entrusted with the power to regulate the business of another, and especially a competitor*" and that legislation conferring such power is both "intolerable" and "unconstitutional."[280] The Court in *Carter* dispatched the delegation as "clearly arbitrary, and so clearly a denial of [the] rights safeguarded by the due process clause of the Fifth Amendment . . . ."[281]

In direct contrast to *Roberge* and *Eubank*, in 1939 the Supreme Court upheld two alleged delegations to private parties in *Currin v. Wallace*[282] and in *United States v. Rock Royal Coop.*[283] In both cases, the rule promulgated by the Secretary of the agency was subject to the approval to those it directly affected.[284] The Court in *Currin* held that the delegation to the Secretary was constitutional because the statute set forth the policy, standards, and requirements of findings.[285] The dispute was over the Secretary of Agriculture's designation of a market for tobacco inspection and grading pursuant to the Tobacco Inspection Act.[286] He was required to designate markets where tobacco was bought and sold at auction, but could not designate the market unless two-thirds of the growers favored it by voting on a proscribed referendum.[287] A primary contested issue was the involvement of the

275. *Id.* at 122.
276. Carter v. Carter Coal Co., 298 U.S. 238, 310 (1936).
277. *Id.* at 311.
278. *See id.*
279. *Id.*
280. *Id.* (emphasis added).
281. *Id.* at 311.
282. Currin v. Wallace, 306 U.S. 1 (1939).
283. United States v. Rock Royal Coop, Inc., 307 U.S. 533 (1939).
284. *Currin*, 306 U.S. at 16; *Rock Royal*, 307 U.S. at 547.
285. *Currin*, 306 U.S. at 16–17.
286. *Id.* at 6.
287. *Id.*

private parties in the decision of the market designation.[288] The Court also found that there was no legislative delegation to private parties because Congress merely placed a restriction on its own regulation by withholding its operation in a market unless two-thirds of the growers approved it.[289] Notably, the delegation was considered as two separate determinations by the court, implying that a situation can exist where a proper delegation was made by statute might nevertheless be found invalid because it delegates to private parties.[290]

The Court explicitly distinguished the *Currin* situation from *Carter* where a group of producers make the law and enforce it upon a minority, and from *Roberge* where the prohibition of legitimate land use is imposed by other property owners rather than by legislature.[291] Congress has the power to make the law regardless of the approval; it only created a condition of going into effect made dependent on the approval by voters in a certain district.[292] On one hand, in *Eubank*, the voter imposed a rule and the public official was bound by the decision, but in *Currin* the Secretary imposed a rule, but was bound by the decision of voters.[293] Therefore, this was not a prohibition imposed by private parties on other private parties; rather, it was the action of a presumptively disinterested public party where the prohibition could not be imposed without the approval of the affected private parties.[294]

Similarly, in *Rock Royal*, the rule promulgated by the Secretary of Agriculture required a similar approval to fix milk prices.[295] The Secretary after determining findings based upon hearings could set prices by issuance of an order.[296] When the order is created without a special determination by the Secretary and the approval of the President, the order must be approved by the milk handlers to become effective.[297] Notwithstanding rejection by the handlers, the order could become effective, with approval of the President, and by a vote of two-thirds of the producers.[298]

The Court examined three issues of delegation: (1) delegation to the Secretary of Agriculture; (2) delegation to the producers; and (3) delegation to the cooperatives to vote on behalf of the producers.[299] Again the statute, unlike in *Schechter*, was well constructed as a lawful

288. *Id.* at 9.
289. *Id.* at 15. If Congress can withhold its power on the condition of private-party approval, then why could Congress not withhold its power upon using its own, monocameral approval requirement. *See* INS v. Chadha, 462 U.S. 919 (1983).
290. *See Currin*, 306 U.S. at 15.
291. *Id.* at 15–16.
292. *Id.*
293. *Id.*
294. *See id.*
295. United States v. Rock Royal Coop, Inc., 307 U.S. 533, 546 (1939).
296. *Id.* at 547.
297. *Id.*
298. *Id.*
299. *Id.* at 574.

delegation to the Secretary.[300] The Court found the statute provided all the elements of a lawful delegation because it allowed the Secretary to fix prices only for specific commodities, contingent on hearings and findings.[301] Additionally, the statute conferred a right to objection by the milk handlers to approve the order and, in turn, for producers to approve the order.[302] "Even though procedural safeguards cannot validate an unconstitutional delegation, they do furnish protection against arbitrary use of properly delegated authority."[303] The power of the producers to approve the order and the representative voting by the cooperatives were considered merely procedural safeguards, because Congress had the power to affect the order without approval by anyone.[304]

Hence, the delegations involved in both *Currin* and *Rock Royal* were not delegations to private parties despite the provision for their approval.[305] It would seem, as a general rule, that where a statute allows private parties to compel a government rule-making action rather than merely provide a safeguard against the arbitrary exercise of delegated power, the statute is unconstitutional.[306] In essence, who makes and enforces the decisions are of paramount importance.

The prohibition of delegation of the power to private parties can include the person of the President, as well as private industry.[307] But where Congress has provided the policy, limits, and standards, the President may be its agent.[308] Without these limits, there would be no system of checks and balances to prevent the natural encroachment by one branch into the power of another.[309] The agent's power would become unfettered and be able to be exercised without the external control provided by the checks and balances of the other branches of government.[310] These limits allow the modern administrative state to function in a debatable constitutional manner.[311] Even if we were to accept the constitutionality of delegation to a single branch administrative agency, any deviation from the limits would render an administrative agency unconstitutional.

300. *Id.* at 575.
301. *Id.* at 576.
302. *Id.*
303. *Id.*
304. *Id.* at 577.
305. *Id.*; Currin v. Wallace, 306 U.S. 1, 15–16 (1939).
306. *See Currin*, 306 U.S. at 15–16 (1939); *Rock Royal*, 307 U.S. at 576.
307. *See* A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495 (1935).
308. *Id.* at 537–42.
309. *See id.*
310. *See id.*
311. *See* BREYER, *supra* note 10, at 43–56.

IV. CONSTITUTIONALITY OF ADMINISTRATIVE AGENCIES

The Executive reorganization that created the DHHS as a government department originated with just one client: the public.[312] If the Legislature had created the DHHS as a delegation to private interest groups, the legislation would have fallen in face of the nondelegation doctrine.[313] Nonetheless, many key employees of the DHHS agencies are on the payroll of various pharmaceutical companies which are private interest groups.[314] Further, these private interests related to the pharmaceutical industry have for some time *unduly influenced* the government.[315] The questions created by private interest involvement in a public federal government agency are three-fold. First, may an agency effectively privatize itself, even to a limited extent, when the legislature provided for a public agency? Second, would this privatization withstand scrutiny under the separation of powers and nondelegation doctrine? Third, what remedies are available once this privatization has occurred?

This status change of agency employees from a purely public servant, concerned only about the public, to a partially privatized interest by virtue of their financial conflicts of interest not only calls into question where their loyalties lie, but also the impartiality of the entire organization.[316] Dr. Arnold S. Relman, Emeritus Editor-in-Chief of the New England Journal of Medicine, warns that when agency employees are receiving sums of money from a company, they will desire the company to perform well.[317] The agency's "permissive culture" is fraught with conflicts of interest.[318] When this privatization is coupled with the fact that 50% of the FDA's funding for drug regulation is the drug companies themselves, and the undue influence of conflicted advisory committees, the issue of the agency's privatization becomes paramount.[319] These factors imply that the agency is substantially operating under the influence of private interests. The result is that the status of an agency whose employees are paid by the parties they are regulating may be regarded as private-in-fact, if not private-in-law.

Although necessity is a ground to support broad delegation of subordinate rule making authority, it does not support delegation to

312. *See generally* Reorganization Plan No. 1 of 1953, 3 C.F.R. 131 (Supp. 1953), *reprinted in* 5 U.S.C.A. app. at 187 (West 1996); John P. Swann, History of the FDA, http://www.fda.gov/oc/history/historyoffda/default.htm (last visited Feb. 1, 2006) (discussing the origins and development of the FDA).

313. *See generally* Carter v. Carter Coal Co., 298 U.S. 238, 311 (1936); *Schechter*, 295 U.S. at 537.

314. *See NIH Ethics Hearing*, *supra* note 5, at 489.

315. *See* MAJORITY STAFF REPORT ON VACCINE POLICY MAKING, *supra* note 9, at 35–36.

316. *See Stealth Merger*, *supra* note 2, at A1.

317. *Id.*

318. *See The Nation*, *supra* note 9, at A1.

319. *FDA Hearings*, *supra* note 138.

private interest groups.[320] The Supreme Court holdings on delegating regulatory functions to private interest groups are clear that it ". . . is unknown to our law and is utterly inconsistent with the constitutional prerogatives and duties of Congress."[321] In this area, the distinction often used to separate legislation from subordinate rule making functions fails.[322] There exists a strict prohibition against delegation of rule making functions to private interest groups, especially those whose interest are adverse to the third parties they affect.[323]

Some argue that the collaboration between government regulators and drug companies is necessary and provides positive benefits.[324] One argument states that conflicts of interest must be allowed because there is a shortage of good scientists and experts in some fields of interest and, therefore, incentives are necessary to attract scientists to government positions.[325] From a common sense perspective, however, it is difficult to imagine that the NIH, one of the most prestigious institutions in academia (that consistently pays some of the highest wages in the federal government), would have a difficult time with recruitment.[326] Further, these conflicts of interest lead others to question the impartiality of the researchers and regulators.[327] In addition, the experts themselves in any function requiring evaluation may bring with them strong bias which can be subtlety encouraged by financial interests.[328] Evidence also suggests that these relationships impact life and death decisions and, therefore, it seems natural that the highest care must be exercised.[329]

Put in a different context, federal drug enforcement officers are not allowed to be the paid consultants of a drug cartel.[330] Similarly, it would be absurd to allow judge's to be on the payroll of the defendants they were prosecuting.[331] Nonetheless, regulators are on the payroll of the regulated, which has deleterious implications.[332] However, deleterious or beneficial implications do not replace constitutional validity, nor does goodwill suffice to legitimize unconstitutional delega-

320. *See generally* Carter v. Carter Coal Co., 298 U.S. 238, 311 (1936); A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495, 537 (1935).

321. *Schechter*, 295 U.S. at 537.

322. *See generally id.*

323. *Carter*, 298 U.S. at 311. However, some scholars believe it can be made constitutionally compliant with additional safeguards. *See* Gilliam E. Metzger, *Privatization as Delegation*, 103 COLUM. L. REV. 1367 (2003).

324. *NIH Ethics Hearing*, *supra* note 5.

325. *Id.*

326. *Id.* (testimony of Elias A. Zerhouni).

327. *Nov. 2004 Autism Hearings*, *supra* note 133 (testimony of Lyn Redwood).

328. *See* MAJORITY STAFF REPORT ON VACCINE POLICY MAKING, *supra* note 9, at 37.

329. *Vioxx Hearing*, *supra* note 9.

330. 18 U.S.C. § 201 (2000) (regarding bribery of public officials and witnesses).

331. *See* MODEL CODE OF JUDICIAL CONDUCT Canon 3 (2004).

332. *Vioxx Hearing*, *supra* note 9.

tion.[333] Therefore, if the goodwill of the President is insufficient, the honor system used by the DHHS should be insufficient to remove the constitutional difficulties of privatization.[334]

Conflicts in the NIH appear more innocuous from the constitutionality standpoint, at least on the surface, because the agency's primary function is the promotion of the science of health.[335] In terms of nondelegation theory, the scientific endeavor might arguably be considered a factual determination exercise, which is clearly permitted under the auspices of the contingency theory of delegation.[336] Although it is easy to imagine arguments where some aspect of the NIH agency would fit into any one of the three governmental functions, to the extent that the NIH performs non-executive functions, it suffers by conflicting with the separation of powers doctrine. And delegation to private interests is prohibited regardless of the governmental function.[337] Additionally, the scientific opinions generated by the NIH are used in regulatory functions,[338] and when they are flawed by conflicts of interest,[339] the regulatory function may in turn be compromised.

The FDA, however, clearly performs a far more substantial regulatory function by regulating drug approval, drug use, and the behavior of drug companies along with taking appropriate action against drugs found to be harmful.[340] In these circumstances, conflicts of interest can compromise the legislative rule-making function of promulgating regulatory decisions, the judicial function of reviewing drug approval, and the executive function of approving only safe drugs and taking action against unsafe drugs.[341] All of these functions impact legislative control of third parties, either as competitor companies, or as private individuals whose protection is the primary purpose of the agency.[342] The impact on the rights of third parties, especially in any prohibitory regulation, implicates an unconstitutional delegation to private parties.[343]

The past Supreme Court cases dealing with delegation issues all examined legislation that was either created with private interests in

333. *See* Pan. Ref. Co. v. Ryan, 293 U.S. 388, 420 (1935). "The point is not one of motives but of constitutional authority, for which the best of motives is not a substitute." *Id.*

334. *Id.*

335. *See* U.S. GOV'T MANUAL, *supra* note 3, at 221–25.

336. *See generally* Field v. Clark, 143 U.S. 649 (1892).

337. *See* A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495, 537 (1935).

338. *See generally* Ctr. for Drug Evaluation & Research, Food & Drug Admin., Transcript of Arthritis Advisory Committee Meeting (July 30, 2002), http://www.fda.gov/ohrms/dockets/ac/02/transcripts/3873T2_01.pdf (discussing dosages, toxicities, and safety data for Vioxx and other acute pain drugs).

339. *See generally id.*

340. *See generally id.*

341. *See generally* U.S. GOV'T MANUAL, *supra* note 3.

342. *See generally id.*

343. *See* Carter v. Carter Coal Co., 298 U.S. 238, 311 (1936).

mind or created with boundless authority.[344] These cases did not consider legislation that was initially created within the confines of the nondelegation doctrine only to be later converted by actions of the public agency into an unlawful delegation of authority to private interests.[345] Clearly, if the weight of the evidence indicates the agency is no longer a public agent, then the nondelegation doctrine will have been violated, and no amount of good-will or intention will save it.[346] But, can the actions of the pubic agent that create an unconstitutional delegation be considered unconstitutional and therefore prohibited?

In this case, the NIH, FDA & CDC took actions that effected privatization. Arguably, in the NIHs case, they were authorized to do so under the waiver clause in 18 U.S.C. § 208.[347] Because the waiver clause permits the public agent to unfetter the limits provided by Congress, then the waiver clause is a boundless delegation.[348] If the waiver clause could convert a constitutional delegation into an unconstitutional delegation, then the clause itself would be unconstitutional in effect.[349] This would not be the case if the waiver was to be granted by a different branch department, because, then it would not be at the public agent's own initiative to unfetter its limits.[350] Albeit, even the authority of Congress would have to answer to the restrictions of the Constitution in allowing waivers that allow private interest involvement in the legislative process.[351] Finally, if the waiver process may be simply ignored by the public agent who violates the bounds of authority provided by Congress, then any act thereof becomes an illegal act. This points to the underlying weakness of the system. Once delegated to the Executive branch, the Congress has no real power to insure the public agent remains within the scope of the delegated authority.

V. A FLAWED SYSTEM

The system of administrative agencies is flawed. From the organization of the FDA drug enforcement division[352] to the general topology

344. *See generally* United States v. Rock Royal Coop, Inc., 307 U.S. 533 (1939); Currin v. Wallace, 306 U.S. 1 (1939); *Carter* 298 U.S. at 238 (1936); A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495 (1935); Pan. Ref. Co. v. Ryan, 293 U.S. 388 (1935); Washington *ex. rel.* Seattle Title Trust Co. v. Roberge, 278 U.S. 116 (1928); Eubank v. City of Richmond, 226 U.S. 137 (1912).

345. *See generally Rock Royal*, 307 U.S. at 533; *Currin*, 306 U.S. at 1; *Carter*, 298 U.S. 238; *Schechter*, 295 U.S. at 495; *Pan. Ref. Co.*, 293 U.S. at 388; *Roberge*, 278 U.S. at 116; *Eubank*, 226 U.S. 137.

346. *See Carter* 298 U.S. at 311.

347. 18 U.S.C. § 208 (2000).

348. *See Schecter*, 295 U.S. at 537–38.

349. *See id.*

350. *See id.*

351. *See id.*

352. *See Vioxx Hearing*, *supra* note 9.

of the administrative state,[353] there is a fundamental weakness—there is no system of checks and balances that is fundamental to our constitutional government. The only real limit on agency action is self-restraint.

Dr. David Graham, in testifying before the Senate Finance Committee, argued that the agency as currently constructed could not protect the public.[354] He may be correct, especially in light of the conflicts of interest in the latest safety advisory panel on COX-2 inhibitor drugs.[355] The process of approving and regulating drugs has an inherent conflict of interest: when drugs present health issues, the same regulators that originally approved the drugs must later take action against the very drugs they approved.[356] Not only are the parties that approved the drug likely to have a strong bias having already convinced themselves of the drug's safety, they must also overcome having been wrong in the first place.[357] The addition of a financial incentive to promote the drug with an existing conviction that a drug is safe creates a potentially lethal combination.[358] In simpler terms, the structure allows human frailties free reign: it mixes the vice of pride with the vice of greed.

It is no small wonder that the DHHS is fraught with a permissive culture of conflicts of interest, because there is a flaw built into the very structure of the administrative agency.[359] Looking from a larger perspective, the delegation of administrative agencies within the Executive Branch poses a serious problem: when an administrative agency breaks the law, the Executive Branch must execute the law against itself.[360] In general, financial conflicts of interest are illegal under 18 U.S.C § 208,[361] however, the section provides for waivers.[362] In this case of the NIH, the agency determined for itself that restriction on conflicts could be relaxed to conform to the more relaxed executive standards.[363] The Executive branch, and more precisely, the agency could determine for itself whether to enforce 18 U.S.C. § 208.[364] The NIH also interpreted federal law to allow employees to have greater

353. *See generally* BREYER, supra note 10, at 43–57.
354. *Vioxx Hearing*, *supra* note 9.
355. Press Release, Ctr. for Sci. in the Pub. Interest, supra note 60.
356. *See Vioxx Hearing*, *supra* note 9.
357. *Id.*
358. *Id.*
359. *See id.*
360. *See* U.S. GOV'T MANUAL, *supra* note 3, at 492–93 (detailing the responsibilities of the Office of Government Ethics).
361. 18 U.S.C. § 208 (2000).
362. *Id.*
363. *Stealth Merger*, *supra* note 2, at A1 (citing Varmus' 1995 memo).
364. *See* U.S. GOV'T MANUAL, *supra* note 3, at 492–93; 18 U.S.C. § 208 (2004). The predecessor law to 18 U.S.C. § 208, 18 U.S.C. § 434, was reviewed by the Supreme Court, which noted: "The statute is directed at an evil which endangers the very fabric of a democratic society, for a democracy is effective only if the people have faith in those who govern, and that faith is bound to be shattered when high officials and their

confidentiality in the income they receive from outside sources.[365] As evidence of this compromised enforcement ability, the investigations regarding conflicts of interest within the NIH did not begin until the power of a free press provided the necessary impetus when David Willman published his article detailing serious conflicts of interest within the NIH.[366]

When the Executive Branch fails to enforce the laws against itself, coupled with the power to interpret or create the law by subordinate rule-making, the very fears of Montesquieu and Madison are fulfilled.[367] "When the legislative and executive powers are united in the same person or body . . . there can be no liberty, because apprehensions may rise lest *the same* monarch or senate should *enact* tyrannical laws to *execute* them in a tyrannical manner."[368] In this case, the failure to execute the enacted law has the tyrannical impact on third parties—the victims of the dangerous drugs represented to be safe. This is why Madison submitted in FEDERALIST NO. 47 that "[t]his, however is not among the vices of [this] constitution. The magistrate in whom the whole executive power resides cannot of himself make a law. . . ."[369] This is the very reason for the separation of powers doctrine and why the Constitution has three branches of government.

But there are larger structural problems with federal government agencies. Under the separation of powers doctrine, modern administrative agencies have tenuous constitutionality.[370] Administrative agencies such as the FDA and CDC have been delegated the legislative functions in fact.[371] An excellent example of the legislation in fact is elaborated by Michael Horwin discussing the development of federal vaccine policy.[372] According to Horwin, the FDA and CDC each have a very influential committee in the development of that policy.[373] These recommendations are universally accepted and adopted as policy.[374] From these policies, rules are promulgated and State and Federal law is influenced with the aide of financial funds.[375] One of the cannons of nondelegation is that subordinate rule making does not develop policy because policy development is a legislative function

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appointees engage in activities which arouse suspicions of malfeasance and corruption." United States v. Miss. Valley Generating Co., 364 U.S. 520, 562 (1961).

365. *Stealth Merger*, *supra* note 2, at A1.

366. *The Nation*, *supra* note 9, at A1; *Stealth Merger*, *supra* note 2, at A1.

367. *See* THE FEDERALIST NO. 47 (James Madison), *supra* note 146, at 140.

368. *Id.* at 141.

369. *Id.* at 140

370. *See* BREYER, *supra* note 10, at 38–39.

371. *See generally* MAJORITY STAFF REPORT ON VACCINE POLICY MAKING, *supra* note 9.

372. *See* Horwin, *supra* note 92, at 322 (discussing the key role played in creation of vaccine policy).

373. *Id.* at 338.

374. *Id.* at 354.

375. *Id.*

that cannot be delegated.[376] These delegations have the effect of accumulating the whole of all three powers within the hands of one group.[377]

Theoretically, Congress retains the power to enact a new law repealing offensive provisions of the prior delegations, but it suffers from bicameral requirements, sufficient definiteness, and the original compromised execution.[378] First, the power has already accumulated in the Executive Branch and Congressional legislation to affect that power requires bicameral passage and presentment to the President, therefore, requiring the approval of Executive Branch to relinquish that power.[379] Second, one of the reasons for delegating legislative power is that laws enacted by Congress lack definiteness and, therefore, without an absolute plain text ban on conflicts of interest, the Executive Branch can interpret the law to its benefit.[380] Finally, even if the law is clear in its text as to prohibit interpretation, the Executive Branch may simply fail to enforce the law. Hence, the analysis returns to the original problem: the Executive Branch continues to be inherently compromised in executing the statute against itself. Arguably, a truly independent agency mandated to investigate and prosecute government corruption may be a viable partial solution.

Congress is likewise hampered in controlling the situation. Once Congress has delegated power it cannot get it back and the result is that power from multiple branches accumulates in one branch of the government.[381] In addition, the Supreme Court terminated the Legislative veto power.[382] The judiciary is unlikely to restore the balance, because the Supreme Court has already held in favor of *Skidmore* and *Chevron* deference as well as to the capitulation to the administrative state on behalf of the legislature.[383] Considering the limitation of bicameralism and presentment placed on the legislature,[384] the deference required of courts to the administrative adjudicative decisions,[385] and the limitations on the President's ability to dismiss senior officials of independent agencies and subordinate officials of executive agen-

376. See Pan. Ref. Co. v. Ryan, 293 U.S. 388, 415–21 (1935).

377. *See id.*

378. *See* CHOPER, *supra* note 154, at 155.

379. *Id.*

380. Mistretta v. United States, 488 U.S. 361, 371–74 (1989).

381. *See* INS v. Chadha, 462 U.S. 919, 951–59 (1983).

382. *Id.* at 959.

383. *See generally* Skidmore v. Swift & Co., 323 U.S. 134 (1944); Chevron U.S.A. Inc. v. Natural Res. Def. Council, 467 U.S. 837 (1984). The Court in *Chadha* not only limited the Legislatures' ability to control the administrative state, but also its own ability by requiring deference to administrative decisions. *Chadha*, 462 U.S. at 951–59.

384. *See Chadha*, 462 U.S. at 957–58.

385. *Id.* at 986.

cies,[386] the ultimate result is a truly independent administrative state uncontrollable by any branch of government. In summary, the executive cannot fire them, the judiciary cannot overrule them, and the legislature cannot repeal them and these administrative agencies exercise all three powers of the government.[387] Hence, the administrative agencies have truly become a fourth branch of government. And now considering the influence of private interests and that the FDA receives almost 50% of its funding for drug regulation from drug manufacturers,[388] its independence even defies Congress's to control the organization with budget constraints. Perhaps a better title would be to call the federal agencies quasi-independent governments.

This problem is precisely what the separation of powers doctrine was created to prevent: the accumulation of power in one branch.[389] Current agencies represent powers of all three branches within one branch, albeit with limited deferential judicial review and with limited control by the legislature.[390] All that power in one place is highly corruptible and difficult to control as clearly demonstrated by the failure of the Vaccine Policy Making Report to prevent the conflicts of interest in the 2005 FDA safety advisory panel on COX-2 Inhibitors.[391] The lack of manageability and controllability can lead to devastating consequences, such as the damage created by bad medicines reaching the market with approval that is based on insufficient or biased studies.[392] The Vioxx unmitigated disaster is only a fragment of the potential damages if the allegations against Thimerosal and vaccines in general turn out to be true.[393]

VI. A PROPOSED SOLUTION

There are numerous discussions of nondelegation and solutions to the never reconciled constitutionality of the administrative agencies with the separation of powers doctrine.[394] Similarly, a variety of solu-

386. *See generally* Edmond v. United States, 520 U.S. 651 (1997); Morrison v. Olson, 487 U.S. 654 (1988).

387. *See* Cass R. Sunstein, *Interest Groups in American Public Law*, 38 STAN. L. REV. 29, 60 (1986).

388. *Vioxx Hearings*, *supra* note 9.

389. *See* THE FEDERALIST NO. 47 (James Madison).

390. *See* Sunstein, *supra* note 387, at 60.

391. MAJORITY STAFF REPORT ON VACCINE POLICY MAKING, *supra* note 103; Press Release, Ctr. for Sci. in the Pub. Interest, supra note 60.

392. *Vioxx Hearing*, *supra* note 9; *Nov 2004 Autism Hearings*, *supra* note 133.

393. *2002 Autism Hearings*, *supra* note 120.

394. *See* Gary Lawson, *Delegation and Original Meaning*, 88 VA. L. REV. 327, 332–33 (2002) (advocating the position taken by Justice Thomas that there could be a delegation with an "intelligible principle" of such significance to make it legislative); Sunstein, *supra* note 234, at 334–35 (2000) (arguing that the nondelegation is alive and well but has changed character to require that administrative agencies cannot make decisions on their own and must consult Congress thereby minimizing ill affects); Hamilton, *supra* note 232, at 809 (advocating revival of the nondelegation doctrine); Brown, *supra* note 156, at 1516 (urging the Supreme Court to apply separation of

tions have also been proposed to solve the problem of conflicts of interest within the DHHS administrative agencies.[395] None have been implemented.[396] Even if implemented, they are not likely to work for the reason underlying Michael Horwin's statement: "[t]he CDC and FDA are likely to reject every one of these ideas," that is, they have accumulated too much power.[397] This Comment proposes that the solution lies in rigid application of the separation of powers doctrine—all administrative agencies must be broken into their constituent legislative, executive and judicial functions and reassigned as separate organizations under the three corresponding branches of government.

The law need not be challenged in court to be changed, although that is one potential option. The courts, however, are saddled with precedent of their own making, from the "switch in time that saved the nine"[398] through continued support of delegations and deference to the Executive Branch agencies.[399] However, the case may still be argued on grounds of separation of powers. Instead of using the formalist versus functionalist approaches,[400] the issue can be raised based on the net effect: the accumulation of power in the DHHS exists, contrary to the separation of powers doctrine, which has allowed corruption resulting devastating effects.

As a solution, Congress should legislate a redistribution of agency functions to the appropriate branches of government. This would create at least three agencies to replace the original agency. The new

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powers to the protection of individual rights); Theodore J. Lowi, *Two Roads to Serfdom: Liberalism, Conservatism and Administrative Power*, 36 AM. U. L. REV. 295, 322 (1986) (advocating the reduction of administrative discretion to restore the constitutionally mandated balance of power between the branches of government); Richard B. Stewart, *Beyond Delegation Doctrine*, 36 AM. U. L. REV. 323, 328–29 (1987) (arguing for transference of decision making to local or private groups because less concerned with abuse than efficiency); David Schoenbrod, *Goal Statutes or Rules Statutes: The Case of the Clean Air Act*, 30 UCLA L. REV. 740, 803–24 (1983) (advocating a return to contingency theory delegation by arguing that Congress should engage in rule statutes and not goal orient statutes in delegating to administrative agencies); Ernest Gellhorn, Commentary, *Returning to First Principles*, 36 AM. U. L. REV. 345, 349 (1987) (arguing that "[m]odern government's constitutional breach has been its failure to abide by the Constitution's requirement that the legislature make all laws" and is being used to create private benefit). Gellhorn's solution is a limited and careful revival of the nondelegation doctrine by allowing a broader application. *Id.* at 353.

395. Horwin, *supra* note 92, at 350–62 (proposing the tightening of the laws against conflicts of interests, implementing a more stringent code against conflicts of interests, changing the composition of committees evaluating vaccine safety, utilizing oversight councils, tax payor derivative suits, and *qui tam* litigation).

396. *See, e.g.*, *id.* at 349–50 (Congressman Dan Burton's failed attempt to pass legislation); *contra* Memorandum from the Nat'l Inst. of Health on Policy Proposal for Management of Conflict of Interest (Sept. 24, 2004), http://www.nih.gov/about/092404coi_policymemo.htm (introducing a shift in NIH policy regarding conflicts of interests).

397. Horwin, *supra* note 92, at 356.

398. *See* CHOPER, *supra* note 154, at 48.

399. *See id.* at 76–80.

400. *See id.* at 155.

agencies would report to their functionally respective branch of government: the executive would remain with the executive, the judicial would move underneath the federal court system, and the legislative would move under legislative committees. Although the change would be minor for the executive functions, the judiciary would then gain control of the judicial process and remove appeals to the legislative-executive board.[401] The Legislature would gain the power to insure that the subordinate rules remain within the scope of the policy they set forward. This arrangement would also provide for a system of checks and balances between the three constituent organizations. Additionally, an independent agency could be formed to investigate and prosecute government corruption relieving the executive branch of the responsibility to investigate itself. This is not to say the task would be easy as it would upend the current administrative state.

Fundamental to the creation of the administrative state is the justification of the necessity that allows the Legislature to delegate subordinate rule-making powers.[402] This necessity is based on the Legislature's inability to provide the necessary detailed consideration to pass administrative rules.[403] The proponents of this view are undoubtedly correct. However, there exists a well equipped organization designed to provide exactly that capability—the current administrative agencies. The problem is that the legislative machinery contained in those administrative agencies is either reporting to the Executive Branch or is formulated as independent agencies instead of reporting to the Legislature.[404] The solution proposed here is a simple one: equip the legislative branch by moving the legislative functions of agencies from the executive back to the legislative branch.

The legality of self delegation of legislative power is questionable, especially in light of the Framers' concern that the Legislature was the most dangerous branch.[405] In response, can it be seriously contended that the legislative power is any less dangerous when merged with executive power? All arguments objecting to legislative self-delegation fail against one simple principle: although controversial, it is at least as valid under the legislative branch as it is under the Executive Branch especially in light of the increased harmony with the separation of powers.[406] Even if disputed, the critical aspect of this self-delegation is by the Supreme Court's own admission, not *law-making*, rather *subordinate rule-making*.[407] Further, as long as the Supreme Court continues to treat these processes as subordinate rule-making func-

401. *See generally* Sunstein, *supra* note 387, at 60.
402. *See* Pan. Ref. Co. v. Ryan, 293 U.S. 388, 415–21 (1935).
403. *See Id.*
404. *See* U.S. GOV'T MANUAL, *supra* note 3, at 217–27.
405. *See* CHOPER, *supra* note 154, at 155.
406. *See* Seth Barrett Tillman, *The Domain of Constitutional Delegations Under the Orders, Resolutions, and Votes Clause*, 83 TEX. L. REV. 1389, 1392 n.8 (2005).
407. *See Pan. Ref. Co.*, 293 U.S. at 421.

tions, Congress is free to place the function wherever they deem fit,[408] excepting subordination to private interest groups.[409] Bicameral passage and presentment is also not an issue, because the bicameral passage and presentment has been met when the law forming the agency was passed, and further bicameral passage and presentment is not required to promulgate rules.[410] Additionally, splitting the agencies may present a form of presentment to the President or Presidential delegate in the corresponding executive agency providing a new system of checks and balances more inline with the Framers' design of the Constitution.[411]

Depending on the final structure, single House resolution[412] objections may offer some resistance which can be addressed. It is clear that encroachment objections would no longer be a solid basis for denying single House resolutions in this formulation because the resolution would not be a final act; it would still require Executive approval.[413] Optionally, the Court (however unlikely) still has the option of holding that because the Constitution allows for single house resolutions in some cases,[414] there might be other cases where it could be applied. And again, the Supreme Court already held that bicameral requirements do not apply to rule-making functions.[415] In general, the justifications that allow delegation of subordinate rulemaking hold equally true for delegations of functions within a branch of the government when it does not offend the separation of powers doctrine.

Opponents to the proposed solution could argue that the change presents a real challenge in that the constituent parts might lose expertise.[416] The importance of expertise has been recognized by the Supreme Court in their *Skidmore* and *Chevron* deference holdings.[417] However, the courts have maintained specialized expertise in other areas.[418] For illustration, under the Vaccine Compensation Act, all vaccine compensation cases are heard by special masters that specialize in vaccine compensation cases.[419] Thus, it appears that a special master, similar to an Administrative Law Judge (ALJ), can maintain

408. *See Id.*
409. *See generally* Carter v. Carter Coal Co., 298 U.S. 238 (1936); A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495, 537 (1935).
410. *See* United States v. Mistretta, 488 U.S. 361, 386 n.14 (1989).
411. *See generally* THE FEDERALIST NO. 47 (James Madison), *supra* note 146; BREYER, *supra* note 10, at 37.
412. *See* INS v. Chadha, 462 U.S. 919, 948–51 (1983).
413. *See id.* at 919.
414. *See id.* at 955.
415. *See Mistretta*, 488 U.S. at 387 n.14.
416. *See* Allentown Mack Sales and Serv. v. NLRB, 522 U.S. 359 (1998).
417. *See generally* Skidmore v. Swift & Co., 323 U.S. 134 (1944); Chevron U.S.A. Inc. v. Natural Res. Def. Council, 467 U.S. 837 (1984).
418. *See generally* Vaccine Compensation Act, 42 U.S.C. § 300aa-1 to 34 (2000).
419. § 300aa-12.

appropriate expertise sufficient to performing judicial functions in highly technical areas.[420] In addition, the detachment may provide more objective evaluation of promulgated regulations.

Currently, rules are often promulgated by boards and when a claim is brought, it is brought before an ALJ.[421] The claim may be appealed for review to the original board that promulgated both the rule and the procedure for claims, which is not only circular but encompasses all three functions of government within one organization.[422] Only then may the claim be appealed for review by a federal appellate judge.[423] Separating the legislative, executive, and judicial nature of the boards is likely to encourage detachment and provide for checks and balances.

There are significant advantages as well. Congress would benefit from greater control and influence over the rule making process and content.[424] If nondelegation logic is to be taken seriously, then it cannot be disputed that a "core function" of Congress is to make policy. By placing the part of the administrative agency that promulgates rules and regulations inferior to Congress, Congress can then insure that its broad policy is followed. Additionally, if a proposed rule required the establishing of policy such that it truly required the passage of law, it could be sent up the new management chain to be submitted as a bill for consideration by Congress. The single greatest gain is that Congress would then have the resources and capability to address the lack of definiteness in laws that propelled the creation of the administrative state in the first place.[425]

This solution, although revolutionary, does provide many positive features: it re-instates a system of checks and balances; it provides organization better in line with the separation of powers principles; it deters administrative acts not in line with delegated policy; and it provides Congress with the power and capability to deliver regulations. This solution is just one of many possible solutions, but it is the surest way to control the difficulties of the influence of private interests within government.

VII. CONCLUSION

On December 7, 2003, the L.A. TIMES ran a major story exposing conflicts of interest in the NIH, a department of the DHHS.[426] Afterwards, the House Government Reform Committee began a series of hearings investigating the nature of the conflict only to discover hun-

420. *Id.*
421. *See generally* Sunstein, *supra* note 387.
422. *See generally id.*
423. *See generally id.*
424. *See generally id.*
425. *See Pan. Ref. Co.*, 293 U.S. 388 (1935).
426. *Stealth Merger*, *supra* note 2, at A1.

dreds of relationships, at least a hundred of which were not reported.[427] Due to the resulting public pressure, the director of the NIH announced the need for drastic changes, severely limiting the conflicts of interest.[428]

Considerable doubt existed when the NIH proposed a partial ban on conflicts of interest.[429] Even the final promulgation of a total ban is not sufficient.[430] This action is not a permanent solution, because it was promulgated by the executive department that it affects and it can either be ignored by the executive department or repealed at their political convenience as was effectively done in 1995.[431] The NIH is not the only department of the DHHS to have serious questions regarding these conflicts of interest; the FDA and CDC are likewise infected.[432] But as it turns out, this action was not taken soon enough to save the victims of Vioxx. It is estimated that 27,000 to 55,000 people are now dead, and nearly 100,000 more may suffer serious complications.[433]

Tragedies like this are preventable and the problem is not new to Congress; they have heard similar and possibly even more condemning testimony, and have even made findings in a report the House regarding incestuous conflicts of interest in U.S. vaccine policy-making five years earlier.[434] Despite all this knowledge, Congress appears powerless. The same criticisms leveled in the Majority Staff Report[435] can still be leveled at FDA safety advisory panels.[436] And this time the actions of the safety panel were in the face of the catastrophic damage done by Voixx.[437] Clearly, Congress does not have the power to stop this behavior and needs greater direct control.

The conclusive solution is to break up the federal executive branch agencies into their constituent legislative, executive, and judicial functions and to reassign them as separate organizations under the three corresponding branches of government. The agency breakup solution presents a massive undertaking. However, the budget of the NIH is approximately $30 billion, which is smaller than the split of Hewlett Packard, Inc. to form Agilent Technologies, Inc.,[438] and it is only one legal system involved unlike addressing the multiple legal systems in-

427. *NIH Ethics Hearing*, *supra* note 5.
428. *Id.*
429. *Id.*
430. *See generally* 5 C.F.R. § 5501.106 (2004).
431. *Stealth Merger*, *supra* note 2, at A1 (citing Varmus 1995 memo).
432. *See Vioxx Hearing*, *supra* note 9; *Nov. 2004 Autism Hearings*, *supra* note 133.
433. *See Vioxx Hearing*, *supra* note 9; *Nov. 2004 Autism Hearings*, *supra* note 133.
434. *See* MAJORITY STAFF REPORT ON VACCINE POLICY MAKING, *supra* note 9; *Nov. 2004 Autism Hearings*, *supra* note 133.
435. MAJORITY STAFF REPORT ON VACCINE POLICY MAKING, *supra* note 9.
436. Press Release, Ctr. for Sci. in the Pub. Interest, supra note 60.
437. *Vioxx Hearing*, *supra* note 9.
438. Steven Lipin & Don Clark, *H-P May Split Into at Least Two Entities*, WALL ST. J., Mar. 2, 1999, at A3.

volved in splitting of a multinational corporation. Therefore, although difficult, it is clearly possible.

Splitting up agencies into functional groups creates the necessary independence of the branch functions and provides for more direct control by the Congress. This would also bring the agencies more fully in line with the Framers' intentions and the textual construction of the Constitution, thereby, improving the constitutional standing of agencies.[439] The resulting executive agency would have more freedom to monitor and prosecute any illegal activity or unethical behavior; thereby installing a system of checks and balances, especially if an independent agency for government investigations were created in the process. In turn, it will minimize the problems of special interest influence and human frailty providing a safer environment for U.S. citizens.

In the immortal words of James Madison, "[i]n framing a government which is to be administered by men over men, the great difficulty lies in this: you must first enable the government to control the governed; and in the next place oblige it to control itself."[440] The creation of the administrative state endowed the great benefit by enabling the government to govern its citizens, but it is clearly time to oblige the government to control itself.

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439. *See* U.S. CONST. art. I–III; THE FEDERALIST NOS. 47, 48 (Madison).
440. THE FEDERALIST NO. 51 (James Madison), *supra* note 146, at 160.