NOTES

USING NUMERICAL STATUTORY INTERPRETATION TO IMPROVE CONFLICT OF INTEREST WAIVER PROCEDURES AT THE FDA

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ABSTRACT

Conflicts of interest frequently arise when industry experts advise federal agencies. Critics claim agencies' decisions to waive conflicts of interest often lack consistency and clarity, but they have yet to propose a comprehensive system to improve the conflict of interest waiver process.

I. INTRODUCTION

Americans have grown accustomed to protections provided by the regulatory state—we rarely need to question the safety of the products in our homes because we believe government processes prevent the sale of unsafe products. Indeed, strengthening controls at regulatory agencies such as the Food and Drug Administration ("FDA") have drastically improved the safety of products.[1] On the other hand, recent failures in regulatory

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1. Before the 1938 amendments to the Food and Drug Act of 1906 that established the FDA, the FDA had little ability to control therapeutic claims made for drugs and devices by manufacturers. *See, e.g.*, Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L.

oversight, such as the Madoff Scandal, have cost billions of dollars and led to accusations that the administrative agencies responsible for protecting the public are in industry's pocket.[2] This Note addresses one of these familiar accusations of conflicting interests: improper agency reliance on advice from industry experts.[3] In particular, the purpose of this Note is to propose a solution to alleviate public mistrust and reduce conflicted advice.[4] To accomplish these goals, this Note provides a numerical statutory interpretation system to improve the clarity and consistency of agencies' application of conflict of interest laws to situations in which industry experts sit on advisory committees.

The FDA regulates sales that account for nearly 25 cents of every dollar spent by U.S. citizens.[5] Despite this expansive oversight, critics argue that the American public is not adequately protected from defective drugs, foods, and various consumer products because of the FDA's reliance on industry experts with conflicts of interest sitting on influential advisory committees.[6] One often-cited example of a "failure" of the FDA advisory committee process was the approval of Rezulin in 1997 and its reevaluation in 1999.[7] After unanimous approval of the diabetes drug in January 1997,

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REV. 1753, 1757–60 (1996). In fact, even the 1938 amendments seem prehistoric by today's standards, targeting quack medical devices such as "slenderizers" and "radium belts" that harmed the public in the 1930s, which are routinely prevented from making therapeutic claims today. *See* 79 CONG. REC. 4840–45 (1935) (statements of Sen. Royal S. Copeland); Carol Rados, *Medical Device and Radiological Health Regulations Come of Age*, FDA CONSUMER MAGAZINE, Jan.–Feb. 2006, *available at* http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/ucm095274.htm.

2. *See, e.g.*, *The Madoff Affair: Con of the Century*, ECONOMIST, Dec. 18, 2008, at 28 ("As a Wall Street fixture, Mr Madoff was close to several SEC officials. His niece, the firm's compliance lawyer, even married a former member of the team that had inspected the marketmaking division's books in 2003 . . . .").

3. *See, e.g.*, Ricardo Alonso-Zaldivar, *Ties to Drug Firms Continue on FDA Review Panel*, L.A. TIMES, Apr. 12, 2007, at A8 ("Prominent lawmakers and other critics have charged that the [FDA] has grown too cozy with the drug industry and has neglected its duty as a safety watchdog.").

4. It is important to note that a conflict of interest does not automatically signify "bias." Even though an individual may have a financial conflict of interest, that person may choose not to make decisions based on that interest. In fact, some have questioned whether members of the medical and scientific communities would "suddenly abandon [their] life's work at the critical moment when [they] can either further science or yield to the desire of a pharmaceutical company." Whitt Steineker, *Who's Guarding the Henhouse?: Conflicts of Interest and the FDA Advisory Committee Regime*, 20 GEO. J. LEGAL ETHICS 935, 944 (2007).

5. *See* FDA, U.S. DEP'T OF HEALTH & HUMAN SERVS., FDA'S GROWING RESPONSIBILITIES FOR THE YEAR 2001 AND BEYOND 2 (2001).

6. *See, e.g.*, Peter Lurie, *The US FDA at a Crossroads*, REG. AFF. J. PHARMA, July 2006, *available at* http://www.citizen.org/publications/release.cfm?ID=7449.

7. *See* Elizabeth R. Glodé, *Advising Under the Influence?: Conflicts of Interest Among FDA Advisory Committee Members*, 57 FOOD & DRUG L.J. 293, 308–10 (2002); Steineker, *supra* note 4, at 941.

the FDA began receiving reports that the drug caused liver problems.[8] British authorities withdrew Rezulin from the market in December 1997 after six deaths were linked to it, while the FDA required increased monitoring of patients taking the drug.[9] After at least thirty-one fatalities were linked to the drug by 1999, an advisory committee of eleven experts, three of whom had financial conflict of interest waivers issued by the FDA due to industry ties, reevaluated the drug.[10]

The expert committee voted to keep Rezulin on the market despite what had transpired, and the FDA accepted the committee's recommendation.[11] Eventually, in 2000, the FDA acted to withdraw the drug after sixty-three deaths.[12] Although there was no proof that financial ties influenced the experts' votes, and the drug could have passed reevaluation even without the votes of members with waivers,[13] some critics and newspapers questioned the FDA's legitimacy.[14] Even if these critics were wrong in this particular instance, the Rezulin story highlights how missteps in the conflict of interest waiver process could have serious effects, or at least create public mistrust.[15]

As the Rezulin story illustrates, regulatory agencies such as the FDA increasingly have to rely on outside expert advice when determining whether to approve a product for sale or establish a standard governing industry.[16] Critics question agencies' legitimacy because many of these experts have financial ties to the very industries they are tasked to help regulate.[17] A 2009 study conducted by a research group contracted by the

8. Glodé, *supra* note 7, at 308.

9. *Id.* at 308–09.

10. *Id.* at 309. The *L.A. Times* printed a news report about the financial ties of this reevaluation committee, resulting in one member recusing himself before the committee met. *Id.*

11. *Id.*

12. *Id.*

13. *See id.* at 309–10.

14. *See, e.g.*, John Abramson & Barbara Starfield, *The Effect of Conflict of Interest on Biomedical Research and Clinical Practice Guidelines: Can We Trust the Evidence in Evidence-Based Medicine?*, 18 J. AM. BOARD FAM. PRAC. 414, 414–16 (2005) (calling the Rezulin approval a "debacle" that was caused by conflicts of interest within the FDA); Merrill Goozner, *FDA Panel Backs Diabetes Drug; Rezulin Has Caused 35 Deaths in 2 Years*, CHI. TRIB., Mar. 27, 1999, at N1.

15. On the other hand, there are instances where experts with waivers did change the outcome of votes. In 2005, ten out of thirty-two advisers had conflict of interest waivers when voting to allow the painkillers Bextra and Vioxx to remain on the market. Gardiner Harris, *F.D.A. Rule Limits Role of Advisors Tied to Industry*, N.Y. TIMES, Mar. 22, 2007, at A1.

16. *See, e.g.*, Steineker, *supra* note 4, at 937.

17. Ricardo Alonso-Zaldivar, *FDA Pledges Conflict Reforms*, L.A. TIMES, July 25, 2006, at A12 ("The American people no longer trust the FDA to protect their health." (quoting Steven Nissen)); Stephanie Saul, *Panel Backs Drug amid Conflict Concerns*, N.Y. TIMES, Sept. 10, 2005, at C3 ("The public's faith in the integrity of the process is undermined when one-third of an advisory committee's

FDA found that in 76 percent of product approval meetings at least one committee member disclosed financial conflicts of interest.[18] Nonetheless, expert advice, when sought by the FDA, is almost always followed.[19] In these situations, the products that consumers think have been approved for sale after strenuous government scrutiny are actually approved based on advice from individuals who may have connections to the very companies that manufacture the product.[20]

In recent years, agencies such as the FDA, the Environmental Protection Agency ("EPA"), and the Federal Trade Commission ("FTC") have faced increasing pressure to reform their treatment of advising experts' conflicts of interest.[21] Public interest groups, Congress, and the Office of Government Ethics ("OGE") have demanded more clarity and consistency from agencies relying on panels of outside experts with possible conflicts of interest in their rulemaking and approval processes.[22] Although agencies have responded with more stringent guidelines,[23] the fundamental problem underlying advisory panels has not been eliminated: Agencies seek the very best independent experts to help make technical decisions. These experts are few in number and are also sought after by industry and thus are likely to have conflicts.[24]

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membership has significant financial ties to the company seeking the product's approval." (quoting Merrill Goozner, Director, Center for Science in the Public Interest's Integrity in Science Project)).

18. NYSSA ACKERLEY ET AL., E. RESEARCH GROUP, INC., FINANCIAL CONFLICT-OF-INTEREST DISCLOSURE AND VOTING PATTERNS AT FDA ADVISORY COMMITTEE MEETINGS, at 4-2 (2009), *available at* http://www.fda.gov/oc/advisory/conflictofinterest/ERGCOIAndVoting011509.pdf [hereinafter 2009 ERG REPORT].

19. *See* Steineker, *supra* note 4, at 941–42.

20. *See id.*

21. *See, e.g.*, Joe G. Conley, Note, *Conflict of Interest and the EPA's Science Advisory Board*, 86 TEX. L. REV. 165, 166 (2007); Kelly M. Falls, Current Development, *A Quorum of One: Redefining Recusal Standards in the Federal Trade Commission*, 19 GEO. J. LEGAL ETHICS 705, 705–06 (2006); Alonso-Zaldivar, *supra* note 17; Diedtra Henderson, *FDA Considers Reforming Use, Selection of Advisory Panels*, BOSTON GLOBE, Sept. 22, 2007, at A7.

22. *See* Henderson, *supra* note 21 ("When members of the advisory committee have conflicts of interest, it not only hurts the public, but it also destroys the credibility of the committee's recommendations . . . ." (quoting Representative Edward Markey, Democrat of Malden)); Larry D. Sasich & Sidney M. Wolfe, Pub. Citizen Health Research Group, Comments on Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees; Draft Guidance (Mar. 5, 2002), *available at* http://www.citizen.org/publications/release.cfm?ID=7157.

23. For example, the FDA recently established more stringent conflict of interest waiver guidance, which is discussed in Part III below.

24. NYSSA ACKERLEY, JOHN EYRAUD & MARISA MAZZOTTA, E. RESEARCH GROUP, INC., MEASURING CONFLICT OF INTEREST AND EXPERTISE ON FDA ADVISORY COMMITTEES, at iii (2007), *available at* http://www.fda.gov/oc/advisory/ERGCOIreport.pdf [hereinafter 2007 ERG REPORT]; Glodé, *supra* note 7, at 301; Scott Gottlieb, Deputy Comm'r, Med. & Scientific Affairs, FDA, Speech

In addition, it is unlikely that completely eliminating outside expert advice would be justified. Whether conflicts of interest actually affect voting patterns of advisory committee members remains controversial. Although a 2006 report by Peter Lurie found the opposite to be true, the Eastern Research Group ("ERG") found that financial conflicts of interest are not correlated with how conflicted members will vote.[25] Moreover, it would defeat the goals of the advisory committee process to hire more in-house experts because of the prohibitive recruitment expense, lack of clinical experience among in-house scientists, and the ability of outside experts to bring cutting-edge information from industry.[26]

One of the tools provided by conflict of interest statutes to prevent overly harsh limits on expert participation,[27] and the focus of this Note, is a conflict of interest waiver for certain experts on advisory panels. Waivers help balance the need for experts with countervailing concerns about experts' financial connections by allowing experts to participate on panels despite conflicts of interest if statutory and policy considerations are met.[28] Agencies have instituted their own guidelines regarding when to grant conflict of interest waivers because federal statutes only provide general criteria.[29] These self-imposed restrictions have created controversies, particularly when advice from panel members who are granted waivers is

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Before the Center for Science in the Public Interest, Conference on Government Advisory Committees (July 24, 2006) (transcript available at http://www.fda.gov/NewsEvents/Speeches/ucm051898.htm) [hereinafter Gottlieb Speech] ("Expert scientific acumen and deep clinical experience is valuable knowledge in high demand, by government, by patients, and also by medical product developers."). Note, however, that some contest the FDA's position regarding the relatively few numbers of experts, arguing instead that the FDA should make greater efforts to find scientists without conflicts. *See* Henderson, *supra* note 21.

25. *See* 2009 ERG REPORT, *supra* note 18, at iv. Because it is unclear whether voting patterns are actually affected by conflicts, whenever this Note uses the term "conflict of interest," it only refers to the presence of an indication that creates the *possibility* of an improper effect on an individual's decisionmaking.

26. *See* Steineker, *supra* note 4, at 950–51; Memorandum from Robert I. Cusick, Dir., Office of Gov't Ethics, to Agency Ethics Officials 13 (Feb. 23, 2007) (on file with the Office of Government Ethics), *available at* http://www.usoge.gov/ethics_guidance/daeograms/dgr_files/2007/do07006.pdf [hereinafter OGE Memo] (explaining that experts having conflicts of interest are often needed because of experience resulting from the source of the conflict).

27. *See, e.g.*, Eric J. Murdock, *Finally, Government Ethics as If People Mattered: Some Thoughts on the Ethics Reform Act of 1989*, 58 GEO. WASH. L. REV. 502, 503 (1990) ("Although sound in general principle, the [conflict of interest] rules have often been unnecessarily harsh in their specific application. The [Ethics Reform] Act mitigates much of that unnecessary harshness . . . [by] mak[ing] some improvements to the principal conflict of interest statute.").

28. *See* Glodé, *supra* note 7, at 301–02.

29. *See* Conley, *supra* note 21, at 184 (comparing various agencies' guidelines for disclosure of financial ties). Also, see the discussion of these statutes in Part II.A below.

implicated in the approval of defective products, as in the Rezulin case.[30]

This Note contends that much of the criticism faced by the FDA regarding conflicts of interest is due to misconceptions that may be resolved by more consistency and clarity, which can lend legitimacy to administrative agencies.[31] The Note is based upon the premise that if the FDA can apply conflict of interest laws more consistently and openly, then (1) the actual likelihood of conflicted advice should decrease and (2) the fog surrounding the process should be lifted, reducing accusations of agency corruption arising from a lack of information.

Though prior scholarship has addressed the complexities of the issues surrounding conflicts of interest in agencies, it has yet to propose a comprehensive method to help resolve these issues.[32] Thus, in addition to providing an analysis of the issues and recent changes in laws relating to conflict of interest waivers, this Note presents a solution that adds clarity and consistency without impairing agencies' sources of technical knowledge. The FDA can use this novel and reproducible evaluation methodology to identify exactly which legal elements favor a waiver for particular advisory committee members and to analyze the consistency of its practice in granting waivers.

This Note also attempts to demonstrate the benefits of the author's "numerical statutory interpretation" technique for agencies interpreting ambiguous statutes. Numerical statutory interpretation, which is the transformation of indefinite legal standards into mathematical expressions of congressional intent, has applications beyond the conflict of interest

30. Glodé, *supra* note 7, at 305, 308–10.

31. SEC v. Chenery Corp., 318 U.S. 80, 94 (1943) ("[T]he orderly functioning of the process of review requires that the grounds upon which the administrative agency acted be clearly disclosed and adequately sustained."); Phelps Dodge Corp. v. NLRB, 313 U.S. 177, 197 (1941) ("The administrative process will best be vindicated by clarity in its exercise."). Furthermore, the FDA recognized the importance of consistency and clarity by expressly stating that the 2008 Waiver Guidance seeks to improve consistency and clarity in the conflicts process. *See infra* Part III.B.

32. *See* Glodé, *supra* note 7, at 321–22 (providing examples of suspect behavior in FDA advisory committees and concluding with some general improvements the FDA should make for its conflict of interest process); Peter Lurie et al., *Financial Conflict of Interest Disclosure and Voting Patterns at Food and Drug Administration Drug Advisory Committee Meetings*, 295 J. AM. MED. ASS'N 1921, 1921, 1928 (2006) (presenting the results of a survey of voting behavior in FDA advisory committees and arguing for general substantive policy changes to limit the magnitude of the overall conflict of interest held by members); Steineker, *supra* note 4, at 949–52 (recognizing the complexities in balancing the need for the best experts with improper advice and concluding that future conflicts laws should observe this balance); Conley, *supra* note 21, at 189 (recommending that greater transparency and fuller disclosure in the conflict of interest process are needed in EPA's advisory committees).

waiver process. Although the use of rigid formulas has sometimes been met with a cold reception in courts,[33] the present methodology relies on traditional tools of statutory interpretation to establish a zone of reasonable interpretations of congressional intent and merely characterizes this zone mathematically.[34] Agencies frequently applying a statute with indefinite legal standards can use the methodology to apply the statute with more consistency, clarity, and transparency, leading to better adherence to the law and the policies that underlie it.

Although the findings of this Note regarding conflicts of interest are applicable to any agency with a conflict waiver process, the FDA has been selected as a case study to identify specific solutions. Conflicts of interest issues are starkly apparent at the FDA because of its important role in approving medical products for public use—a role that highlights the dangers of tainted advice on the one hand, and the prospect of approval without the best technical experts on the other, as illustrated by the Rezulin case.[35]

Part II of this Note begins with an overview of the advisory committee system at the FDA and identifies the laws and institutions that control it. Part II also examines recurring consistency and clarity problems in the conflicts process that led to the replacement of the FDA's 2000 Waiver Guidance[36] with the recently adopted 2008 Waiver Guidance.[37] Part III closely examines the 2008 Waiver Guidance and current waiver procedures. This part concludes that the new guidance has not effectively addressed concerns regarding the lack of consistency and clarity in the

33. *See* Prometheus Radio Project v. FCC, 373 F.3d 372, 402–05 (3d Cir. 2004) (finding that the FCC's use of a formula to measure diversity in local media markets was flawed because the FCC did not adequately justify its choice of weights for specific media outlets); Bechtel v. FCC, 10 F.3d 875, 885 (D.C. Cir. 1993) (criticizing the FCC's use of a formula to determine integration credit in a comparative hearing and rejecting the weighting chosen in the formula as subjective judgments rather than providing procedural advantages).

34. Moreover, unlike *Prometheus Radio Project v. FCC* and *Bechtel v. FCC*, the methodology here is likely to be used as a quality control check on current processes rather than affect the present rights of private parties. *See infra* Part V.A.

35. *See* Lurie, *supra* note 6.

36. FDA, U.S. DEP'T OF HEALTH & HUMAN SERVS., GUIDANCE FOR FDA ADVISORY COMMITTEE MEMBERS AND OTHER SPECIAL GOVERNMENT EMPLOYEES ON CONFLICT OF INTEREST 2000 (2000), *available at* http://www.fda.gov/oc/advisory/conflictofinterest/guidance.html [hereinafter 2000 Waiver Guidance] (Part III.A).

37. FDA, U.S. DEP'T OF HEALTH & HUMAN SERVS., GUIDANCE FOR THE PUBLIC, FDA ADVISORY COMMITTEE MEMBERS, AND FDA STAFF ON PROCEDURES FOR DETERMINING CONFLICT OF INTEREST AND ELIGIBILITY FOR PARTICIPATION IN FDA ADVISORY COMMITTEES (2008), *available at* http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125646.pdf [hereinafter 2008 Waiver Guidance].

conflict of interest process.

In response to these persistent problems, Part IV proposes the adoption of the author's waiver evaluation system ("WES") that could be implemented by the FDA to improve the advisory committee conflict of interest process. Part IV also explains the methodology of this system, which is rooted in a traditional intent-based statutory analysis. Part V discusses possible ways to implement the WES, examines its strengths and weaknesses as compared to prior methods, and identifies the next steps needed to apply it at the FDA. Finally, Part VI concludes that although agencies such as the FDA will continue to struggle with conflicts of interest on its advisory committees, using the system presented in this Note will help the FDA closely adhere to conflicts laws and increase its legitimacy.

II. THE FDA'S ADVISORY COMMITTEE PROCESS

This part provides an overview of the advisory committee process and the conflict of interest laws applicable to the FDA. This part then introduces 18 U.S.C. § 208(b)(3) and OGE regulations, which are the bases of the waiver evaluation system presented in Part IV. Finally, this part summarizes critiques of the FDA's application of these laws.

A. DEVELOPMENT OF FDA ADVISORY COMMITTEES AND CONFLICTS LAWS

Understanding the evolution of advisory committees requires an exploration of the FDA's origins. Originally named the Division of Chemistry, the FDA's function was primarily scientific, as staff performed experiments in laboratories to test for product safety.[38] These experiments, including the famous "poison squad" experiments in which volunteers tested the health effects of food additives by ingesting them, likely did not tax the technical expertise of the skilled chemists working at the agency.[39] After a period of steadily increasing responsibility,[40] with the passage of the 1962 amendments to its organic statute, the FDA's burden dramatically increased from determining only whether a drug was "safe" to also

38. *See* FDA, John P. Swann, FDA History Office, *FDA's Origin* (adapted from A HISTORICAL GUIDE TO THE U.S. GOVERNMENT (George Kurian ed., 1998)), http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm124403.htm (last visited Mar. 1, 2010).

39. *See id.*

40. *See id.* (explaining how the 1906 Act and the 1938 Act expanded the responsibilities of the FDA by adding more types of products under its oversight and requiring premarket approval).

determining whether it was "effective."[41]

As a result of the passage of these amendments, the FDA began to rely on outside expert advice in advisory committees. A combination of factors may have contributed to the formation of these committees, including a greater number of product applications, an increasing technical skill required to review applications, and a limited budget.[42] There were advantages of using outside experts beyond just cost savings, including experts' familiarity with the latest technical material and their "fresh perspectives" on agency processes.[43] In addition, the use of advisory committees may have been instrumental in reducing the amount of time drugs spent in the approval process, which meant the public gained access to life-changing treatments sooner.[44]

Until the Federal Advisory Committee Act ("FACA") was passed in 1972, FDA advisory committees had few formal procedures to control conflicts of interest and disclose information from advisory committee meetings to the public.[45] FACA applies to all federal advisory committees[46] and was the first of many controls Congress would create over the advisory committee process. FACA's three most relevant requirements are (1) that committees should "not be inappropriately influenced by the appointing authority or by any special interest,"[47] (2) that committees should be "fairly balanced in terms of the points of view represented,"[48] and (3) that committee meetings should be open to the public.[49] Ideally, it would be more effective to measure "improper influence" on committee members because this directly correlates to biased advice, but other statutes phrase the issue in terms of "conflict of interest."[50] This is because actually measuring whether an advisory committee member has been or will be improperly influenced is a much harder task than determining whether an advisory committee member has a financial tie to a party affected by the meeting.[51] Note that in some instances the second requirement may support

41. *See, e.g.*, Merrill, *supra* note 1, at 1764–67 ("This shift in responsibility [due to the 1962 Amendments] transformed the way in which drugs are developed, tested and marketed.").
42. *See* Glodé, *supra* note 7, at 294–95; Steineker, *supra* note 4, at 937.
43. Glodé, *supra* note 7, at 295.
44. *See* Gottlieb Speech, *supra* note 24.
45. *See* Glodé, *supra* note 7, at 295–99.
46. Federal Advisory Committee Act (FACA), 5 U.S.C. app. § 2 (2006).
47. *Id.* § 5(b)(3).
48. *Id.* § 5(b)(2).
49. 5 U.S.C. § 552.
50. *See, e.g.*, 18 U.S.C. § 208(b)(3) (2006).
51. *See* Gottlieb Speech, *supra* note 24.

the grant of a waiver if the advisor receiving the waiver would contribute to the balance of the represented viewpoints at the meeting.[52] Aside from this minor point, FACA does not play a major role in the granting of waivers at the FDA today, though it served as an important first step in formalizing the process for advisory committees.[53]

The criminal conflict of interest statute, 18 U.S.C. § 208, applies greater controls on the conflict of interest process by broadly prohibiting acts by government employees influenced by financial conflicts of interest.[54] The statute also provides three main ways to issue conflict of interest waivers, the last of which, § 208(b)(3), is an important means for issuing waivers for outside experts.[55] Under § 208(b)(1), an agency may grant a waiver to a regular government employee with a conflict if the "interest is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect from such officer or employee."[56] Second, under § 208(b)(2), a waiver may be granted to regular government employees if the conflict is "too *remote* or too inconsequential to affect the integrity of the services."[57] Finally, under § 208(b)(3), an agency may grant a waiver only to a "special Government employee" ("SGE") if "the *need* for the individual's services *outweighs the potential for a conflict of interest* created by the financial interest involved."[58] Experts on advisory committees qualify as SGEs and can thus receive this last type of waiver (a "208(b)(3) waiver") under criminal laws. In a 2007 study of conflict of interest waivers, 85 percent of FDA waivers granted to industry experts on advisory committees were granted under § 208(b)(3).[59]

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52. *See, e.g.*, Letter from Igor Cerny, Dir., Advisors & Consultants Staff, Ctr. for Drug Evaluation & Research, to Randall W. Lutter, Deputy Comm'r for Policy, FDA 3 (Apr. 14, 2008), *available at* http://www.fda.gov/ohrms/dockets/ac/08/waivers/2008-4366w1-01-Hussain-208.pdf [hereinafter Waiver for Maha Hussain] (arguing that Hussain should receive a waiver because she would help fulfill the FACA requirements that the committee be "fairly balanced in terms of the points of view represented and the functions to be performed" by the committee).

53. *See* Steineker, *supra* note 4, at 938 ("In essence, [FACA] provides a broad framework within which the federal agencies must manage their advisory committee regimes.").

54. 18 U.S.C. § 208(a).

55. *See id.* § 208(b).

56. *Id.* § 208(b)(1).

57. *Id.* § 208(b)(2) (emphasis added).

58. *Id.* § 208(b)(3) (emphases added). The § 208(b)(1) and (b)(2) waiver provisions were enacted with the original criminal conflict of interest statute in 1962. Bribery, Graft, and Conflicts of Interest, Pub. L. No. 87-849, § 208, 76 Stat. 1119, 1124–25 (1962). The § 208(b)(3) provision, however, was more recently added by the Ethics Reform Act of 1989. Ethics Reform Act of 1989, Pub. L. No. 101-194, § 208, 103 Stat. 1716, 1751–53.

59. 2007 ERG REPORT, *supra* note 24, at 4-1.

Additionally, there are conflict of interest requirements in the FDA's often-amended organic act. Prior to October 1, 2007, the Food and Drug Administration Modernization Act of 1997 ("FDAMA") allowed a waiver of personal or familial conflicts of interest for a committee member with necessary "essential expertise."[60] This "essential expertise" test is generally thought to be a higher bar for granting waivers,[61] despite the inherent ambiguity in determining what constitutes "essential expertise."[62] After Congress passed the Food and Drug Administration Amendments Act of 2007 ("FDAAA"), Congress retained this essential expertise standard.[63] Also, FDAAA requires the FDA to reduce the rate of waivers awarded per total number of committee members by 5 percent each year until 2012.[64] FDAAA also creates additional public disclosure requirements for conflicts of interest on advisory committees.[65] These actions show lawmakers' continued concerns over the appearance of conflicts of interest in the advisory committee process.

B. INFORMAL CONTROLS OVER AGENCY WAIVER PROCESSES

In addition to statutory requirements, more informal means exist for congressional control over the FDA's conflict of interest process. The FDA, perhaps more than most agencies, faces pressure from congressional committees and subcommittees regularly.[66] The composition of these committees and the oversight hearings held by them may have a large role in influencing agency decisionmaking.[67] Many hearings are time

60. Food and Drug Administration Modernization Act (FDAMA) of 1997, Pub. L. No. 105-115, § 355(n)(4), 111 Stat. 2296, 2319.

61. 2008 Waiver Guidance, *supra* note 37, at 7–8.

62. *See* 2007 ERG REPORT, *supra* note 24, at 2-4.

63. Food and Drug Administration Amendments Act (FDAAA) of 2007, Pub. L. No. 100-85, § 712(c)(2)(B), 121 Stat. 823, 901, 21 U.S.C.A. § 379d-1(c)(2)(B) (West Supp. 2009) (amending the Federal Food, Drug and Cosmetic Act, ch 675 (1938)). FDAAA prohibits participation in advisory committee meetings on particular matters if the member or his family "has a financial interest that could be affected by the advice given to the Secretary with respect to such matter." *Id.* § 379d-1(c)(2)(A). Unlike § 208(b)(3), FDAAA applies the essential expertise standard used in FDAMA to determine whether an expert may be granted a waiver. *See id.* § 379d-1(c)(2)(B).

64. *Id.* § 379d-1(c)(2)(C)(iv).

65. *Id.* § 379d-1(c)(1).

66. *See, e.g.*, Aaron Smith, *FDA Gets Grilled over Avandia "Failure": Congress Accuses Commissioner von Eschenbach of Not Doing Enough to Study the Heart Attack Risks of Glaxo's Diabetes Drug*, CNNMONEY.COM, June 6, 2007, http://money.cnn.com/2007/06/06/news/companies/avandia/index.htm ("FDA commissioner Andrew von Eschenbach took a tongue-lashing from members of Congress over the way his agency handled Avandia, the diabetes drug from GlaxoSmithKline that has come under scrutiny for alleged heart attack risks.").

67. *See* Barry R. Weingast & Mark J. Moran, *Bureaucratic Discretion or Congressional Control? Regulatory Policymaking by the Federal Trade Commission*, 91 J. POL. ECON. 765, 791–92

consuming, particularly if the press highlights problems with FDA regulations, leading to embarrassing "grillings" of agency heads and much effort expended by the FDA to prepare for hearings.[68] Furthermore, there is always a looming threat that Congress will enact legislation to restrict agency processes further,[69] as evinced by the statutory limits to the percentage of waivers in FDAAA.[70]

Other agencies and the president also exercise some control over FDA decisions to grant waivers. In addition to the power to appoint and remove agency heads, the president can issue executive orders to address conflict of interest waivers. Under Executive Order 12,674, agencies are asked to consult with the OGE "when practicable" before issuing § 208 waivers,[71] the vast majority of waivers granted by the FDA.[72] The OGE has issued regulations with criteria that agencies must observe in granting waivers[73] and detailed guidances on its views of the statutory requirements of § 208, noting that if an agency grants a waiver that is viewed as inappropriate by the OGE, "records will indicate that the agency was advised against issuing the waiver."[74] These OGE regulations become instrumental in the creation

(1983) (arguing that political changes in oversight committees can significantly influence agency actions, even without publicly held oversight hearings).

68. *See id.* at 768–69 (stating congressional oversight hearings are "resource-intensive activities"); Smith, *supra* note 66. Representative Henry Waxman has historically been actively involved in these hearings. *See* Smith, *supra* note 66.

69. *See* Weingast & Moran, *supra* note 67, at 769 ("The threat of ex post sanctions creates ex ante incentives for the bureau to serve a congressional clientele.").

70. *See supra* note 64 and accompanying text.

71. OGE Memo, *supra* note 26, at 1.

72. *See supra* note 59 and accompanying text.

73. *See* 5 C.F.R. §§ 2640.301, 2640.302 (2009). In particular, § 2640.302 provides some useful interpretations of waivers under § 208(b)(3), which are instrumental in creating the WES explained in Part IV below:

> In determining whether the need for an individual's services on an advisory committee outweighs the potential for a conflict of interest . . . consider the following factors:
> (1) The *type of interest* that is creating the disqualification (e.g. stock, bonds, real estate, other securities, cash payment, job offer, or enhancement of a spouse's employment);
> (2) The identity of the person whose financial interest is involved, and if the interest is not the individual's, the relationship of that person to the individual;
> (3) The *uniqueness* of the individual's qualifications;
> (4) The *difficulty of locating a similarly qualified individual* without a disqualifying financial interest to serve on the committee;
> (5) The *dollar value* of the disqualifying financial interest . . . ;
> (6) The value of the financial instrument or holding from which the disqualifying financial interest arises (e.g. the face value of the stock, bond, other security or real estate) and its value in relationship to the individual's assets. . . . ; and
> (7) The *extent to which the disqualifying financial interest will be affected* individually or particularly by the actions of the advisory committee.

Id. § 2640.302(b) (emphases added). For a discussion of this language in formulating the WES, see Part IV below.

74. OGE Memo, *supra* note 26, at 5.

of the waiver evaluation system discussed in Part IV.[75]

C. THE 2000 WAIVER GUIDANCE

The FDA has issued two guidances in the past decade attempting to synthesize the legal requirements and policy considerations outlined in Sections A and B of this part into concrete rules its staff can follow in granting waivers.[76] Though these guidances do not have the force of law,[77] they are important because they describe the specific procedures and substantive policy choices that determine when conflict of interest waivers should be granted at the FDA.[78]

The FDA first developed a Waiver Criteria Document in 1994 and replaced it in 2000.[79] In addition to laying out general principles taken from the statutes and OGE regulations, the 2000 Waiver Guidance focused on some specific categories of financial conflicts, such as stock investments, employment, consulting, and grants.[80] It further divided these categories by the particular strength of the conflict—for example, stock holdings totaling greater than 15 percent of the SGE's net worth, or greater than $100,000, constitute "high involvement," whereas stock holdings under $5000 constitute "low involvement," in matters involving specific parties.[81] Though this guidance was "commended as a model for use by other Executive Branch agencies,"[82] the FDA decided it needed a new guidance because of the changes imposed by FDAAA and the "complexity and discretionary elements" within the 2000 Waiver Guidance.[83]

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75. *See infra* notes 172–85 (discussing how the OGE regulations serve to fill in for congressional intent).

76. The 2008 Waiver Guidance, the second of these two guidances, is discussed in detail in Part III.

77. 2008 Waiver Guidance, *supra* note 37, at 3 (stating that guidances "do not establish legally enforceable responsibilities" but instead "describe the Agency's current thinking on a topic and should be viewed only as recommendations").

78. *See id.* at 2.

79. 2000 Waiver Guidance, *supra* note 36.

80. *Id.* (Part III.C).

81. *Id.* (Part III.C.1). The Waiver Criteria Document has several tables with cutoff values for "high," "medium," and "low" involvement. *Id.* This criterion is addressed in detail in Part IV and serves as a model for the scoring of inputs in the WES.

82. 2007 ERG REPORT, *supra* note 24, at 2-3.

83. 2008 Waiver Guidance, *supra* note 37, at 5–6. Note that there were likely clarity and consistency motivations to introduce this particular guidance beyond just updating the FDAAA requirements. *See id.* at 6–7. The language in the 2008 Waiver Guidance points to the FDA's belief that the 2000 Waiver Guidance was "poorly understood" by the public and "criticized" because of its complexity, supporting the reasoning that informal pressures such as those explained in Part II.B above could have spurred the creation of this new guidance. *See id.* at 3–4. Moreover, the draft guidance for

Many critiques of the 2000 Waiver Guidance and treatment of conflicts of interest on advisory committees focused on a lack of disclosure of conflicts to the public.[84] For example, critics argued for improved transparency in the advisory committee process to help the public understand the balancing needed to select members.[85] Such transparency would prevent public accusations of agencies based on perceived bias resulting from ties to industry and would uphold the legitimacy of the advisory committee process.[86]

Other critics suggested that the FDA is inconsistent or sluggish in seeking complete conflict of interest disclosures from the members of the advisory committees and in searching for experts without conflicts.[87] These critics contended that the FDA could easily find experts without conflicts to fill advisory committee meetings, without sacrificing information quality.[88] Others found that the FDA's policy of evaluating only financial conflicts existing during the past year may unreasonably exclude the possibility that certain "long-standing financial or institutional ties of prospective panelists . . . may at least create the appearance that a scientist is aligned with a particular position."[89] Moreover, these long-standing ties could be worth many times the financial income from the past year, which is the time period the FDA uses in waiver evaluations.[90] In addition, the 2000 Waiver Guidance does not require the measurement of ideological conflicts of interest, which may in some cases be better correlated with voting bias than financial conflicts.[91]

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the 2008 Waiver Guidance was published in March 2007, before the enactment of FDAAA in November 2007. *See* FDA, U.S. DEP'T OF HEALTH & HUMAN SERVS., DRAFT GUIDANCE FOR THE PUBLIC, FDA ADVISORY COMMITTEE MEMBERS, AND FDA STAFF ON PROCEDURES FOR DETERMINING CONFLICT OF INTEREST AND ELIGIBILITY FOR PARTICIPATION IN FDA ADVISORY COMMITTEES (2007), *available at* http://www.fda.gov/OHRMS/DOCKETS/98fr/07d-0101-gdl0001.pdf.

84. *See* Lurie et al., *supra* note 32, at 1928; Sasich & Wolfe, *supra* note 22.

85. *See* Conley, *supra* note 21, at 185; Sasich & Wolfe, *supra* note 22.

86. *See* Conley, *supra* note 21, at 185.

87. *See* Peter Lurie, Pub. Citizen Health Research Group, Presentation Before the Committee on Conflict of Interest in Medical Research, Education, and Practice 5–6 (Nov. 5, 2007), *available at* http://www.citizen.org/documents/IOMCOILurie2007.pdf.

88. *See* Henderson, *supra* note 21; *We Don't Need FDA Panels with Financial Conflict: Plenty of Other Experts Available but Unused*, GRAND RAPIDS PRESS, Sept. 19, 2006, at E3 [hereinafter *Plenty of Experts Available*].

89. Conley, *supra* note 21, at 184–85. *See also* Sasich & Wolfe, *supra* note 22 (arguing that conflicts disclosure should reach at least two years into the past).

90. *See* Conley, *supra* note 21, at 184–85.

91. *See id.* at 166, 187. Ideological conflicts of interest are not mentioned in the conflict of interest laws, likely because these are more tenuous and difficult to measure than financial conflicts. For example, issues such as birth control may bring out ideological conflicts among members in an advisory committee. In addition, it may be psychologically difficult for a doctor to change past behavior because,

One influential and hotly disputed[92] study published by Peter Lurie and others in the *Journal of the American Medical Association* concluded that "[d]isclosures of conflicts of interest at drug advisory committee meetings are common, often of considerable monetary value, and rarely result in recusal of advisory committee members."[93] The study found a weak correlation between financial conflicts of interest at committee meetings and voting behavior.[94] One of the recommendations of the study was to forbid participation of advisory committee members having "conflicts of interest with higher dollar values,"[95] which is now a cornerstone of the 2008 Waiver Guidance.[96]

III. CURRENT WAIVER PROCESSES AND THE 2008 WAIVER GUIDANCE

This part presents and analyzes the FDA's conflict of interest process under the 2008 Waiver Guidance. Despite the new guidance, consistency and clarity problems persist in the process.

A. THE CURRENT CONFLICTS PROCESS AND PRELIMINARY DETERMINATIONS BEFORE APPLYING WAIVER LAWS

The FDA currently has forty-eight standing advisory committees on subjects such as food regulation, human and animal drugs, and medical devices.[97] Committees generally include a chairperson, FDA employees, and several outside experts appointed for four-year terms.[98] On the one

as Steven Nissen said, "people who are very, very close to a field may have trouble accepting the possibility that a drug they've been using for many years was harmful. There is more conflict of interest in all of this than simply financial." Henderson, *supra* note 21.

92. *See* FDA, Comment on "Financial Conflict of Interest Disclosure and Voting Patterns at Food and Drug Administration Drug Advisory Committee Meetings," http://www.fda.gov/oc/advisory/analysis.html (last visited Mar. 1, 2010) (arguing that fears of tainted advice from conflicts of interest are unfounded because the Lurie study overlooked that advisory committee members actually tend to vote against their financial ties, not for them).

93. Lurie et al., *supra* note 32, at 1921.

94. *Id.* Note that the authors point out that despite the existence of this correlation, removing the committee members with waivers from the vote would not have changed the outcome of the meeting. *Id.* In addition, the 2009 ERG Report disputes this finding of a correlation between voting behavior and conflict of interest. *See* 2009 ERG REPORT, *supra* note 18, at iv ("Overall, ERG found no evidence to suggest that having a financial conflict-of-interest tends to increase votes in favor of that interest.").

95. *See* Lurie et al., *supra* note 32, at 1928.

96. *See* 2008 Waiver Guidance, *supra* note 37, at 7–8.

97. *See* FDA, CONSUMER HEALTH INFORMATION, STRENGTHENING THE ADVISORY COMMITTEE PROCESS 1 (2008), *available at* http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM143318.pdf.

98. *See* FDA, Questions and Answers Regarding Advisory Committee Membership,

hand, some of the benefits of the four-year term include improved efficiency as experts become familiar with FDA processes and rules, and better team dynamics.[99] On the other hand, the four-year term creates conflicts screening problems for the FDA because it is impossible to know what conflicts will arise during experts' terms.[100] Thus, the FDA investigates financial conflicts before appointment and before each advisory committee meeting by requiring each member to fill out a disclosure form asking for information on past and current financial interests.[101]

Before receiving disclosures from committee members, FDA staff must determine whether the purpose of the advisory committee meeting is to address a nonparticular matter of general applicability or a "particular matter."[102] Conflict of interest laws are triggered only if a meeting addresses a "particular matter," in which the focus of the meeting is an agency action or decision that will affect the "interests of specific persons, or a discrete and identifiable class of persons."[103] Thus, if the outcome of a meeting affects a broad, indiscernible group, financial conflicts will not be predictably affected by a biased vote and a waiver is not required.[104]

In addition, FDA staff must determine which individuals may need waivers because advisory committee meetings have a range of participants.[105] FACA does not require disclosure of conflicts of interest by the public in advisory meetings.[106] Moreover, § 208(b) only applies to "regular Government employee[s]" and SGEs, and FDAAA only governs

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http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/CommitteeMembership/ucm117646.htm (last visited Mar. 21, 2010) [hereinafter Advisory Committee FAQ].

99. *See* Gottlieb Speech, *supra* note 24 ("[T]here is a value from having people who have institutional experience from serving on these committees and who have learned how to work together as a scientific group.").

100. *See id.* ("When we appoint these committee members, it is impossible to tell who will eventually have relationships that could present the potential for an appearance of a conflict around a specific issue, since we don't know what issues are going to come up before our advisory committees a year or two in advance.").

101. *See, e.g.*, 2009 ERG REPORT, *supra* note 18, at 2-3; Glodé, *supra* note 7, at 303–04.

102. *See* 2008 Waiver Guidance, *supra* note 37, at 8–9.

103. *See id.*

104. *See, e.g.*, OGE Memo, *supra* note 26, at 3 ("[W]aivers need not be issued . . . where there is no real likelihood that the employee will participate in particular matters that will have a direct and predictable effect on his financial interests.").

105. *See* Lurie et al., *supra* note 32, at 1922. For example, participants in an advisory committee meeting may include non-voting participants such as industry representatives, the public, guest speakers, FDA staff, and representatives of consumer or patient groups. *See id.*; Advisory Committee FAQ, *supra* note 98.

106. Lurie et al., *supra* note 32, at 1922.

conflicts of interest for advisory committee members.[107] Thus, the public, non-voting industry representatives, guest speakers, and consumer groups can generally participate in meetings without any waivers because conflict of interest laws do not apply.[108]

The determination of the purpose of a meeting and of which participants are subject to conflicts laws is made by the FDA center[109] responsible for applying for the waiver by following the steps in the 2008 Waiver Guidance.[110] The guidance greatly simplifies the various conflict of interest laws, combining them into one streamlined document.[111] Instead of the table format of the 2000 Waiver Guidance, which uses a specific numerical range of acceptable financial conflicts for a variety of factors,[112] the 2008 Waiver Guidance is a single document that lists sequential steps to be followed by FDA staff.[113]

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107. *See* 2008 Waiver Guidance, *supra* note 37, at 4–5.

108. *See id.*

109. The FDA is divided into seven centers, which are specialized by groups of products, such as the Center for Drug Evaluation and Research ("CDER") and the Center for Devices and Radiological Health ("CDRH"). *See* FDA, Centers & Offices, http://www.fda.gov/AboutFDA/CentersOffices/default.htm (last visited Mar. 21, 2010). Generally, these centers are responsible for the advisory committee meetings covering products under their jurisdiction. *See id.*

110. 2008 Waiver Guidance, *supra* note 37, at 8–24 (detailing each step an individual subsection within the section "How Does the Algorithm Operate?"). The steps to be followed by staff are the following:

> (1) Is the subject matter of the meeting a 'Particular Matter?'
> (2) Will the particular matter have a direct and predictable effect on the financial interest(s) of any organization?
> (3) Identify potentially affected products/organizations and request that the employee complete the financial disclosure form[.]
> (4) Does the employee, or persons/organizations whose interests are imputed to him, have a financial interest in one or more of the potentially affected products and/or organizations?
> (5) Will the particular matter have a direct and predictable effect on the financial interest of the employee and/or persons/organizations whose interests are imputed to him?
> (6) After applying applicable regulatory exemptions, does the employee or persons/organizations whose interests are imputed to him have a disqualifying financial interest?
> (7) Are there disqualifying financial interests for which a waiver would not be considered?
> (8) Is the combined value of the employee's personal disqualifying financial interests and those of his spouse and minor children $50,000 or less?
> (9) Is the individual's participation necessary to afford the advisory committee essential expertise?
> (10)(a) If the individual is a Special Government Employee, does the need for the individual's services outweigh the potential for a conflict of interest created by the financial interest involved? [or] (b) If the individual is a Regular Government Employee, is the financial interest not so substantial as to be deemed likely to affect the integrity of the services provided by the individual?
> (11) Waiver may be recommended if consistent with waiver cap.

Id.

111. *Id.* at 6–7.

112. *See supra* Part II.C.

113. *See supra* note 110.

Following the analysis in the 2008 Waiver Guidance, the FDA center responsible for the committee submits a written report arguing for a waiver if it believes the criteria in the 2008 Waiver Guidance are met.[114] The written document is then reviewed by staff in the Advisory Committee Oversight and Management Group and signed by the deputy commissioner for policy if the waiver is deemed appropriate.[115] There is no formal adjudicatory process or an explanation detailing why the waiver was appropriate.[116]

B. CHANGES IN THE 2008 WAIVER GUIDANCE AND THE NEED FOR MORE CONSISTENCY AND CLARITY

The 2008 Waiver Guidance has three important differences from the 2000 Waiver Guidance. First, there are no longer any dollar value ranges to signify a "high, medium, or low" level of involvement; instead, the new guidance lists general criteria to be considered in determining the level of conflict.[117] Furthermore, a maximum cap of $50,000 of combined personal or familial conflicts for the past twelve months, regardless of the member's expertise or specific type of conflict, has been instituted for each member.[118] Second, the limits in the percentage of waivers allotted, as imposed by FDAAA, are incorporated into the last step.[119] Lastly, the FDA has chosen, as a policy matter, to apply the more stringent essential expertise standard from FDAAA when issuing waivers to all regular employees and SGEs.[120] Although the law only requires that the "need" for an SGE's expertise outweigh the "potential for a conflict" under § 208(b)(3),[121] the FDA reasons that those SGEs passing the essential expertise test will generally pass the § 208(b)(3) standard.[122] In any case,

114. *See infra* note 235 and accompanying text.

115. Telephone Interview with Michael F. Ortwerth, Dir., FDA Advisory Comm. Oversight & Mgmt. Staff, and Jill Hartzler-Warner, Senior Policy Advisor & Counselor, FDA Office of Accountability & Integrity (Feb. 19, 2009) [hereinafter Ortwerth & Warner Interview].

116. *Id.* The waivers themselves, however, are posted online. *Id.*

117. *See* 2008 Waiver Guidance, *supra* note 37, at 15–17.

118. *See id.* at 7.

119. *See id.* at 23–24 (detailing step 11, *see supra* note 110).

120. *See id.* at 7–8.

121. *See* 18 U.S.C. § 208(b)(3) (2006).

122. 2008 Waiver Guidance, *supra* note 37, at 21–22. The interpretation that the standard in the FDA's organic act is stricter than the general § 208(b)(3) requirements is not always correct, which is why the 2008 Waiver Guidance requires an additional finding that the § 208(b)(3) standard is also satisfied. *See id.* For example, there may be situations where the financial conflict is so high that a 208(b)(3) waiver will not be granted, but where the expertise is also "essential," and thus an FDAAA waiver may be granted. Moreover, there will be cases where an essential expertise test will exclude waivers permitted under § 208(b)(3), raising interesting questions about *Chevron* deference in such a

FDA staff must reapply the § 208(b)(3) standard in step 10(a),[123] though no specifics are provided on how this may be done, as there are in the 2000 Waiver Guidance.

Several of the critiques of the 2000 Waiver Guidance have been addressed by changes in the 2008 guidance.[124] The $50,000 cap on financial conflicts is consistent with Lurie's study, which recommended limitations on the magnitude of an expert's overall conflict.[125] Applying the cap and the essential expertise standard to all waivers resolves some consistency concerns in the application of conflicts laws generally by subjecting all experts to uniform criteria.[126] In addition, the 2008 Waiver Guidance is organized into a reproducible list of steps and provides more clarity than the 2000 Waiver Guidance, which was scattered across topics.[127]

Despite these improvements, additional consistency improvements are still required to fully address existing critiques. Although the 2008 Waiver Guidance presents a $50,000 cap on all financial conflicts and is much simpler to apply, it fails to recognize that not all financial conflicts are

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situation—the FDA is interpreting its own organic act requirements, which would generally get deference, but comparing these requirements to a general criminal statute, which would generally not get *Chevron* deference. *See* STEPHEN G. BREYER ET AL., 2007–2008 SUPPLEMENT: ADMINISTRATIVE LAW AND REGULATORY POLICY 55–56 (6th ed. 2007 & Supp. 2007–2008) (discussing *Dominion Energy Bayton Point, LLC v. Johnson* and questioning whether *Chevron* deference is applicable when an agency can plausibly be determining its own organic act and the Administrative Procedure Act).

However, these issues are tangential with respect to the waiver evaluation system and may practically be inconsequential since the FDA's interpretation is a "policy matter" that does not hold the force of law, and it reapplies § 208(b)(3) standards in any case. *See* Administrative Procedure Act § 3, 5 U.S.C. § 553 (2006) (stating that notice-and-comment rulemaking procedures are not required for "general statements of policy" that do not create rules with the force of law); United States v. Mead Corp., 533 U.S. 218, 226–27 (2001) ("We hold that administrative implementation of a particular statutory provision qualifies for *Chevron* deference when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority. Delegation of such authority may be shown in a variety of ways, as by an agency's power to engage in adjudication or notice-and-comment rulemaking . . . .").

123. *See* 2008 Waiver Guidance, *supra* note 37, at 21–22 (detailing step 10(a), *see supra* note 110).

124. The 2008 Waiver Guidance states that its unified approach will "improve consistency within the agency in considering advisory committee participation and will provide greater clarity to the public regarding how FDA selects members." *Id.* at 6–7.

125. *See* Lurie et al., *supra* note 32, at 1928.

126. *See* 2008 Waiver Guidance, *supra* note 37, at 6–7.

127. *Compare* 2000 Waiver Guidance, *supra* note 36 (Part III.C) (providing tables based on the specific types of conflicts), *with* 2008 Waiver Guidance, *supra* note 37, at 6–7 (arguing that the streamlined approach of the steps in the algorithm created provide greater consistency and clarity).

equal.[128] Therefore, an SGE with a direct and predictable conflict may be treated the same as an SGE with a remote conflict solely because of the monetary value of the conflict, leading to an inconsistent result.[129] This is a step backward from the 2000 Waiver Guidance, which identified the type of conflict and its relative strength.[130] Having this information would allow the FDA to compare and weigh waivers between employees with different types of conflicts, leading to more precise and consistent applications of conflicts laws. Moreover, compiling such information would provide an effective method for screening out possibly inappropriate waivers, thereby helping to meet the new caps on waivers required by FDAAA.[131]

Furthermore, the 2008 Waiver Guidance still lacks clarity because the essential expertise standard is ambiguous. Even researchers fail to concretely define what constitutes "essential expertise."[132] Staff responsible for granting waivers will have to make subjective judgments that will be suspicious if a waiver is publicly questioned.[133] These judgments appear even more untrustworthy because the FDA does not specifically explain why a particular expert has met the legal standard for a waiver.[134] The application of a tenuous expertise concept by staff without greater disclosure of the FDA's reasoning will create an appearance of impropriety surrounding waivers.

In sum, though the 2008 Waiver Guidance is an improvement over past FDA practice, it is still lacking in two key respects: (1) it does not sufficiently resolve the uncertainty of whether waivers are being granted on a relatively consistent basis overall (consistency), and (2) it does not help identify the specific legal factors that led to the granting of a waiver in any

128. *Compare* 2000 Waiver Guidance, *supra* note 36 (Part III.C) (separating each type of conflict into high, medium, and low levels of involvement), *with* 2008 Waiver Guidance, *supra* note 37, at 7 (creating a flat $50,000 limit to the magnitude of the conflict, regardless of levels of involvement).

129. A simple example of this idea follows. Suppose that $25,000 of stock comprising 5 percent of an SGE's net worth is owned in one of many healthcare companies competing with an applicant who is the subject of a meeting. This SGE's conflict would count equally toward the $50,000 bar as a conflict of an SGE who makes $25,000, or 25 percent of the SGE's total income, consulting for the applicant's firm. On the one hand, the stock in the competing firm may be slightly affected through biased actions of the SGE, but there would be little affect on the SGE's net worth. On the other hand, an SGE that works closely with the applicant and is reliant on a yearly income may have more to gain or lose by acting on bias. The 2000 Waiver Guidance may have taken the importance of these differences into account, but the flat $50,000 bar does not. *See supra* note 128.

130. *See* 2000 Waiver Guidance, *supra* note 36 (Part III.C).

131. *See supra* Part II.A.

132. 2007 ERG REPORT, *supra* note 24, at 2-4 ("[A]ttempting to objectively measure expertise, or the proficiency of an expert, is inherently difficult and controversial.").

133. *See id.*

134. Ortwerth & Warner Interview, *supra* note 115.

specific case, nor the relative strengths of these factors (clarity).

IV. A NOVEL WAIVER EVALUATION SYSTEM

This part presents a novel waiver evaluation system ("WES") to address the consistency and clarity issues in the FDA's conflict of interest waiver process. Section A generally summarizes the approach behind this new methodology developed by the author and FDA staff, which is applicable beyond conflict of interest waivers. The remaining sections of this part apply the methodology to § 208(b)(3) conflict of interest waivers.

A. SUMMARY OF THE NUMERICAL STATUTORY INTERPRETATION TECHNIQUE AND ASSUMPTIONS OF THE WES

The WES is a process to check the consistency of the application of conflicts laws and improve the clarity of agency decisions by specifically identifying why a waiver was or was not granted. The key innovation of the WES is the transformation of elusive statutory requirements into a more rigid mathematical equivalent, allowing a consistent and precise application of the statute, as intended by Congress.[135] The author created this numerical statutory interpretation methodology with FDA staff;[136] mathematical formulas used to simplify agency decisions, however, are not novel.[137] In the present case, the FDA could implement the WES as a quality control mechanism for use by FDA ethics staff, or as the primary and determinative tool in granting conflict of interest waivers.

The components of the WES are (1) an intentionalist statutory analysis, identifying elements comprising the legal standard for the grant of a waiver and the relative weights of each element as intended by Congress, (2) a scoring system and guidelines for assigning a score to the specific facts present in any particular waiver for use as inputs for the weighted elements, and (3) a simple analytical tool to compare the overall scores of each waiver. The legal methodology essentially converts congressional intent, either through direct interpretation of a statute or through regulations made pursuant to the statute, into a mathematical expression of that intent.

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135. Although this Note applies this idea to conflict of interest waivers, it has broader applicability. Any multifactor legal test posed in a statute can be transformed into an equivalent mathematical standard, which can be applied far more consistently and precisely, especially when there are several factors to consider under time constraints. *See infra* Part VI.

However, agencies must carefully follow the methodology presented and thoroughly develop their reasoning because courts are likely to review formulas with greater scrutiny. *See supra* note 33.

136. Michael Ortwerth and Jill Warner were instrumental during the design of the WES.

137. *See supra* note 33.

The scoring system and guidelines are applied to convert case-by-case facts, which in this case are the particular type of conflict or the particular level of expertise, into mathematical inputs for the legal methodology. Finally, an analytical tool is used to automatically apply the inputs to the legal methodology and provide an effective way to draw legal conclusions.

The weighted elements of the statute, in this case the § 208(b)(3) legal standard, are derived from an intentionalist analysis of conflicts statutes.[138] Intentionalists, specifically sociological jurisprudes, interpret statutes using various indicators of congressional intent such as the plain meaning of the text, statutory purpose, and legislative history.[139] The Supreme Court has termed these tools the "traditional tools of statutory interpretation,"[140] while William Eskridge and Philip Frickey call a similar approach the "funnel of abstraction" approach.[141]

Although there is a longstanding debate about theories of statutory interpretation, a sociological jurisprudence interpretation fits best with the institutional qualities of federal agencies.[142] Agencies rely on statutory purpose and legislative history as they implement statutes because congressional committees and subcommittees exercise considerable control over agency processes, operations, and budgets.[143] Thus, agencies have an

138. In this case, as will be shown below in Part IV.C, OGE regulations serve to give structure to congressional intent because they were made to fill in gaps, pursuant to instructions in the statute. Thus, whenever this Note mentions the "congressional intent" of § 208(b)(3), it is referring to the fictional congressional intent embodied in OGE regulations and guidances.

139. This school of thought believes that law is policy, that Congress is the source of law, and that extrinsic aids and legislative history can help provide the necessary context to accurately interpret the meaning of statutes. *See, e.g.*, Stephen Breyer, 1991 Justice Lester W. Roth Lecture, *On the Uses of Legislative History in Interpreting Statutes*, 65 S. CAL. L. REV. 845, 847–48 (1992).

140. *See infra* notes 161–63 and accompanying text.

141. The funnel of abstraction approach is a step-by-step process to statutory interpretation: (1) the court determines whether the statute is unambiguous, accepting its plain meaning if it is, but if there is no plain meaning, (2) the court seeks to interpret statutes using (a) canons and dictionaries, (b) legislative purpose, and (c) "extrinsic aids" such as legislative history. *See* William N. Eskridge, Jr. & Philip P. Frickey, *Statutory Interpretation as Practical Reasoning*, 42 STAN. L. REV. 321, 353–62 (1990) (describing the funnel of abstraction approach). This approach is similar to that used in the WES.

142. Many scholars disagree with the notion that congressional intent is readily ascertainable or should be ascertained in interpreting statutes. *See* Frank H. Easterbrook, *The Role of Original Intent in Statutory Construction*, 11 HARV. J.L. & PUB. POL'Y 59, 60–61 (1988); Max Radin, *Statutory Interpretation*, 43 HARV. L. REV. 863, 870–72 (1930). Contrary to these positions, this Note assumes that congressional intent can and should be determined in applying regulatory statutes.

143. *See, e.g.*, Jack M. Beermann, *Congressional Administration*, 43 SAN DIEGO L. REV. 61, 70–71 (2006) (describing methods of congressional control); Mathew D. McCubbins, Roger G. Noll & Barry R. Weingast, *Structure and Process, Politics and Policy: Administrative Arrangements and the Political Control of Agencies*, 75 VA. L. REV. 431, 434 (1989) (describing congressional oversight as "fire alarms").

incentive to follow congressional instructions often hidden in committee reports and other legislative history.[144] Moreover, agencies are naturally inclined to use these tools because they are often active participants during the drafting of statutes and already understand the context behind statutory text.[145]

Extending this principle of determining congressional intent using the "traditional tools of statutory interpretation," a numerical version of congressional intent such as the WES could be created for many sets of laws for any governmental agency. Although Congress never specifically contemplated a particular mathematical version of the law when enacting a statute, nonetheless, under an intentionalist view, a mathematical expression of fictionalized intent should be equivalent to a verbal one. The major difference is that in many circumstances, such as for conflict of interest waivers, mathematical expressions can be more effective in meeting the intent behind the statute.

Turning to our case study, the vast majority of waivers issued by the FDA when the WES was developed were 208(b)(3) waivers, where a waiver may be granted for an SGE if the "need" for the expert outweighs the expert's "potential for a conflict."[146] Determining the meaning of "need" and "potential for a conflict" requires an intentionalist interpretation using the traditional tools of statutory interpretation. Once the meaning of these terms is determined, the WES is used to assign a particular expert a numerical need score and a separate numerical conflicts score and then to compare the scores in order to determine whether a waiver is appropriately granted.[147]

As Part III discussed, the new 2008 Waiver Guidance focuses more on FDAAA's essential expertise standard and the new $50,000 cap on the total dollar value of an SGE's conflicts.[148] The FDA will still apply the 208(b)(3) waivers, however, under the guidance set forth in step 10(a).[149] Moreover, the guidance is merely a statement of policy, and legally, there

144. Beerman, *supra* note 143, at 135–36 ("Congress sometimes produces legislative history containing explicit instructions to the executive branch.").

145. *See, e.g.*, FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 145–51 (2000) (describing the FDA's active participation in the formulation of tobacco policy and finding persuasive the FDA's statements interpreting congressional intent around the time the bill passed).

146. *See* 18 U.S.C. § 208(b)(3) (2006); *supra* Part II.A.

147. The calculus here is a simple one: if the need score is greater than the potential for a conflict score, the waiver is appropriate. *See infra* app.

148. *See* 2008 Waiver Guidance, *supra* note 37, at 6–8.

149. *Id.*

may be instances where the FDA must apply the § 208(b)(3) standard.[150] In addition, the WES could easily be adapted to the essential expertise standard by repeating the general steps below followed in creating the system[151]:

1. Analyze the applicable conflict of interest statute to determine the standard relevant to granting or denying a waiver.[152]

2. Determine the elements of the legal standard as intended by Congress by using the traditional tools of statutory interpretation, including common meanings, statutory purpose, and legislative history.[153]

3. Assign a weight to the individual elements of the legal standard such that, when added together, the sum of the weighted elements approximates the meaning of the legal standard as intended by Congress.[154]

4. Create a scoring system to reliably assign numerical values to each of the inputs in a particular waiver being evaluated by the WES.[155]

5. Develop a simple analytical tool to compare waivers, determine whether legal standards are met, and identify which elements of the legal standard were essential in the grant or denial of a waiver.[156]

The remaining sections in this part provide a detailed explanation of these steps by leading the reader through their application for 208(b)(3) FDA waivers.

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150. *See id.* at 21–22 (discussing that some waivers may pass essential expertise, but not under § 208(b)(3)).

151. It may even be unnecessary to redo the steps in creating the WES. The essential expertise standard is practically similar to the need standard in § 208(b)(3). Thus, the FDA could simply remove the "conflict" comparison from § 208(b)(3) and make minor adjustments to adapt the WES to the essential expertise standard of FDAAA.

152. For § 208(b)(3), this is need outweighing conflict, and for FDAAA waivers, this is essential expertise. *See supra* Part II.A.

153. In this case, the elements comprising the words "need" and "conflict" were determined using congressional intent, derived from OGE regulations and documents. *See infra* Part IV.C.

154. For example, the WES for § 208(b)(3) approximates the legal meaning of "need" by assigning a 70 percent weight to "uniqueness of expertise," a 20 percent weight to "difficulty in locating other experts," and a 10 percent weight to "prior FDA committee experience." *See infra* tbl.A.1. These elements together with their respective weights comprise what legal research showed was the intended meaning of "need." *See infra* Part IV.D.

155. The WES uses a scoring system from 0 to 5, with 5 meaning that the particular element being scored has received the maximum score based on the circumstances provided in the waiver. Zero means that the particular element was not considered in the grant of a waiver, while 1 means that the element was considered but received the lowest possible score.

156. *See infra* app.

B. STEP ONE: ANALYZE THE APPLICABLE CONFLICT OF INTEREST STATUTE TO DETERMINE THE STANDARD RELEVANT IN GRANTING OR DENYING A WAIVER

This is a simple inquiry for 208(b)(3) waivers, as explained in Part II.A: a waiver should be granted to an SGE if "the *need* for the individual's services *outweighs the potential for a conflict of interest* created by the financial interest involved."[157] Thus, one must simply compare the "need" for the expert in the advisory committee meeting with the "potential for a conflict of interest" as determined by the expert's financial disclosure form.[158] Based on this standard, the WES breaks the standard in two, determining the statutory elements of need and potential for a conflict separately, and thus facilitating a comparison of the numerical values of these elements.

C. STEP TWO: DETERMINE THE ELEMENTS OF THE LEGAL STANDARD AS INTENDED BY CONGRESS BY USING THE TRADITIONAL TOOLS OF STATUTORY INTERPRETATION, INCLUDING COMMON MEANINGS, STATUTORY PURPOSE, AND LEGISLATIVE HISTORY

Although Congress may provide a legal standard in some statutes, it generally does not provide explicit directions on how the elements of the standard are to be weighted when deciding a legal issue.[159] The FDA's 208(b)(3) waivers are no exception: the statute contains a legal standard without indicating what in particular Congress intended the standard to mean, if anything.[160] As discussed in Section A, sociological jurisprudes interpret these statutes by creating a fictionalized "congressional intent" that elucidates factors using the statute's plain meaning, overall statutory purpose, canons of construction, and legislative history.[161] Upon application of these traditional tools of statutory interpretation, if courts

157. 18 U.S.C. § 208(b)(3) (2006) (emphases added).

158. *See id.*

159. *See, e.g.*, Copyright Act of 1976, 17 U.S.C. § 107 (2006) (listing four elements courts must consider in determining whether the "fair use" standard has been met, but not describing how much each factor should be weighted).

160. *See* 18 U.S.C. § 208(b)(3) (providing only the legal standard—need outweighing potential for a conflict—without specifying the elements of either standard or how these elements might be weighted).

161. *See* Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs., 545 U.S. 967, 980–81 (2005); FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 132 (2000); Chevron U.S.A. Inc. v. Natural Res. Def. Council, 467 U.S. 837, 842–43 (1984); Elizabeth Garrett, *Step One of* Chevron v. Natural Resources Defense Council, *in* A GUIDE TO JUDICIAL AND POLITICAL REVIEW OF FEDERAL AGENCIES 55, 55–56 (John F. Duffy & Michael Herz eds., 2005).

find that the statute is "ambiguous," they will use the same tools to develop a zone of "permissible" or "reasonable" agency interpretations given the gaps in congressional intent.[162] Courts and scholars generally accept these methods when interpreting regulatory statutes.[163]

Unfortunately in this case, since there are no court decisions determining the congressional intent behind the § 208(b)(3) standard, an independent statutory interpretation is necessary. Referring to dictionaries and common meanings, which is often the first step used by courts in determining congressional intent,[164] does not resolve the issue. Dictionary definitions and common meanings of the word "need" range from a "want" to a "necessity," leaving the standard just as unclear.[165] Moreover, there are several types of financial conflicts of interest,[166] and looking at common usage or dictionaries cannot help identify which ones Congress intended to count more heavily against a waiver.

The legislative history on § 208(b)(3) is also sparse.[167] When changes were made to § 208(b) to add 208(b)(3) waivers in the Ethics Reform Act of 1989, there were no floor debates on the topic in Congress.[168] In general, however, the purpose of the Ethics Reform Act of 1989 seemed to be to mitigate some of the harsh burdens on government employees created by former conflict of interest laws.[169] The legislation was spurred by the President's Commission on Federal Ethics Law Reform in 1989 ("President's Commission"), which found that the "government is needlessly handicapped in obtaining advice and information from individuals with expertise who are located in the private sector."[170] The general recommendations of the President's Commission, along with a facial comparison of the standards, support the view that the 208(b)(3)

162. The acceptance of this zone of reasonable interpretations is a result of the Court's *Chevron* jurisprudence. *See Brand X*, 545 U.S. at 980–81 ("If a statute is ambiguous, and if the implementing agency's construction is reasonable, *Chevron* requires a federal court to accept the agency's construction of the statute, even if the agency's reading differs from what the court believes is the best statutory interpretation."); *Brown & Williamson*, 529 U.S. at 132; *Chevron*, 467 U.S. at 842–43.

163. *See* Garrett, *supra* note 161, at 55–58.

164. *See* MCI Telecomms. Corp. v. AT&T Co., 512 U.S. 218, 225–227 (1994) (using dictionary definitions and debating the merits of different dictionaries in construing the meaning of the word "modify" in a statute); Garrett, *supra* note 161, at 58–59.

165. *See, e.g.*, WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1512 (3d ed. 2002).

166. *See* OGE Memo, *supra* note 26, at 14–25; 2000 Waiver Guidance, *supra* note 36 (Part III.C).

167. *See* Murdock, *supra* note 27, at 503.

168. *Id.* at 503 & n.8.

169. *Id.* at 503–04 (listing the many provisions of the Ethics Reform Act that lift harsh conflict of interest rules and stating that the Act is an improvement because it lifts undue burdens on government employees).

170. PRESIDENT'S COMM'N ON FED. ETHICS LAW REFORM, TO SERVE WITH HONOR 29 (1989).

waivers were intended to be more lenient than existing waivers under § 208(b)(1) and (b)(2).[171]

Perhaps the clearest indicator of congressional intent can be derived from § 208(d)(2), which instructs the OGE to draft regulations describing the requirements of 208(b) waivers.[172] Congress expressly relied on the OGE's expertise and required that it create more definite rules for applying § 208(b)(3), suggesting it recognized that the statute was ambiguous.[173] This is also consistent with the fact that, apart from having the general purpose of mitigating the burden on government employees created by prior conflict of interest laws, Congress did not discuss details of the statute and passed it in less than two weeks.[174] Thus, the WES treats OGE regulations as placeholders for congressional intent in explaining the elements of the legal standard in § 208(b)(3).[175] When developing processes similar to the WES for other statutes outside this specific example, the middle step of considering OGE regulations might be eliminated if the statute being analyzed falls within the interpreting agency's organic act.[176]

As discussed in Part II.B, the relevant OGE regulation that serves to give substance to congressional intent is 5 C.F.R. § 2640.302.[177] This

171. *See id.* at 29–30; Murdock, *supra* note 27, at 519. In addition, upon a close examination of § 208(b)(1) and (b)(2), it seems unlikely that any waiver that satisfies those requirements will not also satisfy § 208(b)(3) requirements. *See supra* Part II.A. This discrepancy may be settled, however, in view of the fact that § 208(b)(3) applies only to SGEs, not regular government employees.

172. Pursuant to § 208(d)(2),

> (2) The Office of Government Ethics, after consultation with the Attorney General, shall issue uniform regulations for the issuance of waivers and exemptions under subsection (b) which shall—
> (A) list and describe exemptions; and
> (B) provide guidance with respect to the types of interests that are not so substantial as to be deemed likely to affect the integrity of the services the Government may expect from the employee.

Ethics Reform Act of 1989, Pub. L. No. 101-194, § 208, 103 Stat. 1716, 1752–53 (codified at 18 U.S.C. § 208(d)(2) (2006)).

173. *See id.*

174. *See* Murdock, *supra* note 27, at 503.

175. *See supra* Part II.A–B. Note that OGE regulations can be just as ambiguous for the FDA as § 208(b)(3) in some instances. Although OGE regulations provide the legal elements comprising need and potential for a conflict, they do not give direction on how these elements should be weighted. *See infra* Part IV.D. Instead, the OGE has issued guidances, not having the force of law, about how to interpret its regulations. *See* OGE Memo, *supra* note 26, at 5. The WES utilizes these OGE regulations and guidances to ultimately create a comprehensive mathematical expression of a fictional idea of "congressional intent."

176. This is because the interpreting agency would directly analyze its own statute rather than analyzing regulations issued by another agency that Congress had singled out as having the expertise needed to develop regulations that give structure to the statute.

177. See note 73 for the language of the relevant sections of 5 C.F.R. § 2640.302 (2009).

regulation specifies seven elements to consider in weighing the need for an expert against the expert's potential for a conflict.[178] Two of these elements, "the uniqueness of the individual's qualifications" and "the difficulty of locating a similarly qualified individual," are elements of the legal standard of need in § 208(b)(3).[179] These two elements are adopted into the WES, as well as another factor, "prior FDA committee experience," which is technically part of "uniqueness" but is quantified separately for clarity purposes. In sum, the OGE regulations yield that the three elements in the WES defining "need" are (1) uniqueness of expertise, (2) difficulty in locating other qualified experts, and as a subfactor to uniqueness, (3) prior FDA committee experience.[180]

The other five elements in the OGE regulations that together compose the standard for "potential for a conflict of interest" in § 208(b)(3) tend to overlap.[181] For clarity, they are grouped into three more exclusive categories in the WES. A portion of factor 6 from the OGE regulation comprises the element "value of interest"; another portion of factor 6 comprises the element "proportion of total assets," and factors 1, 2, 5, and 7 are grouped into the element "remoteness of interest."[182] The term "remoteness" derives from the language of § 208(b)(2), which expresses a concept similar to factors 1, 2, 5, and 7 in the OGE regulations.[183]

Thus, the statutory analysis based in sociological jurisprudence has yielded that 208(b)(3) waivers were likely intended to mitigate harsh applications of conflicts rules[184] and has pointed to the OGE regulations as the source of the definitions of "need" and "potential for a conflict."[185] Three "need" and three "potential for a conflict" elements were identified from the OGE regulations. In Step Three, these elements are assigned a weight proportional to the value intended by Congress, or by the OGE in the absence of congressional intent, in order to create a mathematical expression for the § 208(b)(3) standard.

178. *See* OGE Memo, *supra* note 26, at 12–14; *supra* note 73.
179. *See* OGE Memo, *supra* note 26, at 13.
180. *See infra* tbl.1. See also Part IV.D for an explanation of these elements.
181. See note 73 for the language of the relevant sections of 5 C.F.R. § 2640.302.
182. *See infra* tbl.1. See also Part IV.D for an explanation of these elements.
183. *See* 18 U.S.C. § 208(b)(2) (2006); OGE Memo, *supra* note 26, at 9–14.
184. *See* Murdock, *supra* note 27, at 519.
185. *See* 18 U.S.C. § 208(d)(2).

D. STEP THREE: ASSIGN A WEIGHT TO THE INDIVIDUAL ELEMENTS OF THE LEGAL STANDARD SUCH THAT, WHEN ADDED TOGETHER, THE SUM OF THE WEIGHTED ELEMENTS APPROXIMATES THE MEANING OF THE LEGAL STANDARD AS INTENDED BY CONGRESS

The first element comprising need, uniqueness of expertise, is described by the OGE as what may be "the most important factor in justifying a waiver under § 208(b)(3)."[186] This is likely because uniqueness invokes the strongest policy rationale for providing a waiver—although an expert may have a financial conflict, there may be so few experts in the field with the necessary experience that excluding the expert from participating would lead to an uninformed decision by the committee.[187] Such uninformed decisions could have adverse affects on the public health.[188] At the FDA, this case is not hard to imagine—medical researchers and clinicians are increasingly specialized in their education, often holding several degrees or focusing on narrow indications, and drugs are similarly becoming increasingly narrow in their scope of treatment.[189]

The second element of need, difficulty in locating other experts, illustrates a more logistical policy rationale for 208(b)(3) waivers, though it is not as crucial as uniqueness.[190] The basis for this element is that even if an expert's qualifications are not unique, the unavailability of similar experts increases the need for that particular expert.[191] The OGE specifically acknowledges that those who are qualified to serve on advisory committees "have ties to the entities that are most likely to be affected by, or interested in . . . matters that will come before the committee."[192] This is because other qualified experts are likely to have similar conflicts that bar their participation.[193] Moreover, because of the limited pay and duration of advisory committee membership,[194] it is unlikely that similarly qualified

186. OGE Memo, *supra* note 26, at 13.

187. *See* 2007 ERG REPORT, *supra* note 24, at iii; Glodé, *supra* note 7, at 301. This uniqueness rationale is likely similar to the rationale behind the essential expertise standard in FDAAA.

188. *See* Gottlieb Speech, *supra* note 24 ("The public health will not be served if we are no longer able to attract the kind of very active medical practitioners and clinical trialists who are able to inform our meetings with some very unique medical insights that only comes from years of experience both seeing patients and developing and looking at clinical data, sometimes in some very narrow fields or for specific indications.").

189. *See id.*

190. *See* OGE Memo, *supra* note 26, at 13.

191. *Id.*

192. *Id.*

193. *Id.*

194. *See* Advisory Committee FAQ, *supra* note 98.

experts would relinquish these substantial financial conflicts to attend committee meetings a few times a year.[195] This seems to be the type of undue hardship placed on agencies that Congress and the President's Commission purposefully sought to avoid with the Ethics Reform Act of 1989.[196] Thus, the difficulty in locating other experts without conflicts is a necessary element of need, without which the advisory committee process would be unduly hampered.

The third element of need, prior FDA committee experience, can be considered a part of an expert's uniqueness.[197] This subfactor of uniqueness contributes to an expert's need indirectly because familiarity with FDA rules can make an expert especially valuable in leading committee meetings or quickly understanding issues in product approvals.[198] It is separated from uniqueness in the WES for clarity purposes, however, because prior FDA committee experience can be construed to mean that the FDA is repeatedly using the same conflicted members because it is in industry's pocket.[199] Separation of this subfactor in the WES would allow the FDA to clearly indicate that it is attaching the least amount of weight to this element, illustrating one way to use the WES—to combat public misunderstanding.[200]

Turning now to the second half of the legal standard in the WES, the potential for a conflict, the first element is the monetary value of the interest itself. The magnitude of the financial interest is directly proportional to the potential for a conflict.[201] For example, ownership of public stock with a value of only $5000 in an affected company is unlikely to impact an expert's opinion, whereas ownership of $100,000 of stock is likely to have a greater impact.[202] Temporary employment arrangements, such as giving a speech at a company event for $2000, are also very unlikely to create bias, but consulting agreements worth $50,000 or more

195. OGE Memo, *supra* note 26, at 14.

196. *See supra* notes 169–71 and accompanying text (discussing the Commission's recommendation that the government should not be unduly handicapped by conflicts laws in obtaining advice from the private sector).

197. *See* OGE Memo, *supra* note 26, at 13.

198. *See, e.g.*, Waiver for Maha Hussain, *supra* note 52 (arguing that Hussain's prior experience as chair and member of the Oncologic Drugs Advisory Committee makes her "both qualified and experienced to guide and advise the clinicians on Oncologic Drugs Advisory Committee as to the most scientifically valid interpretation of the topic at hand").

199. *See Plenty of Experts Available*, *supra* note 88.

200. The FDA could also choose to eliminate this factor entirely if it is concerned about the appearance of impropriety in its waivers stemming from this factor.

201. *See* OGE Memo, *supra* note 26, at 9–10, 13.

202. *See id.* at 10, 15.

per year are more likely to create bias.[203] The apparent size of the interest is also important because it is often determinative of the public's perception of improper ties between agencies and industry.[204] Moreover, the value of the interest is a simple criterion to use in applying conflict of interest laws, and unlike some other elements, it is very concrete.[205]

The magnitude of the financial interest is not an effective measure of the potential for a conflict, however, unless it is construed together with the second element, remoteness of the interest. Conceptually, it is simpler to combine the OGE regulations addressing remoteness into one category because they overlap.[206] The basis for this element is that if an expert's financial interest is far removed—either because the conflict is not closely tied to the expert's interests, or because the likelihood that the advisory committee's decision will affect the expert's interest is small—then the conflict should not count heavily against a waiver.[207] For example, a conflict arising from an expert's relative is more remote than a conflict arising directly from an expert's employment.[208] Similarly, a conflict is remote if an advisory committee's decision affects one of many competitors of the expert's employer because the decision is unlikely to have a substantial impact on the expert's employer.[209] Thus, the remoteness determines the proximity of the magnitude of the interest measured in the first element.

The third element, the measurement of the dollar value of the interest as a "proportion of total assets" of the expert, provides another limitation on the magnitude of the financial interest and is necessary to avoid harsh results.[210] Although the value of a financial conflict may seem high to the public, it may not be a significant temptation for a wealthy individual.[211] Thus, a financial conflict that comprises 25 percent of an expert's assets

203. *See* 2000 Waiver Guidance, *supra* note 36 (Part III.C.3).

204. *See, e.g.*, Goozner, *supra* note 14 (focusing on the $150 million monetary value of a study in describing the magnitude of an expert's conflict of interest); OGE Memo, *supra* note 26, at 15 ("[V]ery large holdings of stock . . . may create an appearance concern, even where the likelihood of an effect on the value of that holding appears remote . . . .").

205. The value of the financial conflict is directly disclosed by the expert seeking the waiver. *See* FDA, Policies and Procedures for Handling Conflicts of Interest with FDA Advisory Committee Members, Consultants, and Experts, http://www.fda.gov/oc/advisory/conflictofinterest/policies.html (last visited Mar. 31, 2009) [hereinafter Policies and Procedures Document].

206. *See* 5 C.F.R. § 2640.302 (2009); OGE Memo, *supra* note 26, at 9–13.

207. *See* OGE Memo, *supra* note 26, at 12–14.

208. *See id.* at 12–13.

209. *See id.* at 13–14.

210. *See id.* at 10, 15–16.

211. *Id.*

should count heavily against a waiver, whereas a conflict that comprises less than 1 percent of the expert's assets should not, even if the magnitude of the conflict is high.[212] As the OGE notes, this element is often used if the financial interest is public stock.[213]

While the OGE regulations do not precisely provide the relative weight assigned to each element of need and potential for a conflict, the OGE documents have provided sufficient guidance to reasonably estimate Congress's intentions. As shown above for the need elements, "uniqueness of expertise" is expressly stated by the OGE as possibly the most important of the three elements.[214] In addition, "difficulty in locating other experts," though not as crucial as uniqueness, is also a substantial element because it directly relates to the overall purpose of mitigating harsh results of conflict of interest laws.[215] By contrast, "prior FDA committee experience" is likely a relatively minor element because it is only a small component of uniqueness. The analysis above tends to create a few reasonable estimates as to how these elements should be relatively weighted. For example, need could be comprised of uniqueness weighted at 70 percent, difficulty in locating other experts at 20 percent, and prior FDA committee experience at 10 percent.[216]

Although choosing a viable weighting of these elements is somewhat flexible, the choice should not affect the primary goals of the WES: clarity and consistency. Courts face similar problems when congressional intent or its placeholder offers several reasonable interpretations;[217] however, using the numerical statutory interpretation technique provides a clear and consistent interpretation of intent while providing a tool to evaluate outcomes under alternative interpretations of intent. For example, the analytical tools used in the WES can easily evaluate waivers at more than

212. *See id*.; 2000 Waiver Guidance, *supra* note 36 (Part III.C.1).

213. *See* OGE Memo, *supra* note 26, at 10.

214. *Id.* at 13.

215. *See supra* notes 190–96 and accompanying text.

216. Though this weighting is adopted for estimating need in the WES, other equally reasonable weightings could be 60, 30, and 10 percent, respectively. This is because even the OGE regulations fail to capture congressional intent to this detail, and there is a zone of reasonable interpretations created by the OGE in this regard. *See supra* note 175 and accompanying text. An advantage of the WES is that because it uses software applications to apply inputs for congressional intent, these weights can easily be adjusted and one can determine whether the waiver is still appropriate under another interpretation of congressional intent articulated by the OGE regulations and guidances. If a waiver is appropriate under one set of weighting, but not another, the waiver can be flagged for additional review by FDA staff. Moreover, courts will generally uphold an agency interpretation of an ambiguous statute so long as it falls within a zone of "reasonableness." *See supra* notes 162–63 and accompanying text.

217. *See supra* notes 159–63 and accompanying text (discussing *Chevron* deference).

one combination of weights, thereby creating a broader net to capture possibly inappropriate waivers. In general, if the intent of Congress is clear, there will be fewer reasonable options in weighting the elements.[218] In this case, there may be several equally justifiable weightings of congressional intent given the information available—nonetheless, for each weighting option, the WES can provide a clear and consistent application of the law.

Similarly, using the congressional intent analysis for the potential for a conflict elements leads to more than one reasonable choice in weighting. The options here, however, are more limited. From the analysis of the "remoteness" and "value" elements, it is clear that without the proximity of the conflict provided by remoteness, the magnitude of the conflict is meaningless, and vice versa. Thus, each element is effective only when viewed in light of the other, suggesting that the elements should be weighted equally. The third element, the "proportion of total assets," is generally less important than the other two based on OGE regulations.[219] It still has some significance, however, because the importance of a financial conflict to the SGE depends on the accumulated wealth of the SGE. Thus, in the WES, potential for a conflict is comprised of 40 percent value, 40 percent remoteness, and 20 percent proportion of total assets.[220] The results from Step Three are summarized in table 1, below.

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218. This parallels the reasoning in the *Chevron* line of cases, which find that if congressional intent is "clear" then only one meaning can be attributed to the statute, but if congressional intent is "ambiguous," several permissible interpretations may exist. *See supra* notes 159–63 and accompanying text.

219. *See supra* notes 210–13 and accompanying text.

220. Another reasonable weighting scheme could be 45 percent value, 45 percent remoteness, and 10 percent proportion of total assets.

TABLE 1. Weights Assigned to Elements Constituting Need and Potential for a Conflict

No.	*Legal Standard*	*Element*	*Weight*
n1	Need	Uniqueness of expertise	70%
n2	Need	Difficulty in locating other experts	20%
n3	Need	Prior FDA committee experience	10%
c1	Potential for a conflict	Remoteness of interest	40%
c2	Potential for a conflict	Value of interest	40%
c3	Potential for a conflict	Proportion of total assets	20%

Note: This table can also be expressed mathematically. Assume the total normalized need score given for any expert is "N" and the total normalized potential for a conflict score of that expert is "C." Assume that "n1" represents the element uniqueness of expertise, "c1" represents the element remoteness of interest, and so on. Each element is scored from 1 to 5. N and C are normalized to 1 to facilitate plotting and can be obtained by multiplying their relative weights and input scores together, respectively. Thus, $N = (0.7 \times n1) + (0.2 \times n2) + (0.1 \times n3)$, and $C = (0.4 \times (5 - c1)) + (0.4 \times c2) + (0.2 \times c3)$. Note that a higher value for remoteness (c1) will tend to favor granting a waiver, while higher values for the other two conflicts elements, value (c2) and proportion of total assets (c3), will tend to oppose a waiver. Thus, to take these inverse effects into account, (5 - c1) is substituted for c1 in the formula.

E. STEP FOUR: CREATE A SCORING SYSTEM TO RELIABLY ASSIGN VALUES TO EACH OF THE INPUTS IN A PARTICULAR WAIVER BEING EVALUATED BY THE WES

After the first three steps, the congressional intent for the meaning of the need and potential for a conflict standards has effectively been transformed into a mathematical expression;[221] the inputs for the expression, however, must be converted from the language in a particular waiver into mathematical inputs. Step Four assigns a numerical value to a particular expert's qualifications and conflicts on a consistent scale and establishes guidelines for doing so in a reproducible manner. In other words, Step Four establishes the framework for determining how "unique"

221. *See supra* note to tbl.1.

an individual's expertise is, or whether the dollar value of the conflict is "too high."[222]

Fortunately, in this case, the 2000 Waiver Guidance already grouped several types of financial conflicts into "high, medium, or low" involvement levels for the potential for a conflict legal standard.[223] For example, for the value of interest element, the 2000 Waiver Guidance provides that, for a consulting conflict, income greater than $50,000 per year constitutes "high" involvement,[224] income between $10,000 and $50,000 constitutes "medium" involvement, and income less than $10,000 constitutes "low" involvement.[225] These levels can be translated into scores, with a score of 5 substituting for high involvement, a score of 3 for medium involvement, and a score of 1 for low involvement.[226] The score for each element of the legal standard can then be inserted into the mathematical expression for congressional intent derived in Part IV.C.[227]

By contrast, the 2000 Waiver Guidance does not provide similar scoring guidelines for the need legal standard. This is likely because the need elements, such as uniqueness of expertise, are context dependent and cannot be adequately defined by objective criteria such as the amount of material an expert has published on the topic or the number of clinical trials the expert has managed. In such a case, FDA ethics staff should be provided with a list of factual scenarios to help assign a score, such as a 5 for an expert who is "extremely" unique and a 1 for an expert who has a "general" educational background.[228] In applying Step Four outside of the waiver evaluation context, individual scores may have to be predetermined

222. The inputs determined in Step Four are plugged into the equation from the note to table 1 as n1, n2, n3, c1, c2, and c3 for each of their respective elements. *See supra* tbl.1.

223. *See* 2000 Waiver Guidance, *supra* note 36 (Part III.C).

224. *Id.* Under the 2008 Waiver Guidance, this interest by itself would be sufficient to prevent the expert from participating in the advisory committee because of the $50,000 cap. *See* 2008 Waiver Guidance, *supra* note 37, at 7. The WES does not include this limitation, however, because it is based on the 2000 Waiver Guidance.

225. *See* 2000 Waiver Guidance, *supra* note 36 (Part III.C.3).

226. Note that any scale can be applied as long as it is consistent. Flexibility can be improved by creating a more detailed scale, such as 1–100; however, this should be weighed against increasing complexity. A scale of 1 to 5 was chosen for this particular application because there are a large number of waivers and the level of accuracy demanded is relatively low.

227. *See infra* app. Note that when an element is not considered in the grant of the waiver, the remaining elements are proportionately given more weight. For example, if "prior FDA committee experience is not considered, the other elements of need proportionately increase such that Uniqueness comprises about 78 percent of the need score and difficulty in locating other experts comprises about 22 percent.

228. *See* Saurabh Anand, Waiver Criteria Guidelines Document 3–8 (Aug. 10, 2008) (unpublished agency document, on file with author).

for the relevant factual scenarios.[229]

F. STEP FIVE: DEVELOP A SIMPLE ANALYTICAL TOOL TO COMPARE WAIVERS, DETERMINE WHETHER LEGAL STANDARDS ARE MET, AND IDENTIFY WHICH ELEMENTS OF THE LEGAL STANDARD WERE ESSENTIAL IN THE GRANT OR DENIAL OF A WAIVER

An analytical tool can greatly increase the speed and flexibility of the WES. After Step Four, the mathematical transformation of both the congressional intent behind the legal standards and the factual inputs into the legal standard is complete. The analytical tool should be used to perform calculations of need and potential for a conflict scores based on the weighted equation[230] by entering the inputs (n1 through c3).[231] In addition, the tool can be used to monitor general trends and pinpoint inappropriate waivers with speed.[232] An example of such a method is provided in the appendix.

V. POSSIBLE MODES OF APPLICATION OF THE WES, ITS STRENGTHS AND WEAKNESSES, AND FUTURE STEPS NECESSARY PRIOR TO IMPLEMENTATION

This part discusses the possible ways to implement the WES, including using the WES immediately as a quality control device after waivers have been granted. In addition, this part considers the strengths and weaknesses of the WES and the numerical interpretation technique and identifies additional research needed before the WES can be implemented.

A. POSSIBLE MODES OF APPLICATION OF THE WES

Currently, there is no formal evaluation system in place at the FDA to check the consistency and validity of conflict of interest waivers.[233] Once signed, a waiver is generally not reviewed unless there is a reason to revisit it due to public scrutiny, such as in the Rezulin case described in the Introduction.[234] Staff at the specific FDA center in which the advisory

229. *See* OGE Memo, *supra* note 26, at 14–25 (providing guidance for issues relating to specific types of factual scenarios for conflicts of interest in advisory committees).

230. See the note to table 1 for the weighted equation.

231. *See infra* app. (showing how the inputs can be entered into the analytical tool by ethics staff).

232. *See infra* fig.A.1 (showing how general trends can be monitored through plotting).

233. Ortwerth & Warner Interview, *supra* note 115.

234. *See* Policies and Procedures Document, *supra* note 205 (showing that once a waiver is signed by the appointing official, there is no regular procedure for review).

committee meeting is held typically write the waiver, which includes information about the committee member's financials and expertise.[235] The written document is then reviewed by staff at the Advisory Committee Oversight and Management Group and signed by the deputy commissioner for policy.[236] Though these groups have an extensive knowledge of conflict of interest laws, they generally do not publicly explain the reasoning behind their grant or denial of a waiver, leading to clarity problems.[237]

One simple way to capture the benefits of the WES is to apply it annually or semiannually to waivers that have already been issued. Using the WES as a quality control device retains many of its benefits for ameliorating consistency and clarity concerns without requiring significant FDA investment in the conflict of interest process.[238] Results from such an application of the WES can be used to improve conflict of interest processes by identifying potentially inappropriate waivers granted in the past and by helping the FDA avoid similar mistakes in granting future waivers. In addition, applying the WES as a quality control method likely will not require the agency to go through the extensive notice-and-comment rulemaking procedures required for "rules" under the Administrative Procedure Act.[239]

On the other hand, applying the WES to determine whether a waiver should be granted before an advisory committee meeting would maximize the consistency and clarity of the conflicts process by directly preventing inappropriate waivers, without the redundancy of a quality control system. The results from such an application of the WES could either be dispositive

235. For examples of a 208(b)(3) waiver, see FDA, Advisory Committees: 2008 Waivers for Conflicts of Interest for Voting Members of FDA Advisory Committee Members, http://www.fda.gov/ohrms/dockets/ac/currentcoi.html (last visited Mar. 30 2010) (listing waivers for conflicts of interest for voting members of FDA advisory committee members).

236. Ortwerth & Warner Interview, *supra* note 115. *See also* Policies and Procedures Document, *supra* note 205.

237. The reasoning for the denial of a waiver is explained to the "affected parties" but not publicly. *See* Policies and Procedures Document, *supra* note 205. Also, though the waiver forms for granted waivers are available publicly, these forms do not show which factors eventually led to the decision to grant the waiver. Ortwerth & Warner Interview, *supra* note 115.

238. Ortwerth & Warner Interview, *supra* note 115.

239. *See* 5 U.S.C. § 553 (2006) (stating that notice-and-comment rulemaking procedures are not required for "general statements of policy" or "interpretive rules"). *Compare* Prof'ls & Patients for Customized Care v. Shalala, 56 F.3d 592, 595, 601–02 (5th Cir. 1995) (finding that FDA guidelines that distinguished drug manufacturing from drug compounding were interpretive rules not requiring notice-and-comment procedures because they merely clarify, rather than administer, existing law), *with* Cmty. Nutrition Inst. v. Young, 818 F.2d 943, 946–48 (D.C. Cir. 1987) (finding that the FDA "guidelines" were in fact "rules" requiring notice-and-comment procedures because they had a present, binding effect).

of whether an SGE should receive a waiver, or it could create a presumption for or against the grant depending on whether the results are positive and their degree of certainty. A fully dispositive application of the WES should greatly reduce issues of consistency and clarity because it would decrease subjective decisionmaking in the conflict of interest process and places the FDA's complete reasoning for the grant of a waiver before the public. Creating a presumption for the grant or denial of a waiver based on WES results would, however, allow the deputy commissioner for policy to consider discretionary elements not contemplated by the WES. In either case, however, the agency would likely have to undergo notice-and-comment rulemaking procedures and could ultimately face greater legal challenges in applying the WES.[240] Furthermore, additional research about the efficacy of the WES is necessary before it is applied in such a dispositive manner.[241]

B. STRENGTHS AND WEAKNESSES OF THE WES AND FUTURE STEPS NECESSARY PRIOR TO IMPLEMENTATION

The WES provides a tool to address the concerns of consistency and clarity discussed in Parts II and III of this Note, as well as to systematically improve conflict of interest processes. The consistency of waivers can vary depending on the type of SGE at issue, the FDA center requesting the waiver, and the FDA staff reviewing waivers because of the inherent subjectivity in the need and potential for a conflict standards.[242] The clarity behind waivers is limited because there is no information about why a specific waiver was granted or which elements of the legal standard weighed most strongly toward granting a waiver. Applying the WES as a check can greatly reduce these problems by placing more objectivity and precision in the conflict of interest process. Every time a waiver is evaluated, one can determine how the wavier compares to other waivers granted and which elements favored or disfavored the grant.[243] One can

240. *See* 5 U.S.C. §§ 551, 553 (stating that notice-and-comment rulemaking is required for a "rule," which is an "agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency"); *Cmty. Nutrition Inst.*, 818 F.2d at 946–48.

241. For example, the ability of FDA staff to reliably input scores for credentials and conflicts of experts into the WES needs to be examined. In addition, the sensitivity of the WES to changes in the weighting of the elements should be reviewed using actual waiver data. *See infra* Part V.B (discussing future steps needed).

242. Ortwerth & Warner Interview, *supra* note 115.

243. For example, see Waiver 4 in tables A.1 and A.2 in the appendix. It is evident from examining this waiver that the need score is highly dependent on the expert's excellent uniqueness score (5 out of 5). This could be due to the expert's specific educational background and experience,

also determine whether the margin between need and potential for a conflict was too small or whether the waiver was inappropriate.[244] Additionally, in response to public misperception about the agency being in industry's pocket, the WES may serve to demystify agency actions in order to regain public trust by presenting before the public the agency's reasoning for granting or denying a waiver.[245]

Another benefit of the WES is to improve FDA waiver granting processes. Though the WES is envisioned as a tool that will be applied annually or semiannually after waivers have been granted,[246] lessons learned from it about the FDA center's habits, potential misapplications of legal standards, and inconsistencies in reviewer standards can be used to improve future waivers. Moreover, as part of the FDAAA requirement to reduce the rate of waivers granted per year,[247] the WES can identify the types of waivers where the need only marginally outweighs the potential for a conflict, and those waivers can be eliminated in the future.

On the other hand, there are still some questions remaining in applying the numerical statutory interpretation technique in the WES. The first is the leeway in reasonable weights for the elements of the legal standard determined using congressional intent.[248] Due to the limited information available regarding congressional intent, even with the OGE regulations giving structure to the intent, several reasonable possibilities are available in weighting each element comprising need and potential for a conflict.[249] Another issue is that the system retains some subjectivity when assigning scores to a particular expert's credentials and conflicts in order to create inputs for the mathematical expression of congressional intent. The sensitivity of the WES to these issues remains to be examined. One way to

validating this particular waiver because uniqueness is rooted in the main policy rationale for conflict of interest waivers. The potential for a conflict elements have average scores (each receiving 3 out of 5). Thus, because the WES weights uniqueness at 70 percent, Waiver 4 still passes by a fairly wide margin. Comparing Waiver 4 to other waivers, one can see that only one other waiver presented, Waiver 2, passes with a higher margin.

244. For example, see Waiver 1 in tables A.1 and A.2 in the appendix. The results show that this waiver received about an average need score and about an average potential for a conflict score. Thus, Waiver 1 passed by only a fairly narrow margin—Waiver 2 passed with a margin many times this size. Waiver 1 has been flagged for further review in figure A.1 in the appendix.

245. For example, the WES separates the prior committee experience element from uniqueness for clarity purposes, showing its relatively minor importance in the FDA's conflict of interest process.

246. Ortwerth & Warner Interview, *supra* note 115.

247. See *supra* notes 63–65 (discussing FDAAA).

248. *See supra* Part IV.D.

249. One way to resolve this issue in practice would be to review waivers under several different weightings of the elements, and only grant waivers if a certain minimum percentage of these weightings yield passing results.

resolve this is by collecting data on actual waivers granted by the FDA and inputting the data into several reasonable expressions of congressional intent with differently weighted elements.

VI. CONCLUSION

Federal agencies are increasingly dependent on outside experts for advice on critical decisions, sometimes issuing conflict of interest waivers to obtain expert opinions despite experts' known ties to industry. Prior scholarship has identified the lack of consistency and clarity in agencies' decisions to issue waivers to experts on federal advisory committees and the disastrous effects of potentially biased expert advice on society. At the FDA, the integrity of expert advice can often literally be a life-or-death matter, as illustrated by the controversy surrounding the deaths resulting from an approval and reapproval of Rezulin. The mere appearance of impropriety in that case led critics to question the agency's legitimacy.

It is also generally well accepted, however, that attempting to eliminate all conflicts of interest from advisory committees would ultimately reduce the quality of decisions made by agencies by excluding valuable expert advice. Thus, a more precise adherence to conflicts laws, appropriately balancing the need for qualified experts with the integrity of expert advice, is more effective than an overly strict conflict of interest regime. Though scholars and public interest groups have advocated for improvements to the conflict of interest process, such as a cap on the overall magnitude of waivers, and the FDA has responded by creating a stricter process in the 2008 Waiver Guidance, no critics have posed a comprehensive method for the FDA to clearly and consistently adhere to conflict of interest laws.

This Note presents such a method and argues that its adoption would address critiques of lacking consistency and clarity and result in better adherence to conflicts laws. Unlike the recently adopted 2008 Waiver Guidance, the WES allows the FDA to compare the consistency of granted waivers, identify specifically which elements favored the grant of a waiver, and determine whether a waiver was granted inappropriately. These improvements are possible in large part because the WES systematically uses traditional tools of statutory interpretation to convert congressional intent behind ambiguous legal standards into mathematical expressions. This numerical statutory interpretation technique removes some subjectivity and adds transparency by giving the public access to the agency's reasoning. In addition, the WES converts case-by-case facts into

mathematical inputs by using scoring guidelines, allowing for reproducible and consistent applications of the legal test.

The numerical statutory interpretation technique used to develop the WES can also be adapted to other ambiguous legal standards, resulting in similar benefits. If the WES is adopted as a quality control mechanism at the FDA for its conflict of interest waiver process, the results will show whether widespread agency use of similar processes outside the conflict of interest field would be beneficial. Meanwhile, in the conflict of interest field, this novel system is an effective tool in combating consistency and clarity problems. The improved transparency and closer adherence to conflict of interest laws achieved through the WES can only add to the FDA's legitimacy.

APPENDIX

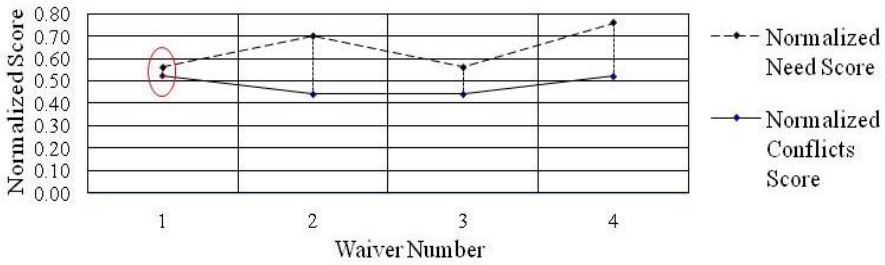
TABLE A.1. Sample WES Analytical Tool for Need Elements

No.	*Need Elements*	*Weight*	*Waiver 1*	*Waiver 2*	*Waiver 3*	*Waiver 4*
n1	Uniqueness of expertise	0.700	3	4	3	5
n2	Difficulty in locating other experts	0.200	3	3	3	1
n3	Prior FDA committee experience	0.100	1	1	1	1
Need Score	...	...	2.8	3.5	2.8	3.6
Normalized Score	...	...	0.56	0.70	0.56	0.72

TABLE A.2. Sample WES Analytical Tool for Potential for a Conflict Elements

No.	*Potential for a Conflict Elements*	*Weight*	*Waiver 1*	*Waiver 2*	*Waiver 3*	*Waiver 4*
c1	Remoteness of interest	0.400	4	4	3	3
c2	Value of interest	0.400	4	3	3	3
c3	Proportion of total assets	0.400	3	3	1	3
Conflict Score	...	...	2.6	2.2	2.2	2.6
Normalized Score	...	...	0.52	0.44	0.44	0.52

FIGURE A.1. Normalized Need v. Potential for a Conflict



Note: This figure plots the results from tables A.1 and A.2. The top line represents the normalized need score (N) for each waiver, and the bottom line shows the normalized potential for a conflict score (C) for each waiver. In addition, to illustrate graphically when the margin between N and C is narrow, Waiver 1 is circled. When evaluating hundreds of waivers, this technique can be used to quickly spot inappropriate or suspect waivers.