Washington University Law Review

Volume 90 | Issue 1

2012

License to Deal: Mandatory Approval of Complex Financial Products

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Saule T. Omarova, *License to Deal: Mandatory Approval of Complex Financial Products*, 90 WASH. U. L. REV. 064 (2012).
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LICENSE TO DEAL: MANDATORY APPROVAL OF COMPLEX FINANCIAL PRODUCTS

SAULE T. OMAROVA*

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INTRODUCTION

"There is definitely going to be another financial crisis around the corner because we haven't solved any of the things that caused the previous crisis," said hedge fund legend Mark Mobius, speaking in Tokyo nearly a full year after the United States officially embarked upon the greatest reform of financial services regulation since the New Deal.[1] Today, the world is still reeling from the recent financial crisis, which ravaged even the strongest economies and left them battling recession, budget deficits, soaring unemployment, and political discontent.[2] Facing

1. Kana Nishizawa, *Mobius Says Another Financial Crisis 'Around the Corner'*, BLOOMBERG.COM, May 30, 2011, http://www.bloomberg.com/news/2011-05-30/mobius-says-fresh-financial-crisis-around-corner-amid-volatile-derivatives.html. At the time of his remarks, Mobius was the head of the $50-billion emerging markets investments operations at Templeton Asset Management. *Id.*

2. For a discussion of the economic and societal costs of the recent financial crisis, see Cheryl D. Block, *Measuring the True Cost of Government Bailout*, 88 WASH. U. L. REV. 149, 159 (2010) ("A simple tally of dollars authorized or disbursed, of course, is wholly inadequate to accurately assess the

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another financial crisis in this situation is a frightening prospect. National governments, individually or in any G-denominated combination, may simply be out of magic bullets—as well as money and goodwill of their citizens—with which to fight the next war.

In this context, preventing the next financial meltdown becomes a survival imperative. To be effective, however, crisis prevention efforts must be comprehensive and coherent, and target the fundamental problems in financial markets instead of getting mired in the sea of small "fixes" to the system. One of the fundamental causes of the recent crisis was the unprecedented degree of complexity and interconnectedness in modern financial markets, and the woeful inability of both private market actors and public authorities to understand and manage the risks these factors posed to systemic financial stability.[3] Complex financial instruments, markets, and institutions create levels of opacity, interdependence, and unpredictability which significantly increase the potential for market inefficiency and systemic failure of dangerous proportions.[4] Complexity enables private market actors to engage in excessive financial speculation and tax and regulatory arbitrage, which further increase systemic risk and contribute little to productive economic growth. Despite their ambitious reach, post-crisis regulatory reforms do not appear to offer effective solutions to the fundamental dilemma of regulating complexity and systemic risk[5] in financial markets.[6] Much of the current academic and

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ultimate taxpayer cost of government bailouts."); Claire R. Kelly, *Financial Crises and Civil Society*, 11 CHI. J. INT'L L. 505 (2011) (describing societal consequences of the financial crisis from a global perspective).

3. There is a vast collection of literature analyzing the dynamics of risk accumulation in the financial system, which ultimately led to the crisis. For a sample of this literature, see generally Markus K. Brunnermeier, *Deciphering the Liquidity and Credit Crunch 2007–2008*, 23 J. ECON. PERSP. 77 (2009); Viral V. Acharya & Matthew Richardson, *Causes of the Financial Crisis*, 21 CRIT. REV. 195 (2009); Gary Gorton, *The Subprime Panic*, 15 EUR. FIN. MGMT. 10 (2008); Oren Bar-Gill, *The Law, Economics and Psychology of Subprime Mortgage Contracts*, 94 CORNELL L. REV. 1073 (2009); William K. Sjostrom, Jr., *The AIG Bailout*, 66 WASH. & LEE L. REV. 943 (2009); *see also infra* note 11.

4. For scholarly analyses of complexity in financial markets and its implications for systemic stability and efficiency, see, e.g., Steven L. Schwarcz, *Regulating Complexity in Financial Markets*, 87 WASH. U. L. REV. 211 (2010); Dan Awrey, *Complexity, Innovation and the Regulation of Modern Financial Markets* (U. of Oxford Legal Res. Paper No. 49, 2011), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1916649; Manuel A. Utset, *Complex Financial Institutions and Systemic Risk*, 45 GA. L. REV. 779 (2011).

5. Systemic risk can be defined as the risk "of widespread failures of financial institutions or freezing up of capital markets that can substantially reduce the supply of capital to the real economy." Viral V. Acharya et al., *Prologue: A Bird's-Eye View*, *in* RESTORING FINANCIAL STABILITY: HOW TO REPAIR A FAILED SYSTEM 1, 1 (Viral V. Acharya et al. eds., 2009). Another popular definition refers to systemic risk as "the risk that (i) an economic shock such as market or institutional failure triggers (through a panic or otherwise) either (X) the failure of a chain of markets or institutions or (Y) a chain

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policy debate tends to focus on discrete reform measures, mostly aimed at enhancing or finessing the same regulatory tools and approaches that failed to prepare us for the devastating effects of the latest crisis.[7] Ultimately, these measures fail to answer directly the fundamental normative question: how much financial risk is too much for society to bear?

This Article pushes the boundaries of the debate by directly confronting that fundamental policy issue. It starts with a simple premise: if we cannot effectively regulate and control systemic risk associated with the increasing complexity in financial markets, we need to reduce and control the overall level of complexity in the system. Because much of that risk-generating complexity is a result of strategic efforts of financial intermediaries that structure, market, and deal in complex financial instruments, the most radical and direct method of reducing systemic risk is to insert regulatory controls at the point of product development, before the risk is introduced into the financial system. This Article argues that one potentially effective form of such *ex ante* regulatory control is pre-market government licensing of complex financial instruments—including derivatives, asset-backed securities, and other structured products.

Product approval has long been the model of pharmaceutical drug regulation in the United States and has recently been introduced in the European Union's chemicals regulation. It is not commonly known, however, that a similar system of pre-trading "contract designation" also existed in the area of the U.S. commodity futures regulation prior to 2000.[8]

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of significant losses to financial institutions, (ii) resulting in increases in the cost of capital or decreases in its availability, often evidenced by substantial financial-marketplace volatility." Steven L. Schwarcz, *Systemic Risk*, 97 GEO. L.J. 193, 204 (2008).

6. *See infra* notes 57–64 and accompanying text.

7. For a provocative critique of the current reform efforts in the United States, see SIMON JOHNSON & JAMES KWAK, THIRTEEN BANKERS: THE WALL STREET TAKEOVER AND THE NEXT FINANCIAL MELTDOWN (2010); DAVID SKEEL, THE NEW FINANCIAL DEAL: UNDERSTANDING THE DODD-FRANK ACT AND ITS (UNINTENDED) CONSEQUENCES (2010).

8. *See infra* Part II.C. In today's financial markets, there are numerous examples of substantive review of financial products and transactions by public authorities and various quasi-public and private parties. These include merit-based review of securities offerings under state Blue Sky laws, various levels of pre-approval of certain insurance policies and rates by state insurance regulators, regulatory pre-approval of certain new activities and investments by federally-insured depository institutions and their parent companies, and the review of proposed horizontal mergers by the Department of Justice and the Federal Trade Commission. *See generally* PATRICIA A. MCCOY, BANKING LAW MANUAL §§ 5.015.03 (2012) (analyzing limitations on powers and activities of banks and bank holding companies); THOMAS LEE HAZEN, THE LAW OF SECURITIES REGULATION 329–34 (Rev. 5th ed. 2006) (describing state regulation of securities transactions); RICHARD SCOTT CARNELL ET AL., THE LAW OF BANKING AND FINANCIAL INSTITUTIONS (4th ed. 2009) (detailing regulation of banking organizations and insurance companies). Product design assessment also takes place in the process of listing

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Building on these three examples, the Article offers the first comprehensive examination of whether, and how, the concept of product approval regulation can be applied to reduce systemic risk posed by complex financial instruments.[9]

The core of the proposal advanced in this Article is the *process* for product approval, which would require financial institutions to make an affirmative showing that each complex financial product they intend to market meets three statutory tests: (1) an "economic purpose" test, which would place the burden of proving the social and commercial utility of each proposed financial instrument on the financial institutions seeking its approval; (2) an "institutional capacity" test, which would require a review of the applicant firm's ability to effectively manage the risks and monitor the market dynamics of the proposed product; and (3) a broad "systemic effects" test, which would require a finding that approval of the proposed product would not pose an unacceptable risk of increasing systemic vulnerability and otherwise will not raise significant public policy concerns.

The proposed approach does not prohibit any financial activities. It merely imposes the duty to provide information necessary for evaluating potential risks and benefits of a specific financial product on the party that has the best access to such information and the greatest incentives not to disclose it voluntarily. The proposed approval process would provide a mechanism for ensuring that financial innovation and the creation of complex financial instruments actually advance productive economic enterprise and offer real public benefits. By eliminating socially

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approval by securities exchanges, issuance of credit ratings by the credit rating agencies, and issuance of legal opinions by law firms evaluating the validity and legal effects of specific financial products and transactions. In this broader sense, the concept of product approval regulation advocated in this Article may be viewed as a variation on this well-established theme in financial services regulation and private market ordering. Generally, however, the scope and purposes of these product review schemes limit their usefulness as directly comparable models of approval-based risk regulation.

9. As discussed below, several proposals for regulatory approval of *consumer* financial products were advanced in 2008–09. The main justification for those proposals was the need to protect ordinary Americans from potentially "unsafe" financial products that could damage their financial well-being. *See infra* Part I.C. By contrast, this Article proposes introducing a mandatory licensing scheme for *complex* financial instruments that typically are not sold directly to retail consumers. The primary policy focus of the proposed scheme should be prevention of excessive accumulation of systemic risk in the financial sector. Recently, Professors Eric Posner and E. Glen Weyl advocated a similar idea of a licensing regime to reduce speculation in derivatives. Eric A. Posner & E. Glen Weyl, *An FDA for Financial Innovation: Applying the Insurable Interest Doctrine to the Twenty-First-Century Financial Markets* (John M. Olin Law & Econ. Working Paper No. 589, 2012), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2010606. Their proposal, however, differs in several important respects from the proposal advanced here and offers the more traditional economic analysis that focuses on curbing welfare-reducing financial speculation.

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counterproductive complexity, this approach would also potentially enhance the efficiency of financial markets and the reliability of traditional mechanisms of private market discipline.

The proposed model of mandatory approval of complex financial products is bound to generate controversy and invite criticism. It raises many legitimate questions about the proper scope, feasibility, and potential consequences of instituting such an intrusive regulatory scheme. This Article does not purport to give complete answers to all of these questions. Rather, it offers an intellectual experiment, an exploratory attempt to flesh out an idea that may appear too radical and politically untenable today. The next big crisis may very well change that perception.

The Article is structured as follows. Part I sets forth a normative justification for an *ex ante* approach to managing complexity and reducing systemic risk in financial markets. Part II examines key features of three historical experiments with product approval regulation: pre-approval of new drugs by the U.S. Food and Drug Administration ("FDA"), the new system of registration and authorization of chemicals in the European Union, and a mandatory contract approval scheme administered by the Commodity Futures Trading Commission ("CFTC") from 1974 to 2000. Part III outlines a proposal for product approval regulation of complex financial instruments and transactions. It also discusses some of the key criticisms and challenges of implementing this idea in practice.

I. A CASE FOR PRODUCT APPROVAL REGULATION IN THE FINANCIAL SECTOR

A. Strategic Complexity and Systemic Risk

The financial crisis of 2007–09 was the first truly global and systemic crisis.[10] Many factors contributed to the accumulation of excess risk and hidden leverage in the financial sector, which led to massive near-failure and taxpayer-funded bailouts of the world's largest financial institutions.[11]

10. *See* Saule T. Omarova, *The New Crisis for the New Century: Some Observations on the "Big-Picture" Lessons of the Global Financial Crisis of 2008*, 13 N.C. BANKING INST. 157 (2009).

11. For a sample of detailed analyses of the causes of the financial crisis of 2007–09, *see, e.g.*, FIN. CRISIS INQUIRY COMM'N, THE FINANCIAL CRISIS INQUIRY REPORT: FINAL REPORT OF THE NATIONAL COMMISSION ON THE CAUSES OF FINANCIAL AND ECONOMIC CRISIS IN THE UNITED STATES (2011), *available at* http://www.gpoaccess.gov/fcic/fcic.pdf; UNITED STATES SENATE PERMANENT SUBCOMMITTEE ON INVESTIGATIONS, WALL STREET AND THE FINANCIAL CRISIS: ANATOMY OF FINANCIAL COLLAPSE (2011) [hereinafter THE LEVIN REPORT], *available at* http://hsgac.senate.gov/public/_files/Financial_Crisis/FinancialCrisisReport.pdf; UNITED KINGDOM'S FIN. SERV. AUTHORITY, THE TURNER REVIEW: A REGULATORY RESPONSE TO THE GLOBAL

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One of the fundamental causes of that crisis, however, was the unprecedented level of complexity of financial products and markets, which resulted from the great successes of financial innovation of the pre-crisis decades.[12]

Since the 1980s, rapid proliferation of increasingly complex financial instruments, including over-the-counter ("OTC") derivatives, asset-backed securities, and other structured products, transformed the dynamics of the financial sector's operation and created a qualitatively new source of systemic instability in financial markets.[13] Derivatives are financial instruments whose value derives from the value of other assets, referred to as underlying or reference assets.[14] Anything that has a quantifiable value subject to fluctuation can serve as a reference asset, either alone or in an endless variety of combinations: interest and currency exchange rates, prices of securities or commodities, changes in the creditworthiness of third parties, or macroeconomic indicators. Asset-backed securities and structured notes also derive their value from the value of underlying assets generating streams of payments: pools of mortgages and other loans, certain loan-like leases or other asset-backed securities.[15] In essence, all of these instruments enabled unbundling, reconfiguring, and trading of financial risk as an asset in its own right, separate from any physical asset or financial instrument that initially gave rise to such risk.

By allowing market actors to tailor investments to their individual risk appetites and needs, these instruments unlocked great potential for more effective hedging of financial exposure and for greater flow of capital and

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FINANCIAL CRISIS (2009) [hereinafter TURNER REVIEW], *available at* http://www.fsa.gov.uk/pubs/other/turner review.pdf.

12. Omarova, *supra* note 10, at 157; Schwarcz, *supra* note 4; Kathryn Judge, *Fragmentation Nodes: A Study in Financial Innovation, Complexity and Systemic Risk*, 64 STAN. L. REV. 657 (2012). This is not to say that complexity was the sole cause of the financial meltdown in 2007–09. Greed, recklessness, incompetence, corruption, and misguided policies all played a role in making it happen. The point here is that complexity was one of the key variables that linked many of these ever-present factors in a way that created qualitatively new dynamics of risk in the financial system. *See infra* note 29.

13. *See, e.g.*, Mark J. Roe, *The Derivatives Market's Payment Priorities as Financial Crisis Accelerator*, 63 STAN. L. REV. 539 (2011); Lynn A. Stout, *Derivatives and the Legal Origin of the 2008 Credit Crisis*, 1 HARV. BUS. L. REV. 1 (2011); Margaret M. Blair, *Financial Innovation, Leverage, Bubbles, and the Distribution of Income*, 30 REV. BANKING & FIN. L. 225 (2010).

14. *See* R. STAFFORD JOHNSON, INTRODUCTION TO DERIVATIVES: OPTIONS, FUTURES, AND SWAPS 1–10 (2009).

15. *See generally* Kenneth C. Kettering, *Securitization and Its Discontents: The Dynamics of Financial Product Development*, 29 CARDOZO L. REV. 1553 (2008) (examining the mechanism and legal basis of securitization); Jonathan C. Lipson, *Re: Defining Securitization*, 85 S. CAL. L. REV. (forthcoming 2012) (revisiting the definition of securitization).

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liquidity in the market.[16] By the same token, however, these complex financial instruments empowered market participants to engage in highly sophisticated financial speculation and regulatory arbitrage that masked excessive levels of leverage and risk, thereby threatening systemic stability.[17] This crucial connection between increasing complexity and the growth of socially undesirable speculative and arbitrage activities is one of the key determinants of systemic risk in the financial sector.

Complex financial instruments are difficult to understand and value, because their risks are not easily measured and controlled.[18] This is attributable to the potential complexity of the specific reference assets[19] and the structure of the transactions.[20] Financial institutions use sophisticated, proprietary mathematical models to establish values of derivatives and structured instruments.[21] Although such models' accuracy and reliability are inherently limited, their availability enables and encourages financial engineering of even more complex financial instruments.[22] Opacity and lack of reliable valuation create a heightened

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16. *See, e.g.*, Kimberly D. Krawiec, *More than Just "New Financial Bingo": A Risk-Based Approach to Understanding Derivatives*, 23 J. CORP. L. 1, 6 (1997); Roberta Romano, *A Thumbnail Sketch of Derivative Securities and Their Regulation*, 55 MD. L. REV. 1, 2 (1996).

17. *See* Arthur E. Wilmarth, Jr., *The Transformation of the U.S. Financial Services Industry, 1975-2000: Competition, Consolidation, and Increased Risks*, 2002 U. ILL. L. REV. 215, 339–41 (2002). For an economic analysis of socially harmful effects of speculation and arbitrage, see Posner & Weyl, *supra* note 9, at 8–10 (arguing that speculation enables socially-undesirable tax and regulatory arbitrage by sophisticated investors, reduces welfare, and contributes to systemic risk).

18. *See, e.g.*, Henry T.C. Hu, *Misunderstood Derivatives: The Causes of Informational Failure and the Promise of Regulatory Incrementalism*, 102 YALE L.J. 1457, 1463 (1993) (arguing that financial regulators cannot keep up with development of complex derivatives).

19. Pools of assets underlying a securitized transaction may contain loans with different maturities, different interest rates, and different risk of prepayment or default. *See* Schwarcz, *supra* note 4, at 217. Derivatives may reference even more complex "baskets" of synthetic exposure to various risks.

20. For example, the terms of the financial instrument may establish complex payout schemes and create additional linkages to other contracts between the same counterparties. *See* Schwarcz, *supra* note 4, at 220.

21. *See* TURNER REVIEW, *supra* note 11, at 22. According to this report,

> The very complexity of the mathematics used to measure and manage risk . . . made it increasingly difficult for top management and boards to assess and exercise judgment over the risks being taken. Mathematical sophistication ended up not containing risk, but providing false assurance that other prima facie indicators of increasing risk (e.g., rapid credit extension and balance sheet growth) could be safely ignored.

Id.

22. These models fundamentally depend on numerous assumptions that may not hold if circumstances change, which happens during crises. Behavioral biases also explain the tendency toward over-reliance on models. *See, e.g.*, Erik F. Gerding, *Code, Crash, and Open Source: The Outsourcing of Financial Regulation to Risk Models and the Global Financial Crisis*, 84 WASH. L. REV. 127 (2009); Geoffrey P. Miller & Gerald Rosenfeld, *Intellectual Hazard: How Conceptual*

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danger of misleading or even defrauding market participants.[23] This informational asymmetry also creates an inherently unstable environment, as market participants are more likely to over-invest in markets for such instruments in good times and then flee them at the first sign of trouble, triggering old-fashioned investor panics and creditor runs.[24]

Markets for trading such instruments are themselves increasingly complex, with many different market participants connected through an intricate network of direct contractual links and indirect common exposure to risks.[25] Complex structured transactions effectively separate and repackage ownership, payment, and other rights associated with the reference assets.[26] This, in turn, reduces transparency and flexibility in these markets, leading to greater systemic risk and instability.[27] As a result of this complexity, opacity, interconnectedness, and fragmentation, individual financial institutions lack the ability to measure and analyze not only the overall pattern of risk distribution in the financial system, but also the true level of their own risk exposure.[28] Importantly, they can also purposely obscure risk from regulators' view. Thus, complexity remains "the greatest financial-market challenge of the future."[29]

Biases in Complex Organizations Contributed to the Crisis of 2008, 33 HARV. J.L. & PUB. POL'Y 807 (2010).

23. Schwarcz, *supra* note 4, at 221–29.

24. *See, e.g.*, Gorton, *supra* note 3; DARRELL DUFFIE, HOW BIG BANKS FAIL AND WHAT TO DO ABOUT IT (2011).

25. *See* GROUP OF THIRTY, ENHANCING FINANCIAL STABILITY AND RESILIENCE: MACROPRUDENTIAL POLICY, TOOLS, AND SYSTEMS FOR THE FUTURE 22–23 (2010), *available at* http://www.group30.org/images/PDF/Macroprudential_Report_Final.pdf; Schwarcz, *supra* note 4, at 233–35.

26. *See* Judge, *supra* note 12; David A. Dana, *The Foreclosure Crisis and the Antifragmentation Principle of State Property Law*, 77 U. CHI. L. REV. 97 (2010) (arguing that the complex, multi-layered structure of mortgage securitization created excessive fragmentation of property interests, which caused the mortgage crisis and impedes its resolution). The argument that excessive complexity of financial products may violate some of the basic principles of state property law, including the rule against unreasonable restraints on alienation of property interests, provides a potentially powerful alternative basis for advocating ex ante regulatory controls on product development. I owe this insight to Professor Heather Hughes.

27. *See* Judge, *supra* note 12.

28. *See* Awrey, *supra* note 4; Utset, *supra* note 4; Judge, *supra* note 12.

29. Schwarcz, *supra* note 4, at 213. Some may argue that the role of complexity in bringing about the latest financial crisis is exaggerated and that the regulators understood the problems and had the proper tools to remedy them but chose not to take the necessary action. This is a valid argument, especially with respect to federal bank regulators' refusal to stop abusive mortgage lending practices or the SEC's failure to police instances of improper disclosure or conflict of interest. However, it tends to understate the significance of regulatory and jurisdictional gaps created by the emergence of complex financial instruments. For example, no federal regulatory agency had direct authority to regulate OTC derivatives markets. Moreover, systemic risk is often not connected to fraud or other illegal conduct. This argument also misses the crucial link between the explosive growth of risk in "simple" asset categories (such as mortgage loans) and the demand for such risk from institutions that

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It is important to emphasize that both complexity and financial innovation are normatively neutral concepts. Complex and innovative financial instruments, activities, and interrelationships are neither inherently harmful nor invariably beneficial. They make the financial system less stable and more prone to shocks, but also enable it to develop and adjust to new circumstances. The prevailing economic theory tends to over-emphasize the positive role of financial innovation as "a rational demand-driven response to market imperfections."[30] That explanation, however, ignores what Dan Awrey calls "supply-side incentives" of financial intermediaries—dealers and market-makers—to continue creating complex financial products, not in response to natural market demand, but in order to generate short-term, monopoly-like rents.[31]

The typical narrative of various market participants' interactions as "buyers" and "sellers" in an individual transaction often obscures the central role of dealers in generating complexity and systemic risk. Dealers are essential players in the markets for derivatives and structured products: they design complex instruments offering various combinations of financial risk and return, and market them to clients by taking either side of the transaction.[32] Dealers build large portfolios of positions in various instruments and hedge their risks by entering into trades with other clients or, more commonly, other dealers. Thus, it is the dealer institutions that create, distribute, and maintain markets in financial risk, expand linkages among market participants, and multiply potential channels of contagion in the financial system.

Financial intermediaries do not typically enjoy legal monopoly rights—through patent protection or otherwise—on their innovative products, which can be reverse-engineered and reproduced by their competitors. Dealers derive the highest profits from being the first to design and sell a new financial instrument that is perceived as offering some unique benefits to investors, mostly by enhancing their ability to engage in speculation and arbitrage, and therefore commands a high premium. Once a new product becomes commoditized, the original dealer loses its ability to extract monopolistic rents and seeks to introduce the next innovation to

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structured and invested in complex financial instruments referencing such assets. *See* THE LEVIN REPORT, *supra* note 11, at 17–25.

30. Awrey, *supra* note 4, at 30.

31. *Id.* at 32–37. Highlighting the intimate link between financial innovation and complexity, Awrey notes, "It is in their quest to maximize and exploit their superior tolerance for complexity that financial intermediaries have driven us toward—and perhaps even beyond—the complexity frontier." *Id.* at 39.

32. *Id.*

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recapture lost rents.[33] Modern technology enables financial institutions to artificially accelerate the pace of this "socially useless" over-innovation.[34]

A direct result of this strategy is constant introduction of new complex financial instruments into the market, even in the absence of any "natural" demand for such instruments—a phenomenon best described as *strategic complexity*.[35] According to one influential study,

> [I]t seems likely that some and perhaps much of the structuring and trading activity involved in the complex version of securitized credit, was not required to deliver credit intermediation efficiently. Instead, it achieved an economic rent extraction made possible by the opacity of margins, the asymmetry of information and knowledge between end users of financial services and producers, and the structure of the principal/agent relationships between investors and companies and between companies and individual employees.[36]

Understanding these dynamics is the key to developing an informed and pragmatic normative basis for managing complexity in the financial system. Whether the increasing complexity of financial products and activities is beneficial to society depends ultimately on what they are used for and how they affect—intentionally or unintentionally—not only individual firms and financial markets, but also broader social and economic policies and values. Similarly, an optimal or desirable level of innovation and complexity in financial markets is relative to society's capacity to manage and regulate risks associated with these phenomena. The key challenge, therefore, is to develop a mechanism for determining which innovative financial instruments and transactions offer economic

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33. *Id.* at 34–35. As Awrey describes it,

> This strategy does not necessarily rely on the existence of any natural demand in the marketplace, nor on the innovation itself being "new" in any material respect. Rather, it can theoretically be premised on little more than, *inter alia*, capitalizing on investor short-termism, other behavioral factures, or simply tapping the innate human desire for the "next new thing." The practical effect of this strategy is to reset the diffusion clock—in essence creating more (albeit shorter) monopoly-like periods—thereby enabling intermediaries to extract greater rents from their innovations.

Id. at 37–38 (footnotes omitted).

34. *Id*. at 38 (quoting Adair Turner, Chairman of the U.K. Financial Services Authority).

35. For an insightful analysis of this phenomenon in the mortgage finance market, see Adam J. Levitin & Susan M. Wachter, *Explaining the Housing Bubble*, 100 GEO L.J. 1177 (2012) (arguing that the main "supply-side" cause of the recent crisis was the growth of unregulated private securitization market in which financial institutions exploited complexity to misprice credit risk).

36. TURNER REVIEW, *supra* note 11, at 49.

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and social benefits that outweigh potential increases in systemic risk and strategic complexity in financial markets.[37]

The recent crisis underscored the reasons for not relying primarily on private actors in financial markets to make these types of measured and socially responsible determinations.[38] It exposed the dangers of keeping naïve faith in the "natural" alignment between private actors' rational self-interest and the broader public interests in preserving systemic stability, especially in the context of today's complex and inherently unstable financial markets.[39]

Several factors explain the inability of private financial institutions to effectively manage systemic risk associated with complexity. As influential behavioral finance studies show, various cognitive biases increase the chances of presumably rational actors making irrational choices.[40] In an increasingly complex and uncertain environment, individuals and organizations tend to rely heavily on heuristic devices that produce sub-optimal results.[41] Even setting aside the role of behavioral biases, the crisis experience demonstrated how the inherent logic of financial-market rationality, without corrective government intervention, leads to instability and systemic failure.[42] Private profit-seeking enterprises

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37. According to one study,

> The alternative [to current incremental approach to reforms] is to challenge, rather than take as inevitable, a complex, integrated, and securitized system of finance, and to consider possibilities for redesigning financial infrastructures themselves. If we take seriously the notion that regulation constitutes markets, rather than merely intervening in markets "after the fact," then the current moment becomes an opportunity to rethink market architecture, in light of the problems of complexity and tight coupling.

Marc Schneiberg & Tim Bartley, *Regulating or Redesigning Finance? Market Architectures, Normal Accidents, and Dilemmas of Regulatory Reform*, RESEARCH IN SOCIOLOGY OF ORGANIZATIONS 281, 283 (M. Lounsbury & P. Hirsh eds., 2010).

38. *See* Iman Anabtawi & Steven L. Schwarcz, *Regulating Systemic Risk: Towards an Analytical Framework*, 86 NOTRE DAME. L. REV. 1349 (2011).

39. One of the most revealing moments in this respect came in October 2008, when the former Chairman of the Board of Governors of the Federal Reserve System (the "Federal Reserve"), Alan Greenspan, publicly admitted that he had erred in putting too much faith in the self-correcting powers of free markets. *See* Edmund L. Andrews, *Greenspan Concedes Error on Regulation*, N.Y. TIMES, Oct. 23, 2008, *available at* http://www.nytimes.com/2008/10/24/business/economy/24panel.html.

40. Scholars in behavioral finance offer sophisticated theoretical accounts of such biases, or heuristic devices commonly used by market actors as short cuts for their decision-making. *See, e.g.*, ADVANCES IN BEHAVIORAL FINANCE (Richard H. Thaler ed., 1993); BEHAVIORAL LAW & ECONOMICS (Cass R. Sunstein ed., 2000); RICHARD H. THALER & CASS R. SUNSTEIN, NUDGE: IMPROVING DECISIONS ABOUT HEALTH, WEALTH, AND HAPPINESS (2008).

41. *See, e.g.*, Miller & Rosenfeld, *supra* note 22; Donald C. Langevoort, *Chasing the Greased Pig Down Wall Street: A Gatekeeper's Guide to the Psychology, Culture, and Ethics of Financial Risk-Taking*, 96 CORNELL L. REV. 1209 (2011).

42. *See, e.g.*, RICHARD A. POSNER, A FAILURE OF CAPITALISM: THE CRISIS OF '08 AND THE DESCENT INTO DEPRESSION (2009) (discussing the causes of the recent financial crisis and arguing that

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rationally act in a self-regarding manner when assessing and taking risks. They do not internalize the spillover effects of such selfish risk-taking, which are particularly dangerous in the context of today's interconnected financial markets.[43] As Professors Anabtawi and Schwarcz conclude, this "tragedy of the commons suggests that, absent intervention, financial market participants will progressively pursue their self-interest in the form of socially excessive risk-taking."[44] Finally, the recent crisis provided numerous examples of private market participants intentionally acting with reckless disregard for potentially harmful effects of their conduct on their counterparties or the broader economy.[45] The opacity and complexity of financial products amplified the ability of financial institutions to profit from this type of socially destructive behavior and, at the same time, made it more difficult to hold them legally accountable for it.[46]

As private market participants lack the capacity and the incentives to solve the fundamental tension between private and public costs and benefits of financial innovation and increasing complexity, developing a mechanism for balancing these factors becomes a task primarily for lawmakers and regulators.

B. Regulating Complexity

How to regulate complexity that results from financial innovation is a vexing question, both in practice and in theory. The recent crisis was not only a systemic market failure, but also a systemic regulatory failure.[47] In the wake of the crisis, policymakers and academics face the challenge of reassessing the pre-crisis regulatory philosophy and articulating a new set of principles for redefining the public-private balance in financial services regulation.

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rational profit-maximizing behavior of market actors produces negative externalities that cannot be controlled without government regulation); *See also* Utset, *supra* note 4.

43. *See* Anabtawi & Schwarcz, *supra* note 38, at 1374–76.

44. *Id.* at 1375.

45. For detailed case studies of such behavior, see THE LEVIN REPORT, *supra* note 11. *See also* Kathleen C. Engel & Patricia A. McCoy, *Turning A Blind Eye: Wall Street Finance of Predatory Lending*, 75 FORDHAM L. REV. 2039, 2041–42 (2007) (arguing that securitization enabled predatory lending and growth of subprime mortgage markets).

46. *See, e.g.*, THE LEVIN REPORT, *supra* note 11, at 318–636 (detailing the instances of abusive market conduct by Deutsche Bank and Goldman Sachs).

47. *See generally* FIN. CRISIS INQUIRY COMM'N, *supra* note 11 (concluding that various federal regulatory agencies' failure to exercise proper oversight of financial institutions and markets was a major contributing factor behind the crisis).

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1. *From Greenspan to Dodd-Frank: Regulatory Responses to Complexity*

For decades before the recent financial crisis, the so-called "Greenspan doctrine" was the dominant ideology underlying and guiding regulatory developments in the U.S. financial services sector.[48] Driven by an unwavering faith in the supremacy and self-regulatory wisdom of free markets, the Greenspan doctrine held that all financial innovation was an unqualified public good, that complex financial instruments always transferred risk to those "who were better able to bear it," and that unregulated hedge funds and other speculators were indispensable and benign sources of liquidity in financial markets.[49] Accordingly, under this ideological creed, the goal of regulation was, quite simply, to not interfere with the victorious march of financial innovation.[50]

Regulatory agencies dealt with the growing informational asymmetry with respect to complex financial instruments by relying increasingly on the financial services industry's internal capacity to identify, measure, and control the risks arising out of its business activities. The concept of "risk management" on an individual-entity level became the cornerstone of the regulatory approach used to accommodate the increasing complexity of financial products and the institutions that created and traded them.[51] Regulators viewed individual enterprise-wide risk management as the principal tool for maintaining system-wide financial stability.[52] This approach essentially rejected the validity of imposing limits on private

48. This neoliberal ideological creed, as applied to financial services regulation, was named after Alan Greenspan, the former Chairman of the Federal Reserve and the "Maestro" of financial markets, who was its most influential proponent. *See* JOHNSON & KWAK, *supra* note 7, at 100–04 (describing Greenspan's beliefs and ideological influence).

49. *See* Cristie Ford, *Macro and Micro Level Effects on Responsive Financial Regulation*, 44 U.B.C. L. REV. 589, 612 (2011) ("[T]he prevailing assumption in the years leading up to the financial crisis was that all innovation was by definition beneficial, because unsound ideas would be winnowed out by market forces.")

50. *Id.*

51. In the pre-crisis decade, the concept of Enterprise Risk Management ("ERM") dominated the discussions among industry experts, academics, and policy makers. *See generally* NEIL DOHERTY, INTEGRATED RISK MANAGEMENT (2000); JAMES LAM, ENTERPRISE RISK MANAGEMENT: FROM INCENTIVES TO CONTROL (2003); DAVID L. OLSON & DESHENG WU, NEW FRONTIERS IN ENTERPRISE RISK MANAGEMENT (2008).

52. One example of this approach is capital adequacy regulation, which ties financial institutions' leverage to the riskiness of their assets and is widely viewed as the cornerstone of prudential regulation. For a description of the international framework of capital adequacy regulation, see HAL S. SCOTT & ANNA GELPERN, INTERNATIONAL FINANCE: TRANSACTIONS, POLICY, AND REGULATION 412–73 (18th ed. 2011).

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actors' risk-taking, instead tying the levels of socially acceptable risk to financial market participants' ability to manage such risk internally.[53] This approach, however, had two fundamental flaws. First, it significantly overestimated the ability and, more importantly, the incentives of financial institutions to manage risk, especially in the face of high uncertainty and potential profitability of risky activities.[54] Second, it incorrectly assumed a direct link between firm-level risk management and system-wide stability.[55]

The centerpiece of the post-crisis U.S. reform legislation, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (the "Dodd-Frank Act"),[56] explicitly focuses on systemic risk regulation. Despite the ambitious sweep of the envisioned reforms, however, the Dodd-Frank Act falls short of offering a new approach to regulating complexity. The new law seeks to control systemic risk primarily through an array of familiar measures, including restructuring and creating new regulatory agencies, mandating a significantly greater amount of information to be disclosed by market participants, enhancing capital requirements for certain institutions or activities, extending the jurisdictional reach of financial regulators to a wider universe of entities, and shoring up the market infrastructure. Whether the voluminous provisions of the Dodd-Frank Act will ultimately have a significant practical impact depends greatly on their implementation by the regulatory agencies. It is clear, however, that the Dodd-Frank Act does not offer any direct solution to the fundamental dilemma of how to reduce and control complexity and interconnectedness in financial markets.

The Dodd-Frank Act's provisions dealing with regulation of OTC derivatives illustrate this approach.[57] The statute mandates, subject to some exceptions, central clearing of standardized derivatives through regulated clearing organizations and trading through either regulated exchanges or so-called swap execution facilities.[58] It also introduces new regulatory

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53. Saule T. Omarova, *The Quiet Metamorphosis: How Derivatives Changed the "Business of Banking"*, 63 MIAMI L. REV. 1041, 1107 (2009).

54. *See supra* notes 38–46 and accompanying text.

55. *See, e.g.*, Eric J. Pan, *Understanding Financial Regulation* 43 (Cardozo Legal Studies Working Paper No. 329, 2011), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1805018 ("Regulators cannot expect that private actors will be capable of identifying how the actions of individual firms may make the financial system less stable.").

56. Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. No. 111-203, 124 Stat. 1376 (2010) (codified in scattered sections of 12 U.S.C.A. (West Supp. 2011)).

57. 12 U.S.C.A. §§ 701–74 (West Supp. 2011).

58. 12 U.S.C.A. § 723 (West Supp. 2011).

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categories of financial actors: swap dealers and major swap participants.[59] The Securities Exchange Commission ("SEC") and the Commodity Futures Trading Commission ("CFTC") share oversight of OTC derivatives markets in a manner largely consistent with the historical jurisdictional divisions between these agencies.[60] Market participants must report swap transactions to regulators and special data repositories, while the SEC and CFTC are required to adopt rules on real-time public data reporting of swap transactions.[61] The new law also requires the regulators to develop business conduct rules for swap dealers and major swap participants, as well as special capital and margin rules for various types of swaps.[62] The Act does not, however, directly aim to lower the level of risk or complexity present in the OTC derivatives market. While encouraging standardization of derivatives products, the law exempts individually tailored, or "bespoke," instruments—which are most likely to be highly complex and risky—from the mandatory exchange trading and central clearing.[63] Ultimately, the statute fails to articulate a fundamental principle for balancing the benefits of increasingly complex derivatives transactions and markets against their potential risks to long-term financial and economic stability.[64]

2. *From Economic to Risk Regulation: Potential Alternatives in the Academic Debate*

The recent crisis underscored the lack of a conceptual framework for regulating complexity and systemic risk in the financial services sector and reignited scholarly debate on the proper scope and objectives of financial regulation reform.

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59. 12 U.S.C.A. § 731 (West Supp. 2011).

60. *See* DAVIS POLK & WARDWELL, LLP, SUMMARY OF THE DODD-FRANK WALL STREET REFORM AND CONSUMER PROTECTION ACT, ENACTED INTO LAW ON JULY 21, 2010, at 52 (2010), *available at* http://www.davispolk.com/files/Publication/7084f9fe-6580-413b-b870-b7c025ed2ecf/Presentation/PublicationAttachment/1d4495c7-0be0-4e9a-ba77-f786fb90464a/070910_Financial_Reform_Summary.pdf.

61. 12 U.S.C.A. §§ 727–30 (West Supp. 2011).

62. 12 U.S.C.A. § 719 (West Supp. 2011).

63. 12 U.S.C.A. § 763 (West Supp. 2011). In a somewhat confusing manner, the Dodd-Frank Act contains provisions authorizing some form of pre-market review of securities futures and "novel derivative products." 12 U.S.C.A. §§ 717–18 (West Supp. 2011). These provisions, however, establish the process for clarifying the jurisdictional lines between SEC and CFTC with respect to products that combine elements of securities and commodity futures. Although it is not clear how these provisions will be implemented in practice, the language of the Act itself does not mandate substantive pre-approval of complex derivatives.

64. *See* Saule T. Omarova, *The Dodd-Frank Act: A New Deal for A New Age?*, 15 N.C. BANKING INST. 83 (2011).

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Broadly, there are three interrelated approaches to theorizing regulation.[65] The first approach focuses on the rationale and the goals of regulation (normative theories of regulation); the second approach focuses on the process and efficacy of regulation (theories of regulatory design);[66] and the third approach focuses on the origins and political basis of regulatory choices (theories of political economy of regulation).[67] From a normative perspective, it is possible to draw broad distinctions among three types of regulation:[68] (1) *economic regulation* aimed primarily at correcting specific market inefficiencies in order to enable the frictionless operation of free market forces;[69] (2) *social regulation* that seeks to allocate economic and political rights in accordance with broader societal values and norms;[70] and (3) *risk regulation* seeking to protect society from significant and potentially catastrophic risks.[71] While, in reality, these three types of regulation operate along a continuum,[72] the relative salience of normative claims along that continuum often signifies a fundamental shift in the nature of the regulatory regime.[73]

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65. Elsewhere, these three approaches were referred to as the Public Interest, Public Administration, and Public Choice perspectives, respectively. *See* JEFFREY L. HARRISON ET AL., REGULATION AND DEREGULATION: CASES AND MATERIALS 19–39 (2d ed. 2004).

66. For a classic example of this approach, see IAN AYRES & JOHN BRAITHWAITE, RESPONSIVE REGULATION: TRANSCENDING THE DEREGULATION DEBATE (1992).

67. Various versions of the public choice analysis fall in this category. *See* George J. Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT. SCI. 3 (1971); BARRY M. MITNICK, THE POLITICAL ECONOMY OF REGULATION: CREATING, DESIGNING, AND REMOVING REGULATORY FORMS (1980); ROGER G. NOLL & BRUCE M. OWEN, THE POLITICAL ECONOMY OF DEREGULATION: INTEREST GROUPS IN THE REGULATORY PROCESS (1983); DANIEL A. FARBER & PHILIP P. FRICKEY, LAW AND PUBLIC CHOICE (1991).

68. These three categories are not mutually exclusive. In reality, many forms of regulation pursue complex policy objectives and have significant implications in all three areas. This grouping is meant as an analytical roadmap for situating the proposal advanced in this Article in the broader academic debate on financial regulation reform.

69. For a classic analysis of economic regulation, see STEPHEN BREYER, REGULATION AND ITS REFORM (1982).

70. *See, e.g.*, CASS R. SUNSTEIN, FREE MARKETS AND SOCIAL JUSTICE (1997).

71. This category includes, most notably, environmental, health, and safety regulation. *See* Julia Black, *The Role of Risk in Regulatory Processes*, *in* THE OXFORD HANDBOOK OF REGULATION 302, 305–06 (Robert Baldwin et al. eds., 2010).

72. In some fundamental sense, all regulation aims to control some form of risk. For a thorough and nuanced discussion of the role of risk in regulation, see Black, *supra* note 71.

73. According to Julia Black,

> [N]ot all regulation is described as being about "risk". The regulators of water, rail, telecommunications, competition, and energy are typically referred to by policy makers and academics not as "risk" regulators but as "economic" regulators. These economic regulators are the archetypal "regulatory state" regulators . . . , established to regulate liberalised markets in the 1980s and 1990s across a wide range of countries. In accordance with the canons of economic liberalism, the object of regulation for those regulators is defined in terms of the market, and regulation is justified principally in terms of its role in correcting market failures:

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Before the latest crisis, financial services regulation was generally viewed as just another case of economic regulation whose primary goal was to correct market inefficiencies (such as informational asymmetries, monopolistic tendencies, or agency problems), minimize the possibility of market failure (such as infamous bank runs), but otherwise to not impose excessive costs on, or interfere with the proper functioning of, private financial markets.[74] Disclosure requirements of federal securities laws, federal deposit insurance and access to the lender of last resort for depository institutions, conflict-of-interest rules for financial intermediaries, and prudential regulation of banking institutions are examples of such corrective regulatory mechanisms targeting specific problems in the operation of free market forces.[75]

The crisis of 2007–09, however, exposed the growing saliency of policy objectives associated with the risk-regulation model. While correcting specific market inefficiencies and allowing free-market mechanisms to work remains an important regulatory goal, it is now clear that government regulation has to protect the national (and, ultimately, global) economy and citizenry from potentially catastrophic consequences of financial market failure. Prioritizing systemic financial and economic stability over market participants' freedom to pursue private gain makes financial services regulation more fundamentally similar to regulatory systems aimed at protection of human health, safety, and environment. The post-crisis pragmatic imperative, thus, necessitates a shift in the underlying paradigm of financial services regulation.

To date, however, such a shift has not been fully conceptualized, as the academic community struggles to reconcile the new post-crisis emphasis on risk regulation with the powerful traditional focus on pure market efficiency. The pre-crisis normative assumptions regarding the limits of government intervention in financial markets continue to shape the

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> monopolies, barriers to entry or exit, externalities, information asymmetries, or principal-agent problems.

Id. at 305 (internal citations omitted).

74. *See* TURNER REVIEW, *supra* note 11, at 39 ("The predominant assumption behind financial market regulation—in the US, the UK and increasingly around the world—has been that financial markets are capable of being both efficient and rational and that a key goal of financial market regulation is to remove the impediments which might produce inefficient and illiquid markets.")

75. U.S. banking law has strong elements of risk regulation, insofar as it seeks to prevent systemic effects of bank failure and to safeguard the federal deposit insurance fund. Nevertheless, the U.S. system of bank regulation and supervision focuses primarily on protecting the safety and soundness of individual deposit-taking institutions by addressing their inherent vulnerability to runs. In that sense, it remains essentially a form of economic regulation.

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ongoing debate on how to make those markets less dangerous not only to market participants, but also to citizenry at large.

The majority of current reform proposals continue to rely primarily on market-based solutions to the problem of systemic risk caused by increasing complexity of financial products and markets. These solutions generally aim at creating incentives for individual firms, their agents, and various gatekeepers to act in a *more* informed, rational, and efficient way, which is expected to reduce the risk to both the individual firms' own financial health and the financial system as a whole. In effect, they pursue the familiar objective of eliminating specific inefficiencies that distort market dynamics. Examples of such proposed measures include enhanced disclosure of financial and transactional data,[76] strengthened corporate governance and changes in executive compensation at financial firms,[77] heightened capital requirements,[78] improving the quality and reliability of credit ratings,[79] creation of contingent capital instruments,[80] and even tying regulators' compensation to performance of regulated financial institutions.[81] Scholars also focus on strengthening and improving the existing mechanisms of regulation and supervision in the financial services sector. Some of the proposed measures include tougher regulation of credit rating agencies' rating processes,[82] extending regulatory oversight to non-bank financial actors operating in the so-called shadow banking system,[83]

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76. *See, e.g.*, Howell E. Jackson, *Loan-Level Disclosure in Securitization Transactions: A Problem with Three Dimensions* (Harv. Law School Pub. L. & Legal Theory Working Paper Series, Paper No. 10-40, 2010), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1649657 (arguing for mandating public disclosure of loan-level information in securitizations).

77. *See, e.g.*, Lucian A. Bebchuk & Holger Spamann, *Regulating Bankers' Pay*, 98 GEO. L.J. 247 (2010); Frederick Tung, *Pay for Banker Performance: Structuring Executive Compensation for Risk Regulation*, 105 NW. U. L. REV. 1205 (2010).

78. *See, e.g.*, Hal S. Scott, *The Reduction of Systemic Risk in the United States Financial System*, 33 HARVARD J.L. & PUB. POL'Y 671 (2010).

79. *See, e.g.*, John Patrick Hunt, *Credit Rating Agencies and the "Worldwide Credit Crisis": The Limits of Reputation, the Insufficiency of Reform, and the Proposal for Improvement*, 2009 COLUM. BUS. L. REV. 109 (2009); Jeffrey Manns, *Rating Risk After the Subprime Mortgage Crisis: A User Fee Approach for Rating Agency Accountability*, 87 N.C. L. REV. 1011 (2009).

80. *See, e.g.*, John C. Coffee, Jr., *Systemic Risk After Dodd-Frank: Contingent Capital and the Need for Regulatory Strategies Beyond Oversight*, 111 COLUM. L. REV. 795 (2011).

81. Frederick Tung & M. Todd Henderson, *Pay for Regulator Performance* (U. Chi. L. & Econ., Olin Working Paper No. 574, 2011), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1916310.

82. *See, e.g.*, Hunt, *supra* note 79; Manns, *supra* note 79; Frank Partnoy, *Rethinking Regulation of Credit Rating Agencies: An Institutional Investor Perspective* 3 (2009), *available at* http://www.cii.org/userfiles/file/CRAWhitepaper04-14-09.pdf.

83. *See, e.g.*, Morgan Ricks, *A Regulatory Design for Monetary Stability* (Harv. John M. Olin Ctr. for L. Econ. & Bus., Discussion Paper No. 706, 2011), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1933890.

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and eliminating the preferential treatment of derivatives contracts under federal bankruptcy laws.[84] Finally, a few proposals offer more radical structural solutions, such as breaking up financial institutions that are "too big to fail."[85]

While these proposals contain valuable insights into important issues in financial regulation reform, they generally offer only partial solutions to the problem of systemic risk control. Discrete reform measures are likely to work only if they are part of a broader strategic process. More importantly, the tools and methods of traditional "economic" regulation of financial services, such as disclosure or use of contingent capital instruments, are likely to do little to resolve the more fundamental problems posed by the increasing complexity and interconnectedness in the financial system.[86]

A different strand in the academic debate shifts focus to the process of regulation itself. Building on basic insights from behavioral finance,[87] New Governance theories,[88] and the concept of responsive regulation,[89] scholars engaged in this conversation on regulatory design generally advocate a more self-reflexive, dialogic, iterative regulatory process that is better able to adapt to the complex and dynamic reality of financial markets.[90] This approach rejects unquestioning reliance on market mechanisms, but at the same time is skeptical of static "command-and-control" solutions to the problem of systemic risk prevention. Despite the differences in their methodological and normative arguments, these scholars explicitly acknowledge complexity as the central challenge for

84. *See* Roe, *supra* note 13.

85. *See, e.g.*, Jonathan R. Macey & James P. Holdcroft, Jr., *Failure Is an Option: An Ersatz-Antitrust Approach to Financial Regulation*, 120 YALE L.J. 1368 (2011); JOHNSON & KWAK, *supra* note 7.

86. *See supra* Part I.A. The crisis clearly exposed the limits of mandatory disclosure as the remedy for market inefficiencies caused by excessive complexity of financial products and structures. *See* Levitin & Wachter, *supra* note 35 (discussing the pernicious effects of informational opacity in complex securitizations). The risk-regulation paradigm acknowledges the limits of disclosure even more explicitly. *See, e.g.*, SUNSTEIN, *supra* note 70, at 338 ("Information may be an inadequate strategy when greater safety is a public good.").

87. *See supra* note 40.

88. For an overview of the New Governance theories, see Orly Lobel, *The Renew Deal: The Fall of Regulation and the Rise of Governance in Contemporary Legal Thought*, 89 MINN. L. REV. 342 (2004). *See also* Scott Burris et al., *Changes in Governance: A Cross-Disciplinary Review of Current Scholarship*, 41 AKRON L. REV. 1 (2008); Cristie L. Ford, *New Governance, Compliance, and Principles-Based Securities Regulation*, 45 AM. BUS. L.J. 1, 27–28 (2008).

89. *See* AYRES & BRAITHWAITE, *supra* note 66, at ch. 3.

90. *See, e.g.*, Ford, *supra* note 49 (advocating a shift toward "meta-regulation" as a more iterative and reflexive regulatory model that focuses regulators' attention on the unknown).

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effective regulation and search for regulatory design solutions to that challenge.[91]

This promising line of research highlights a critically important set of issues in regulatory reform. It is hard to deny that effective regulation of complex financial markets is itself a complex undertaking. Designing and implementing a dynamic and self-reflexive regulatory system is likely to be a long, difficult, and politically complicated process. In the meantime, however, it is necessary to address the increasing incongruity between financial services markets and financial services regulation. It stands to reason that until we are able to establish a sufficiently sophisticated and adaptive regulatory system, the only practical solution to this dilemma is trying to control, and even reduce, the level of complexity in the financial markets.

Reconceptualizing financial services regulation as a form of risk regulation rather than purely economic regulation broadens our normative perspective and expands the range of potential methods of decision-making. Thus, one of the central themes in risk regulation is how to operationalize precaution in making regulatory choices. One method of expressing this broad norm of precaution is the so-called precautionary principle that "emphasize[s] anticipation of harm and taking preventive measures in the face of uncertainty. . . ."[92] Various formulations of the precautionary principle differ in the degree of presumptive risk-aversion.[93] Generally, the strong version of the principle (1) creates a presumption that regulatory action is necessary whenever a private activity potentially poses serious risks to important public interests, even in the absence of scientific certainty with respect to the nature or extent of such risks; and (2) explicitly places the burden on the private proponent of the risk-creating activity to overcome the default by proving that risks are acceptable or reasonable.[94]

The implementation of the precautionary principle involves highly politicized and contestable policy choices.[95] Not surprisingly, the

91. *See, e.g.*, Brett McDonnell & Daniel Schwarcz, *Regulatory Contrarians*, 89 N.C. L. REV. 1629 (2011); Miller & Rosenfeld, *supra* note 22.

92. Noah Sachs, *Rescuing the Strong Precautionary Principle From its Critics*, 2011 U. ILL. L. REV. 1285, 1295 (2011).

93. *See id.* at 1292–95 (distinguishing between the weak and strong forms of the principle); Jonathan B. Wiener, *Precaution in a Multirisk World*, *in* HUMAN AND ECOLOGICAL RISK ASSESSMENT: THEORY AND PRACTICE 1509, 1513–18 (Dennis T. Paustenbach ed., 2002) (discussing three versions of the precautionary principle).

94. Sachs, *supra* note 92, at 1295.

95. *See* Black, *supra* note 72, at 319–21.

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precautionary principle is a controversial matter and its practical efficacy is a subject of continuing debate and criticism.[96] It is not the goal of this Article to advocate direct application of any particular formulation of precautionary principle to financial services regulation. Nevertheless, adopting and operationalizing the general *concept of precaution* in the context of post-crisis financial systemic risk regulation may be a worthwhile, and even necessary, exercise.

C. The Concept of Product Approval Regulation

This Article argues that one potentially effective method of operationalizing the concept of precaution in financial services regulation is to introduce a system of mandatory government licensing of complex financial products. Requiring regulatory pre-approval of financial products can function as a gatekeeping mechanism designed to discourage and reduce socially unproductive strategic complexity of financial instruments and markets and impose dynamic controls on the process of financial innovation. This regime would explicitly adopt an anticipatory approach to managing systemic risk and shift the burden of meeting the standards for approval to the financial institutions. By reducing the complexity and systemic vulnerabilities it creates, this model is likely to enhance the efficiency and integrity of financial markets. Thus, if successful, a system of mandatory pre-approval of complex financial products could serve as a hybrid regulatory model based on pragmatic considerations of precaution and efficiency.

Professors Daniel Carpenter and Michael Ting define "approval regulation" as a regime in which "government entities exercise discretion over whether the firm or product can enter the market, such that firms must make an empirical case for admission that the regulator must accept if legal market entry is to be granted."[97] Two key elements—regulatory discretion with respect to granting approval and a built-in "proof" requirement[98]—distinguish this form of regulation from Breyer's classic definition of "regulation of entry" that typically sets forth purely

96. *See* CASS R. SUNSTEIN, LAWS OF FEAR: BEYOND THE PRECAUTIONARY PRINCIPLE (2005); Cass R. Sunstein, *Beyond the Precautionary Principle*, 151 U. PA. L. REV. 1003 (2003); THE REALITY OF PRECAUTION: COMPARING RISK REGULATION IN THE UNITED STATES AND EUROPE (Jonathan B. Wiener et al. eds., 2011) [hereinafter THE REALITY OF PRECAUTION].

97. Daniel Carpenter & Michael M. Ting, A Theory of Approval Regulation 2 (Feb. 10, 2004) (manuscript).

98. *Id.* at 2 n.1.

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procedural conditions on market entry, such as licensing fees.[99] In the approval regulation system, "the state acts as a discretionary market gatekeeper and potential entrants provide not a fee but a proof of quality or necessity."[100]

The idea of extending approval regulation to financial products became a subject of academic discussion in 2008–09, in the context of the debate on the creation of a new financial consumer protection agency. In 2008, Professors Elizabeth Warren and Oren Bar-Gill published a proposal to create a Financial Product Safety Commission ("FPSC") with a broad mandate to ensure that financial products sold to consumers meet certain safety standards, in a manner similar to the Consumer Product Safety Commission's monitoring of safety of tangible consumer products.[101] In many respects, Warren and Bar-Gill's proposal was similar to the familiar model of a "market conduct regulator" proposed earlier by the Treasury Department.[102] By framing the issue as one of safety of financial products for consumers, however, their proposal effectively shifted the debate into the realm of risk regulation and democratic politics, as opposed to purely technocratic solutions to market inefficiencies.

Other scholars elaborated on the FPSC concept and advanced their own versions of what the commission could and should do.[103] Professor Carpenter proposed a model of an FPSC with broad *ex ante* approval power over consumer financial products, similar to the FDA.[104] Under his proposal, the commission would have a "veto power over market entry" for consumer financial products, based on the "experimental or quasi-experimental evidence" of the products' safety, quality, and efficacy.[105] Such evidence, for example, could come from the observable results of a

99. *See* BREYER, *supra* note 69.

100. Carpenter & Ting, *supra* note 97, at 2.

101. Oren Bar-Gill & Elizabeth Warren, *Making Credit Safer*, 157 U. PA. L. REV. 1 (2008).

102. *See* U.S. DEP'T OF THE TREAS., BLUEPRINT FOR A MODERNIZED FINANCIAL REGULATORY STRUCTURE (2008); U.S. DEP'T OF THE TREAS., FINANCIAL REGULATORY REFORM: A NEW FOUNDATION: REBUILDING FINANCIAL SUPERVISION AND REGULATION (2009), *available at* http://www.financialstability.gov/docs/regs/FinalReport_web.pdf.

103. JOSEPH E. STIGLITZ, THE FINANCIAL CRISIS OF 2007/2008 AND ITS MACROECONOMIC CONSEQUENCES 29–30 (2009), *available at* http://www2.gsb.columbia.edu/faculty/jstiglitz/download/papers/2008_Financial_Crisis.pdf; Daniel Carpenter, *Particulars of a Financial Product Safety Commission*, *in* THE TOBIN PROJECT, CONSIDERING A FINANCIAL PRODUCT SAFETY COMMISSION 8 (May 2009).

104. Carpenter, *supra* note 103, at 9–10.

105. *Id.* at 9. Professor Stiglitz emphasized that the FPSC had to ensure that all financial products had a bona fide risk management purpose and were proven to achieve that stated objective. Stiglitz, *supra* note 103, at 29.

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limited product roll-out or modeling and simulations.[106] According to Carpenter, information generated as a result of pre-approval experimentation would improve consumers' ability to make an informed choice and increase consumer confidence in the financial markets. This in turn would strengthen the demand for financial products deemed to be safe for consumers.[107] By standardizing and collecting such information, the proposed FPSC would, in effect, improve market efficiency.[108]

Later, Carpenter proposed a modified version of the financial product approval process, based on the file-and-use system similar to that adopted in the insurance industry.[109] Under that model, every originator would be required to file a notice of intent with the FPSC to introduce a new "safety-regulated retail financial product," including mortgages, payday loans, and credit cards.[110] The filing would include a marketing plan and a mandatory schedule for experimental data collection. The FPSC would have 180 days to review the notice and stop the roll-out of the product if it found evidence that the product posed potential danger to consumers. If the commission failed to act within that period, the originator would be free to distribute the product. To ensure the reliability and fairness of the process, Carpenter emphasized the importance of public scrutiny of the products. He proposed appointing an advisory committee consisting of academics and stakeholder representatives, and ensuring public availability of the experimentation data and other pertinent product information. These procedural features of the model were meant to enhance the essential confidence-building function of the consumer financial product approval scheme.[111]

In 2009, several bills proposing the creation of the FPSC were introduced in both the Senate and the House. After an intense political struggle, the Dodd-Frank Act created the Bureau of Consumer Financial Protection ("CFPB") within the Federal Reserve, charged with exercising consistent and unified oversight of the implementation of federal financial consumer protection laws.[112] The CFPB, however, does not have explicit

106. Carpenter, *supra* note 103, at 9.

107. Daniel Carpenter et al., Approval Regulation and the Endogenous Provision of Confidence: Theory and an Analogy between Financial and Safety Regulation (Oct.26, 2009) (manuscript).

108. *See* Daniel Carpenter et al., Proposal for a Financial Product Approval Process with Modified File-and-Use Elements, Public Scrutiny, and Commitment Experimentation (June 10, 2009) (manuscript).

109. *Id.* at 1.

110. *Id.* at 4.

111. *Id.* at 2.

112. The Dodd-Frank Act, Title X, Consumer Financial Protection Act of 2010, Pub. L. No. 11-203, 124 Stat. 1955 (codified in scattered sections of 12 U.S.C. and 18 U.S.C.).

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authority to review and approve any consumer financial product before it enters the market. Thus, despite the undeniable influence of the FPSC debate on the legislative process, the Dodd-Frank Act did not create a system of approval regulation with respect to consumer financial products.[113]

The debate on the FPSC focused primarily on *consumer* financial services and framed the key issues in terms of *consumer protection*. Professors Eric Posner and Glen Weyl recently proposed what they called an "FDA for Financial Innovation" approach aimed specifically at limiting speculation in derivatives.[114] Under their proposal, a government agency would have to approve all new financial products—most clearly, derivatives—for marketing and trading only if such products pass a "social utility" test that "focuses on whether the product will likely be used more often for hedging than for speculation."[115] Posner and Weyl argue that their approach would revive the common-law doctrine of insurable interest, which helped to limit financial speculation before the deregulatory changes in the 1990s unleashed its dangerous potential.[116] Although their proposal shifts the focus to product approval as a form of *systemic risk* regulation, it identifies and targets one specific source of systemic risk in financial markets—"the welfare-reducing effects of speculation on the speculators themselves."[117] In effect, their article offers a traditional economic argument for introducing a speculation-curbing product approval scheme, but does not address specific details of regulatory design.[118]

According to Posner and Weyl, financial products are fundamentally similar to pharmaceutical drugs and, therefore, should be subject to similarly rigorous controls.[119] First, a full evaluation of the risks and benefits of financial products generally requires professional expertise that

113. Interestingly, the U.K. financial regulators appear to be moving toward instituting a product approval regime as a more effective and deliberately interventionist form of consumer protection. Thus, in early 2011, the UK FSA published a discussion paper proposing targeted reviews of specific financial instruments used by retail customers—including deposits, insurance policies, mortgages, and investment products—at an early stage of product design and marketing. *See* UNITED KINGDOM'S FIN. SERV. AUTHORITY, DISCUSSION PAPER: PRODUCT INTERVENTION, DP 11/1 (Jan. 2011), *available at* http://www.fsa.gov.uk/pubs/discussion/dp11_01.pdf.

114. *See* Posner & Weyl, *supra* note 9.

115. *Id.* at 2. Posner and Weyl discuss additional factors that regulators would have to consider, but only if the quantitative market demand analysis does not produce an unambiguous answer. *Id.* at 15–17.

116. *Id.* at 5.

117. *Id.* at 6.

118. *See id.* at 35.

119. *Id.* at 36–38.

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most investors and consumers do not possess. Relying on non-professionals' subjective preferences is not likely to produce optimal results.[120] Second, financial decisions tend to have delayed and uncertain feedback, which reduces individuals' ability to correct their mistakes promptly.[121] Finally, as the latest crisis demonstrated, the extent of potential harm that financial market failure may cause not only to individuals, but to society as a whole necessitates a more intrusive *ex ante* approach to financial regulation.[122]

To this list, one can add the importance of public perceptions—not only of the extent of potential systemic risk in financial markets, but also of the nonconsensual nature and highly asymmetrical distributional effects of such risk.[123] To gain legitimacy, regulatory choices must reflect public perceptions of how strictly a particular risky activity should be regulated.[124] In the wake of the latest crisis, the general public is weary and disappointed in the integrity of financial markets and regulation. There is a widespread sense of dissatisfaction with a system that allows Wall Street insiders to reap exorbitant private profits from risky speculative activities, while the equally exorbitant costs of their failure are borne by unsuspecting taxpayers. This public perception is an important factor that supports putting risky financial instruments in the same category of strictly regulated products as medical drugs and hazardous chemicals.

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120. *Id.* at 36–37.

121. *Id.* at 37–38.

122. *Id.* at 38.

123. Scholars of regulation have observed that people evaluate the gravity of specific risks—and the need to regulate such risks—not merely on the basis of purely statistical or other scientific evidence but in the broader qualitative and relational context. As Cass Sunstein argues, citizens' judgments about risk depend on many factors, including:

> (1) the catastrophic nature of the risk; (2) whether the risk is uncontrollable; (3) whether the risk involves irretrievable or permanent losses; (4) the social conditions under which a particular risk is generated and managed, a point that connects to issues of consent, voluntariness, and democratic control; (5) how equitably distributed the danger is or how concentrated on identifiable, innocent, or traditionally disadvantaged victims, which ties to both notions of community and moral ideals; [and] (6) how well understood the risk process in question is . . . .

SUNSTEIN, *supra* note 70, at 133.

124. This fundamental concern with democratic legitimacy must be carefully balanced against the potential danger of "elevat[ing] mass prejudice to public policy." Wiener, *supra* note 93, at 1512. In the wake of the recent financial crisis, however, the lack of popular support for the regulatory status quo and general dissatisfaction with the pace and direction of the current reform seem to present a far more serious problem than any realistic possibility of ultra-populist prejudice-based over-regulation of the financial services industry.

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II. PRODUCT APPROVAL REGULATION IN PRACTICE: PHARMACEUTICAL DRUGS, CHEMICALS, AND COMMODITY FUTURES

The best-known model of product approval regulation in the United States is the mandatory licensing of pharmaceutical drugs, biologics, and medical devices by the FDA. In many respects, it is a quintessential form of public safety regulation, an example of the precautionary approach in practice.[125] Although the FDA's administration of the drug approval scheme is a target of continuing criticisms, it provides a valuable basis for thinking about potential transferability of its key features into financial services regulation.

Another potentially relevant example is the European Union's Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals ("REACH").[126] This regulation was adopted in 2006 in order to bring all existing chemical substances under a comprehensive regulatory regime that includes, among other things, pre-approval requirements for certain hazardous chemicals. The implementation of this ambitious E.U.-wide program exemplifies the challenges of extending a comprehensive regulatory scheme to a large number of previously unregulated products.

Both the FDA and the REACH program operate in areas that are substantively different from financial services regulation. It is not widely known that, until relatively recently, a similar system of market-entry control also existed in the U.S. financial sector. Thus, from 1974 to 2000, all exchange-traded commodity futures were subject to mandatory pre-approval by the CFTC.[127] Although that system was abandoned after the adoption of the Commodities Futures Modernization Act of 2000 (the "CFMA"),[128] it is an important source of substantive and normative principles that can potentially guide a search for an effective system of licensing a broader range of complex financial products.[129]

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125. *See, e.g.*, Jonathan B. Wiener, *Whose Precaution After All? A Comment on Comparison and Evolution of Risk Regulatory Systems*, 13 DUKE J. COMP. & INT'L L. 207 (2003) (arguing that the FDA regulatory regime is one of the examples of the United States implementing precautionary principle).

126. For general information on REACH Regulation, see *Regulations*, ECHA, http://echa.europa.eu/web/guest/regulations (last visited May 11, 2012).

127. 7 U.S.C. § 7a(a)(12) (1999) (repealed 2000).

128. Commodity Futures Modernization Act of 2000, Pub. L. No. 106-554, 114 Stat. 2763 (codified as amended in scattered sections of 7, 11, 12, & 15 U.S.C.).

129. This Article does not discuss the effect of the Dodd-Frank Act on the commodity futures regulation, because the mandatory product approval regime was abolished in 2000, well before its enactment. *See id.*

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This Part examines these three models of product approval regulation and attempts to draw potential lessons for evaluating the idea of approval regulation with respect to complex financial products. The purpose of this discussion is not to provide a full appraisal of each regime's operation. Far more modestly, the goal is to identify some of the key features of these regulatory schemes in order to frame our inquiry into whether, and how, a similar scheme can operate in the financial services sector.

A. The FDA Model: Focus on Public Safety

The FDA, an agency within the U.S. Department of Health and Human Services, is responsible for protecting and promoting public health and assuring the safety of foods, dietary supplements, pharmaceutical drugs, medical devices, cosmetics, and many other products.[130] The FDA is a complex organization comprising several specialized centers, offices, and laboratories, and its regulations affect a significant number of economic activities.[131] The agency implements several federal statutes, including the Food, Drug, and Cosmetics Act of 1938 ("FDCA").[132] The scope and intensity of the FDA's safety regulation differs depending on the risks and other peculiar characteristics of different categories of products.

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130. For general information on the FDA's mission, organization, and operation, see *What does FDA do?*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194877.htm (last visited May 11, 2012).

131. According to one commentator,

> The F.D.A. regulates more than $1 trillion worth of consumer goods, which amounts to about 25 cents of every consumer dollar spent in this country. This includes $466 billion in food sales, $275 billion in drugs, $60 billion in cosmetics and $18 billion in vitamin supplements. The agency is responsible for monitoring a third of all imported goods, from eggplant to eyeliner, microwave ovens to monoclonal antibodies, slaughterhouses to cellphones.

Gardiner Harris, *The Safety Gap*, N.Y. TIMES, Oct. 31, 2008, at B44.

132. 21 U.S.C. § 301 *et seq*. (2006). Adopted in response to the deaths caused by the solvent-tainted antibiotic Elixir Sulfanilamide, the law initially operated more like a pre-market notification scheme. A formal product approval regime for new drugs was established in 1962, in response to a massive wave of severe birth defects associated with an anti-morning sickness drug, Thalidomide:

> This event fueled public pressure for more stringent regulation of the rapidly growing pharmaceutical industry. The 1962 Drug Amendments to the FDCA established a rigorous pre-market approval process that placed the burden of proof on drug manufacturers to demonstrate, under a substantial evidence standard, the safety and efficacy of their drug products. Equally remarkable, these sweeping reforms were passed unanimously by the House and Senate, despite substantial political opposition prior to the shock of the thalidomide debacle.

David E. Adelman, *New Directions in Environmental Law: A Cautiously Pessimistic Appraisal of Trends in Toxics Regulation*, 32 WASH. U. J.L. & POL'Y 377, 403 (2010).

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Pharmaceutical drugs are subject to the most intense regulatory oversight, including the mandatory pre-market licensing of new drugs.[133] The main purpose of the FDA's new drug approval process is to prevent potentially unsafe drugs from entering the market. In that sense, the FDA serves as a true gatekeeper agency guarding the entrance to the market and, in effect, controlling its composition. This regulatory scheme reflects an important normative principle that places individual humans' health and safety above the economic interests of private market participants.

In administering its drug approval program, the FDA makes decisions that have significant medical and economic consequences. The FDA has a corps of in-house scientists conducting independent research necessary to support the agency decisions. Pharmaceutical companies present their own research and test data, which is often voluminous and complex. In addition to the strain on the agency's resources, the FDA's in-house review of this scientific evidence often faces a further challenge of coping with significant uncertainty. Thus, some have argued that the FDA's in-house research tends to be excessively conservative and prevents potentially valuable drugs from reaching the market.[134] At the same time, given the irreversibility and potentially catastrophic nature of harm that an unsafe drug can cause, such conservatism may not be unwarranted.[135]

From an institutional perspective, the FDA drug approval process involves a fundamental trade-off.[136] On the one hand, the FDA faces a strong incentive to maintain its reputation as a safety regulator, which necessitates caution in accepting the industry's data and a more thorough probing of the scientific evidence.[137] These reputational concerns at least partially explain why the FDA sets higher substantive standards for approving new drugs.[138] The approval of an "unsafe" drug typically has

133. Virtually every aspect of drug production and distribution, including research, testing, advertising, prescription, and safety, is subject to the FDA regulation. By contrast, foods and cosmetics are generally regulated only for labeling and safety. Medical devices and biological therapeutic agents, such as vaccines and blood or tissue products, are also subject to pre-market approval by the FDA. The discussion here focuses on new drug approval.

134. *See* Lars Noah, *Scientific "Republicanism": Expert Peer Review And the Quest for Regulatory Deliberation*, 49 EMORY L.J. 1033, 1035–36 (2000).

135. This debate about the practical efficacy of the FDA's regulatory philosophy is tied to the academic debate on the virtues and limits of the precautionary principle as a default policy choice under conditions of uncertainty. *See supra* notes 92–96 and accompanying text.

136. Daniel P. Carpenter, *The Political Economy of FDA Drug Review: Processing, Politics, And Lessons For Policy*, 23 HEALTH AFFAIRS 52, 53 (2004).

137. *Id.* Carpenter refers to this as "the learning incentive."

138. Carpenter argues that the FDA is strongly driven by concerns about maintaining its reputation as an effective safety regulator. *Id.* at 54; *See also* DANIEL CARPENTER, REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT FDA (2010).

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high visibility and may irreversibly damage the FDA's reputation.[139]

On the other hand, however, the FDA operates under strong political pressure, as pharmaceutical firms lobby for faster approval of their products. The agency's decision to deny approval often has significant economic consequences for the pharmaceutical firm:

> The agency's drug review decisions are essentially final (contesting them is extremely difficult and costly) and immensely consequential (regulators in other nations frequently cue off of the FDA's decisions). If the FDA so chooses, it can materially impede the flow of new products to the pharmaceutical marketplace, or it can help accelerate that flow.[140]

Pharmaceutical companies frequently criticize the FDA for being too rigid, conservative, and slow in granting drug approvals. From the start, the industry attacked the FDA drug approval regime as stifling innovation and blocking patient access to new drugs.[141] Since the 1980s, pharmaceutical firms have also successfully mobilized, and often cultivated, patient-advocacy groups that had greater legitimacy as a public critic of the FDA's supposed failures to approve potentially beneficial drugs.[142] This trend exacerbated the FDA's political dilemma and further complicated its decision-making process.

One of the mechanisms the FDA employs to address the problem of scientific uncertainty and potential policy bias is the use of outside scientific peer-review of drug approval applications.[143] Most of the FDA's advisory committees are established either by the Secretary of Health and Human Services or by the FDA Commissioner.[144] The FDA typically solicits public nominations and applications for its scientific advisory committees. To be selected, the members must be technical experts in various areas, including "clinical medicine, engineering, biological and

139. Carpenter, *supra* note 136, at 55.

140. *Id.* at 52–53.

141. *See* Adelman, *supra* note 132, at 404.

142. Carpenter, *supra* note 136, at 56.

143. The FDA currently uses fifty scientific expert committees and panels that provide independent expertise and advise the FDA on scientific issues of regulatory importance. *See Advisory Committees*, U.S. FOOD & DRUG ADMIN, http://www.fda.gov/AdvisoryCommittees/default.htm (last visited May 11, 2012).

144. PETER BARTON HUTT ET AL., FOOD AND DRUG LAW 1576 (2007). Some of the FDA's scientific expert councils are statutorily established. These include the color additive advisory committees, 21 U.S.C. § 376(b)(5)(C)(D) (2006), and the advisory review panels for medical devices, 21 U.S.C. § 360c(b) (2006).

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physical sciences, biostatistics, and food sciences."[145] In addition to proven substantive expertise, the members of the FDA's technical advisory committees must not have financial conflicts of interest.[146]

The FDA's use of independent expert committees is typically justified as an important method of improving the quality of administrative decision-making under the condition of scientific uncertainty.[147] Scientific advisory committees play the key role in the FDA's drug approval process. The FDA uses these institutions "to legitimate the soundness of its analysis of a given product, as a public forum for discussion of controversial issues, and, on occasion, as an 'appeals court' for disputed agency decisions."[148] Thus, these committees serve not only a substantive, but also an important political function. The FDA's practice of using outside scientific committees for drug approval has also been controversial. The FDA's expert advisory committees have been criticized for not being truly independent from the FDA and for merely serving as a legitimizing device for the agency's decisions.[149] There are also persistent suspicions that the FDA experts tend to favor the industry because of various hidden or indirect financial conflicts of interest.[150]

Another important feature of the FDA drug approval process is post-approval review, whereby the regulator allows a limited roll-out of the drug and requires the firm to collect and produce data on its safety and performance. This conditional approval process helps to generate valuable information on which to base the final decision about the potential benefits versus potential harms of a particular product. This information-generating potential of the FDA-type approval regulation strengthens markets by making them more predictable and safer for consumers.[151] Some commentators, however, criticize the FDA's post-approval monitoring practices as insufficiently rigorous.[152]

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145. *Membership Types*, U.S. FOOD & DRUG ADMIN, http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/CommitteeMembership/MembershipTypes/default.htm (last visited May 11, 2012).

146. *See* HUTT ET AL., *supra* note 144, at 1588.

147. *See* Noah, *supra* note 134, at 1034.

148. *See* HUTT ET AL., *supra* note 146, at 1573.

149. *See id*. at 1060.

150. *See, e.g.*, HUTT ET AL., *supra* note 146, at 1588.

151. *See* Carpenter et al., *supra* note 107, at 36.

152. *See, e.g.*, Frances H. Miller, *Medical Errors, New Drug Approval, and Patient Safety*, *in* THE REALITY OF PRECAUTION 265, *supra* note 96 ("The efficacy of post-market surveillance leaves much to be desired in both the United States and the EU.").

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B. Chemicals Regulation in the European Union: REACH

Regulation of chemical substances aims at protecting human health and the environment from potentially catastrophic risks. The principle of exercising precaution, therefore, is of particular salience in this regulatory area.[153]

In the U.S., the Environmental Protection Agency ("EPA") regulates chemicals under the Toxic Substances Control Act of 1976 ("TSCA").[154] The TSCA established a system of pre-manufacturing notification and review by the EPA for all "new" chemicals introduced into the market after the law was passed. Chemicals already in commerce as of that date were labeled "existing" substances and were not subject to EPA review.[155] For "new" chemical products, the TSCA does not require companies to submit hazard data to the EPA unless the EPA requests such data in the course of its 90-day pre-manufacturing review.[156] Under the TSCA, the EPA must demonstrate that the chemical is dangerous enough to warrant testing and hazard data submission, which inhibits the agency's ability to demand pre-market risk assessments and forces it to rely on the voluntary submission of test data.[157] As a result, the EPA lacks adequate scientific information on the toxicity of most chemicals.[158] This allocation of the burden of proof under the TSCA creates incentives for chemical companies to maintain "strategic ignorance" and avoid developing toxicity data on their products.[159]

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153. *See* Ortwin Renn & E. Donald Elliott, *Chemicals*, *in* THE REALITY OF PRECAUTION, *supra* note 96, at 223, 224.

154. 15 U.S.C. § 2601 *et seq*. (2006).

155. *See* Felice Cooper & Rebecca Lawson, *Environmental Liability: Chemicals Reform in the United States* (17 May, 2010), *available at* http://www.allenovery.com/AOWEB/Knowledge/Editorial.aspx?contentTypeID=1&contentSubTypeID=7944&it.

156. *Id.*

157. 15 U.S.C. § 2603 (2006); *See also* Sachs, *supra* note 92; John S. Applegate, *Synthesizing TSCA and REACH: Practical Principles for Chemical Regulation Reform*, 35 ECOLOGY L.Q. 721 (2008).

158. *See* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-09-428T, CHEMICAL REGULATION: OPTIONS FOR ENHANCING THE EFFECTIVENESS OF THE TOXIC SUBSTANCES CONTROL ACT (2009), *available at* http://www.gao.gov/assets/130/123792.pdf. As the report noted,

> As a result, EPA does not routinely assess the risks of the over 83,000 chemicals already in use. Moreover, TSCA does not require chemical companies to test the approximately 700 new chemicals introduced into commerce each year for toxicity, and companies generally do not voluntarily perform such testing.

Id. at 1.

159. *See* Wendy E. Wagner, *Commons Ignorance: The Failure of Environmental Law to Produce Needed Information on Health and the Environment*, 53 DUKE L.J. 1619, 1685 (2004); Sachs, *supra* note 92, at 1301.

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Prior to 2006, the European Union had a similar system of chemicals regulation, which required pre-market notification and testing only for "new" chemicals introduced after 1981 but not for "existing" chemicals as of that cut-off date. A total of 100,106 chemicals that were on the market as of 1981 were exempt from the regulatory requirements.[160] Under that regime, companies had to test and notify the regulators of any "new" chemicals in production volumes as low as ten kilograms per year, while they could manufacture and import any "existing" chemicals without going through this expensive procedure.[161] That policy created perverse incentives to continue using the untested "existing" chemicals, and inhibited research and innovation.[162]

In 1999, the European Commission ("EC") began working on a new regulatory framework, REACH, which, after years of negotiations, was formally adopted in December 2006.[163] A new European Chemicals Agency ("ECHA") was formed to administer the new EU-wide regulatory regime.[164] In contrast to the prior regulatory scheme, REACH brings all existing and new chemicals under a comprehensive system of registration, pre-market risk assessment, and mandatory pre-approval for certain dangerous substances.[165] The new scheme is designed to produce an extensive body of data on all chemicals in the EU market.[166]

REACH explicitly shifts the burden of testing chemicals for toxicity and ensuring their safety from the regulatory authorities to private industry actors.[167] REACH "is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment."[168] Instead of mandating regulatory pre-approval for all chemical substances, however, the program adopts a tiered

160. Renn & Elliott, *supra* note 153, at 236. Between 1981 and 2006, only about 3,000 "new" chemicals were put on the EU market. *Id.*

161. *Id.*

162. *Id.*

163. *See* Commission Regulation 1907/2006, 2006 O.J. (L 396) 1 (EC) [hereinafter REACH], *available at* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:396:0001:0849:EN :PDF.

164. For more information about the ECHA, see *About Us*, ECHA, http://echa.europa.eu/web/guest/about-us;jsessionid=E54AD754F846A0D1507849D89B41DD09.live2 (last visited May 11, 2012).

165. *See REACH*, EUROPEAN COMM'N, http://ec.europa.eu/enterprise/sectors/chemicals/reach/index_en.htm (last visited May 11, 2012).

166. *See* Sachs, *supra* note 92, at 1302 ("By rewarding knowledge and making chemical manufacturers responsible for data production, REACH is helping to end the data drought that has plagued European chemical regulation since the early 1980s.").

167. Renn & Elliott, *supra* note 153, at 237.

168. REACH, *supra* note 163, at 47.

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approach that differentiates among categories of chemicals, depending on their quantity in commerce and toxic characteristics.[169]

The quantity of a substance manufactured or used in the EU is the key factor in determining applicable testing requirements. Under REACH, only companies that produce or import more than one ton of any chemical substance per year must register that substance in a central database and submit to the ECHA extensive testing and risk data.[170] Once the REACH registration requirement is triggered, the level of testing required varies, depending on whether a particular chemical is sold or produced in quantities above ten, one hundred, and one thousand metric tons annually.[171]

In their submissions to the ECHA, manufacturers, importers or their customers must also identify the *uses* of each substance and, for chemicals produced or imported in volumes over ten tons per year, provide chemical safety reports.[172] These reports pertain specifically to the identified uses of the chemical: they must contain an assessment of risks such uses pose to human health and the environment, and define the conditions of use under which those risks can be adequately controlled.[173]

REACH further differentiates among categories of chemicals depending on their toxic characteristics, so that the most hazardous substances require the most extensive and rigorous testing and are subject to additional regulatory controls. Certain highly dangerous chemicals, which the ECHA designates as Substances of Very High Concern ("SVHC"),[174] are placed on the official Authorization List and cannot be

169. *See* Adelman, *supra* note 132, at 393 ("Classification based on quantities in commerce and chemical characteristics are defining features of REACH.").

170. Renn & Elliott, *supra* note 153, at 236. Registration dossiers include the data on the intrinsic properties and hazards of each substance, which may be established through testing, computer modeling, or epidemiologic studies. *Id.* at 238. The ECHA manages the central database containing collected data.

171. Adelman, *supra* note 132, at 393 ("For chemicals sold or manufactured in quantities of one to ten metric tons annually, testing should be limited to in vitro testing of acute hazards. The testing requirements are elevated to a standard base set of toxicology testing for chemicals sold or manufactured in quantities of ten to one hundred metric tons annually. Rigorous 'substance-tailored testing for long-term effects' is required for quantities that exceed one thousand metric tons annually.")

172. *See Information Requirements*, ECHA, http://echa.europa.eu/web/guest/regulations/reach/substance-registration/information-requirements (last visited May 11, 2012).

173. *Id.*

174. The SVHC group includes, for example, substances that are carcinogenic, mutagenic, and toxic to reproduction ("CMR") and other substances identified on a case-by-case basis, for which there is scientific evidence of probable serious effects that present similar concerns. *See Authorisation*, ECHA, http://echa.europa.eu/web/guest/regulations/reach/authorisation (last visited May 11, 2012).

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used or put on the market unless granted exemptions for specific uses.[175] Both the SVHC designation and the subsequent authorization process involve public consultations and detailed review of scientific data and opinions.[176]

The purpose of this pre-market approval scheme is to control the use of hazardous chemicals and to encourage the industry to substitute such chemicals with less dangerous substances. Requests for authorization of specific SVHCs must be accompanied by a substitution plan and evidence that either the particular SVHC can be used safely or that the socioeconomic benefits of its use outweigh its risks.[177] Public consultations are an important part of the process, which allows the industry and the broader public to submit comments and provide information on potential substitutes and alternative technologies.[178] In addition, the ECHA has the authority to propose bans or restrictions on the manufacture, marketing or use of chemicals posing unacceptable risks to human health or the environment.[179]

The program's official goal is to "ensure a high level of protection of human health and the environment," while also "enhancing competitiveness and innovation."[180] Implementation of this program, however, presents daunting challenges. Eliminating the distinction between "new" and "existing" chemicals under REACH means that the industry could potentially be required to test and register over 100,000 previously untested chemical substances, all within a relatively short period of three to five years.[181] The tiered regulatory approach helps to

175. *Id.*

176. For example, in early 2011, after more than two years of public consultations and studies, the ECHA put six chemicals on the Authorization List. *See Authorisation List*, ECHA, http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list (last visited May 11, 2012).

177. REACH creates some flexibility by introducing two groups of CMRs for purposes of authorization: those with a "safe threshold" of toxicity and those for which no threshold of "safe use" can be established. For the first group, an authorization will be granted if the producer can show that the risks associated with the proposed use of such substances can be controlled effectively. For all other hazardous substances, an authorization will be granted only if there is no safer alternative and the socioeconomic benefits of their use significantly outweigh the risks. *See* Renn & Elliott, *supra* note 153, at 240.

178. *See Applications for Authorisation*, ECHA, http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/applications-for-authorisation (last visited May 11, 2012).

179. *See Restriction*, ECHA, http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/restriction (last visited May 11, 2012).

180. REACH, *supra* note 163, at 2.

181. The EC mandated that the process of testing, assessing, and registering all chemicals had to be completed by 2012, while the registration of very high-volume (above one thousand tons per year) and highly toxic or hazardous chemicals (such as CMR in volumes above one ton per year) had to be

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limit the scope of this undertaking by targeting only those chemicals that, based on their volume and toxicity, create the highest potential human and environmental exposure to risk. In 2003, it was estimated that only about 30,000 chemicals were produced or imported in quantities exceeding the new threshold for registration, although some of the later studies raised that estimate to about 68,000 chemicals.[182] Only a small percentage of these substances are likely to be classified as SVHCs and require mandatory authorization.[183]

Chemical companies objected to the adoption of REACH as imposing exorbitant costs on the industry, potentially stifling research and innovation, and creating a competitive disadvantage for the EU.[184] The industry also argued that REACH would render manufacturing of certain lower-volume chemicals less profitable, which would limit market supply and may cause withdrawal of substances from the market, and have a disproportionally negative effect on economic viability of small and medium-sized chemical companies.[185] The program's proponents, however, argued that its implementation costs were not excessively high in comparison to the industry's total revenues, and should be viewed as socially desirable internalization of externalities.[186]

Still, the overall cost and administrative complexity of transitioning from the pre-2006 system to the REACH regime present a significant problem. In addition to monetary costs, the ECHA has to balance companies' concerns regarding disclosure of proprietary data against the need to ensure transparency and public access to information on hazardous substances. Another controversial issue relates to the increase in animal testing in order to produce the mandatory risk assessment data.[187] Animal rights activists have been extremely critical of this controversial aspect of

completed by 2010. Renn & Elliott, *supra* note 153, at 236.

182. *See* Renn & Elliott, *supra* note 153, at 239. In over thirty years before the enactment of REACH, government regulators required only seventy chemical risk assessments, which pales in comparison even to the lower estimate of 30,000 high-volume substances on the market. *See* Noah M. Sachs, *Jumping the Pond: Transnational Law and the Future of Chemical Regulation*, 62 VAND. L. REV. 1817, 1833–34 (2009).

183. *See* Adelman, *supra* note 132, at 394 (estimating that a total of about 1400 chemicals are likely to require authorization as SVHCs).

184. Calculating potential direct costs of REACH to the chemical industry has been a hotly debated issue, with estimates ranging from €2.3 billion to €5.2 billion. These estimates, however, may be too optimistic. Renn & Elliott, *supra* note 153, at 239.

185. *Id.* at 240.

186. Sachs, *supra* note 92, at 1333.

187. Renn & Elliott, *supra* note 153, at 239. According to some estimates, the mandatory testing of the existing chemicals may require fifty-four million research animals. *Id.*

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REACH and lobbied to reduce the impact of tests on animals.[188] Introducing new testing technologies and more efficient methods of sharing existing experimental data, advocated by animal-rights groups, potentially reduces the rise in the number of research animals killed in the process.[189]

As some scholars have observed, REACH is predominantly a data and information collection regime, which shifts the cost of producing such information to the private sector and empowers regulators to assess the tolerability of risk.[190] It remains to be seen how effective REACH will be in achieving its proclaimed goals in practice.[191] Nevertheless, the sheer magnitude of this E.U.-wide undertaking to build a regime for registering, tracing, and controlling the use of chemical substances demonstrates the feasibility of ambitious reforms that reflect an explicit political commitment to protect human health and environment.

Similar to the FDA drug licensing scheme, REACH is based on the requirement for pre-market testing of regulated products. Conditioning market access on the pre-market experimental assessment of systemic risk posed by financial contracts, however, may not be feasible. It is difficult, if not impossible, to create a self-contained test market for a new financial instrument and to ensure that no risk will spill over into the broader financial system and cause irreversible damage to systemic stability. The centrality of experimental testing and pre-market empirical data collection to the product approval regulation of pharmaceutical drugs and chemicals potentially limits our ability to draw meaningful substantive lessons directly applicable to financial services regulation.

At the same time, however, the requirement of empirical testing of individual products' safety may not be the only way to ensure a workable product licensing regime. A system of product pre-approval, which existed in the U.S. commodity futures sector before 2000, provides an example of a regime that was not based on mandatory pre-market testing of financial contracts.

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188. See *The Truth About REACH Animal Testing*, EUROPEAN COALITION TO END ANIMAL EXPERIMENTS, http://www.eceae.org/de/what-we-do/campaigns/reach/the-truth-about-reach-animal-testing (last visited May 11, 2012).

189. *See id.*

190. *See* Renn & Elliott, *supra* note 153, at 242.

191. *See, e.g.*, Adelman, *supra* note 132, at 379–80 (arguing that agency discretion in implementing the regulation may mute the intended effects of procedural burden-shifting and that REACH "opens the door to evasion through its tiered chemical classification scheme and the flexibility it affords manufacturers to use alternative testing methods."); Applegate, *supra* note 157, at 724 (arguing that REACH was conceived as a Hegelian "antithesis" to the TSCA and that the truly precautionary chemicals regulation has to offer a greater "synthesis" of these two schemes).

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C. Product Approval in Commodity Futures Regulation: Focus on Market Manipulation and Speculation

1. Commodity Futures Regulation—Overview

A futures contract is a form of derivative instrument.[192] Commodity futures are standardized bilateral contracts that obligate one party (the buyer, or "long") to purchase, and the other party (the seller, or "short") to deliver a specified quantity of a specified asset, or underlying commodity, at a specified future date and at a specified price.[193] In the United States, the Chicago Board of Trade ("CBOT") began listing grain futures in the mid-1860s.[194] In the early twentieth century, rampant speculation in commodities and commodity futures, and the spread of "bucket shops,"[195] led the farming community to lobby for federal regulation of futures trading.[196] In 1921, Congress enacted the Future Trading Act, which sought to outlaw bucket shops.[197] After the statute was declared unconstitutional by the Supreme Court,[198] Congress enacted the Grain Futures Act of 1922.[199] The statutory scheme for regulation of futures was revised several times after 1922.[200] In 1974, Congress enacted the Commodity Exchange Act (the "CEA"),[201] and created the CFTC as an independent federal agency overseeing the markets for commodity futures and options.[202]

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192. *See supra* note 14 and accompanying text.

193. Futures are functionally similar to forward contracts. Unlike forwards, however, futures are standardized, traded on organized exchanges, and typically settled in cash. *See* Krawiec, *supra* note 16, at 10.

194. *From Water Street to the World*, CHI. MERCANTILE EXCH. GRP., http://www.cmegroup.com/company/history/magazine/Summer2007/FromWaterStreetToTheWorld.html (last visited May 11, 2012).

195. A "bucket shop" was a gambling operation whereby the shop operator took customers' bets on price movement of various commodities but did not place orders on an exchange. *See, e.g.*, Thomas Lee Hazen, *Public Policy: Rational Investments, Speculation, or Gambling?—Derivatives Securities and Financial Futures and Their Effect on the Underlying Capital Markets*, 86 NW. U. L. REV. 987, 1014–17 (1992).

196. For an analysis of the political origins of federal futures regulation, see Roberta Romano, *The Political Dynamics of Derivative Securities Regulation*, 14 YALE J. ON REG. 279 (1997).

197. 42 Stat. 187 (Aug. 24, 1921).

198. Hill v. Wallace, 259 U.S. 44 (1922).

199. 42 Stat. 998 (Sept. 21, 1922), 7 U.S.C. § 1 *et seq*. (1922).

200. *See* Jerry W. Markham, *Manipulation of Commodity Futures Prices—The Unprosecutable Crime*, 8 YALE J. ON REG. 281 (1991) (detailing the history of the commodity futures regulation).

201. 7 U.S.C. § 1 *et. seq* (2006).

202. The CFTC consists of five Commissioners appointed by the President, with advice and consent of the Senate, for five-year terms. The President designates one of the Commissioners as the

The CEA, administered by the CFTC, regulates the offer and sale of futures contracts and commodity options, the operation of futures exchanges, and the activities of various futures market participants. Under the broad statutory definition of "commodity," almost all futures contracts are subject to the CEA.[203] In contrast to disclosure-based securities regulation, the CEA establishes broad categories of permissible and impermissible transactions. Unless specifically exempted, commodity futures and options must be offered and sold on futures exchanges or other organized contract markets.[204] Contracts entered into in contravention of the statutory requirements are illegal and unenforceable, and participants in such illegal transactions are subject to a wide array of civil and criminal penalties.[205]

The CEA's key policy objectives are:

> To deter and prevent price manipulation or any other disruptions to market integrity; to ensure the financial integrity of all transactions subject to this chapter and the avoidance of systemic risk; to protect all market participants from fraudulent or other abusive sales practices and misuses of customer assets; and to promote responsible innovation and fair competition among boards of trade, other markets and market participants.[206]

Preventing fraud and price manipulation in the U.S. futures and related cash commodity markets has always been the central driving force behind the federal regulatory scheme.[207] The CEA emphasizes that futures serve "a national public interest by providing a means of managing and assuming price risks, discovering prices, or disseminating pricing information."[208] As a result of this special "utility" function, "futures trading occupies a somewhat unique economic position in the eyes of the law."[209]

Chairperson. For more information on the CFTC, see U.S. COMMODITY FUTURES TRADING COMM'N, http://www.cftc.gov/index.htm (last viewed May 11, 2012).

203. *See* 7 U.S.C. § 1a(4) (defining the term "commodity").

204. 7 U.S.C. § 6.

205. 7 U.S.C. § 13.

206. 7 U.S.C. § 5(b).

207. The federal regulatory regime for futures markets was initially created in response to producers' complaints about the economically-harmful effects of widespread commodity and futures market manipulation through "corners", "squeezes", and "bucket shop" speculation. *See* Romano, *supra* note 196.

208. 7 U.S.C. § 5(a).

209. PHILIP MCBRIDE JOHNSON & THOMAS LEE HAZEN, COMMODITIES REGULATION 261 (2d ed. 1989).

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2. *Pre-CFMA Regulatory Regime: Contract Designation and the Concept of Economic Purpose*

Before the enactment of the CFMA in 2000, one of the most significant provisions of the CEA was section 5a(a)(12) that required the terms and conditions of all futures contracts to be pre-approved for trading by the CFTC.[210] This requirement reflected the statute's original concern with excessive speculation that negatively affected the underlying commodity markets. As the leading treatise explained:

> At nearly every turn, the Act reiterates the utility of futures trading for (1) hedging against price risks, (2) the discovery of prices through vigorous competition, and (3) the actual pricing of commercial commodity transactions. While futures contracts offer, certainly, an investment opportunity as well, that feature seems in the Act to be subordinate or secondary in importance to the commercial uses that those markets offer. . . . [I]t does not appear that a futures contract with a pure investment purpose must *necessarily* be foreclosed, but the history of administration of the Act leaves little doubt that a futures contract without a commercial purpose faces long odds of ever being approved by the Commission.[211]

This dichotomy between commercial and "purely investment" purposes of futures contracts reflects a fundamental tension in the CEA regime. The CEA has never contained an explicit requirement of commercial utility as a condition of contract designation. Prior to 1974, the statute did not specify whether or not futures contracts with purely investment (as opposed to bona fide commercial hedging or price discovery) purposes should be approved for trading.[212] In 1974, the House of Representatives passed a bill, H.R. 13113, which sought to prohibit authorization of any contract unless that contract served a bona fide economic function, either as a price discovery mechanism or as a device for those in the related cash

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210. 7 U.S.C. § 7a(a)(12) (1999). Before the CFMA, this subsection was "one of the most important in both legal and practical effect." PHILIP MCBRIDE JOHNSON & THOMAS LEE HAZEN, DERIVATIVES REGULATION 180 (2004) [hereinafter DERIVATIVES REGULATION].

211. JOHNSON & HAZEN, *supra* note 209, at 261 (footnote omitted).

212. Before 1974, the statute did not explicitly require an affirmative regulatory pre-approval of the terms of futures contracts. Since 1968, the Secretary of Agriculture had only the power to disapprove any trading rule of a contract market, which violated the statute. 7 U.S.C. § 7a(8) (pre-1974).

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commodity markets to hedge their commercial, as opposed to investment, risks.[213] The industry objected to this prospective economic purpose test, arguing that it was difficult to predict the ultimate uses of a new product.[214] In response to industry pressure, the Senate rejected an explicit "economic purpose" test for approval of futures contracts and substituted it with a more vaguely stated "public interest" test.[215] As adopted, the CEA contained the Senate's provision that conditioned approval of futures contracts on the affirmative demonstration by the board of trade that "transactions for future delivery in the commodity for which designation as a contract market is sought will not be contrary to the public interest."[216]

At the same time, however, the Conference Committee report that accompanied the original enactment of this provision in 1974 noted that the "broader language of the Senate provision would include the concept of the 'economic purpose' test provided in the House bill subject to the final test of the 'public interest.'"[217] The newly established CFTC interpreted this language as requiring that every futures contract had to meet both the broad "public interest" and the more specific "economic purpose" tests.[218]

The key requirements for contract designation were set forth in sections 5 and 5a of the CEA.[219] In essence, the statute required the exchange applying for designation to make an affirmative showing that the contract provided for delivery of the underlying commodity at a location where there was a sufficiently active and liquid cash market and where the

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213. Specifically, H.R. 13113 stipulated that the contract should not be approved unless

> [T]he board of trade demonstrates that the prices involved in transactions for future delivery in the commodity for which designation as a contract market is sought are, or reasonably can be expected to be, generally quoted and disseminated as a basis for determining prices to producers, merchants, or consumers of such commodity or the products or byproducts thereof or that such transactions are, or reasonably can be expected to be utilized by producers, merchants or consumers engaged in handling such commodity or the products or byproducts thereof in interstate commerce as a means of hedging themselves against possible loss through fluctuations in price.

JOHNSON & HAZEN, *supra* note 209, at 262 (quoting REPORT ON H.R. 13113 OF THE HOUSE COMMITTEE ON AGRICULTURE, H.R. REP. NO. 93-975, at 103 (2d Sess. 1974)).

214. *Id.* at 263 n.3.

215. *Id.* at 263 (citing REPORT ON H.R. 13113 OF THE SENATE AGRICULTURE AND FORESTRY COMMITTEE, S. REP. NO. 93-1131, at 72 (2d Sess. 1974)).

216. 7 U.S.C. § 7(7) (1999) (repealed 2000).

217. JOHNSON & HAZEN, *supra* note 209, at 263 (citing REPORT ON H.R. 13113 OF THE COMMITTEE OF CONFERENCE, H.R. REP. NO. 93-1383, at 14 (2d Sess. 1974)).

218. *Id.* at 264.

219. 7 U.S.C. §§ 7, 7a (1999).

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exchange had official inspection facilities.[220] This provision aimed to ensure the existence, at a point of delivery, of a liquid cash market in which the "shorts" could buy the necessary quantities of the underlying commodity for delivery and the "longs" could resell the commodity after taking delivery.[221] Clearly, this language contemplated an actual delivery of the underlying commodity, thus tying the futures instrument to a commercial activity: trade in the underlying commodity.

The new contracts also had to pass the statutory "public interest" test.[222] Despite the open-ended nature of this standard, the CFTC's view was that, as a practical matter, only futures contracts that had commercial utility and had potential to facilitate bona fide commercial hedging or price discovery in the underlying commodity markets could also pass the "public interest" test of Section 5(g). As a practical matter, it was assumed that futures contracts that had no economic purpose other than financial investment were not viable in the long run, as trading in such futures would be especially vulnerable to speculative ups and downs.[223] Thus, futures exchanges were expected to design and list for trading contracts that had "a solid base of commercial hedging or pricing participation."[224]

In addition to the substantive review of the terms of the proposed contracts, the CFTC had to scrutinize the exchanges' internal policies, procedures, and practices to ascertain their ability to monitor trading in the proposed futures contract. If the CFTC was not satisfied with an exchange's ability to ensure market integrity and limit the potential for market manipulation and other trading abuses, it could deny designation.[225] Thus, the statute linked the viability and functional utility of a futures contract to the exchanges' self-regulatory capacity.

As part of the contract designation process, the CFTC had statutory authority to mandate changes in the specific terms of the proposed futures contracts if such changes would "tend to prevent or diminish price manipulation, market congestion, or the abnormal movement of such

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220. 7 U.S.C. § 7(1) (1999) (repealed 2000). The statute required that the commodity was deliverable "at a terminal market where [it] is sold in sufficient volumes and under such conditions as fairly to reflect the general value of the commodity and the differences in value between the various grades of such commodity." *Id.*

221. JOHNSON & HAZEN, *supra* note 209, at 267.

222. 7 U.S.C. § 7(7) (1999) (repealed 2000).

223. JOHNSON & HAZEN, *supra* note 209, at 270 ("While, . . . the threshold public interest standard for designation of new futures contracts may not embrace, necessarily, the specific economic purpose test that the Congress considered in 1974, it seems clear that a proposed futures contract that is not sound as an economic matter will rarely if ever serve either public or private interests.").

224. *Id.* at 264.

225. 7 U.S.C. § 7(4) (1999) (repealed 2000).

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commodity in interstate commerce."[226] The exercise of power, however, was subject to strict procedural constraints, which showed Congressional reluctance to allow the regulator to substitute its judgment for that of an exchange.[227] Even though the CFTC did not use this power often, it functioned as a credible threat prompting exchanges to be responsive to the regulator's comments.[228]

The statute imposed other procedural requirements on the CFTC, including various timeframes for approval decisions[229] and requirements to consult with other federal regulatory agencies.[230] In addition, the CFTC had to publish in the Federal Register notice of proposed exchange rules and amendments that were of "major economic significance" and afford all interested persons an opportunity to submit comments on the proposals.[231] Applications for contract designation were typically viewed as having such significance.

To assist exchanges in preparing applications for product approval, the CFTC adopted Guideline No. 1, which detailed the information to be submitted to the agency.[232] Reflecting the CFTC's original position that the statutory public interest standard encompassed an economic purpose test, the Guideline required that an exchange make an affirmative showing that the proposed new contract was "reasonably expected to serve, on more than occasional basis," as a price discovery or hedging tool for commercial users of the underlying commodity.[233] The Guideline required the applicants to describe and justify specific economic terms of the

226. 7 U.S.C. § 7a(a)(10) (1999) (repealed 2000).

227. *Id.* Before directing the change in contract terms, the CFTC had to provide the applying exchange with an initial notice and an opportunity to correct the problem within seventy-five days. If the CFTC was not satisfied, it had to give the exchange another notice and opportunity for a hearing before exercising its power to change the terms of the contract. The exchange could file an exception to the changes before the CFTC's order became effective. *Id.*

228. JOHNSON & HAZEN, *supra* note 209, at 268–69 ("To date, the Commission has not formally exercised its authority under section 5a(10), but like the gunboat in the harbor, its existence has proven effective in encouraging the markets to rethink certain of their contracts.").

229. Since 1983, the CFTC generally had up to one year to render a final decision on contract designation. 7 U.S.C. § 7a(12)(A) (1999) (repealed 2000). In 1997, in response to the industry's complaints about the competitive harm caused by the long product roll-out timetable, the CFTC adopted a rule that allowed certain contracts to be approved on a "fast track." Such contracts were deemed approved within ten days of application for designation, in the absence of an adverse action by the CFTC. All the other new contracts were deemed approved within forty-five days, unless the CFTC notified the exchange otherwise. 17 C.F.R. § 5.1 (1999).

230. Thus, the CEA required the CFTC to provide the Treasury Department and the Federal Reserve with at least forty-five days to comment on any proposed futures contract involving U.S. Government obligations. 7 U.S.C. § 4a(g)(2) (1999) (repealed 2000).

231. 7 U.S.C. § 7a(a)(12)(A) (1999) (repealed 2000).

232. 17 C.F.R. § 40, App. A (formerly 17 C.F.R. § 5, App. A).

233. *Id.*, items (a)(4) (physically-settled contracts), (b)(4) (cash-settled contracts).

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contracts, such as delivery points, price differentials for different commodity grades, and many others.[234] In particular, the application had to explain and justify any deviation of contract terms and conditions from standard industry practices.[235]

Thus, between 1974 and 2000, commodity futures were subject to the statutory regime of mandatory product approval regulation. Under that regime, futures exchanges had an affirmative obligation to demonstrate, to the CFTC's satisfaction, that every contract they intended to list was reasonably expected to facilitate efficient pricing and hedging against commercial risks in the underlying commodity markets. Under the CFTC's approach, only contracts that satisfied this economic purpose requirement could also be expected to meet the statutory "public interest" test for contract designation.

It is difficult to tell with certainty how rigorously the CFTC fulfilled its product approval mandate in practice, particularly given the structure of the industry dominated by a few powerful exchanges. The dynamics of the CFTC's relationship with futures exchanges, which themselves act as quasi-public authorities in their capacity as self-regulatory organizations, are inherently more cooperative than adversarial.[236] In this context, regulators may prefer using less formal methods of persuasion and communication with the industry rather than public exercises of punitive power.[237] It also increases the likelihood of agency capture by the industry interests.

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234. *Id.*, items (a)(3) (physically-settled contracts), (b)(3) (cash-settled contracts). These justifications generally had to be based on appropriate economic data and not solely on expert opinion. *See* JOHNSON & HAZEN, *supra* note 209, at 273.

235. 17 C.F.R. § 40, App. A, items (a)(3) (physically-settled contracts), (b)(3) (cash-settled contracts).

236. This is widely understood as an important factor explaining the "cultural" differences between the CFTC and the enforcement-oriented SEC. *See* Jerry W. Markham, *Merging the SEC and CFTC—A Clash of Cultures*, 78 U. CIN. L. REV. 537, 591–92 (2009) (contrasting the "hands-off regulatory attitude" of the CFTC staff with the "pro-regulatory stance" of the attorney-dominated SEC).

237. Nevertheless, it is important not to overstate the effects of this "cozy" relationship between the CFTC and the futures exchanges. One example of the CFTC's use of its statutory product approval powers was the unusually intense controversy over the CBOT's corn and soybean futures contracts in 1996–98. In December 1996, the CFTC notified the CBOT that the delivery terms for its long-standing corn and soybean futures were "no longer adequate to prevent price manipulation, market congestion, or abnormal movement of the commodities in commerce," as required by the CEA. *Delivery for CBT Corn, Soybean Contracts No Longer Adequate, CFTC Tells Exchange*, 29 SEC. REG. & L. REP. (BNA) 21, 21 (Jan. 3, 1997). After the CBOT finally changed the outdated delivery terms, the CFTC approved its application for contract market designation in corn and soybean futures on May 7, 1998. *CFTC Approves CBT Proposals for Corn and Soybean Futures Contracts*, 30 SEC. REG. & L. REP. (BNA) (May 8, 1998).

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These important issues, however, are beyond the scope of the present discussion, which focuses on the statutory design of the contract designation regime as a model of financial product approval regulation. The core purpose of the CEA contract designation scheme was to prevent market manipulation, fraud, excessive speculation, and other abusive trading practices that threatened the integrity and efficiency of the U.S. commodities markets. One of the fundamental normative principles underlying that regime was the belief that futures markets fulfilled an important social function by supporting productive economic activity and, therefore, had to be protected from being turned into a venue for pure financial speculation.[238]

3. *The CFMA and the Demise of the Mandatory Product Approval Regime*

Before the enactment of the CFMA, mandatory approval of contract market rules was one of the CFTC's "most formidable powers and one of the exchanges' most burdensome duties."[239] It was also one of the key factors that made the CEA "an important—if often overlooked—antispeculation law."[240] In the 1990s, futures exchanges and financial institutions active in the growing OTC derivatives markets heavily lobbied for deregulating commodity futures trading and eliminating the requirement of prior contract approval.

The political pressure to liberalize the CEA regime reflected the fundamental changes in the nature of the futures markets.[241] When the Future Trading Act was enacted, the majority of futures were tied to agricultural commodities, and manipulative trading strategies in the futures markets directly affected farmers and other commercial producers and users of the physical commodities. With the advent of financial futures—contracts with the underlying financial assets rather than physical commodities—financial institutions and professional investors became the dominant players in the futures markets.[242] These financially sophisticated investors did not see the need for the governmental "micromanagement" of futures markets and pushed for liberalization of the existing rules.[243]

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238. *See supra* note 206–207 and accompanying text.
239. DERIVATIVES REGULATION, *supra* note 210, at 180.
240. Lynn A. Stout, *Why The Law Hates Speculators: Regulation and Private Ordering in the Market for OTC Derivatives*, 48 DUKE L.J. 701, 705 (1999).
241. DERIVATIVES REGULATION, *supra* note 210, at 182.
242. *Id.*
243. *Id.*

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As trading in financial futures came to dominate futures trading and financial investors far outnumbered commercial users of futures, the entire dynamics of the commodity futures markets changed fundamentally. The futures market became intricately tied to the exploding OTC derivatives markets, which had an advantage of being unregulated and offering financial players far more flexibility and greater potential returns.[244] Non-U.S. derivatives exchanges began entering the U.S. markets and offering a wider range of financial products to U.S. investors.[245] U.S. futures exchanges forcefully argued that the CFTC approval process caused significant delays in product listing and prevented them from competing with foreign exchanges and the OTC derivatives markets.

In 1997, the CFTC responded by creating a "fast-track" contract approval procedure for certain commodities, under which a contract was deemed approved within ten days after submission unless the CFTC notified the exchange otherwise.[246] That did not satisfy the futures industry, however. The new opportunity to liberalize the product approval regime came after Brooksley Born, an outspoken advocate of stronger derivatives regulation, resigned from her post as the Chair of the CFTC on June 1, 1999. William Rainer, a private investment manager with reported ties to President Clinton, was nominated as the new CFTC head on June 23, 1999, and quickly confirmed by the Senate.[247] On June 25, 1999, the CBOT, the Chicago Mercantile Exchange, and the New York Mercantile Exchange petitioned the CFTC, among other things, to exempt U.S. futures exchanges from the regulatory contract approval process.[248] On November 17, 1999, responding to this petition, the CFTC adopted new regulation that permitted futures exchanges to list new contracts for

244. *See generally* REPORT OF THE PRESIDENT'S WORKING GROUP ON FINANCIAL MARKETS, OVER-THE-COUNTER DERIVATIVES MARKETS AND THE COMMODITY EXCHANGE ACT (Nov. 1999), *available at* http://www.treasury.gov/resource-center/fin-mkts/documents/otcact.pdf (discussing the growth of the OTC derivatives markets and its impact on the futures markets and regulation). The growth of OTC derivatives in the 1980s–90s raised difficult legal and regulatory questions and created a bitter jurisdictional and administrative turf war between the CFTC and the SEC. *Id.* at 6–15. An examination of this inter-agency struggle is beyond the scope of this Article.

245. In the late 1990s, the CFTC granted no-action relief to several foreign boards of trade, including Germany's Eurex, France's ParisBourse, and England's LIFFE, allowing them to establish electronic terminals in the U.S. without having to meet contract market designation requirements of the CEA. *See, e.g.*, *Eurex, ParisBourse Gain Access to Systems from Within U.S.*, 31 SEC. REG. & L. REP. (BNA) 1095 (Aug. 13, 1999).

246. 17 C.F.R. § 5.1 (1999). *See also supra* note 229.

247. *See William Rainer*, MARKETS WIKI, http://www.marketswiki.com/mwiki/William_J._Rainer #cite_note-5 (last visited Apr. 3, 2012).

248. *See* 64 Fed. Reg. 46,356 (Aug. 25, 1999).

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trading pursuant to exchange certification, without prior Commission approval.[249]

In January 2000, the CFTC published a report entitled "A New Regulatory Framework," which laid down a program of massive liberalization of U.S. commodity futures regulation.[250] Among other things, the report advocated a switch from the traditionally prescriptive rules-based regulatory regime to a principles-based framework, which would give far greater operational flexibility to futures exchanges.[251] As part of that switch, the CFTC recommended eliminating the mandatory contract designation process in favor of exchange certification of new products' compliance with the CEA.[252]

On December 15, 2000, Congress passed the CFMA, a comprehensive piece of legislation that incorporated most of the CFTC's proposals and radically liberalized the regulatory regime for futures and OTC derivatives.[253] Among other things, the CFMA repealed section 5a(a)(12) of the CEA and eliminated the requirement of prior approval by the CFTC of exchanges' rules and products. The new law allowed regulated exchanges to list futures contracts upon a written self-certification that such products complied with the requirements of the CEA, as amended.[254] Exchanges could also voluntarily request the CFTC's pre-trading approval for their contracts, which gave them the right to label such contracts as approved by the CFTC.[255]

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249. *See* Press Release, Commodity Futures Trading Commission, CFTC Approves Action to Advance Regulatory Reform (Nov. 17, 1999), *available at* http://www.cftc.gov/opa/press99/opa4339-99.htm.

250. COMMODITY FUTURES TRADING COMMISSION, A NEW REGULATORY FRAMEWORK: REPORT OF THE COMMODITY FUTURES COMMISSION STAFF TASK FORCE (2000) [hereinafter NEW FRAMEWORK], *available at* http://www.cftc.gov/files/opa/oparegulatoryframework.pdf.

251. The principles-based approach to regulation was made popular by, and became associated with, the United Kingdom's Financial Services Authority ("FSA"). In the decade before the crisis, the FSA was widely praised as a "risk-based" and "principles-based" regulator that built a more business-friendly regulatory environment, which attracted more financial institutions and transactions to London. *See* Markham, *supra* note 236, at 544–47 (describing the prevailing attitudes toward the FSA's principles-based regulatory approach before and after the crisis).

252. NEW FRAMEWORK, *supra* note 250, at 14.

253. Commodity Futures Modernization Act of 2000, H.R. 5660, 106th Cong. (2d Sess. 2000). The CFMA created several tiers of contract markets, subject to different levels of regulatory oversight. In addition to fully regulated "designated contract markets" ("DCMs"), the statute created a new category of a "derivatives trade execution facility" ("DTEF") that was subject to less stringent regulation. 7 U.S.C. § 7a (2000). Finally, certain markets could qualify as "exempt boards of trade" subject only to the anti-fraud and anti-manipulation provisions of the CEA. 7 U.S.C. § 7a-3(a) (2000).

254. 7 U.S.C. § 7a-2(c)(1).

255. 7 U.S.C. § 7a-2(c)(2)(A). Curiously, Rainer submitted his resignation from the post of the CFTC Chairman on December 20, 2000, only five days after Congress passed the CFMA, in order to return to private industry. *See* Press Release, Commodity Futures Trading Comm'n, CFTC Chairman

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These fundamental changes in the market profile, dynamics, and the regulatory framework put the traditional notion of commercial utility of futures contracts under an increasing strain. Nevertheless, even the post-CFMA futures regulation retained a strong built-in anti-speculative tendency. Thus, under the CFMA, regulated exchanges do not have to get separate designation for each futures contract, but must comply with the applicable core principles.[256] One such core principle requires an exchange to list "only contracts that are not readily susceptible to manipulation."[257] Potential for market manipulation is particularly high where a futures instrument is designed primarily as an instrument of speculative investment. The revised Guideline No. 1, which provided guidance to exchanges seeking voluntary pre-approval of their contracts, retained the same basic requirements with respect to showing the economic function of the proposed contracts as a hedging or pricing mechanism for the underlying commodity markets.[258] In addition, the CFMA retained the requirement that exchanges establish position limits for speculators in order to "reduce the potential threat of market manipulation or congestion."[259] Thus, even the greatly financialized, globalized, and liberalized futures markets, which are very different from the futures markets of the 1920s, cannot entirely extricate themselves from the underlying cash markets and the policy goal of preventing potential harm to such markets from excessive financial speculation.[260]

D. Learning from Experience: Politics, Precaution, and Efficiency

Despite their many differences, the experiences of the FDA, REACH, and the CFTC allow us to draw some potentially relevant generalizations. One important insight is the central role of interest group dynamics and political factors in determining how robust and successful the product approval regime is in practice. One of the most bitterly contested issues is

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William J. Rainer Resigns (Dec. 20, 2000), *available at* http://www.cftc.gov/opa/press00/opa4480-00.htm. While it is difficult to draw definitive conclusions, the changes that took place during Rainer's tenure at the CFTC and the timing of his resignation suggest that his mission at the agency was to accomplish a comprehensive deregulatory reform.

256. 7 U.S.C. § 7(d).

257. 7 U.S.C. § 7(d)(3).

258. *See supra* notes 232–35 and accompanying text.

259. 7 U.S.C. § 7(d)(5).

260. The Dodd-Frank Act significantly amended the CEA, primarily to reflect the new clearing and trading requirements applicable to certain standardized derivatives. *See* Dodd-Frank Act, Title VII, Pub. L. No. 111-203, 124 Stat. 1955 (codified in scattered sections of 7 and 15 U.S.C.). However, an analysis of these amendments is beyond the scope of this Article.

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the length of the approval process, as the industry actors protest the delay in their product marketing. In the futures industry, the exchanges successfully argued that the CFTC's contract designation process hurt their ability to compete with OTC derivatives and foreign futures markets. Their political lobbying has finally led to the elimination of the mandatory contract designation requirement. Similarly, pharmaceutical companies fight against what they see as unreasonable delays in approving new drugs by the overly cautious FDA. On the other hand, the EC's ability to introduce an ambitious program that mandates massive and costly testing for all existing high-volume chemicals, despite the industry's resistance, exemplifies the power of a political commitment to making the world safer for human beings and their environment. The industry's complaints about the exorbitant costs, while certainly affecting how the REACH program operates, failed to stop the EU authorities from enacting the regulation.

In all of these cases, the industry groups' political lobbying was particularly successful when they invoked a sufficiently strong countervailing public interest. Thus, pharmaceutical firms were able to shift power away from the FDA only when they mobilized patient advocacy groups to push for faster approval of certain drugs by the FDA, in the interests of patients who could potentially benefit from those drugs. Similarly, in the late 1990s, commodity futures exchanges made global competitiveness and efficiency of U.S. financial markets their battle cry in the struggle for repeal of the mandatory contract designation requirements. These legitimate public interest arguments provided a normative alternative to the policies underlying the statutory product approval schemes.

Yet, the FDA drug approval regime remains beyond a serious threat of abolition, despite the increasing pressure from pharmaceutical firms and patient advocates to change the agency's practices. Although REACH is still in the early stages of implementation, there is hardly any doubt that it is going forward. By contrast, the CFTC's mandatory contract designation was dismantled under industry pressure and without much public attention. The substance of the underlying policy goals may explain, at least partly, the difference in their relative viability.[261] Thus, both REACH and the FDA's system of new drug approval serve the purpose that is difficult to contest politically: protection of human life and health. These

261. There may also be important differences in the regulatory capacity and culture of these different agencies, the structural context in which these agencies operate, and a variety of other factors that affect their respective ability to enforce statutory requirements in practice. These issues, however, are not directly relevant for the purposes of the present discussion.

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regulatory regimes embody, with some variations, the model of explicitly precautionary risk regulation. The CFTC's contract designation scheme was aimed primarily at preventing excessive speculation that increased chances of market manipulation. That policy priority, however, is highly contestable and vulnerable to competing visions of "public good" advanced by the financial services industry. To the extent the CFTC's product approval scheme was conceptualized primarily as a matter of market efficiency, it had a much weaker normative basis to support its continuation as a socially desirable precautionary measure, especially in the face of concerted private efforts to deregulate.

It is reasonable to conclude that one of the critical factors in designing any product approval regime is a clear articulation and justification of policy priorities that such regime seeks to implement. It is, however, a complicated task that involves potentially difficult political choices. This is particularly true to the extent a proposed product approval scheme is structured similarly to the CFTC's pre-2000 model. Given the high degree of contestability of policy priorities in financial services regulation, it is critical to assert clearly the normative basis on which the proposed product approval system would operate and to address explicitly the competing public and private interests. Reflecting key lessons of the recent crisis, this new normative paradigm should explicitly incorporate both the principle of precautionary risk regulation and the goal of enhancing economic and market efficiency and utility by reducing excessive speculation and arbitrage. An unequivocal statement of these overriding policy priorities may not eliminate political opposition to the proposal entirely, but may enhance the regulatory regime's ability to withstand it in the long run.

Of course, it is easy to overdraw the parallels between these three models of product approval regulation and an idea of instituting a licensing regime for complex financial products. Significant differences in the nature of the regulated activity, the structure of the regulated industry, and the dynamics between private market participants and government regulators limit our ability to emulate unique features of any particular regime in a different regulatory realm. For instance, one of the central elements of both the FDA regime and REACH program is the requirement of pre-market testing of drugs and chemicals. In both cases, companies must produce scientific data to demonstrate that their products do not pose unacceptable risks. Although the validity of specific scientific claims is often uncertain and disputed, as a general matter, regulatory decisions to grant or deny market entry fundamentally rest on an objective experimental basis. In the area of financial services regulation, experimental testing is generally not feasible and mathematical modeling

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is not fully reliable as the basis for decision-making. Even the CFTC's experience with mandatory approval of futures may not be directly applicable to the broader universe of financial products. Futures contracts were created and submitted for approval by a small number of futures exchanges, self-regulatory organizations whose interests were more clearly aligned with the public interest in protecting market integrity. Dealing with a far greater number of diverse private firms whose interests are not so aligned may fundamentally alter the regulatory dynamics and introduce a different set of challenges.

Finally, it is important to remember that none of the three models of product licensing examined above directly targeted systemic risk as the main object of regulation. Devising a regime of financial product approval, which explicitly seeks to minimize systemic risk posed by private economic activities, is a uniquely challenging task. Nevertheless, even though none of these three regulatory schemes is a perfect analogy, understanding their basic features is helpful in framing the discussion of whether—and, more importantly, *how*—a product approval regime can work in the financial services sector.

III. MANDATORY APPROVAL OF COMPLEX FINANCIAL PRODUCTS: CONSIDERING THE POSSIBILITIES

This Part examines the potential structure and process of approval regulation for complex financial products. It does not purport to present a complete prescription for immediate action. Rather, it is an intellectual experiment, an attempt to push the boundaries of what is conceivable and start outlining the basic contours of a new *ex ante* regulatory approach to controlling systemic risk.

A product approval regime envisioned here targets one of the core causes of systemic risk in the financial services sector: *strategic complexity* introduced into the system by financial intermediaries primarily for the purposes of extracting higher rents and enabling excessive speculation and regulatory arbitrage.[262] This Part discusses key elements of a statutory scheme establishing such a regime, and identifies potential problems with designing and implementing it in practice. Despite the remaining open questions and feasibility challenges, the proposed system of mandatory pre-approval for complex financial products may serve as an effective gatekeeping device that limits socially useless

262. *See supra* notes 32–36 and accompanying text.

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financial engineering and offers a potentially powerful new solution to the seemingly intractable problem of systemic risk regulation.

A. Licensing of Complex Financial Products: Could It Work?

It is difficult to articulate in full all of the important details of a new regulatory mechanism for pre-approval of complex financial products. Many instruments and transactions that would be subject to this regime are currently regulated under different schemes, and some may not be regulated in a meaningful way at all. Many instruments cross the functional lines among various economic and regulatory categories of products, which further complicates the task of formulating clear definitions. Today's financial markets bring together a variety of participants that often pursue complex trading and investment strategies blurring the boundaries among issuers and investors, lenders and borrowers, market-makers and end-users. Finally, as a result of the enactment and ongoing implementation of the Dodd-Frank Act, the entire regulatory structure is currently in a state of flux, as the new and old agencies are trying to map out their new responsibilities and substantive rules.[263]

In this context, designing a workable system of product approval regulation presents substantial challenges. As the first step toward that goal, this section outlines the key elements of such a system and, to the extent precise definitions are hard to formulate, attempts to sketch out some basic principles for approaching that task. Inevitably, this is more of an exercise in creative thinking than a detailed legislative proposal.

1. Purposes and Criteria of Product Approval

The overarching policy objective of the proposed product approval regime should be to control the proliferation of complex financial products that potentially pose heightened systemic risk. As a corollary to that policy, the new regulatory regime should explicitly aim at preventing excessive speculation and reducing regulatory arbitrage in the financial sector. It is critical that the enabling statute clearly establishes that, in the

263. While it may be possible to build a financial product approval scheme into the emerging post-Dodd-Frank regulatory structure, doing so may create internal inconsistencies and redundancies and potentially compromise the integrity of the proposed regime. Fundamentally, the proposal advanced here is an alternative, rather than a supplement, to the Dodd-Frank Act. Therefore, the following discussion assumes that Congress will have to pass a new statute establishing the proposed product approval scheme and mandating the necessary changes to the broader regulatory framework.

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absence of compelling policy reasons to do otherwise, these goals take precedence over any considerations based on the economic interests of private market participants.[264]

This is a different set of objectives than ensuring the safety of financial products for their users or consumers, as proposed by Stiglitz, Carpenter, Bar-Gill, and Warren.[265] One of the criticisms of their proposals was the inherent difficulty of defining the concept of "safety," especially given its relative nature. Thus, a certain level of risk associated with a product may be "unsafe" for one category of consumers but "safe" for another, depending on their financial sophistication and resources. One potential solution is to mandate full disclosure warning prospective consumers of a product's risks, but allow so-called "off-label" use.[266] This solution, however, may undermine the integrity of the safety oriented product approval regime by allowing potentially unsafe products to enter the market. In the financial market, this could cause potentially irreversible damage to systemic stability. Framing the policy goals of the mandatory financial product licensing regime in terms of systemic risk associated with strategic complexity, financial speculation, and arbitrage removes this problem of differentiating among target users of a financial instrument. Because the regime proposed here focuses explicitly on protection of the legitimate public interest in reducing systemic risk, it should deflect criticisms of excessively "paternalistic" government interference with individual market participants' choices.[267]

The key objective of the product licensing review should be to evaluate each complex financial product from *functional*, *institutional*, and *policy* perspectives. Regulatory approval should be granted only if the application meets a three-part statutory standard: (1) an "economic purpose" test, which would place the burden of proving the commercial and social utility of each proposed financial instrument on the financial institutions seeking approval; (2) an "institutional capacity" test, which would require a review of the applicant firm's ability to monitor and

264. Arguments based on "market efficiency" are often employed to promote private industry actors' profit-enhancing interests. Economic or market efficiency is a normative concept, despite its deliberately cultivated appearance of political neutrality and scientific objectivity: it reflects and presumes certain configurations of economic and political power as the "natural" state of market. For an insightful discussion of this issue, see SUNSTEIN, *supra* note 70.

265. *See supra* Part I.C.

266. *See* Carpenter, *supra* note 108.

267. To the extent the government seeks to protect a generalized public interest that private parties are not in a position to protect, the government is inherently "paternalistic." Legal and regulatory mandates routinely override individual preferences for various public policy reasons.

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manage the risks of the proposed product effectively; and (3) a "systemic effects" test, which would require a finding that approval of the proposed product does not pose an unacceptable risk of increasing systemic vulnerability and does not raise significant public policy concerns.

a. The "Economic Purpose" Test

First, the applying financial institution would have to make an affirmative showing that the proposed complex financial instrument has a bona fide economic purpose that promotes productive enterprise and does not merely provide another means of financial speculation or regulatory arbitrage. The goal of the product approval regime is to discourage financial institutions from creating and marketing complex financial instruments, where the benefits of such complexity for the economy and broader society do not outweigh potential increases in systemic risk. Thus, this test specifically targets *strategic* complexity that enables market actors to avoid regulatory constraints, hide the true extent of their leverage, and engage in financial speculation.

The main conceptual difficulty here is defining precisely what constitutes an impermissibly "speculative" investment. Speculation is often an elusive concept.[268] Because of the inherent uncertainty of future returns on any financial investment, all investing activity may be viewed as a form of speculation.[269] At the same time, it is hard to deny a common intuition that some forms of speculative investment are fundamentally different from traditional investing, not only in terms of their economic motivation, but also in moral terms.[270] While this definitional difficulty is a legitimate theoretical concern, it is not necessary to provide a statutory definition of speculation to establish an effective product approval regime.

268. *See* Stout, *supra* note 240, at 735. *See also* Timothy Lynch, *Gambling by Another Name? The Challenge of Purely Speculative Derivatives* (Ind. Univ. Maurer School of Law-Bloomington Legal Research Paper No. 188, 2010), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1788219&rec=1&srcabs=1785634.

269. The basic distinction between "speculation" and "hedging" as the key categories of potential uses of complex financial products, such as derivatives, may be used to draw the line between permissible and impermissible transactions. *See* Posner & Weyl, *supra* note 9, at 13–15 (discussing how the regulator would estimate and balance potential hedging and speculative market demand for a product). This approach, however, tends to over-simplify the relationship between these two categories. For instance, what should be done with a product that is as a bona fide hedge for an underlying speculative position? It may not be readily ascertainable that a specific position that is being hedged is a speculative one. Moreover, there may be a long chain of intermediate "hedging" transactions that ultimately build up to a highly speculative bet.

270. Stout, *supra* note 240; Hazen, *supra* note 195.

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Instead, the goal should be to outline the key factors which the regulator would have to analyze as part of the product review.

To meet the economic purpose test, an applicant firm will have to: (1) identify the intended market for the proposed financial product and describe potential users of the product; (2) show that the product will fulfill a specific business need of potential "product users," which existing financial products fail to fulfill; and (3) demonstrate that this legitimate business need significantly outweighs any potential uses of the product for speculative investment or regulatory arbitrage as the core motivation for the product user (or the applicant firm) to enter into the proposed transaction.[271]

Who the intended users are is an important element of the inquiry, as it is closely tied to the determination of the core economic function of the proposed financial product. As a general rule, financial instruments designed either to allow for hedging of pre-existing risk incurred by the user in the course of its ordinary business or to otherwise enhance the user's ability to conduct productive economic activity would pass the economic purpose test.[272] However, it may be necessary to create a rebuttable presumption against approving financial products whose identified prospective users include only financial institutions that ordinarily engage in financial risk management and transfer as part of their core business—banks and their affiliates, securities or insurance firm, and hedge funds or other private investment vehicles. The applicant firm can overcome this presumption by showing that, for example, the proposed financial instrument would enable a financial intermediary to hedge a specific financial risk arising directly out of its core business: providing capital to productive economic enterprise.[273]

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271. The statutory burden of meeting this test will operate to reduce socially useless financial innovation driven primarily by supply-side incentives of financial intermediaries. *See* Awrey, *supra* note 4.

272. Hedging pre-existing risk is a core economic function of derivatives instruments. *See, e.g.*, Krawiec, *supra* note 16; Romano, *supra* note 16. Loan securitization is an example of a financial transaction that enhances the originating banks' ability to remove loans from their balance sheets and free up more funds for increased lending to businesses and individuals, presumably for use in productive economic activity. To the extent a particular securitization transaction serves to achieve that goal, it has a valid economic purpose.

273. Importantly, the application would have to specify that, whenever used for hedging purposes, the proposed product is structured as a direct hedge narrowly tailored to a specific risk and does not create any additional risks likely to be speculative in nature. *See, e.g.*, Lynch, *supra* note 268. It is also important to consider whether the dealer-to-dealer hedging of large portfolio risks should be subject to additional restrictions and conditions. There may be a legitimate policy reason to discourage such dealer-to-dealer hedging as significantly increasing systemic interconnectedness, complexity, and opacity. *See supra* Part I.A. There may be a strong argument for forcing dealers in complex financial

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It is important that the application describes the target market for the product and the intended economic purpose of the product with sufficient specificity.[274] For instance, it would not be enough to describe the intended users of the proposed product in generic terms as "long-term investors searching for yield." Similarly, a claim that the proposed instrument would allow financial institutions to broaden their client base, get higher trading returns, or receive higher fees would not be enough of an economic purpose to justify approval. Vague claims to the effect that the product would improve these actors'—or their clients'—ability to manage risk in their existing portfolio would not be a sufficient basis for approval. The key is a reasonably specific and direct link to some productive economic activity that exists outside the confines of financial markets.[275]

Ultimately, the economic purpose standard is a "facts and circumstances" test.[276] While it is difficult to give a clean theoretical definition of what types of products should not be approved as lacking a bona fide economic purpose, in reality, it is often not so difficult to see what is going on. For example, if a transaction between a hedge fund and a dealer-bank is structured as a total return swap tied to performance of a basket of equity stock, the dealer-bank applying for approval of that transaction will have to explain what the economic substance of that swap is, and why it is necessary for the hedge fund to enter into that swap instead of borrowing money from a bank and investing it in the underlying stock directly. The only real explanation for such a transaction is likely to

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instruments to manage their risks primarily through reducing their leverage, holding more capital and liquid reserves, demanding more and better collateral, and instituting more conservative counterparty and other risk management procedures.

274. Financial institutions may also be required to provide good-faith estimates of the volume of transactions they expect to conduct. If the actual volume exceeds the original estimates, the institution would have to request additional approval for the excess deal flow.

275. It may be desirable to create an explicit presumption against financial instruments where the rights to payments are separated from the ultimate underlying assets by a series of intermediate instruments. Examples of such multi-layered complex financial instruments are so-called CDO^2 and CDO^3 that invest in pools of interests in other CDOs. *See Re-securitizing CDOs*, RISK.NET (Aug. 1, 2004), http://www.risk.net/credit/feature/1522744/re-securitising-cdos (discussing various types of re-securitizations). This approach would effectively prohibit multi-layered securitizations, which greatly contributed to the latest financial crisis. *See* TURNER REVIEW, *supra* note 11, at 15–16 (discussing the role of securitized credit in increasing systemic risk).

276. In that sense, the "economic purpose" test envisioned here differs from the simple quantitative market analysis of "social utility" proposed by Posner and Weyl. *Cf.* Posner & Weyl, *supra* note 9, at 13–15. As most model-based quantitative tests, their approach appears elegantly simple and purports to offer a degree of certainty inherently lacking in a context-sensitive "facts and circumstances" analysis. Yet, as most judges, regulators, and practicing lawyers would attest, achieving the "right" practical result in a complex situation often involves working through the messy pile of individual facts and circumstances.

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be some form of regulatory arbitrage and the hedge fund's search for higher leverage to boost profits from betting on stock prices. Unless the applicant is able to convince the regulator that (1) the proposed swap would produce tangible economic benefits (other than generating profits for the counterparties) or directly contribute to some productive economic activity, and (2) such socially desirable effects are significant enough to overcome the statutory presumption against complexity driven by speculation and arbitrage, that total return swap would not pass the economic purpose test.

The firms will have to monitor on an ongoing basis the markets for their approved products and report any significant changes in the market composition and uses of the relevant products, as these changes may alter considerations on which the original approval grant was based.[277] By tying regulatory approval not only to a broad category of transactions—such as swaps, equity options, or mortgage-backed securities—but also to specific target uses and target users, the proposed regime will ensure continuous generation and collection of valuable information on important market trends.[278] This would potentially enable the regulators to monitor these trends more effectively, so that they are more likely to react in a timely manner when familiar financial instruments start morphing into something different in terms of their functions and risk profile.[279]

It is difficult to overestimate the information-producing potential of the proposed product approval regime. It would effectively require financial institutions to provide complete quantitative and qualitative disclosure and analysis of their activities as dealers and market-makers in complex financial products. That alone would provide the regulators with meaningful access to internal business and market information that is currently unavailable to them. This burden-shifting mechanism would go a

277. This is an important element of the proposed regime, insofar as it would help to detect significant post-approval changes in the risk profile of the existing financial products as a result of financial innovation and regulatory arbitrage. For an insightful analysis of this phenomenon in the context of securitization, see Adam J. Levitin et al., *The Dodd-Frank Act and Housing Finance: Can It Restore Private Risk Capital to the Securitization Market?*, 29 YALE J. ON REG. 155 (2012) (arguing that the informational opacity in securitization markets was the key cause of the housing market collapse); *See also* Levitin & Wachter, *supra* note 35 (arguing that the recent U.S. housing bubble was a result of the fundamental shift in the mortgage finance market from regulated to unregulated, private-label securitization).

278. In many respects, this feature of the regime would make it similar to the FDA's post-approval market monitoring and continuing generation of empirical data on safety and efficacy of new drugs. *See supra* notes 147–48 and accompanying text.

279. The transformation of traditional residential mortgages and relatively straightforward mortgage-backed securitizations into a complex form of financial speculation provides an example of such dynamics. *See supra* note 277.

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long way toward correcting both the informational asymmetries between the regulators and the industry and the existing incentive structure that encourages socially harmful risk-taking by financial market actors. In effect, the proposed approach would reformulate the currently dysfunctional concept of cost-benefit analysis of financial services *regulation* as a more risk-based and socially conscious cost-benefit analysis of financial *services*.[280] Importantly, it would also allocate the duty to produce information necessary to conduct such analysis on the party that has full access to such information.

The proposed regime, however, goes far beyond mere information gathering.[281] By putting the economic purpose test at the center of the approval process, the scheme envisioned here builds upon the traditional pre-2000 CEA approach that recognized the heightened potential of derivative contracts to be used for speculative purposes. The present proposal takes that approach to a different level, reflecting the overarching policy goal of reducing strategic complexity and systemic risk in financial markets.

b. The "Institutional Capacity" Test

The second part of the statutory standard would require the applicant to demonstrate its internal organizational, operational, and financial capacity

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280. In 1981, President Reagan issued an Executive Order requiring administrative agencies to submit to the Office of Management and Budget (OMB) and the Office of Information and Regulatory Affairs (OIRA) complete regulatory plans and cost-benefit analyses for all of their "major rules." *See* Steven Croley, *White House Review of Agency Rulemaking: An Empirical Investigation*, 70 U. CHI. L. REV. 821, 824–26 (2003) (outlining the history and impact of Executive Orders 12291 and 12498 on OMB). All regulatory agencies other than those specifically exempted under the Paperwork Reduction Act, Pub. L. No. 96-511, 94 Stat. 2812 (1980) (codified at 44 U.S.C. §§ 3501–3520), are required to submit to OIRA drafts of their proposed rules that constitute "significant" regulatory action (generally, rules that have an expected annual effect on the economy of $100 million or more) for review. *See* Croley, *supra*, at 825. This mandatory cost-benefit analysis of regulatory actions tends to overstate the more easily quantifiable "costs" to private market actors and understate the far more diffuse and often unquantifiable "benefits" to the public. *See, e.g.*, Nicholas Bagley & Richard L. Revesz, *Centralized Oversight of the Regulatory State*, 106 COLUM. L. REV. 1260 (2006) (criticizing the deregulatory impact of cost-benefit review of agency rules by OIRA); Daniel A. Farber, *Rethinking the Role of Cost-Benefit Analysis*, 76 U. CHI. L. REV. 1355 (2009) (discussing the drawbacks of cost-benefit analysis for environmental regulation). Moreover, there is evidence that the financial services industry is using the mandatory cost-benefit analysis of agency rules as a procedural tool to slow down the implementation of the Dodd-Frank Act. *See, e.g.*, Silla Brush, *U.S. Regulators Paralyzed by Cost-Benefit Suits, Chilton Says*, BLOOMBERG (Mar. 8, 2012), http://www.bloomberg.com/news/2012-03-08/u-s-regulators-paralyzed-by-cost-benefit-suits-chilton-says.html (quoting a CFTC member, Bart Chilton, as stating that the CFTC is battling the financial industry's lawsuits challenging the agency's new rules on speculation limits as inadequately supported by cost-benefit analysis).

281. For a discussion of potential benefits and disadvantages of the purely informational pre-screening of financial products, see *infra* Part III.B.4.

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to monitor and manage risks associated with the proposed product. This requirement is similar to the CFTC's review of exchanges' internal capacity to support markets for a new futures contract.[282]

Again, this part of the test ties regulatory approval to the specific context in which a particular product would be used. Thus, even if the proposed financial product may have proven economic and social utility, as a general matter, it may not be appropriate for a particular financial institution that fails to prove its ability to understand, identify, measure, monitor, and manage potential risks the product poses to the institution's own financial health, as well as to the financial well-being of the product's users and overall market stability.

To meet this test, the applicant would have to satisfy certain capital adequacy or similar requirements limiting an entity's ability to incur leverage. In addition to meeting the applicable overall regulatory capital requirements, regulators may require a higher capital buffer to support the specific proposed financial transaction and related market activities. It is important, however, not to overestimate the regulatory capital measures as effective indicators of a firm's financial soundness. Additional factors to be considered may include (1) the firm's overall business and risk profile, (2) the relationship between the proposed activity and the rest of the firm's business and resources (including human and technological resources), (3) internal systems of risk management and regulatory compliance, and (4) regulatory and compliance record and history of enforcement against the firm or its affiliated entities. It is important to review and evaluate whether the firm has effective and thoughtful risk management policies and procedures in place, designed specifically for the proposed financial product or activity.

An important consideration in this respect is the actual or potential conflict of interest a particular financial institution may face in connection with the proposed activity. The inquiry at this point should not be limited only to the firm's general ability to handle the economic demands of dealing in the specific product. It is also necessary to assess how the proposed activity may alter the firm's economic incentives and overall business strategy, and whether or not that change potentially poses reputational risks to the firm or raises significant concerns about broader market integrity.[283] To put it simply, the key question has to be, "Do we want this particular institution to trade and deal in this particular product?"

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282. *See supra* note 225 and accompanying text.

283. One example highlighting the importance of assessing this type of risk both to the firm's reputation and to the broader market integrity is Goldman Sachs' infamous "Big Short" strategy in

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This institutional test would also involve assessing the extent to which the proposed activity is likely to increase the size or systemic significance of an applicant firm so that it becomes "too big to fail" ("TBTF") or "too interconnected to fail" ("TITF"). While a product approval mechanism alone is not likely to solve the TBTF/TITF problem, it may help to control it by limiting financial intermediaries' ability to expand trading volumes and create additional linkages and channels of contagion in the financial markets.[284]

c. The "Systemic Effects" Test

Finally, in order to get regulatory approval for its new complex financial product, the applicant firm will have to demonstrate that such a product does not pose potentially unacceptable systemic risk or is otherwise likely to increase the vulnerability of the financial system. This broadly stated requirement aims to give the regulator statutory authority to consider a wide variety of potentially relevant factors—and public policy considerations—that may not be directly included in the description of the product or the immediate market needs.

For instance, this part of the statutory test would operate to prevent transactions like the infamous ABACUS 2007 AC-1 deal, whereby Goldman Sachs structured and marketed a synthetic collateralized debt obligation ("CDO")[285] referencing a pool of U.S. subprime residential mortgage-backed securities. The CDO was structured specifically to enable Paulson & Co., one of the world's largest hedge funds and Goldman Sachs' client, to take a large short position against subprime mortgage-backed securities, which allowed the fund to collect significant profits from the collapse of the U.S. housing market.[286] If Goldman Sachs

early 2007. One of the major CDO originators, Goldman Sachs accumulated a large short position in the mortgage-backed assets it was aggressively securitizing and marketing at the same time. *See* THE LEVIN REPORT, *supra* note 11, at 376–636.

284. It may be desirable to subject TBTF institutions to stricter scrutiny in the product approval process, with the goal of discouraging them from engaging in socially useless financial innovation. Thus, these large and sophisticated firms would have to meet a higher standard of proof with respect to their institutional capacity to manage the entire spectrum of risks in connection with the proposed activity.

285. A synthetic CDO references a pool of assets that consists of credit default swaps (CDS) instead of actual loans or securities. *See* Michael S. Gibson, *Understanding the Risk of Synthetic CDOs* (July 2004), *available at* http://www.federalreserve.gov/pubs/feds/2004/200436/200436pap.pdf.

286. In April 2010, the SEC brought a lawsuit against Goldman Sachs, accusing the firm of intentionally misleading investors about the true risk profile of the ABACUS CDO and Paulson's direct involvement in the selection of the reference assets in the CDO. Press Release, U.S. Sec. & Exch. Comm'n, Goldman Sachs to Pay Record $ 550 Million to Settle SEC Charges Related to

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had to disclose the details of this transaction in order to receive a prior regulatory approval, as proposed in this Article, it would have faced significant difficulties in meeting both the economic purpose and the systemic effects tests. Even if such a CDO was structured not for Paulson's hedge fund but for commercial companies seeking to hedge their bona fide business exposure to residential housing prices (such as construction companies or real estate developers), the potentially destabilizing effect of this transaction on the U.S. housing market would have allowed the regulator to block the deal from going forward.[287]

This test would explicitly bring in broader public policy considerations that the proposed new product potentially implicates. Many existing statutes mandate that financial regulators exercise their discretion only if doing so is in the public interest. This part of the product approval process is designed to allow for this type of deliberation, where the applicant firm bears the burden of proving that the financial instrument it seeks to market is not likely to have a negative impact on broader socioeconomic policies and political goals.[288]

2. Scope and Structure

Designing a system of mandatory product approval for complex financial instruments raises fundamental structural questions. Which financial products and transactions should be subject to the approval regime? Who should be required to apply for regulatory approval of a

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Subprime Mortgage CDO (July 15, 2010), *available at* http://www.sec.gov/news/press/2010/2010-123.htm. In July 2010, Goldman Sachs settled the SEC's charges and agreed to pay $550 million and reform its business practices. *Id.*

287. The existing legal theories and concepts, such as investor protection or fiduciary duty, did not fully capture what was "wrong" with Goldman Sachs' conduct in structuring the ABACUS deal. The proposed product approval scheme offers a potential alternative to using these and other traditional concepts in corporate and securities laws to fit more complex situations.

288. A quintessential example of a financial product banned on public policy grounds are terrorism futures, conceived in 2003 by Pentagon as a market-based predictor of the level of risk posed by terrorist attacks. Justin Wolfers & Eric Zitzewitz, *The Furor Over 'Terrorism Futures,'* WASH. POST, July 31, 2003, at A19. As the proponents of this product explained,

> The idea was simple: By creating a market in which people can buy and sell contracts that pay $100 if certain political events occur in the Middle East, we can infer from the price of such securities the probability of these outcomes. By explicitly pricing such risks, we can better understand them and better respond to them.

Id. Despite this rhetoric, Congress discarded this idea on public policy grounds. In July 2011, the CFTC adopted a rule pursuant to section 745 of the Dodd-Frank Act prohibiting the listing and trading of contracts referencing "terrorism, assassination, war, gaming, or an activity that is unlawful under any State or Federal law." 17 C.F.R. § 40.11(a)(1) (2011).

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specific product? Finally, who should be in charge of administering the approval scheme?

a. "Covered Products"

Defining what exactly qualifies as a "complex financial product" is perhaps the single most challenging task in designing an approval regime. On the one hand, there is a danger of creating an over-inclusive definition that may have a chilling effect on products with relatively low potential for causing systemic disruptions or increasing strategic complexity. On the other hand, by stressing specific product characteristics, this definition may be dangerously under-inclusive. Ultimately, developing a full set of detailed legal definitions is a task for lawmakers drafting new legislation and regulatory agencies implementing it. The following discussion aims only to sketch out possible approaches to that problem.

As the basis for developing a statutory definition, it is possible to start with a group of "Covered Products" that includes: (1) derivative instruments and structured products;[289] (2) asset-backed securities and structures set up to issue such securities; and (3) any other financial transaction or instrument that, alone or in combination with other financial transactions or instruments, is determined by the regulator to constitute a "complex financial product" subject to mandatory approval.[290] An alternative approach may be to define Covered Product broadly as any financial instrument or transaction and provide exceptions from that all-inclusive category for (1) certain traditional deposit, credit, and investment products;[291] and (2) any other financial instrument or transaction that the

289. There is no single legal definition of a "structured product." The term is generally used to refer to a financial instrument with payoff "structured" to reflect specific risk exposure. A typical example is a debt security with a derivative component.

290. This catch-all category is designed to provide the regulator with the necessary flexibility to extend approval requirements to new types of complex financial products that may emerge in the future.

291. The statute may define each of these traditional financial products by enumerating specific criteria, using various existing legal definitions in banking and securities laws as a starting point. The key criteria, however, should be the absence of any derivative component, so that the value of the instrument and the payment rights and obligations are calculated on a simple basis and not by reference to the value of any other asset. Thus, a deposit account that pays interest at a specified fixed rate or a variable rate linked to certain commonly used benchmark interest rates would qualify as a "Traditional Deposit Product." By contrast, a certificate of deposit with interest payments linked to the performance of a broad-based stock index would not constitute a Traditional Deposit Product and would be subject to pre-approval, unless exempted by regulation. Similarly, shares of common or preferred stock, where the return on such shares is not "structured" to create a specific risk/return profile, would qualify as a "Traditional Investment Product," whereas an asset-backed security would not fall in that category.

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regulators may exempt by regulation.[292]

Another problem is how to define what constitutes a "product" that requires a separate regulatory approval. A financial institution cannot apply for a blanket pre-approval of all "swaps" or "equity swaps" and proceed to structure and market a wide variety of such instruments with different risk profiles. Thus, one of the critical tasks in designing the new regulatory regime is to develop a set of criteria for determining when a particular instrument has sufficiently unique features to make it a separate "product." As a first approximation, that list of factors should include key terms related to payment and other significant rights and obligations of the parties to the transaction, the nature of reference assets, and the intended uses for the instrument and target markets. To the extent any new version of a previously approved Covered Product contains a significant change in any of these terms, the financial institution planning to market it would have to make a written determination whether the changes alter the Covered Product's key features or overall risk profile significantly enough so as to require a separate regulatory approval.[293]

Finding a workable solution to these definitional problems—where and how exactly to draw the lines between separate "products" and which of those products should be subject to mandatory licensing—may be the key to the viability of the proposed scheme. Among other things, it would determine the volume of deals to be reviewed and approved by the regulator under the new regime. It is difficult to estimate the exact numbers at this point. However, given the size and diversity of today's financial markets, it is likely that regulators may be overwhelmed by the volume of products subject to the new licensing requirements.[294]

It may be worth considering a specific exemption from mandatory pre-approval for Covered Products actively traded on registered and regulated exchanges that meet certain criteria. Such an exemption would make the implementation of the statutory scheme more manageable by carving out a

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292. Regulatory discretion to exempt certain financial instruments from the requirement of mandatory pre-approval is necessary to ensure the flexibility and adaptability of the regulatory regime in the dynamic market environment. Regulators' discretion, however, must be subject to certain conditions, both substantive and procedural. Thus, it is important that the regulators do not have the authority to grant exemptions by individual order or through informal interpretation.

293. If several previously approved Covered Products are used in a complex trading or investment strategy, that strategy itself may require separate approval as a new Covered Product.

294. This is one of the key differences between the proposed model and the CFTC's pre-CFMA contract designation scheme. The average volumes of futures that the CFTC had to review and approve were relatively low. For example, in December 1997, Brooksley Born stated that, since the spring of that year, exchanges submitted fifteen new contracts for the CFTC's approval. Brooksley Born, *Derivatives and Risk Management: Keynote Address*, 66 FORDHAM L. REV. 761, 763 (1997).

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broad universe of financial products, including standardized exchange-traded derivatives, with deep and liquid markets. To limit the potential risk of creating a dangerous loophole, however, it is important to tailor an exemption for such publicly traded Covered Products in a way that balances various policy considerations.

The EU's experience with REACH offers valuable insight into designing a regulatory regime capable of managing a high volume of products. REACH calibrates regulation of different categories of chemicals depending on their volume and toxicity. Low-volume, low-risk substances are generally subject only to registration requirements, while potentially high-risk chemicals are subject to pre-market approval and even product bans. It may be desirable to apply a similar "tiered" approach to licensing complex financial products. For instance, one way to differentiate among various products is to look at the firms' projections of the monetary value and volume of deals. If the firm expects to deal and trade in a particular Covered Product in the aggregate amount exceeding a certain threshold, it would have to undergo the full approval process and satisfy all three statutory tests. In all other cases, the proposed Covered Product would be exempt from pre-approval requirements.[295] One potential concern with this approach is that it may be easy to evade regulation by breaking up big deals into separate transactions to fly under the regulatory radar.

An alternative approach may be to create different tiers within the system depending on the characteristics of the financial institution, rather than the product it intends to market. Thus, all systemically important financial institutions ("SIFIs") would be subject to the most stringent form of the product approval regime, which would require them to obtain a license for all of their Covered Products. Because many SIFIs are likely to be considered TBTF, it may also be desirable to heighten the scrutiny of their products.[296] Smaller, less diversified financial institutions that are less likely to be systemically significant may be subject to less stringent product approval requirements. This approach also raises significant concerns, especially because it is often difficult to identify which entities are "systemically important" until it is too late.

Another useful and commonly used regulatory technique is to phase in the application of product approval requirements, targeting the most

295. There can also be an intermediate category of products that require an abbreviated approval process, so that the firms would either have to satisfy some but not all of the statutory tests or otherwise bear a lighter burden of proof.

296. *See supra* note 284 and accompanying text.

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systemically risky or significant financial products and institutions first and then gradually expand the scope of the regime to include other products and actors. This phase-in implementation would potentially allow for necessary adjustments along the way, as more information on the practical operation of the new regime becomes available.

There is no guarantee that any of these mechanisms would succeed in making the proposed product approval regime more manageable without sacrificing its integrity. Combined with careful definitional carve-outs and narrowly tailored exemptions, however, they can serve as the basis for designing a practical solution to that problem.

The mandatory product approval scheme would allow the creation of an individual identification and tracking system for complex financial instruments. Under that system, each approved Covered Product would be assigned a unique alpha-numerical identifier containing the key information about the product category, the financial institution that received regulatory approval to market it, and other relevant data.[297] This system would allow consumers and regulators to trace the path of financial products or trading strategies to the institutions responsible for their origination. In addition to generating and organizing transactional data, it may heighten financial institutions' sensitivity to reputational risks associated with complex financial transactions. This tracking system would also make it easier for the authorities to conduct investigations and bring enforcement actions against individual institutions.[298]

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297. This identifier would be similar to the CUSIP (Committee on Uniform Securities Identification Procedures) number assigned to each class of securities of the U.S. and Canadian publicly held companies and U.S. government and municipal bonds. The CUSIP system is owned by the American Bankers Association, administered by Standard & Poor's, and is used to facilitate the clearing and settlement of securities. *See CUSIP Number*, U.S. SEC & EXCH. COMM'N, http://www.sec.gov/answers/cusip.htm (last visited May 12, 2012).

298. One of the problems during the recent financial crisis was that, in many instances of significant market failures, it was virtually impossible to establish the degree of any individual institution's fault, as many toxic products were continuously repackaged throughout the system, spreading and amplifying risk. The conspicuous lack of criminal prosecutions of Wall Street institutions and executives implicated in questionable deals that led to the crisis continues to draw significant public criticism and potentially undermines political legitimacy of financial regulation reforms. *See* Matt Taibbi, *Why Isn't Wall Street in Jail?*, ROLLING STONE, Feb. 16, 2011, http://www.rollingstone.com/politics/news/why-isnt-wall-street-in-jail-20110216. In June 2012, the Financial Stability Board, an international body that coordinates national authorities' efforts to regulate financial systemic risks, announced an initiative to establish a global Legal Entity Identifier ("LEI") system that would assign unique alphanumeric identifiers to parties to financial transactions. Fin Stability Bd., A Global Legal Entity Identifier for Financial Markets (June 8, 2012), *available at* http://www.financialstabilityboard.org/publications/r_120608.pdf. If successfully implemented, the LEI initiative would make financial transactions more transparent and may serve as the basis for developing a system of financial product identifiers.

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b. "Covered Institutions"

The statute would impose the duty to apply for regulatory approval of each Covered Product on the "Covered Institution" seeking to introduce the product into the market. Typically, that would be a financial intermediary that acts as an originator, issuer, underwriter, structurer, dealer or market-maker with respect to the Covered Product. In certain cases, two or more Covered Institutions—the issuer and the underwriter of a structured note, or the originator and the securitizer of an asset-backed instrument—may have to submit a joint approval application for the same Covered Product.[299]

In principle, the product approval scheme envisioned here aims at financial intermediaries: commercial banks, securities firms, insurance companies, and their affiliates or subsidiaries specializing in derivatives and securitization activities. However, if a non-intermediary institution—such as a hedge fund or a commercial company—wants to enter into complex financial transactions directly with other non-dealer entities, it would be a Covered Institution and would have to apply for regulatory approval of its proposed transactions. Such an entity will have to satisfy, among other things, the institutional capacity test. In effect, that would make such a fund or company subject to prudential requirements applicable to financial intermediaries. In other words, anyone can become an independent player in the markets for complex financial products, as long as they agree to be regulated for their ability to take on their financial risks. In practice, however, this approach is likely to preclude "free dealing" in complex financial instruments.

To strengthen this barrier to entry, it may be desirable to mandate registration of each Covered Institution as an "Approved Dealer" in the specific Covered Product. There is a wide range of potential regulatory requirements that such registration may imply. It may serve merely as a recording device—a roster of all entities that successfully applied for approval of specific Covered Products. On the other end of the spectrum, registration as an Approved Dealer in any single Covered Product may subject an entity to stringent regulation with respect to its capital and liquidity levels, limits on leverage, conflicts of interest and affiliate transactions, internal risk management, customer relations, financial reporting, and regulatory examinations. Such an extensive regulatory and

299. In these situations, it may make sense for the financial institutions to designate one Covered Institution as the lead applicant.

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supervisory regime would be largely parallel to the currently separate regimes for securities broker-dealers, commercial banks, savings associations, and other regulated intermediaries.[300] As a practical matter, introducing a system of comprehensive regulation and supervision of Approved Dealers in Covered Products may necessitate a major structural reorganization of the financial services industry.[301] Therefore, the advantages and disadvantages of such a system, and its potential interaction with the existing regulatory regimes for financial intermediaries, would require careful consideration and policy analysis.

c. The Financial Product Approval Commission

An important structural element of the proposed product approval regime is the choice of where to locate this new regulatory function. One option would be to grant this new regulatory power to one of the existing financial regulators. The Federal Reserve, the SEC, and the CFTC are the most likely candidates for this new role. However, this is likely to create a variety of complications and potential conflicts with other policy and regulatory goals of these agencies. The existing organizational culture may also significantly interfere with their ability to perform this new regulatory role.

A better option would be to establish a new regulatory agency—the Financial Product Approval Commission ("FPAC")—charged specifically with the implementation and administration of the new statutory scheme. The new agency may be structured in different ways. To enhance its independence, it may be preferable to set it up as an independent commission, either multi-member or headed by a single Commissioner. It is critical that the newly established FPAC has highly skilled and well-compensated staff, as well as sufficient resources to support the hiring of outside consultants, if necessary.[302]

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300. The regulatory and supervisory requirements for registered Approved Dealers in Covered Products may be more stringent than general requirements for banks, securities firms or other financial intermediaries. For instance, given the heighten potential risks associated with complex financial instruments, it may be desirable to impose significantly higher capital adequacy and liquidity requirements on Approved Dealers than those mandated under the Basel III framework. *See generally* BASEL COMMITTEE ON BANKING SUPERVISION, BASEL III: A GLOBAL REGULATORY FRAMEWORK FOR MORE RESILIENT BANKS AND BANKING SYSTEMS (June 2011), *available at* http://www.bis.org/publ/bcbs189.pdf.

301. Financial institutions may respond by "pushing out" the bulk of their structuring and dealing in complex financial products into separate subsidiaries registered and regulated as Approved Dealers in Covered Products. To avoid negative effects of further regulatory fragmentation, broader structural reforms redefining existing regulatory categories may be necessary.

302. An important issue in this respect is the funding model for the new agency. To ensure greater

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A more interesting question is the scope of substantive jurisdiction of the new agency. There may be a strong argument for combining the new product approval function with the broader oversight of systemic risk in the financial services sector. The Dodd-Frank Act created a new interagency body, the Financial Stability Oversight Council ("FSOC"), to fulfill this function.[303] Reassigning the systemic risk oversight responsibilities to the FPAC would require a major restructuring of the Dodd-Frank framework, which may be too disruptive. On the other hand, there are legitimate reasons to doubt the practical efficacy of the FSOC and the entire emerging systemic risk regulation regime. Thus, it may be too early to foreclose a thorough discussion of alternative substantive and structural solutions to the problem of systemic risk regulation.

Another dilemma arises if the new product approval regime also involves mandatory registration and comprehensive regulation of Approved Dealers in Covered Products. To the extent the FPAC administers this new system of centralized oversight of Approved Dealers, there may be jurisdictional overlaps and conflicts between the new agency and the SEC, CFTC, federal and state bank regulators, and state insurance regulators. Resolving these conflicts is likely to require a fundamental reorganization of the existing fragmented, silo-based regulation and supervision of financial intermediaries. This type of institutional reform is challenging and politically difficult. The idea of regulating and supervising all financial institutions that create, market, and trade complex financial products under a single statutory scheme, however, may create the basis for a much-needed overhaul of the current regulatory structure.[304]

Finally, an interesting issue to consider is how the FPAC would interact with, and affect the functioning of, the recently established CFPB. There is a fertile ground for extensive cooperation and coordination between these two agencies. Many Covered Products may directly or

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political independence and ample financial resources, it may be desirable to fund the FPAC's activities through industry assessments. On the other hand, funding through Congressional appropriations may better insulate the agency from private industry influence.

303. Dodd-Frank Act of 2010, Pub. L. No. 111-203, §§ 111, 124 Stat. at 1392–94 (codified at 12 U.S.C.A. § 5321 (West Supp. 2011)) (establishing the FSOC). The voting members of the FSOC, headed by the Secretary of the Treasury, include the heads of the key financial regulatory agencies, such as the Federal Reserve, the SEC, the CFTC, and the Office of the Comptroller of the Currency ("OCC"). *Id.*

304. A more general objection to the proposed structure is that the creation of yet another federal agency would further complicate the already fragmented system of financial services regulation. This is a legitimate concern that further underscores the importance of broader structural reforms, which would streamline and reassign jurisdictional functions among various government agencies in a manner consistent with the realities of today's financial marketplace. A discussion of these broader reforms is beyond the scope of this Article.

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indirectly affect consumer markets or be directly subject to the CFPB's jurisdiction. To the extent the CFPB does not possess explicit product approval powers, however, there is a limited potential for jurisdictional conflicts between these agencies.

3. Procedural Issues; Enforcement

Product review and approval is a form of agency adjudication that would have to satisfy the minimum procedural requirements of the Due Process Clause[305] and the Administrative Procedure Act (the "APA").[306] The enabling statute and the FPAC's rules would set forth the specific and detailed procedural requirements governing the agency review and decision-making with respect to product approval applications.[307]

a. Review Process

The statute would have to specify general timeframes for agency action. For example, the statute could require that the FPAC make a final decision on each application—by issuing either an Approval Order or an Order of Denial—within ninety days of its receipt, but may extend the review period for up to three additional ninety-day periods, if doing so is necessary to make a fully informed decision and the agency notifies the applicant in writing of each extension.[308]

The applicant entity would bear the burden of showing that the proposed product meets all of the statutory and regulatory criteria for approval. To facilitate its deliberations, the FPAC would have the right to request any additional information from the applicant, engage in

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305. The agency adjudication would need to satisfy the Due Process Clause, because a decision to deny approval for a specific product may potentially be viewed as a "deprivation" of the applicant's "property" rights. *See* RICHARD J. PIERCE, JR., ADMINISTRATIVE LAW 27–39 (2008) (discussing the applicability of the Due Process Clause to agency adjudications).

306. 5 U.S.C. § 551 *et seq.* (2006). The enabling statute, however, does not need to require the approval agency to engage in a formal adjudication "on the record after opportunity for agency hearing." 5 U.S.C. § 554(a).

307. It is important that the FPAC has extensive rule-making authority in order to be able to continue adapting the product approval regime to evolving market conditions.

308. The financial industry is likely to resist any such timeframes as unacceptably long. As the CFTC's experience demonstrates, even a ten-day review period was too much of a delay from the industry actors' perspective. *See supra* notes 239–42 and accompanying text. Nevertheless, it is crucial to allow the regulator an opportunity to complete the review process giving full consideration to all interests involved, including the public interest in protecting systemic stability. In many situations, the FPAC may arrive at a decision well before the maximum statutory review period expires. In addition, applicants may have a right to request an expedited review of their application, on the basis of specific evidence that such an expedited review is warranted.

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consultations with outside experts, hold formal or informal hearings, and take any other action it deems necessary. By submitting an application for product approval, each Covered Institution would be deemed to have agreed to cooperate with the FPAC and to submit all additional information, as requested by the agency, and failure to do so would constitute grounds for an automatic Order of Denial.

In its discretion, the FPAC would have the authority to impose conditions on approval of any specific product. For instance, the FPAC could require the applicant to make specific changes to the terms of the proposed financial product. This element of the proposed scheme is similar to the pre-2000 CEA provisions that granted the CFTC the power to mandate changes to futures contracts.[309] Unlike the CFTC, however, the FPAC would merely condition approval on the applicant's compliance with the agency's request for specific changes; it would not have the authority to mandate such changes unilaterally. If the applicant and the agency fail to agree on the necessary changes, the agency would have discretion to issue an Order of Denial.

When necessary, the FPAC would have the power to grant a conditional approval allowing the applicant to test-market the proposed product for a specified period of time, subject to various limitations.[310] The FPAC's Order of Conditional Approval would define the length of the trial period and specify the requirements and conditions to be satisfied in order for the applicant to obtain a final Approval Order for the product at the end of such trial period. During the trial period, the firm would be required to gather and analyze the relevant market data, which would provide an empirical basis for the FPAC's re-evaluation of the product. In principle, this is similar to the FDA's post-approval testing and review[311] and Professor Carpenter's earlier proposal involving a limited roll-out for consumer financial products.[312] It is important, however, to realize the inherent difficulty of conducting tightly controlled limited roll-out experiments in the financial market. If a product has negative systemic consequences, even a single transaction may cause irreversible damage to the stability of the entire financial system. Moreover, most complex and

309. *See supra* notes 226–28 and accompanying text.

310. For example, the FPAC may require that the applicant enter into the proposed transaction with, or sell the proposed financial product to, a limited number of target users that meet certain criteria. The applicant may also be required to set aside additional capital and liquidity cushion for trading and dealing in such conditionally approved instruments.

311. *See supra* note 151 and accompanying text.

312. *See supra* notes 109–11 and accompanying text.

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potentially risky financial instruments are structured as bespoke instruments, not meant for mass marketing.

The FPAC's Orders of Denial would be subject to judicial review in the same manner as similar decisions made by other administrative agencies. It is important, however, to avoid excessive and prolonged litigation of the FPAC's decisions. The well-funded and organized financial services industry, which stands to lose a great deal of profits under the proposed product approval regime, is likely to fight the FPAC at every turn and challenge the agency's every decision.[313] Designing procedural rules governing the product approval process would require a careful balancing of legitimate due process concerns against the need to prevent potential abuses of procedural rights by private interests seeking to undermine the new regime.[314]

Establishing a fair and effective process of administrative review of the FPAC's Orders of Denial may provide a viable alternative to litigation. Thus, it may make sense to establish internal appeals panels that would hear aggrieved applicants' appeals of the FPAC's orders. Such panels may be presided over by Administrative Law Judges and include not only FPAC employees but also outside experts and representatives.

b. Public Advisory Council

The FDA's practice of using independent expert councils suggests a potentially fruitful method of leveraging the FPAC's resources and introducing an important element of tripartism into the product approval process.[315] The FPAC could establish the Public Advisory Council (the "Council") specifically charged with representing an independent public interest perspective in the process of licensing individual financial products. The Council would comprise individuals who are independent from both the industry and regulators and who are competent in issues of financial regulation, such as academic experts, but also certain public

313. *See, e.g.*, Brush, *supra* note 280 (describing recent industry lawsuits against the CFTC).

314. Again, it is critical that the statute leaves little ambiguity with respect to its policy priorities. To this end, Congress may have to mandate a strong explicit presumption against excessive complexity of financial products and to place the burden of overcoming that statutory presumption on the Covered Institutions applying for approval of specific Covered Products.

315. For a discussion of the role of tripartism in financial services regulation, see Saule T. Omarova, *Bankers, Bureaucrats, and Guardians: Toward Tripartism in Financial Services Regulation*, 37 J. CORP. L. 621 (2012).

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figures (not holding any official post) and representatives of consumer and other public interest groups.[316]

The Council would function much like the FDA's scientific expert committees.[317] Its members would participate in the review and approval process, along with the FPAC's staff. The Council would provide an independent intellectual perspective on substantive and policy issues, which is a key factor in overcoming deep cognitive effects of complexity on regulators' thought process and in counteracting the tendencies toward agency ossification and parochialism.[318] As an active third-party participant in the regulatory process, the Council would serve as a safeguard of the integrity of that process and a mechanism diminishing the threat of regulatory capture.[319]

The creation of such an advisory body raises difficult issues with respect to the process and criteria for selecting its members, the scope of its powers and responsibilities, and the confidentiality of product-related information. The FDA's independent expert committees could provide a model for working out the operational details of the system.

c. Enforcement

The statute would generally prohibit offering to enter, or entering into, a financial transaction directly or indirectly involving any Covered Product in the absence, or not in accordance with the terms, of a valid Approval Order issued by the FPAC with respect to such Covered Product. Such transactions would be deemed void and unenforceable. The statute would provide broad rescission rights and rights to sue for damages to all third parties who, in good faith and without prior knowledge of the violation, entered into such illegal transactions.

The statute would also provide a full range of familiar penalties, such as monetary fines, disgorgement of profits from the illegal transaction, and criminal liability for certain reckless or intentional violations. In addition, the FPAC would have the authority to impose a wide range of administrative sanctions, including imposition of specific prohibitions or restrictions on business activities of the violating financial institutions and

316. *See id.*; *see also* Carpenter, *supra* note 108.

317. *See supra* notes 143–50 and accompanying text.

318. For a thoughtful argument on the importance of an independent intellectual perspective for improving agency decision-making, see McDonnell & Schwarcz, *supra* note 91.

319. *See* Omarova, *supra* note 315.

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partial or total exclusion of such institutions and their individual executives and employees from the market.[320]

B. But Would It Work? Potential Challenges and Criticisms

This Part outlines some of the key elements of the proposed regulatory regime. Much of this discussion seeks to identify important issues that require further analysis, rather than provide a complete design blueprint. Undoubtedly, this proposal is likely to face serious implementation challenges and invite numerous criticisms.

1. Financial Innovation and Global Competitiveness

Perhaps the most common criticism of any reform proposal involving government pre-approval of financial instruments is that it would stifle financial innovation and hurt the global competitiveness of the U.S. financial markets and institutions. As the examples of the FDA and REACH show, this is a typical argument private industry actors use to attack product approval regulation in any setting.[321] Despite being framed in purely economic terms, this objection is based on a normative assumption that financial innovation and uninhibited growth of financial markets are inherently beneficial and that their social utility is never to be questioned. Therefore, the argument goes, the purpose of government regulation should not be to interfere with financial innovation, but to enable and support it.

Without denying the many benefits of financial innovation, it is critical to remember that these phenomena can also cause significant economic and social harms. The recent crisis demonstrated that unregulated financial innovation can impose an unacceptably high price on society and, especially, on its poorest members. The proposed product approval scheme would not aim to stop all innovation. It would seek to control it in order to ensure that only those innovations that are likely to produce real economic benefits enter the market. To the extent this approach would "stifle" unproductive financial speculation and arbitrage, it may strengthen

320. This is typically achieved through revoking professional licensing and similar measures. If the FPAC is set up to exercise comprehensive regulatory and supervisory oversight of the new category of Approved Dealers in Covered Products, such market exclusion would involve temporary suspension or termination of the offender's registration as an Approved Dealer.

321. *See, e.g.*, Adelman, *supra* note 132, at 404 (discussing how large, globally-active chemical manufacturers lobbied against REACH).

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the long-term resilience and viability of the financial system and broader economy.

Maintaining global competitiveness presents a more difficult challenge. Large financial institutions operate on a global scale and may easily relocate their activities abroad in search of a less stringent regulatory environment. There is often a trade-off between the policy goal of making domestic markets more competitive and the goal of making those markets safer and more stable in the long run. A thoughtfully designed product approval regime could provide a framework for balancing these competing policy considerations in the context of specific financial activities. Ultimately, however, establishing a successful product approval regime in the United States may require coordinated efforts to create similar regimes in the key non-U.S. financial markets.[322]

2. "Command-and-Control" Regulation

Another potential criticism of the proposed product approval scheme is that it represents a paternalistic and obsolete "command-and-control" regulatory approach that is ill-suited for today's complex and dynamic financial marketplace. Some variations of this argument may target primarily the conceptual underpinnings of this proposal and extol the dynamic adaptive qualities of complex systems or, on a more concrete level, the virtues of a more collaborative regulatory regime involving all stakeholders as equal participants. Other variations of this argument may emphasize investor autonomy as a normative ideal or express distrust of the government's ability to make better economic decisions.

These are all valid arguments. Product approval regulation is inherently a top-down process, whereby the government controls market entry. In that sense, it is paternalistic and has "command-and-control" elements. At the same time, however, the proposed product approval scheme is designed to operate primarily as a burden-shifting device rather than a direct prohibition on individual products. It does not automatically deprive financial institutions of vital business opportunities; it merely cures the inherent informational asymmetry between private firms and government regulators.

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322. This problem is likely to accompany any significant domestic regulatory reforms in the financial services market. For an analysis of the complex architecture and dynamics of international financial regulation, see Christopher J. Brummer, *How International Financial Law Works (And How It Doesn't)*, 99 GEO. L.J. 257 (2011).

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From a practical standpoint, it is difficult to envision a workable near-term solution to the problem of regulating an increasingly complex financial system which would not rely at least on some form of "hard" legal constraints on the excessive risk-taking and speculation that such complexity enables.[323] Because reducing systemic complexity has significant potential to enhance both financial stability and market efficiency, instituting an *ex ante* product approval regime is better viewed as a pragmatic approach that defies simple ideological labels.

3. Feasibility Challenges

Finally, the critics of the proposed product approval scheme may emphasize various technical and conceptual difficulties with designing and implementing it. For instance, it is difficult to delineate precisely the scope of the scheme's application, or to define with sufficient specificity what constitutes an acceptable "economic purpose" of a complex financial instrument. This indeterminacy directly affects potential costs and overall viability of suggested reforms. Although this Article acknowledges and addresses some of these issues, it does not purport to offer complete solutions. Its purpose is to examine the basic concept of product licensing and to offer a general approach to operationalizing it in the context of financial services regulation.

It is also true that introducing a comprehensive product approval regime is likely to be an expensive undertaking. Yet, whatever the ultimate price tag of these reforms, it will pale in comparison with the potential aggregate cost—monetary, social, and political—of another major financial crisis. The world's leading economies simply cannot afford another crisis of the same, or greater, magnitude as the last one. The costs and benefits of this proposal should be assessed against that alternative.

Another potential challenge is the regulators' ability to administer a comprehensive product approval regime in practice. Financial regulators have lost credibility in recent years in light of the evidence of regulatory capture, incompetence, and complacency in the pre-crisis era.[324] To many,

323. In certain contexts, traditional command-and-control regulatory methods may produce greater benefits than market-based economic incentives. *See, e.g.*, Daniel H. Cole & Peter Z. Grossman, *When Is Command-And-Control Efficient? Institutions, Technology, and the Comparative Efficiency of Alternative Regulatory Regimes for Environmental Protection*, 1999 WIS. L. REV. 887 (1999) (arguing that command-and-control environmental regulation can be, and has been, more efficient than alternative market-based approaches).

324. *See, e.g.*, THE LEVIN REPORT, *supra* note 11, at 161–243 (detailing how the Office of Thrift Supervision consistently failed to prevent highly risky business practices at Washington Mutual, the

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the idea of regulatory agencies as effective gatekeepers, especially in the complex and dynamic area of finance, may appear naïve and misguided.[325] While regulatory capacity is a legitimate concern, it is hardly unique to the current proposal.[326] Any regulatory regime may fail if the agencies are not able or willing to implement it efficiently and responsibly. How to improve regulators' capacity and incentives to act in the public interest is an intensely debated question that is not likely to have a simple answer.[327] Yet, it may be easier for the real-life imperfect regulators to cope with the complexity of their regulatory terrain if the law imposes the burden of explaining and justifying the need for such complexity on private market participants who generate it.

As discussed above, implementation of the proposed product approval scheme may require significant reform of the broader system of financial sector regulation. Reorganizing and rationalizing the complex and fragmented regulatory framework requires the presence of strong political will, which does not appear likely in the near term.[328] At the same time, however, the political climate may change unexpectedly, often in response to an economic crisis or another exogenous shock.[329] In the meantime, it is important to continue exploring the possibilities for devising more effective regulatory mechanisms to reduce systemic risk in the financial sector.

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largest thrift under its jurisdiction).

325. *See, e.g.*, Daniel Schwarcz, *Reevaluating Standardized Insurance Policies*, 78 U. CHI. L. REV. 1263 (2011) (arguing that state insurance regulators often fail to review homeowners insurance policies in an effective manner).

326. *See, e.g.*, Saule T. Omarova, *From Gramm-Leach-Bliley to Dodd-Frank: the Unfulfilled Promise of Section 23A of the Federal Reserve Act*, 89 N.C. L. REV. 1683 (2011) (detailing the Federal Reserve's practice of granting banks exemptions from statutory restrictions on affiliate transactions).

327. *See, e.g.*, PREVENTING CAPTURE: SPECIAL INTEREST INFLUENCE IN REGULATION, AND HOW TO LIMIT IT (Daniel Carpenter & David Moss eds., 2012); McDonnell & Schwarcz, *supra* note 91.

328. *See* Linda Feldmann, *Pew Survey: Partisan polarization in U.S. hits 25-year high*, THE CHRISTIAN SCI. MONITOR (June 4, 2012), *available at* http://www.csmonitor.com/USA/Politics/2012/0604/Pew-survey-Partisan-polarization-in-US-hits-25-year-high.

329. The unfolding sovereign debt crisis in Europe demonstrates that policy-makers and legislators are increasingly prepared to impose strict top-down controls and prohibitions on certain types of speculative financial transactions. Thus, in November 2011, the European Parliament adopted a regulation banning any person in the European Union from entering into "naked," or uncovered, credit default swaps referencing sovereign debt. *See* Short Selling and Certain Aspects of Credit Default Swaps (COM(2010)0482), *available at* http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P7-TA-2011-0486&language=EN.

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4. Informational Screening as a Potential Alternative

Given the various feasibility challenges described above, it may be prudent to consider less radical alternatives to the proposed approach. One such alternative measure could be the establishment of a purely informational pre-market product screening regime.[330] As discussed above, one of the key benefits of an *ex ante* product approval regime is the mandatory shifting of the burden to produce crucial information about the products to the financial institutions designing and marketing them.[331] It may be possible to retain these informational benefits of an *ex ante* product review without necessarily giving the regulators the power to prohibit the marketing of any product. Better informational access should improve the government's ability to regulate financial markets more effectively and to take timely action with respect to potentially troublesome systemic trends.[332] The need to explain the purposes and the nature of the financial products to the regulators should deter financial institutions from creating instruments likely to raise too many difficult questions. The firms would be expected to try to avoid negative comments by the regulators reviewing their products, because it may lead to further regulatory inquiries and tarnish the firm's reputation.

It is far from certain, however, that a purely informational regulatory review of financial products, not backed by direct statutory authority to stop them from entering the market, is likely to achieve its proclaimed objectives. It is not clear what level of scrutiny would be appropriate for this type of "soft" regulatory review and, more importantly, what effect regulators' findings would have on financial intermediaries' ability to increase systemic complexity, interconnectedness, and risk. Without a clear threat of regulatory prohibition of the proposed activity, financial institutions that stand to profit from such activity will be less forthcoming with the relevant information. In the context of a purely information-gathering review, it would be more difficult for the regulators to justify their demands for further disclosure and discussions over firms'

330. *See, e.g.*, P. M. Vasudev, Credit Derivatives and the Dodd-Frank Act: Is the Regulatory Response Appropriate? (Jan. 13, 2012) (unpublished manuscript), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1984878 (proposing a pre-market screening procedure for financial products).

331. *See supra* notes 277–80 and accompanying text.

332. Given this link to systemic risk regulation, it may make sense to assign this pre-market review function to the FSOC or the OFR, although that would require significant reconfiguration of their current structure and duties.

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complaints about unnecessary and meaningless delays. Routinely issued pre-market regulatory comments on potential risks of individual financial products, without any binding legal power, are likely to be ignored by market participants and even the regulators themselves, especially in times of rising asset prices.[333]

Altering the financial services industry's conduct requires powerful and tangible deterrents.[334] In effect, a pre-screening regime would act purely as "disinfecting sunlight"[335] and leave far more room for a variety of responses, public and private, to the uncovered information. It is doubtful, though, that, without a "well-oiled shotgun behind the door,"[336] any such responses will be effective enough to prevent the excessive accumulation of systemic risk and avert the next financial crisis.[337]

CONCLUSION

This Article explores the possibility of creating a system of mandatory pre-approval of complex financial products as an *ex ante* solution to the problem of systemic risk containment. Building on the concept of regulatory precaution borrowed from environmental and health law, and elements of pre-CFMA regulation of commodity futures, the Article outlines the broad contours of a new licensing scheme that would place the burden of proving social and economic utility of complex financial instruments on the intermediaries that structure and market them. Fundamentally a thought experiment, this proposal seeks to enrich the current policy debate by expanding the range of potentially plausible reform options.

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333. In our fragmented system of financial regulation, one can easily imagine a situation where the agencies or staff responsible for prudential regulation and supervision of financial institutions would go about their daily duties without much regard for the non-binding commentary by the regulatory personnel that had reviewed specific products before they began trading.

334. *See* Saule T. Omarova, *Wall Street as Community of Fate: Toward Financial Industry Self-Regulation*, 159 U. PA. L. REV 411, 486–87 (2011) (arguing that a credible threat of government intervention is necessary to alter the financial industry's conduct).

335. *See* LOUIS BRANDEIS, OTHER PEOPLE'S MONEY AND HOW THE BANKERS USE IT 62 (1933) ("Sunlight is said to be the best of disinfectants; electric light the most efficient policeman.").

336. WILLIAM O. DOUGLAS, DEMOCRACY AND FINANCE 82 (1940).

337. It is important to emphasize the utmost significance of "disinfecting sunlight" for systemic risk regulation. For a variety of reasons, however, it may be desirable to entrust the task of publicly scrutinizing the actions of financial market actors and financial regulators to an independent public interest representative. *See* Omarova, *supra* note 315 (proposing the creation of an independent government instrumentality to act as a designated pubic interest representative with the broad statutory authority to gather and publicize information relevant to financial systemic risk regulation).