EXCEPTIONS MEET ABSOLUTISM: OUTLAWING GOVERNMENTAL UNDERREACH IN HEALTH LAW

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ABSTRACT

Health measures are sometimes struck, not for "overbreadth," but for "underbreadth." Short of an equal protection problem, a guaranteed right, an unconstitutional condition, or other constitutional problem, how does the effort to moderate a law by carving out exceptions to accommodate important concerns necessarily doom the underlying legal provision itself? Is there any pattern to the courts' use of relatively malleable administrative law review doctrines to strike down health rules, not just because of what they do, but ostensibly because of what they leave undone?

This Article tackles the underappreciated vulnerability of exceptions-based rules in health law. I look at three examples: New York City's notorious Soda Portion Cap Rule that exempted refills; the FDA's decision to allow age-restricted, over-the-counter (OTC) emergency contraception; and Pennsylvania's Medicaid rules providing eyeglasses, an optional benefit, to beneficiaries with eye disease but not to those with refraction error. Each case exhibits three common elements that characterize how a rule's exceptions, deliberately tailored to prevent overreach, can turn out to be the rule's Achilles' heel. The courts in each of these cases insist upon an extra-legal policy absolutism that challenges not only our assumptions of a default judicial posture favoring cost-benefit analysis but also deeper assumptions about the rule-based nature of law.

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INTRODUCTION

Health law perches at an intersection where disciplines and values collide. A longtime observer, in an article entitled *Can Health Law Become a Coherent Field of Law?,* opens with the following declaration: "I want to concede at the outset that health law, today, is not yet a coherent

field of law. It is, rather, a disjointed set of statutes and doctrines . . . based on different principles and paradigms . . . ."[1]

Major health laws, from Medicare to the recent Affordable Care Act, are products of intense normative struggle.[2] The results are often highly detailed statutory and regulatory regimes memorializing each round of combat over enactment and implementation. These regimes are inevitably littered with rules containing built-in exceptions.[3]

In this Article, I will show that this design, employed extensively throughout the health law field, is vulnerable in court. This Article identifies a phenomenon of judicial antagonism towards rules with built-in exceptions. This phenomenon exhibits a pattern, which spans the political spectrum, whereby judges intervene to strike such health-related rules precisely because the exceptions signal value conflict. Next under the pattern, judges divert the underlying disputes to extra-legal arenas of decision-making, such as politics, science, or medicine. Finally, they justify their intervention using distinctly rule-averse forms of reasoning derived from the self-same, extra-legal arenas that they anointed as the appropriate normative fora. The existence of this three-part judicial subroutine challenges some of our assumptions about the judicial default posture favoring cost-benefit analysis, as well as deeper assumptions about the rule-based nature of law.[4]

My thesis starts from the feature of exceptions built into a rule before the time of application.[5] I acknowledge that the parameters of a rule's applicability are sometimes framed linguistically as an exception and sometimes as one of the rule's conditions, requirements, or "elements."[6] I will refer to both as exceptions, stipulating that the phenomenon I am describing is a rule's "underinclusion," regardless of how it appears as an artifact of language.

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1. Einer R. Elhauge, *Can Health Law Become a Coherent Field of Law?*, 41 WAKE FOREST L. REV. 365, 365 (2006).

2. For the ACA's accommodation of multiple different goals and ideas, see, for example, Paul Krugman, *The Big Kludge*, N.Y. TIMES, Oct. 28, 2013, at A27 (describing the ACA as "a clumsy, ugly structure that more or less deals with a problem"); *see also* Atul Gawande, *Testing, Testing*, NEW YORKER, Dec. 14, 2009, http://www.newyorker.com/magazine/2009/12/14/testing-testing-2 (comparing the strategy of the ACA on health cost rationalization to agricultural policy at the turn of the twentieth century, not "a grand solution[,]" but "a hodgepodge").

3. The Supreme Court has declared ERISA "a 'comprehensive and reticulated statute[.]'" Great–W. Life & Annuity Ins. Co. v. Knudson, 534 U.S. 204, 209 (2002) (quoting Mertens v. Hewitt Assocs., 508 U.S. 248, 251 (1993)). For the proposition that Medicare is filled with detailed, highly specified provisions, see Nicholas Bagley, *Bedside Bureaucrats: Why Medicare Reform Hasn't Worked*, 101 GEO. L.J. 519, 524 (2013).

4. For the default posture of cost-benefit analysis, see Cass R. Sunstein, *Cost-Benefit Default Principles*, 99 MICH. L. REV. 1651, 1667–68 (2001). For the rule-based nature of law according to legal positivism, see *infra* notes 7, 19 & 23.

5. This is in contrast to those exceptions that result from rule defeasibility.

6. *See, e.g.*, Frederick Schauer, *Exceptions*, 58 U. CHI. L. REV. 871, 872–73 (1991). *But see* Frank H. Easterbrook, *Statutes' Domains*, 50 U. CHI. L. REV. 533, 533–36 (1983) (differentiating between jurisdictional parameters that define a statute's applicability and proscriptive parameters that define the conduct to be prohibited).

Why should judges invalidate rules narrowly drawn to fit diverse considerations?[7] What account can we give for why judges limit lawmakers to a seemingly all-or-nothing range of action with no ability to trim a measure to accommodate different factors? My discussion of three illustrative health law cases will show that doctrine alone cannot answer these questions.

In seeking the unstated fit norms that rein in exceptions, I examine these cases and find that these judges disfavor rules in the face of the value conflict that is inevitable given the normative pluralism characterizing health law.[8] Exceptions are often indicators of a highly salient value conflict,[9] and the examples show that judges are hesitant to depend

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7. Throughout this Article, I will use "rule" in the thin, abstract sense, as a norm characterized by a certain degree of detailed specificity, and which applies pressure to conform where the reason for conforming is the fact of the rule itself. H.L.A. HART, THE CONCEPT OF LAW 21, 55–57 (1961). I will refer to such a norm as a "rule" whether it is in fact an agency "regulation," technically an "order" under the Administrative Procedure Act, a statutory or constitutional provision, or judge-made doctrine. This Article focuses on "rules" made at the agency level, but we observe such patterns in regimes that impose substantive review on legislation as well. *See, e.g.*, Florida v. U.S. Dep't of Health & Human Servs., 648 F.3d 1235, 1310–11 (11th Cir. 2011) (declaring the ACA's individual mandate outside Congress's authority in part because of the exceptions carved out of the mandate), *aff'd in part, rev'd in part sub nom.* Nat'l Fed'n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566 (2012); *see also* Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 566 (2001) (invalidating ban on indoor tobacco advertising near schools if placed less than five feet from the ground, citing failure to protect children taller than five feet); Jones v. State Bd. of Med., 555 P.2d 399, 411, 416–17 (Idaho 1976) (explaining that a state malpractice damages cap might be constitutional under the equal protection clause of the Fourteenth Amendment but that the cap violated the state constitution in part because it did not cap liability for other types of defendants). *But see* Williamson v. Lee Optical of Okla., Inc., 348 U.S. 483, 489 (1955) (declaring that "the reform may take one step at a time, addressing itself to the phase of the problem which seems most acute . . . . The legislature may select one phase of one field and apply a remedy there"). For articles that document similar "exceptions" or all-or-nothing phenomena in non-health constitutional law fields, see Mitchell N. Berman, *Commercial Speech and the Unconstitutional Conditions Doctrine: A Second Look at "The Greater Includes the Lesser,"* 55 VAND. L. REV. 693 (2002); John Fee, *Greater-or-Nothing Constitutional Rules*, 64 CASE W. RES. L. REV. 101 (2013); Michael Herz, *Justice Byron White and the Argument that the Greater Includes the Lesser*, 1994 BYU L. REV. 227 (1994); Elena Kagan, *The Changing Faces of First Amendment Neutrality:* R.A.V. v. St. Paul*,* Rust v. Sullivan*, and the Problem of Content-Based Underinclusion*, 1992 SUP. CT. REV. 29, 32.

8. These cases are not meant to be representative, but they are also not isolated examples of this phenomenon of invalidation for underinclusion. *See, e.g.*, FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 133–36 (2000) (ruling that the regulation of cigarettes as a drug-delivery device is outside the statutory authorization because FDA only banned marketing to minors when such an unsafe product should have been banned entirely); *see also* Burwell v. Hobby Lobby Stores, Inc., 134 S. Ct. 2751, 2779–82 (2014) (striking HHS regulation mandating for employer provision of contraceptive coverage as part of the ACA requirement that employers provide preventative care as contrary to the Religious Freedom and Restoration Act in part because carve outs from that mandate for grandfathered plans and for non-profits suggested a less restrictive alternative); Am. Trucking Ass'ns v. EPA, 175 F.3d 1027, 1034–40 (D.C. Cir. 1999) (invalidating the 0.08 ppm ozone standard because the underlying statutory delegation, by prohibiting cost-benefit analysis with respect to public health, provided "no intelligible principle" for standard setting short of complete elimination), *aff'd in part, rev'd in part sub nom.* Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001).

9. Many scholars discuss this feature of exceptions, limitations, balancing, and underinclusion. *See, e.g.*, Claire Oakes Finkelstein, *When the Rule Swallows the Exception*, *in* Rules and Reasoning: Essays in Honour of Fred Schauer 147–49 (Linda Meyer ed., 1999), *reprinted in* 19 QUINNIPIAC L. REV. 505, 505–08 (2000); *see also* John F. Manning, *The Supreme Court, 2013 Term—Foreword: The Means of Constitutional Power*, 128 HARV. L. REV. 1, 4 (2014) (stating of the Court's fidelity to accommodations in Congressional text that "[b]y adhering, instead, to the

upon "rules" in these contexts—whether the rules are regulatory or judge-made, substantive or "jurisdictional." The reasons they give fit a pattern, suggesting that courts are eliding rules with their underlying justifications.[10] This phenomenon amounts to a policy-absolutist counterstrand to the implicit cost-benefit default principles that Cass Sunstein has identified, which purport to give agencies latitude to weigh competing concerns.[11]

A. Conventional Wisdom: Courts Employ Cost-Benefit Defaults

Sunstein has argued for an emerging "federal common law of regulatory policy" consisting of presumptions that federal courts, particularly the D.C. Circuit, employ to construe statutes in such a way as to allow agencies to accommodate countervailing costs and benefits.[12] Sunstein examines the case law to show that, absent clear congressional prohibition, agencies are by default permitted under a variety of statutory authorizations to make *de minimis* exceptions; to consider health-health tradeoffs; to weigh costs as well as benefits; and to reject nonfeasible regulation.[13] Indeed, he argues that at least some of these cost-benefit defaults, by placing a clear-statement burden on Congress when it prescribes "policy absolutism" to the exclusion of offsetting concerns, are part of an arsenal of nondelegation canons that limit unconfined agency action and thereby protect the values of Article I, Section I of the Constitution.[14] Thus, Sunstein's cost-benefit default principles reflect the judicial stance that rules are less arbitrary and more legitimate when they do acknowledge competing considerations.[15]

While Sunstein restricts his gaze to federal courts reviewing federal agency action, cost-benefit analysis is also prevalent, potentially even

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words of the statute as written, today's Court enables Congress more predictably to express its preference for outcomes that may not be so coherent — that include rough accommodations, take only baby steps toward some broader purpose, or adopt crisp rules that favor certainty over achieving a perfect means-ends fit"); Linda Ross Meyer, *Unruly Rights*, 22 CARDOZO L. REV. 1, 1–9 (2000) (discussing the significance of balancing and limitation in the context of "interest" based theories of rights); James G. Wilson*, Surveying the Forms of Doctrine on the Bright Line-Balancing Test Continuum*, 27 ARIZ. ST. L.J. 773, 773–75 (1995).

10. *See generally* RONALD DWORKIN, TAKING RIGHTS SERIOUSLY 3–6 (1977) (discussing the perennial jurisprudential question of whether law consists of rules or whether law consists in part of the underlying moral principles behind those rules).

11. *See* Sunstein, *supra* note 4, at 1667–68. I am not proposing these exceptions are precisely contoured for nor governed by utilitarian welfare calculations, but they do exhibit a kind of balancing, or trade-off orientation. And Sunstein's orientation toward trade-offs or accommodations reflects this broader perspective rather than a narrower utilitarianism. *See, e.g.*, Cass R. Sunstein, Commentary, *Incompletely Theorized Agreements*, 108 HARV. L. REV. 1733, 1739–41 (1995).

12. Sunstein*, supra* note 4, at 1654–56.

13. *Id.* at 1668–70.

14. *See* Cass R. Sunstein, *Nondelegation Canons*, 67 U. CHI. L. REV. 315, 323, 334–35 nn.93–94 (2000).

15. *See* Sunstein, *supra* note 11 (advancing a view that law allows people in a society to proceed without forcing convergence or coherence on larger abstract values and principles).

normatively privileged, in states as well.[16] Yet in the three health law cases I examine, instead of following a common law that favors accounting for offsetting values, courts seem to be striking those rules that acknowledge competing considerations.[17] Such a view, if extended, would render rules unsuited to the management of plural values.

B. Contrasting Pattern

My approach in this project is to look at three cases, spanning both time and the political spectrum. These cases involve New York City's Soda Portion Cap Rule, the Food and Drug Administration's (FDA's) decision to allow age-restricted, over-the-counter status for emergency contraception, and Pennsylvania's Medicaid rule that provided eyeglasses to those with eye disease but not refraction error. In each case, the rule is struck because it contains a built-in exception. I identify the commonalities that underlie the decisions across three doctrinal areas, namely, the New York State separation of powers doctrine, the "arbitrary and capricious" standard under the Federal Administrative Procedure Act, and statutory interpretation of the federal Medicaid statute's "reasonableness" standard for state programs.

Three common elements emerge from the three examples:

1) First, the court in each instance identifies the exception-laden provision's ambition to confront value conflict as the crucial misstep that dooms the measure. The design of the soda portion cap balanced health against "economic" as well as political turf or even liberty considerations. The Plan B age-restricted switch decision balanced legitimate "safety and efficacy" considerations against sexual morality. Pennsylvania balanced health needs against cost considerations.

2) Next, each judge, having decided that the rule improperly handled value conflicts, assigned the decision to some extra-legal arena—politics in the soda portion cap, science in the Plan B OTC switch, and clinical medicine in the Pennsylvania eyeglasses benefits. The judge disabled positive law in each of these cases, preferring the governance of other, arguably more robust social institutions instead.

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16. Indeed in the New York state case I examine here, Judge Pigott declares, "[C]ost-benefit analysis is the essence of reasonable regulation; if an agency adopted a particular rule without first considering whether its benefits justify its societal costs, it would be acting irrationally." N.Y. Statewide Coal. of Hispanic Chambers of Commerce v. N.Y.C. Dep't of Health & Mental Hygiene, 16 N.E.3d 538, 546 (N.Y. 2014). And the dissent states, "Cost-benefit analysis has long been a staple of state and federal regulatory processes (*see e.g.*[,] State Administrative Procedure Act § 202–a [1] ['In developing a rule, an agency shall, to the extent consistent with the objectives of applicable statutes, consider utilizing approaches which are designed to avoid undue deleterious economic effects or overly burdensome impacts of the rule upon persons']." *Id.* at 559 n.3 (Read, J., dissenting) (second alteration in original) (emphasis omitted) (quoting N.Y. A.P.A. LAW § 202-a(1) (McKinney 2015)).

17. *See* Abbe R. Gluck, *The Federal Common Law of Statutory Interpretation:* Erie *for the Age of Statutes*, 54 WM. & MARY L. REV. 753, 755–58 (2013) (arguing that canons of statutory interpretation are a form federal common law).

3) Third, despite the ostensible deference of the judge to these other justificatory arenas, the judge in each case determines the outcome herself in the guise of a decision to divert jurisdiction over the matter away from the agency to her favored arena.[18] However, the judge never articulates a jurisdictional rule. Instead, the judge decides the jurisdictional question by applying her own conception of the methodology borrowed from the non-legal institution she has predetermined. The dispositive analysis was balancing in the soda portion cap case, extrapolation to an undersampled population in the emergency contraception OTC case, and reference to ophthalmologist affidavits in the Medicaid eyeglasses case.

This three-step maneuver is profoundly rule averse. Steps one and two are common enough insofar as legal institutions often sidestep the declaration of substantive rules and use jurisdictional rules instead to assign the substantive decision to another actor. However, step three in these cases shows that the jurisdictional decision is also decided by recourse to rule-averse reasoning.

I begin by examining the scholarship on the nature of rules and their justifications to discover what in our expectations surrounding rules might prompt resistance to exceptions.

I. RULES, COMPOUND JUSTIFICATIONS, AND EXTERNAL EXCEPTIONS

A. Legal Scholarship and Definitional Matters

Much has been written of exceptions, but mostly to identify the circumstances under which exceptions should be, or are likely to be, crafted.[19] The exceptions literature does not speak to the question of why, once a rule *has* been agreed upon through a process granted social authority, it should then be struck, especially when one of positive law's uses is held to be "the authoritative settlement of moral and political issues."[20]

B. Exceptions as a Superficial Category or as Underinclusion?

Above, I note that when I speak of exceptions, I am referring to ex ante exceptions written into the rule at its inception. Of course, as Frederick Schauer points out, an exception is hard to distinguish from any other

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18. I use the term "jurisdiction" here not in the technical sense, but to refer to the substantive arena governing decision-making.

19. *See, e.g.*, Alfred C. Aman, Jr., *Administrative Equity: An Analysis of Exceptions to Administrative Rules*, 1982 DUKE L.J. 277, 280 (1982); Colin S. Diver, *The Optimal Precision of Administrative Rules*, 93 YALE L.J. 65, 74–75 (1983); Louis Kaplow, *Rules Versus Standards: An Economic Analysis*, 42 DUKE L.J. 557, 588–90 (1992); Peter H. Schuck, *When the Exception Becomes the Rule: Regulatory Equity and the Formulation of Energy Policy Through an Exceptions Process*, 1984 DUKE L.J. 163, 167 (1984); Cass R. Sunstein, *Problems with Rules*, 83 CAL. L. REV. 953, 957–58 (1995).

20. Scott J. Shapiro, *The "Hart-Dworkin" Debate: A Short Guide for the Perplexed*, *in* RONALD DWORKIN 22, 24 (Arthur Ripstein ed., 2007).

qualifying parameter set forth in the rule.[21] Thus, condemnation of a rule for having an exception is hard to distinguish from condemnation of any other aspect of the rule's scope or content. However, Claire Oakes Finkelstein shows that some exceptions or carve-outs can be identified with significance beyond linguistic fortuity or stylistic choice.[22] She suggests that certain exceptions are usefully thought of as external to the rule that they condition[23]: "An exception is a qualification of a rule that stands in a certain relation to it, namely it stands outside the rule it qualifies."[24] In her account, an exception's "outsider" status obtains if the exception can be said to have a different "justification" from that which underlies the rule.[25] She even ascribes this view to Schauer himself[26]: "The logic of exceptions . . . is more correctly understood in terms of what Schauer calls 'external' failure, namely conflict between a rule and something other than the rule's own background justification."[27]

C. Rules as Distinct from Justifications

Schauer also supplies the notions of underinclusion and compound justifications to help us specify the relationship of rules to exceptions. In his rigorously considered account of "rule-ness," Schauer tells us that a rule, by definition, diverges from its justification, and he explores the phenomena of underinclusion and overinclusion of rules relative to their justifications.[28] With these resources in hand, I contend that the type of ex ante exceptions I examine here can be understood as underinclusions relative to some justification.

Schauer tells us that for a rule to be a rule, it must apply some pressure distinct from what the justification would suggest if one were to rely directly on the justification to make decisions:

> If a rule applies even when its application would not serve the rule's justification, and if a rule does not apply even when application

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21. Finkelstein, *supra* note 9, at 152–53 (describing Schauer's position on this point).
22. *Id.* at 149.
23. *Id.* at 149, 155 (conceding that Schauer recognizes external exceptions too).
24. *Id.* at 150 (emphasis omitted).
25. *Id.* at 155.
26. *Id.* (distinguishing internal and external exceptions).
27. *Id.*; *see also* FREDERICK SCHAUER, PLAYING BY THE RULES 117–18 (1991) ("By comparison, rules with some resistance to internal failure . . . might still be subject to being overridden by particularly exigent factors external both to the rule and *its* justification. When rules are inapplicable (or, more accurately, non-controlling) on the basis of such factors not themselves a function of what this rule itself is designed to accomplish, we can say that such rules are *externally defeasible*, subject to being defeated or rendered non-controlling by factors external to the rule itself."). Of course, under a single-valued justificatory system, like utilitarianism, this distinction collapses, as he points out. Schauer goes on to explain that rules should exert some resistance to external defeasibility: "[F]or a rule to be a reason for action" it must have "weight." SCHAUER, *supra*, at 118.
28. *See* SCHAUER, *supra* note 27, at 61–62; *see also id.* at 76 ("A rule exists . . . insofar as an instantiation of a justification is treated . . . as entrenched, having the power to provide a reason for decision even when that instantiation does not serve its generating justification. The form of decision-making that we can call rule-based, therefore, exists insofar as instantiations resist efforts to penetrate them in the service of their justifications.").

> would serve that justification, is it a bad rule? Or have we just misapplied the rule? Or is this just part of what rules are all about?[29]

Rules and justifications will inevitably diverge due in large part to the unavoidable generality of the rule. However, if one could anticipate the particular cases where the rule would prove overinclusive, or more to our purposes, underinclusive, one could then articulate and build in exceptions in advance.[30]

One reason that a rule's fit might be predictably bad is based on "internal" reasons, namely, where the rule does not fit the justification because the justification itself is undermined by the rule. An example would be what Sunstein calls "health-health trade-off[s]" when one of the justifications for the rule is health promotion, yet the health-promoting measure may itself have adverse side effects for health, justifying limitation of the rule based on "health" concerns as well.[31] Sunstein gives a hypothetical example where "the regulation of one risk, like . . . asbestos, may give rise to further risks as a result of the substituted products[,]" which may be just as harmful.[32] An "external" failure of the rule, by contrast, would arise where a different countervailing justification, e.g., a non-health reason such as economic cost, could be known in advance to exceed what we would consider justified by the health gains from regulating asbestos.[33] For example, we might find the countervailing cost justification convincing for some subset of instances, such as in small businesses with ten or fewer employees.

D. Plural Justifications

Thus, characterizing a failure of fit as "internal" or "external" to a rule, indeed framing the notion of fit at all, or even understanding whether a rule is even a rule, all depend on each rule having an identifiable "justification." Yet justifications are often plural. The phenomenon of compound justifications for any one rule has been noted in other contexts, including statutory interpretation, and with respect to rationality review under the Equal Protection Clause of the Constitution.[34] "If legislation is often a rough-hewn compromise, then testing its validity against 'actual' legislative purpose risks attributing unwarranted coherence to the legislative process, which may entail logrolling or other strategic voting,

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29. *Id.* at 34. For a thorough consideration of the role of rules in various health-related decisions, using Schauer's account of rules, see DAVID ORENTLICHER, MATTERS OF LIFE AND DEATH: MAKING MORAL THEORY WORK IN MEDICAL ETHICS AND THE LAW 11–15 (2001).

30. SCHAUER, *supra* note 27, at 36–37.

31. *See, e.g.*, CASS R. SUNSTEIN, THE COST-BENEFIT STATE 124 (2002).

32. *Id.*

33. *See id.*

34. *See, e.g.*, Note, *Legislative Purpose, Rationality, and Equal Protection*, 82 YALE L.J. 123, 132 (1972) (criticizing the handling of cases under the rational review doctrine for formulating the purpose against which the statutory means would be measured for rationality as "a unit rather than as a mix of policies").

making concessions to strongly felt but outlying interests, or papering over disagreements to ensure the legislation's passage."[35]

In sum, justifications associated with a particular rule can be multifarious. Often, the limiting boundary narrowing the scope of the rule is justified by "external" values, or concerns that differ from the value or policy underlying the rule. To the extent the rule contains such narrowing parameters, one could say that the parameters render the rule "underinclusive" relative to that particular animating justification. In other words, even if the narrower rule better fits the constellation of justifications that might impinge in particular situations, it does not realize the single presumed animating value to the fullest extent possible because of a limiting parameter or "carve-out."

Schauer tells us that the nature of rule-based practice is to recognize that a rule presumptively governs, even when the rule-generated outcome is not congruent with the resolution of the situation were it to be decided by resort to the animating justification.[36] Thus, if such a narrowed rule (or exception) is applied, even when the animating justification might argue for fuller application, that is because in our system of law, we recognize the normative force of rules, rather than reverting in every instance to decision by justification. [37]

Yet as we will see, exceptions, if they arise from competing values limiting a rule, are sometimes not given effect. These are the examples we turn to next.

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35. John F. Manning, *The Absurdity Doctrine*, 116 HARV. L. REV. 2387, 2450 (2003) (footnote omitted). *See also* Easterbrook, *supra* note 6, at 540–41 ("Almost all statutes are compromises . . . . What matters to the balancers is reducing the chance that their work will be invoked subsequently to achieve more, or less, than they intended, thereby upsetting the balance of the package. . . . Legislators seeking only to further the public interest may conclude that the provision of public rules should reach so far and no farther . . . . No matter how good the end in view, achievement of the end will have some cost, and at some point the cost will begin to exceed the benefits."); Note, *supra* note 34, at 131–32 (citing John Hart Ely's suggestion that courts must be "restrict[ing] the range of acceptable goals"). The Note author then goes on to state that to strike a rule for underinclusion denies multiple justifications. If multiple justifications define the rules' contours, many rules may be "'tautologically' rational," unless the court privileges some of the justifications. *Id.*

36. SCHAUER, *supra* note 27, at 93–100.

37. *See generally* JOSEPH RAZ, PRACTICAL REASON AND NORMS (1990) (providing an account of rules as norms that substitute for the underlying justification). The project of this Article is to probe that assumption that our system of law is rule-based, rather than infused with what exclusive positivists would deem "extra-legal" elements. *C.f.*, Zadvydas v. Davis, 533 U.S. 678, 699 (2001) (demonstrating that natural law elements enter into judicial decisionmaking, where the court cites the maxim "[c]essante ratione legis cessat ipse lex" meaning that where a law's rationale ceases to apply, so does the law itself (quoting 1 EDWARD COKE, INSTITUTES 70b (1628))). In *Zavydas*, the Supreme Court granted habeas relief even though the statute set no limit on the length of time for detention beyond removal and "the applicability of due process to aliens subject to removal is at least questionable." Michael W. McConnell, *The Ninth Amendment in Light of Text and History*, 2009-2010 CATO SUP. CT. REV. 13, 25.

II. CASES

A. NY Statewide Coalition v. NYC Health Department*: Soda Portion Cap Rule*

1. Description

In May of 2012, then-mayor of New York City, Michael Bloomberg, publicly proposed to cap the containers that Food Service Establishments (FSEs) use to sell sugary drinks at sixteen ounces.[38] The provision defined a "sugary drink" as a nonalcoholic beverage sweetened with sugar or another caloric sweetener, with more than twenty-five calories per eight fluid ounces of beverage, and with milk or milk-substitute ingredients constituting fifty percent or less of the beverage by volume.[39]

On June 9, the City published a notice of public hearing to be held by the New York City Department of Health and Mental Hygiene (DOHMH) in late July.[40] Afterwards, DOHMH sent a memo to its rule-making arm, the City's Board of Health (BOH), summarizing the hearing.[41]

Shortly thereafter, on September 13, the BOH, composed of eleven members appointed by the mayor, passed New York City Health Code § 81.53 establishing the Soda Portion Cap Rule.[42]

Under the City Charter, the DOHMH has jurisdiction to regulate all "matters affecting health in the City, including conditions hazardous to life and health, by, among other things, regulating the food and drug supply of the City, and enforcing provisions of the New York City Health Code."[43] The BOH is charged with establishing the code of health with respect to anything within the DOHMH's jurisdiction.[44]

The soda portion cap measure met opposition throughout the process. Two days after it was announced, a group of city council members wrote to the mayor, objecting and demanding a council vote.[45] One month after it was adopted, a coalition of plaintiffs sued the DOHMH in state court over the rule.[46] The county court, in an opinion by Judge Tingling, invalidated the rule as both "arbitrary and capricious" and as improper "legislation" by an administrative entity in violation of the state

38. N.Y. Statewide Coal. of Hispanic Chambers of Commerce v. N.Y.C. Dep't of Health & Mental Hygiene (*New York Statewide II*), 970 N.Y.S.2d 200, 205 (N.Y. App. Div. 2013).
39. N.Y.C., N. Y., N.Y.C. HEALTH CODE § 81.53 (2012) (repealed 2013).
40. *New York Statewide II*, 970 N.Y.S.2d at 205.
41. *Id.*
42. *Id.* at 204–05.
43. *Id.* at 204.
44. N.Y.C. CHARTER §§ 553, 558 (2009).
45. *New York Statewide II*, 970 N.Y.S.2d at 204.
46. *Id.* at 206.

constitutional separation of powers test laid out in a prior case,[47] *Boreali v. Axelrod*.[48] This outcome was upheld on appeal by Judge Renwick, relying upon the separation of powers' grounds for invalidation and, therefore, declining to reach the issue of the rule's arbitrariness.[49] The highest court in New York then affirmed the intermediate appellate court decision 4–3 on June 26, 2014, with a majority opinion by Judge Pigott and dissent by Judge Read.[50]

2. Exceptions

The Soda Portion Cap Rule was characterized as riddled with exceptions. These exceptions were then blamed as the telltale sign that the health department improperly balanced political considerations, thus violating one of the four prongs of the *Boreali* test for forbidden legislation by an executive agency.

Judge Renwick describes the rule as follows: "The rule thus targeted non-diet soft drinks . . . but contained carve-outs for alcoholic beverages, milkshakes, fruit smoothies and mixed coffee drinks, mochas, lattes, and 100% fruit juices."[51]

These exclusions arose from the definition of "sugary drink."[52] The definition stipulates that a sugary drink is "non-alcoholic."[53] It also defines "sugary drinks" as "sweetened by the manufacturer or establishment," thus excluding 100% fruit juices.[54] The caloric threshold and stipulation of "caloric sweetener" presumably exclude diet soft drinks.[55] Finally, the definition excludes drinks that are constituted by more than fifty percent milk or milk substitute.[56] This parameter thus exempts some lattes, smoothies, mixed coffee drinks, and milkshakes.

Furthermore, because the Soda Portion Cap Rule stated that it applies to "food service establishments," whose scope is elsewhere defined,[57] the petitioners challenging the rule complained that the rule

47. N.Y. Statewide Coal. of Hispanic Chambers of Commerce v. N.Y.C. Dep't of Health & Mental Hygiene (*New York Statewide I*), No. 653584/12, 2013 WL 1343607, at *7–8, *19–20 (N.Y. Sup. Ct. Mar. 11, 2013).

48. Boreali v. Axelrod, 518 N.Y.S.2d 440, 443–45 (N.Y. App. Div. 1987) (striking the New York Public Health Commission's indoor smoking ban as improper legislation by a state agency).

49. *New York Statewide II*, 970 N.Y.S.2d at 213.

50. N.Y. Statewide Coal. of Hispanic Chambers of Commerce v. N.Y.C. Dep't of Health & Mental Hygiene (*New York Statewide III*), 16 N.E.3d 538, 540, 549–50 (N.Y. 2014).

51. *New York Statewide II*, 970 N.Y.S.2d at 205.

52. N.Y.C., N. Y., N.Y.C. HEALTH CODE § 81.53(a)(1)(A)–(D) (2012) (repealed 2013).

53. *Id.* § 81.53(a)(1)(A).

54. *Id.* § 81.53(a)(1)(B).

55. *Id.*

56. *Id.* § 81.53(a)(1)(D).

57. N.Y. Statewide Coal. of Hispanic Chambers of Commerce v. N.Y.C. Dep't of Health & Mental Hygiene (*New York Statewide II*), 970 N.Y.S.2d 200, 204 (N.Y. App. Div. 2013) (quoting the code's definition of a "food service establishment" (FSE) as "a place where food is provided for individual portion service directly to the consumer whether such food is provided free of charge or sold, whether consumption occurs on or off the premises or is provided from a pushcart, stand or

"would appear to exempt grocery stores, convenience stores, bodegas and markets from having to comply with the Rule. . . . [Such exempt establishments would] includ[e] the 7-11 market chains and their famous, or infamous, Big Gulp containers . . . ."[58]

Finally, because the rule regulates size, but not number, of portions, the petitioners could characterize refills as an exception and persuade New York's highest court that the entire approach of capping portion size was underinclusive. [59]

3. *Boreali* Test

The principal complaint that emerges in the suit is that the health department, as an executive agency, has engaged in an act of impermissible "legislation." Petitioners contend that under the New York State Constitution, agencies like the BOH "may not bypass the legislature, under the guise of public health, and make fundamental policy choices and establish far-reaching new policy programs all by themselves, no matter how well-intentioned they may be."[60] How does the presence of exceptions pertain to whether the Soda Portion Cap Rule constitutes improper "legislation," violating state separation of powers doctrine? The answer is that *Boreali*, the seminal case defining the test for such a doctrine, contains a prong designating exceptions as a sign of such improper legislating.[61]

The *Boreali* test identifies four prongs, the first of which speaks most directly to the issue of exceptions. The first prong looks at "whether the challenged regulation is based upon concerns not related to the stated purpose of the regulation, i.e., is the regulation based on other factors such as economic, political or social concerns?"[62] In other words, "The first factor in *Boreali* probes whether the challenged regulation *carves out exemptions* based on economic, political and social considerations."[63]

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vehicle" (quoting N.Y.C., N.Y., N.Y.C. HEALTH CODE § 81.03(s))). The definition of FSEs also "excludes food processing establishments, retail food stores, private homes . . . and food service operations where a distinct group mutually provides . . . and consumes the food." N.Y. Statewide Coal. of Hispanic Chambers of Commerce v. N.Y.C. Dep't of Health & Mental Hygiene (*New York Statewide I*), No. 653584/12, 2013 WL 1343607, at *8 (N.Y. Sup. Ct. Mar. 11, 2013). According "to [the] 2010 Memorandum of Understanding (MOU) . . . [with] the State's Department of Agriculture and Markets, an FSE is subject to inspection by a local health department only if it generates 50% or more of its total annual dollar receipts from the sale of food for consumption on the premises or ready-to-eat for off-premises consumption." *New York Statewide II*, 970 N.Y.S.2d at 204.

58. *New York Statewide I*, 2013 WL 1343607, at *8.

59. *See id.*; *see also* N.Y. Statewide Coal. of Hispanic Chambers of Commerce v. N.Y.C. Dep't of Health & Mental Hygiene (*New York Statewide III*), 16 N.E.3d 538, 547 (N.Y. 2014).

60. *New York Statewide II*, 970 N.Y.S.2d at 206 (quoting Petition, *New York Statewide I*, No. 653584/12 (N.Y. Sup. Ct. Oct. 11, 2012), 2013 WL 1343607).

61. Boreali v. Axelrod, 517 N.E.2d 1350, 1355 (N.Y. 1987).

62. *New York Statewide I*, 2013 WL 1343607, at *8.

63. *Id.* (emphasis added).

The second prong asks whether the agency filled in the "interstitial" details of "legislation describing the over-all policies to be implemented" or if it "wrote on a clean slate, creating its own comprehensive set of rules without [the] benefit of legislative guidance."[64] The third prong inquires, "[D]id the regulation intrude upon ongoing legislative debate? In other words, did the regulation address a matter the legislature has discussed, debated or tried to address prior to this regulation?"[65] And finally, the fourth prong weighs whether "the regulation require[d] the exercise of expertise or technical competence on behalf of the body passing the legislation."[66]

Thus, if an agency engages in line drawing to pursue public health without excessive economic cost, the first *Boreali* prong would tend to characterize the agency's action as legislative because such a measure aims "to resolve difficult social problems by making choices among competing ends."[67]

The *Boreali* court, in striking a state public health regulation on indoor smoking, noted:

> The exemptions . . . carved out for bars, convention centers, small restaurants . . . as well as the . . . 'waivers' based on financial hardship, have no foundation in considerations of public health. Rather, they demonstrate the agency's own effort to weigh the goal of promoting health against its social cost and to reach a suitable compromise.[68]

Boreali declares that exemptions are a sign that this compromise is occurring because, precisely as Finkelstein argued, exemptions typically "run counter to such goals and, consequently, cannot be justified as simple implementations of legislative values."[69]

Even as the *Boreali* framework assumes that exceptions are "external," presupposing a justificatory value apart from and competing with the value embodied in the rule, the city health organs tried to argue that the soda portion cap's exceptions were "internal" and "based solely on health-related concerns."[70] While this argument does not account for all the exemptions,[71] the health agencies explained that the exceptions for milk or juice were justified insofar as each of these items have some nu-

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64. *Boreali*, 517 N.E.2d at 1356.
65. *New York Statewide I*, 2013 WL 1343607, at *8.
66. *Id.*
67. *Boreali*, 517 N.E.2d at 1356.
68. *Id.* at 1355.
69. *Id.*
70. *New York Statewide II*, 970 N.Y.S.2d at 209.
71. For instance, alcohol or convenience store Big Gulp drinks were exempted because other executive agencies had claims of jurisdiction. *See, e.g.*, Katherine Pratt, *The Limits of Anti-Obesity Public Health Paternalism: Another View*, 46 CONN. L. REV. 1903, 1921, 1928 (2014).

tritional value.[72] However, Judge Renwick remained unconvinced because she regarded the entire design of the provision as underinclusive: the rule, she observed, in manipulating portion size, does not ban sugary drinks entirely.[73] She said it instead "relies upon the behavioral economics concept that consumers are pushed into better behavior when certain choices are made less convenient."[74]

Remarkably, for Renwick and Pigott, it is this regulatory modesty which proves that the agency was balancing, not just considering health: "By restricting portions, the Board necessarily chose between ends, including public health, the economic consequences associated with restricting profits by beverage companies and vendors . . . and personal autonomy . . . ."[75]

The courts also found it damning that the health department framed the obesity toll in economic terms. The health department had observed that "[o]besity related health care expenditures in New York City now exceed $4.7 billion annually . . . Medicare and Medicaid programs funded by tax dollars, pay approximately 60 per cent [sic] of those costs."[76] This economic quantification spurred the court to say that the city was inappropriately considering economic counterweights to health concerns.[77]

The health agency also accommodated the jurisdiction of the New York State Department of Agriculture and Markets by avoiding direct regulation of grocery stores, which are otherwise under their sister agency's inspection purview. To Tingling, though, "[t]his could be construed as evidencing political considerations outside of the Statement of Basis and Purpose."[78] The vision that the judges furnish for proper agency behavior is quite puzzling. If agencies were to disregard jurisdiction, political considerations, economic costs, and all other ends, that tunnel vision would seem itself to pose threats in the form of agency overreach.[79]

4. Value Conflict

The Soda Portion Cap exceptions thus signify the resolution of conflicting purposes and prompt judicial invalidation of the rule.

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72. *New York Statewide II*, 970 N.Y.S.2d at 209.

73. *Id.*

74. *Id*.

75. N.Y. Statewide Coal. of Hispanic Chambers of Commerce v. N.Y.C. Dep't of Health & Mental Hygiene (*New York Statewide III*), 16 N.E.3d 538, 547 (N.Y. 2014); *see also New York Statewide II*, 970 N.Y.S.2d at 209.

76. N.Y. Statewide Coal. of Hispanic Chambers of Commerce v. N.Y.C. Dep't of Health & Mental Hygiene (*New York Statewide I*), No. 653584/12, 2013 WL 1343607, at *9 (N.Y. Sup. Ct. Mar. 11, 2013) (alteration in original) (quoting N.Y.C. Health Commissioner Farley).

77. *Id.* at *9.

78. *Id.* at *8; *see also New York Statewide II*, 970 N.Y.S.2d at 210.

79. *See* Paul A. Diller, *Local Health Agencies, the Bloomberg Soda Rule, and the Ghost of Woodrow Wilson*, 40 FORDHAM URB. L.J. 1859, 1898–99 (2013).

The formulation of the *Boreali* prong illustrates that the way the rule confronts value conflict is one, if not *the* decisive issue in the case. But we also find support in the fact that the battle was joined precisely at the issue of whether the exception was "internal," serving other health needs, rather than a reflection of some external purpose.[80] With an internal justification, the value conflict dissolves to a mere question of which means one should use to pursue the unitary value of health. That judges in each of these cases refuse to recognize the exceptions as "internal" signals there is something more going on in these cases apart from the means-ends analysis associated with the ordinary fit tests of substantive review for rationality.

Instead, the courts seem wedded to showing that the exceptions are external and that each rule, despite its alignment with the constellation of ends that it is navigating, is "unfit." The courts are therefore positing a single, unalloyed justification for the rule. They then proceed to vigorously interrogate "fit" relative to the rule's posited justification. In this case, the court derived the requirement that health serves as the sole justification for BOH action from the state's constitutional separation of powers doctrine. What is curious about the unitary justification approach is that if it prevails, any standard setting is doomed, not just the delineation of a standard's scope through exceptions.[81] It simply fails the plausibility test to pretend that standard setting can avoid settling among competing ends.

Furthermore, the courts' insistence upon rationalization of every aspect of the rule to its one recognized justification seems to run counter to the very function of a rule. As Schauer clarifies, the nature of a rule is applicability even at the point where the justification would not fit.[82] Thus, the rule applied in some instances will not match the rule's justification. Even Ronald Dworkin, who includes background justifications along with rules as part of the corpus of law, distinguishes "rules," which have all-or-nothing force, from their supporting principles and policies, which merely exert "weight."[83] Of principles, he says, "When principles intersect . . . one who must resolve the conflict has to take into account the relative weight of each."[84] However, "[i]f the facts a rule stipulates are given, then either the rule is valid, in which case the answer it supplies must be accepted, or it is not, in which case it contributes nothing to

80. *See supra* text accompanying note 71.

81. *See, e.g.*, Rick Hills, *Why Did Bloomberg's Soda Portion Ban Bite the Dust? Was it Mayoral Imperialism, Judicial Activism, or Both?*, PRAWFSBLAWG (Mar. 11, 2013, 8:23 PM), http://prawfsblawg.blogs.com/prawfsblawg/2013/03/bloombergs-soda-portion-ban-bites-the-dust-defeat-for-an-imperial-mayor-or-victory-for-activist-judg.html ("Is Justice Tingling really demanding that agencies jettison consideration of cost, administrative feasibility, personal privacy, or financial feasibility when they pursue their primary mandate?").

82. SCHAUER, *supra* note 27, at 75–76.

83. *See* DWORKIN, *supra* note 10, at 22–28, 71–80.

84. *Id.* at 26.

the decision."[85] Thus Dworkin, like Schauer, believes that rules apply even when an underlying principle runs out, or conversely, that the rule may stop short of an underlying principle, including in those situations when the rule accommodates a competing principle.[86]

That the soda portion cap's fatal flaw was its attempt to perform this very function of resolving value conflict by fiat is also paradoxically evident in that the argument against the rule was framed as a lack of limiting principle. On June 4, 2013, when the appellate court heard oral arguments, the judge repeatedly queried the scope of the Board's jurisdiction and asked whether there was any principle limiting the Board's jurisdiction.[87] This argument is ironic because, in fact, the health agency was trying to limit its jurisdiction and promote health while not overreaching. It was steering clear of other social and cultural practices while respecting the Memorandum of Understanding (MOU) that divided inspection and oversight between health and agriculture agencies. Why was the soda portion rule's limitation, ostensibly condemned as underinclusive relative to its health objectives, then viewed as an indication that its scope of purpose was too broad and lacking a "limiting principle?" Perhaps the key word is "principle." The judiciary demands that jurisdiction should not be limited or designated ad hoc, or even by ex ante decision rule, but by background principle.

Here, the argument of underinclusion is turned on its head. And we see the germ of the court's conception of rules, namely, its elision of rules and principles, which leads it to reject these particular measures.[88]

5. Assign to Non-Legal Sphere

Having invalidated rule-based line drawing, the courts' next maneuver is to assign the decision to another decision-making sphere. In the

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85. *Id.* at 24.

86. *Id.* at 26–27; *see also id.* at 77 ("[T]hese rules have a different shape than they would have had if the principle [that no man may profit from his wrongs] had not been given any weight in the decision at all. The long length of time generally required for acquiring title by adverse possession might have been much shorter, for example, had this not been thought to conflict with the principle. Indeed, one of my reasons for drawing the distinction between rules and principles was just to show how rules often represent a kind of compromise amongst competing principles in this way . . . ."); RONALD DWORKIN, LAW'S EMPIRE 180–84 (1986) (expressing Dworkin's views on compromise). Thus, Dworkin would recognize exceptions as binding even if they embodied a principle competing with the one underlying other parts of the rule; it would be binding because the exception would be part of the rule itself.

87. *See* Glenn Blain, *New York City's Soda Ban Bubbles Up to the State's Highest Court – Updated*, N.Y. DAILY NEWS (Jun. 4, 2014, 5:04 PM), www.nydailynews.com/blogs/dailypolitics/new-york-city-soda-ban-bubbles-state-highest-court-blog-entry-1.1817197.

88. *See* DWORKIN, *supra* note 10, at 73 (responding to Joseph Raz, of occasions for such elision "[b]ut I did not deny, in my original article, that conflicts in rules might exist. I said that in our legal system such conflicts would be occasions of emergency, occasions requiring a decision that would alter the set of standards in some dramatic way. . . . [H]e may amend one or both of them to provide for the conflict, or he may revise his attitude towards one or both so as to convert them from rules into principles").

opinions striking the Soda Portion Cap Rule, the courts' eagerness to offload this decision to another decision-making mode is not matched by clarity about what that mode might be.[89] The judges assume, rather than argue, that because the agency was improperly legislating, the politically accountable legislature should have been the appropriate arena. However, this assumption is perhaps too hasty on their part.

The prongs of the *Boreali* separation of powers test presuppose "politics" or the legislature as the mode of decision-making illegitimately displaced by the agency rule, and by extension, the default arena to which this decision would revert. After all, the court introduces the test as the means to judge whether the agency has "impermissibly trespassed on legislative jurisdiction."[90] Moreover, the test's second prong probing for "interstitial" gap filling or writing on "a clean slate" elevates the guiding instructions of the legislature as dispositive.[91] The third prong further asks whether the legislature has otherwise proposed or taken action such that the regulation at issue intrudes upon this ongoing debate.[92] The assumption is that the legislative sphere is proper.

Yet while the first prong, with which we are most concerned, designates economic, political, and social concerns as competing considerations, it does not necessarily command the political, rather than economic or social sphere, as the arena through which one should negotiate the resolution of those concerns. In this particular case, the courts do embrace political contest as the appropriate alternate mode; however, that choice is underdetermined, even by the very terms of the *Boreali* test.

Indeed, the judges in this case sporadically advert to what they conceive of as the alternate decisional mode of science.[93] Judge Renwick, in examining the fourth *Boreali* prong, which counts agency expertise as a factor favoring validity, chastises the BOH for failing to employ its public health expertise, rather than its political judgment.[94] Thus, "scientific expertise" could have been an alternate domain for resolving conflicting values. However, the judges choose not to assign the decision there, but rather to politics, without much in the way of explanation for their choice. The nostrum that "science" and "scientific reasoning" can objectively and conclusively recommend a course of action has been so thor-

89. For an explanation of why and how that offloading occurs in health law, see Christina S. Ho, *In Defense of Circular Reasoning: The Affordable Care Act and the Resilience of Law and Self-Reference*, 5 WM. & MARY POL'Y REV. 1 (2013).

90. N.Y. Statewide Coal. of Hispanic Chambers of Commerce v. N.Y.C. Dep't of Health & Mental Hygiene (*New York Statewide I*), No. 653584/12, 2013 WL 1343607, at *6 (N.Y. Sup. Ct. Mar. 11, 2013)

91. Boreali v. Axelrod, 517 N.E.2d 1350, 1356 (N.Y. 1987).

92. *Id.*

93. *See* N.Y. Statewide Coal. of Hispanic Chambers of Commerce v. N.Y.C. Dep't of Health & Mental Hygiene (*New York Statewide II*), 970 N.Y.S.2d 200, 212–13 (N.Y. App. Div. 2013).

94. *Id.* (complaining that "the Board did not bring any scientific or health expertise to bear in creating the Portion Cap Rule").

oughly debunked that I need not do so here.[95] My argument depends not upon the truth but rather on the court's implicit use of that misconception, i.e., its lingering reliance upon the illusory notion of an objective and determinate realm of scientific decision-making.[96]

While the courts proffer "politics" and "science" as the two chief social decision-making institutions ostensibly distinct from and preferable to decision by legally promulgated rules, it is worth mentioning a distant third. Judges Pigott and Renwick also suggest that perhaps the appropriate decision-making arena should be private ordering. By this mode, the decision of portion size would fall not to health regulation but to individual choice. Renwick suggests this approach when she rebuts the health department's internal justification argument by insisting that the board must have balanced health concerns and concluded that they "outweigh the cost of infringing on *individual rights to purchase a product* that the Board has never categorized as inherently dangerous."[97] Pigott echoes the sentiment: "This preference for an indirect means of achieving compliance with goals of healthier intake of sugary beverages was itself a policy choice, relating to *the degree of autonomy a government permits its citizens to exercise . . . .*"[98]

The court never fully develops the argument that such background "rights" exist, but one can imagine a decision where the court defended the principle of open individual choice and that arena as the proper mode for prioritizing among health and other considerations. Had it done so, then the court would have had to deny the legislatively enacted instruction to the agency to protect health, which inevitably limits open individual choice, and has even recently been understood to include near-complete bans of substances like artificial trans fats.[99] The judges here opted for the other extreme instead, which is to maintain, rather remarkably, that health should have been protected without balancing and with-

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95. *See, e.g.*, Cary Coglianese & Gary E. Marchant, *Shifting Sands: The Limits of Science in Setting Risk Standards*, 152 U. PA. L. REV. 1255 (2004).

96. Here my use of the category "science" or "scientific expertise" follows CHRISTOPHER F. EDLEY, JR., ADMINISTRATIVE LAW: RETHINKING JUDICIAL CONTROL OF BUREAUCRACY 7–10 (1990) (describing "the trichotomy of decision making paradigms—adjudicatory fairness, scientific expertise, and politics" which anchor the distinctions that judges implicitly and expressly draw upon in administrative law disputes). Edley fully recognizes that science cannot operate without the exercise of some judgment which is inevitably "political," acknowledging that "virtually all sciences, involve[] uncertainties of prediction and measurement. Science alone, to the extent one can conceive of it, cannot determine what to do with those uncertainties." *Id.* at 75. Instead he argues that despite the conceptual instability of "science" as a distinct paradigm, it is this confused notion that courts rely upon time and time again to discharge their duties in deciding administrative law cases. *Id.* at 72–77.

97. *New York Statewide II*, 970 N.Y.S.2d at 209 (emphasis added).

98. N.Y. Statewide Coal. of Hispanic Chambers of Commerce v. N.Y.C. Dep't of Health & Mental Hygiene (*New York Statewide III*), 16 N.E.3d 538, 547 (N.Y. 2014) (emphasis added).

99. N.Y.C., N.Y., N.Y.C. HEALTH CODE § 81.08 (2012); *see also* Lindsay F. Wiley, Commentary, *Sugary Drinks, Happy Meals, Social Norms, and the Law: The Normative Impact of Product Configuration Bans*, 46 CONN. L. REV. 1877, 1881 n.9 (2014) (discussing the lack of principled distinction between trans fat ban and soda portion cap).

out regard to other concerns, including such "individual [background] rights to purchase a product."[100] Judge Pigott is accused by the dissent of the same but disclaims support for an absolute ban by invoking a rights-inflected argument that prohibition of sugary beverages altogether would also amount to "policy-making, not rule-making" because it "interferes with commonplace daily activities preferred by large numbers of people."[101]

What if the court had claimed squarely that this decision belonged to individual choice? Would such a presumptive "right" or principle come from the state separation of powers doctrine? Would it come from some extreme theory of due process? Meanwhile, we need hardly rehearse the arguments that just as "pure" objective scientific decision-making is a myth, no such unstructured realm of free individual choice exists either. Market dynamics constrain individual choice, and the market itself is already shaped by regulatory choices.[102] Indeed this market-norming argument underlies the soda portion cap measure itself. The notes accompanying the BOH proposal stated that "People tend to consume more calories at meals that include large beverage sizes. [This measure's] intent is to address the super-size trend and reacquaint New Yorkers with smaller portion sizes, leading to a reduction in consumption of sugary drinks among New York City residents."[103]

Thus, the availability of individual choice as an arena apart from law depends, among other things, on whether one believes that the individual can exercise her private preferences or whether market ordering permits exploitation of cognitive biases to manipulate individual choice. Indeed, the above-mentioned justification that the health department cites in its memo is the argument that an individual's true preferences are distorted by the super-sizing trend and that the rule is designed to give the individual the opportunity to choose consciously whether he or she wants additional amounts of beverage.[104]

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100. *New York Statewide II*, 970 N.Y.S.2d at 209; *see also New York Statewide III*, 16 N.E.3d at 558 (Read, J., dissenting) ("The Appellate Division . . . appears to conclude that the Board would have acted properly if only it had completely banned all sugary drinks within the City's borders.").

101. *New York Statewide III*, 16 N.E.3d at 548.

102. *See, e.g.*, CASS R. SUNSTEIN, FREE MARKETS AND SOCIAL JUSTICE 17 (1997) ("Whether people have a preference for a commodity, a right, or anything else is in part a function of whether the government has allocated it to them in the first instance. There is no way to avoid the task of initially allocating an entitlement (short of anarchy)." (footnote omitted)); *see also* Mark Kelman, *Legal Economists and Normative Social Theory* (1987), *reprinted in* FOUNDATIONS OF THE ECONOMIC APPROACH TO LAW 326, 330–32 (Avery Wiener Katz ed., 1998); Robert L. Hale, *Coercion and Distribution in a Supposedly Non-Coercive State*, 38 POL. SCI. Q. 470, 479–81 (1923).

103. N.Y. Statewide Coal. of Hispanic Chambers of Commerce v. N.Y.C. Dep't of Health & Mental Hygiene (*New York Statewide I*), No. 653584/12, 2013 WL 1343607, at *3 (N.Y. Sup. Ct. Mar. 11, 2013) (quoting notes accompanying N.Y.C., N.Y., N.Y.C. HEALTH CODE § 81.53 (2012) (repealed 2013)).

104. *New York Statewide II*, 970 N.Y.S.2d at 205 (providing the DOHMH's summary of the debate regarding the Soda Portion Cap Rule after the public hearing and quoting the DOHMH's

These alternate arenas of science or private ordering are never expressly analyzed by the courts, and the courts seem to designate the political arena as its favored arena by virtual acclamation.

6. Judge Arrogates the Decision and Simulates a Non-Legal Method

The court's adoption of politics as the preferred forum for this matter poses its own puzzles. When should the presence of value conflict require a diversion to "politics," much less some alternate decision-making arena for resolution? The mere presence of value balancing cannot be the answer because, if so, then all law would be legislative and the distinction that the *Boreali* factors attempt to draw would collapse. If the case is stripped of distracting and inconclusive doctrinal garb, we are left with merely a judge, deciding that a particular balance or configuration of competing values is unacceptable.[105] And perhaps to avoid the chagrin of nakedly substituting her own conception of balance, the judge then confers that task upon a different organ, in this case the legislature.[106]

To consider this explanation, we look at what the court claims to be doing to identify the instances of "improper" balancing that prompt diversion of the matter away from legal rule setting. The court uses the *Boreali* test, but the approach that test employs is one of balancing, which hardly allays our suspicions that the judge comes close to nakedly substituting her own preferred resolution of competing values.[107] Indeed, the *Boreali* test is particularly indeterminate because, as the court re-

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conclusion that "[i]f the proposal is adopted, customers intent upon consuming more than 16 ounces would have to make conscious decisions to do so").

105. The Court of Appeals dissent says as much: "With all due respect to my colleagues, their proposed ends-means test . . . harks back to long discredited formalistic approaches to administrative law, which were seemingly objective but instead served as camouflage for enforcement of judicial preferences." *New York Statewide III*, 16 N.E.3d at 560 (Read, J., dissenting).

106. *See* Jeremy Waldron, *Did Dworkin Ever Answer the Crits?*, *in* EXPLORING LAW'S EMPIRE: THE JURISPRUDENCE OF RONALD DWORKIN 155, 173–76 (Scott Hershovitz ed., 2006) (discussing how the judge, in confronting the materials before him, each side with its own conflicting account of how to balance different competing values, is in the end choosing simply by conducting and insisting on his own balance, and imposing it as the tiebreaker). *But see* Ronald Dworkin, *Response*, *in* EXPLORING LAW'S EMPIRE: THE JURISPRUDENCE OF RONALD DWORKIN 291, 304 (Scott Hershovitz ed., 2006) (responding that it is not Hercules' own balance but what he believes to be the balance dictated by the principle that best fits the rest of the law, assuming that there is such a fit to be found or constructed while maintaining political integrity).

107. T. Alexander Aleinikoff might characterize this "totality of the circumstances" test as less strictly a "balancing" method, but rather a factor checklist or "analogical" type of reasoning, where "one starts with [a] conception of what constitutes voluntariness and involuntariness and then asks whether the particular situation shares more of . . . [those] elements." T. Alexander Aleinikoff, *Constitutional Law in the Age of Balancing*, 96 YALE L.J. 943, 945 (1987). But Aleinikoff also classifies *Commodity Futures Trading Commission v. Schor* as a "balancing" case, Aleinikoff, *supra*, at 947, even though in *Schor*, O'Connor weighs factors to determine whether "the 'essential attributes of judicial power' are reserved to Article III courts" when the agency adjudicates. Commodity Futures Trading Comm'n v. Schor, 478 U.S. 833, 851 (1986). If O'Connor's approach there constitutes balancing, rather than analogy, in a similar assessment under separation-of-powers doctrine of whether agency action too closely resembles that of a coordinate branch, then the distinction is much less meaningful than Aleinikoff assumes.

minds us, in this test no one factor is dispositive, and the test instead "must be viewed in combination and in totality."[108]

Admittedly, balancing factors in a legal test is not identical to first-order balancing of competing values.[109] There is a large and vigorous literature on proportionality and balancing, which I do not, for my purposes, need to enter here.[110] My argument merely depends upon the court engaging in its own version, if slightly deflected, of the analysis it denounces. It is enough that most would agree that it remains an open question whether such judicial balancing is conclusively distinct from political balancing.

Such judicial substitution for political balancing could not, of course, proceed too baldly. Indeed, the courts engage in a sleight of hand to disguise who decides. This imperative may explain why a profusion of non-legal realms is implicated. Ostensibly, the doctrine says the legislature should decide, yet the judge is deciding when the legislature decides. And what of the other realms we considered?

In deciding that science does not support the agency's decisions, insofar as the agency's clear authority to take strong public health measures either in the event of epidemic or to ban health hazards was not triggered, the judges employed their lay version of scientific reasoning to suggest that obesity is not an epidemic.[111] Judge Tingling attempted to ground his decision in "scientific" distinctions—that the obesity threat could not technically constitute an epidemic if the nature of the hazard was chronic rather than infectious disease.[112] This claim is fairly risible, as epidemic has been used to refer to noninfectious disease since the second half of the twentieth century.[113]

Renwick also treads on science when she argues that for the rule to be valid, sugary soda itself would have to be declared a health hazard without qualification.[114] Otherwise, the health department has long been understood as authorized to simply ban hazardous foods to protect health, well within the "interstices" of the power delegated to the agency. Indeed, the department exercised this authority in banning artificial trans

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108. *New York Statewide I*, 2013 WL 1343607, at *7.

109. *See, e.g.*, RAZ, *supra* note 37, at 35–40, 46–47 (discussing the problems of balancing first-order concerns against second-order concerns).

110. *See, e.g.*, Mark Antaki, *The Rationalism of Proportionality's Culture of Justification*, *in* PROPORTIONALITY AND THE RULE OF LAW: RIGHTS, JUSTIFICATION, REASONING 284, 284 & n.1 (Grant Huscroft et al. eds., 2014); Richard H. Pildes, *Avoiding Balancing: The Role of Exclusionary Reasons in Constitutional Law*, 45 HASTINGS L.J. 711 (1994).

111. *See, e.g.*, *New York Statewide I*, 2013 WL 1343607, at *16.

112. *See id.*

113. Paul M.V. Martin & Estelle Martin-Granel, *2,500-Year Evolution of the Term Epidemic*, 12 EMERGING INFECTIOUS DISEASES 976, 979 (2006).

114. *See* N.Y. Statewide Coal. of Hispanic Chambers of Commerce v. N.Y.C. Dep't of Health & Mental Hygiene (*New York Statewide II*), 970 N.Y.S.2d 200, 209 (N.Y. App. Div. 2013).

fats.[115] Renwick dismisses such authority as inapplicable to the current case, finding that soda cannot be a health hazard by virtue merely of consumption in "excess quantity."[116] What reasoning skill does she bring to bear in identifying hazards to health and the appropriate conditions under which they pose a hazard? And why should an exposure fail to constitute a health hazard if its effects require a threshold quantity? Some hazards have zero-threshold dose-response curves, and some have U-shaped curves.[117] Numerous substances like fluorine, selenium, and other nutrients are healthy at low doses and do not become hazards until they cross a certain threshold. Renwick must make these dubious technical claims to find that the rule fails prong two, namely, that it is not interstitial rulemaking within the authority clearly delegated to the agency over health hazards.[118] Scientific identification of a hazard and legal determination defining the statutory meaning of "health hazard" resemble distorted mirror doubles.

Renwick's approach to hazard identification is by no means a foregone conclusion, but instead a methodological choice. Other jurisdictions have chosen differently. As Sunstein has noted, federal administrative law takes a different approach to the question of hazard identification in the face of qualifying considerations.[119] In his account, federal courts grant federal agencies default permission to craft *de minimis* exceptions,[120] whereas Renwick requires a per se ban of even insignificant levels of risk from sugary soda.

Finally, while the court briefly mentions markets, i.e., private choice or ordering, as another regime, it did not pursue its own suggestion of private ordering as the proper mode. Had it chosen to do so, however, there is a ready-made form of judicial discourse, law and economics, which also involves the judicial performance of an ersatz methodology to approximate the efficient results that might emerge from market processes.[121]

In the soda portion cap case, the *Boreali* test itself is indeterminate, but the underinclusiveness of the rule, by exposing the unavoidable balancing of health against other ends, provokes the court to act upon its anxiety about the highly reticulated agency-crafted rule as the social tool

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115. N.Y.C., N.Y., N.Y.C. HEALTH CODE §81.08(a) (2006); *see, e.g.*, Paul A. Diller, *Why do Cities Innovate in Public Health? Implications of Scale and Structure*, 91 WASH. U. L. REV. 1219, 1238 (2014).

116. *New York Statewide II*, 970 N.Y.S.2d at 211.

117. *See* J.M. Davis & D.J. Svendsgaard, *U-Shaped Dose-Response Curves: Their Occurrence and Implications for Risk Assessment*, 30 J. TOXICOLOGY & ENVTL. HEALTH 71 (1990).

118. *See New York Statewide II*, 970 N.Y.S.2d at 210–11.

119. *See supra* notes 11–17 and accompanying text.

120. *See supra* notes 11–17 and accompanying text.

121. *See, e.g.*, A. MITCHELL POLINSKY, AN INTRODUCTION TO LAW AND ECONOMICS (4th ed. 2011); RICHARD A. POSNER, ECONOMIC ANALYSIS OF LAW (8th ed. 2011); STEVEN SHAVELL, FOUNDATIONS OF ECONOMIC ANALYSIS OF LAW (2004).

governing and accommodating value conflict. Politics, or even science or markets, would be preferable. Is distinction between portion size and number of portions somehow particularly irrational?[122] Are judges recognizing some presumptive "right" to health protection, or presumptive "right" to autonomy that ought not be easily outweighed by other considerations? But where would such a right come from? These cannot plausibly inhere in the separation of powers doctrine alone. Is it implicit in the delegation to the City Council? But the analysis used to identify when agencies ought not compromise was hardly a statutory analysis.

When we examine what judges use to determine when the matter should be deflected away from the domain of rules, we find, notably, a pidgin science, and a "balancing" test where no one or more prongs can be said to be dispositive and where no particular threshold has been articulated for satisfaction of the test. Rather than applying a clear rule, or even a consistent principle, the courts engage in an elaborate disguise of where rule-ness runs out.

B. Tummino v. Hamburg*: Plan B OTC Switch*[123]

Plan B is a drug approved by the FDA in 1999 for use as an emergency contraceptive.[124] The active ingredient in the drug, a synthetic progesterone called levonorgestrel, was approved decades ago for uses other than emergency contraception.[125] Levonorgestrel is a component of many daily oral contraceptives and intrauterine devices (IUDs).[126] These long-approved indications refer to the use of levonorgestrel prior to and during intercourse.[127] However, within a certain window of time post-intercourse, levonorgestrel is also effective in reducing the risk of unwanted pregnancy.[128] Thus, in 1997, the FDA solicited and approved applications to market prescription-only levonorgestrel in specific doses for this new post-intercourse, or "emergency contraception," use.[129] The approved product was called Plan B.

The chapter of this history that concerns us now arose in the mid-2000s. At that time, the FDA came under public pressure to make a product that was well-documented to be non-toxic available over-the-counter (OTC). Eventually, the FDA did approve a switch to OTC status for Plan B levonorgestrel as an emergency contraceptive, but only after

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122. *Cf.* Pac. Box & Basket Co. v. White, 296 U.S. 176 (1935).
123. I am indebted to Bernard Bell for suggesting this case.
124. Tummino v. Torti (*Tummino I*), 603 F. Supp. 2d 519, 522 (E.D.N.Y. 2009).
125. *See* Emergency Contraception Fact Sheet, WORLD HEALTH ORG. (July 2012), http://www.who.int/mediacentre/factsheets/fs244/en/. *See generally* Lisa Heinzerling, *The FDA's Plan B Fiasco: Lessons for Administrative Law*, 102 GEO. L.J. 927, 931–33 (2014).
126. *See id.* at 931.
127. *Id.* at 931–33.
128. *Tummino I*, 603 F. Supp. 2d at 522.
129. *Id.* at 525.

much delay, and crucially, only for women 18 and older.[130] This decision for age-restricted OTC availability was immediately challenged and resulted in extensive judicial action, memorialized in a series of opinions by Judge Korman of the Eastern District of New York, who was the presiding judge in the lawsuit over this matter.[131]

1. FDA Background: Narrow Indications and Scope of Regulatory Action

I pause to describe the drug approval regime in brief as it explains how the contours of FDA regulatory action, including regulatory "carve-outs," are generally defined with respect to particular drugs. Since 1962, drugs for humans have been subject to the modern pre-market approval regime in the United States.[132] Section 505(a) of the Food Drug & Cosmetic Act (FDCA) prohibits the introduction of an unapproved "new drug" into interstate commerce.[133] To obtain the approval of the FDA, a "new drug" must be demonstrated by substantial evidence to be safe and effective "for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof."[134]

This "use" is the key parameter. Some may also refer to it as the "claim," as "the effect [the product] purports or is represented to have," or the "indicated use."[135] Because the pre-approval requirements are only triggered for "a new drug," the definition of "new drug" is crucial. The FDCA defines a "new drug" as a drug "not generally recognized . . . as *safe and effective for use under the conditions prescribed*."[136] Thus, the "use" is the matter whose newness triggers regulatory requirements, not the chemical entity itself.

Moreover, the safety and efficacy required for approval are judged relative to that "use" or "indication."[137] Certainly a drug that is effective against headaches might not be effective against brain tumors. Moreover, a highly toxic drug that might be deemed "safe" for use in treating an otherwise life-threatening brain tumor could be too dangerous for mere headaches.

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130. This age range was subsequently expanded to women 17 and older. *See* Diana R. H. Winters, *Intractable Delay and the Need to Amend the Petition Provisions of the FDCA*, 90 IND. L.J. 1047, 1066 & 1067 n.148 (2015). On delay, see *id.* at 1067 & n.148.

131. Tummino v. Hamburg (*Tummino II*), 936 F. Supp. 2d 162 (E.D.N.Y. 2013); *Tummino I*, 603 F. Supp. 2d at 519; Tummino v. Hamburg (*Tummino III*), No. 12-CV-763, 2013 WL 2631163 (E.D.N.Y. June 12, 2013).

132. Drug Amendments of 1962 (Kefauver-Harris Amendment), Pub. L. No. 87–781, 76 Stat. 780, 784 (codified as amended at 21 U.S.C. § 355 (2012)).

133. Federal Food, Drug, and Cosmetic Act § 505(a), 21 U.S.C. § 355(a) (2012).

134. *Id.* § 355(d), (e).

135. *Id.* § 355(d)(5).

136. *Id.* § 321(p)(1) (emphasis added).

137. *See id*. § 355(d) ("If the Secretary finds . . . there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof . . . he shall issue an order refusing to approve . . . .").

If the indication is the all-important reference for the approval regime, who then determines the indication? In practice, the drug manufacturers themselves, often called the "sponsors," define the indications.[138] The sponsor is held to the indication in the sense that they must prove safety and efficacy against that indication, must label adequately for that indication, and cannot, at least in theory, actively market their products for other indications.[139] However, the sponsor's ability to stipulate the indication has gone largely unchallenged with a few exceptions I describe below.[140]

The malleability of indication engenders regulatory difficulties. Clinical trial data is needed to supply evidence of drug's safety and efficacy for any given indication, so the clinical trial's parameters are usually narrowed to the indication's parameters.[141] However, those controlled parameters often fail to reflect circumstances of actual use in the general population. The FDA must engage in a particular type of inference, generalizing the results obtained in the enrolled clinical trial population to predict the results in the actual population. The threat that the clinical trial population might skew compared to the actual users of the drug once it is marketed always lurks in the background.[142] For this and many other reasons, drug approval requires judgment, rather than mechanical calculation of scientifically determinate outcomes. To inform and exercise this judgment, the FDA has a number of tools, including in-house experts in various offices within the Center for Drug Evaluation and Research (CDER).[143] They also have the authority to convene advisory committees to weigh in on the decision.[144]

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138. Ass'n of Am., Physicians & Surgeons, Inc. v. FDA, 226 F. Supp. 2d 204, 206, 216 (D.D.C. 2002); *see id.* at 218 (contending that it is "Congress' will . . . [that] the 'manufacturer . . . through his representations in connection with its sale . . . determine the use to which the article is to be put'" (quoting S. REP. NO. 73-493, at 3 (1934))).

139. However, they often approach promotion of the off-label use through various indirect means, and indeed are arguably protected by the First Amendment in engaging in at least as much. *See* United States v. Caronia, 703 F.3d 149, 160–62 (2d Cir. 2012); *see also* Wash. Legal Found. v. Henney, 202 F.3d 331, 337 n.7 (D.C. Cir. 2000) ("In disposing of the case in this manner, we certainly do not criticize the reasoning or conclusions of the district court."), *vacating in part* 56 F. Supp. 2d 81 (D.D.C. 1999); Wash. Legal Found. v. Friedman, 13 F. Supp. 2d 51, 60–61, 74 (D.D.C. 1998), *injunction amended by*, 36 F. Supp. 2d 418 (D.D.C. 1999).

140. *See, e.g.*, Michael J. Malinowski, *Doctors, Patients, and Pills—A System Popping Under Too Much Physician Discretion? A Law-Policy Prescription to Make Drug Approval More Meaningful in the Delivery of Health Care*, 33 CARDOZO L. REV. 1085, 1102 (2012) ("Industry sponsors hold broad discretion to tailor clinical research and to apply (or not) for approval of specific uses in applications for market access, which provides an incentive to limit the scope of applications for market access, get approval, and then exploit physician off-label use through sponsorship of research and conferences and the distribution of medical journal publications.").

141. *See* 21 U.S.C. § 355(d).

142. *See, e.g.*, Michelle N. Meyer, *Regulating the Production of Knowledge: Research Risk-Benefit Analysis and the Heterogeneity Problem*, 65 ADMIN. L. REV. 237, 241–42 (2013).

143. *See CDER Offices and Divisions*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm075128.htm (last updated June 26, 2015).

144. 21 U.S.C. § 355(n).

Because the indication is often defined by the drug sponsor, it comes as no surprise that the indication's scope serves the sponsor's interests. For instance, if a drug is possibly effective in a broad, and thus high-revenue indication (such as depression or anxiety), but it is easier and cheaper to run trials and get approval for a narrow indication (such as schizophrenia), the sponsors may design a study for a narrow indication to get the drug to market.[145] Because the FDA approvals regulate labeling and how drugs are marketed, but do not limit the "practice of medicine" by physicians,[146] the drug sponsor may still reap profits if doctors happen to prescribe the drug "off-label" to patients with other conditions.[147]

Furthermore, indications, like rules, can be narrowed along a number of different dimensions, not merely along the lines of disease diagnosis. Indications are frequently narrowed to subpopulations to minimize the sponsor's cost and risk as well. Drug manufacturers maintain that they can define their chosen indication to exclude individuals with heart conditions or compromised immune systems from the use indicated in the labeling if they did not enroll those groups in the clinical trial.[148] It is risky and expensive to enroll pregnant women, for instance, in clinical trials, so drug manufacturers may often simply stipulate in the labeling that such product is not approved for use in pregnant women.[149]

Some of the same risks and difficulties in obtaining effective consent for pediatric patients led drug sponsors to decline to enroll children

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145. There were a number of drugs, like gabapentin originally approved for narrow indications like schizophrenia or seizures, then sold more broadly in the 1990's for conditions like depression or anxiety. *See, e.g.*, Duff Wilson, *Side Effects May Include Lawsuits*, N.Y. TIMES, Oct. 3, 2010, at BU1. Such drugs have been the subject of recent litigation. *See, e.g.*, Neurontin Mktg. & Sales Practices Litig. v. Pfizer, Inc., 712 F.3d 60, 61 (1st Cir. 2013), *cert. denied sub nom.*, Pfizer, Inc. v. Kaiser Found., 134 S. Ct. 786 (2013).

146. *See, e.g.*, Aaron S. Kesselheim, *Off-Label Drug Use and Promotion: Balancing Public Health Goals and Commercial Speech*, 37 AM. J.L. & MED. 225, 225 (2011).

147. Much has been written on this subject of off-label use. *See id.* at 225–26; *see also* Ryan Abbott & Ian Ayres, *Can Bayesian Extrapolation Improve FDA Regulation of Off-Label Uses of Drugs and Devices?*, 4 FOOD & DRUG POL'Y FORUM 1, 1–2 (2014); Aaron S. Kesselheim & Michelle M. Mello, *Prospects for Regulation of Off-Label Drug Promotion in an Era of Expanding Commercial Speech Protection*, 92 N.C. L. Rev. 1539, 1539 (2014); Malinowski, *supra* note 140, at 1085–86.

148. *See* Ass'n of Am., Physicians & Surgeons, Inc. v. FDA, 226 F. Supp. 2d 204, 217–18 (D.D.C. 2002) ("I need to acknowledge the limits of FDA's authority. It is our job to review drug applications for the indications suggested by the manufacturer. We do not have the authority to require manufacturers to seek approval for indications which they have not studied. Thus, as a matter of law, if an application contains indications only for adults, we're stuck." (quoting a speech by FDA Commissioner, David Kessler)); David Loughnot, Note & Comment, *Potential Interactions of the Orphan Drug Act and Pharmacogenomics: A Flood of Orphan Drugs and Abuses?*, 31 AM. J. L. & MED. 365, 370–71 (2005) (calling this practice of testing treatments for medically differentiable subgroups of a disease "salami slicing"); *see also* Lars Noah, *Constraints on the Off-Label Uses of Prescription Drug Products*, 16 J. PRODUCTS & TOXICS LIABILITY 139, 144–45 (1994).

149. Barbara A. Noah, *The Inclusion of Pregnant Women in Clinical Research*, 7 ST. LOUIS U. J. HEALTH L. & POL'Y 353, 355–57 (2014).

in their clinical trials.[150] Meanwhile, because of physiological and other differences distinguishing children from adults, including developing organ systems or higher metabolism rates, drug sponsors and regulators were reluctant to generalize adult trial results to the pediatric population.[151] Often, they would simply narrow the indication to, for example, the treatment of depression in patients over the age of eighteen, making no claim as to the drug's safety or efficacy in children.[152]

These examples, however, suggest the limits of the prevailing paradigm that allows manufacturers by and large to control how the drug is presented for use and, therefore, the standards to which the manufacturers are subjecting themselves.[153] Should entire populations be denied information on safety, efficacy, and dosing simply because manufacturers can restrict indications at will? Does our food and drug law take no account of the social expectations of that drug's use? Are boundaries drawn along the lines of age, pregnancy, or immune function equivalent to line drawing based on other population parameters? As it turns out, the paradigm that defers to the manufacturers' stated claims in defining the indication has been checked to some extent by Congress and the FDA. Now, manufacturers must report certain demographics of their clinical trial enrollment.[154] Drug sponsors are prohibited from excluding men and women of reproductive age from their trials.[155] The FDA also tried to issue a regulation mandating pediatric testing and labeling for drugs that it deemed therapeutically meaningful, needed by substantial numbers of children, and feasible for study in the pediatric subpopulation.[156] The regulation was struck as ultra vires by a federal district court, but subsequently codified by Congress, which also authorized six-month addition-

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150. *See, e.g.*, Kurt R. Karst, Comment, *Pediatric Testing of Prescription Drugs: The Food and Drug Administration's Carrot and Stick for the Pharmaceutical Industry*, 49 AM. U. L. REV. 739, 748 n.44 (2000).

151. *See id.* at 748 & n.44.

152. *See id.* at 747.

153. Malinowski, *supra* note 140, at 1119 ("Similarly, using the regulatory process to attempt to impose commercial uses on new drug candidates or specific types of human clinical trials on drug developers would invite allegations of undue impediment on the commercial freedom that is the touchstone of our private market system and introduce susceptibility to legal challenges.").

154. Federal Food, Drug, and Cosmetic Act § 505(b)(1), 21 U.S.C. § 355(b)(1) (2012) ("The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by clause (A)."); *see also* U.S. FOOD & DRUG ADMIN. ET AL., GUIDANCE FOR INDUSTRY: COLLECTION OF RACE AND ETHNICITY DATA IN CLINICAL TRIALS 1–2 (2005). For a more recent example, see Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, § 907, 126 Stat. 993, 1092–93 (2012).

155. PETER BARTON HUTT ET AL., FOOD AND DRUG LAW: CASES AND MATERIALS 699 (4th ed. 2014).

156. *See* Karst, *supra* note 150, at 753–55. The FDA may waive the requirement if studies are impossible or highly impracticable, if the product is not likely to be used in substantial numbers of pediatric patients, or if it provides no meaningful therapeutic benefit over existing therapies, among other reasons. Federal Food, Drug, and Cosmetic Act § 505B(a)(4)(A), 21 U.S.C. § 355c(a)(4)(A) (2012).

al exclusivity to reward such pediatric studies.[157] These measures now give drug sponsors some duty and incentive to generate pediatric safety, efficacy, and dosing information.[158]

2. Plan B Background

When levonorgestrel was finally expressly approved for emergency contraception in 1999, this indication proved controversial—especially among abortion opponents and others who raised concerns about the incentives for sexual promiscuity.[159]

Progestin compounds, of which levonorgestrel is one, are similar to hormones naturally present in the body, especially during pregnancy.[160] Progestin has a number of effects, including "reduc[ing] the number of sperm cells in the uterine cavity, immobili[zing] sperm, and . . . delay[ing] or prevent[ing] ovulation."[161] While some of these effects occur prefertilization, some have contended that progesterone-like hormones could also change the uterine lining, possibly rendering it less hospitable to the implantation of a fertilized egg, an effect that could constitute a postfertilization event, though this has never been shown.[162] This implantation blockage is particularly controversial among those who consider human life to begin at fertilization, as they construe the postintercourse interference with implantation of a fertilized egg to be the termination of human life.[163]

However, it has been impossible to verify that levonorgestrel blocks postfertilization implantation. Judge Korman notes that "it would be 'unethical and logistically difficult to conduct the necessary research' to

157. See Karst, *supra* note 150, at 762–63.

158. Draft Guidance for Industry on the Pediatric Research Equity Act, 70 Fed. Reg. 53,233, 53,234 (Sept. 7, 2005); *see also* 21 U.S.C. § 355(i)(1)(D). The author helped to draft this Act as a legislative assistant to then-Senator Hillary Clinton.

159. *See, e.g.*, Russell Shorto, *Contra-Contraception*, N.Y. TIMES MAG., May 7, 2006, at 48.

160. Tummino v. Torti (*Tummino I*), 603 F. Supp. 2d 519, 522 (E.D.N.Y. 2009).

161. MARCIA CROSSE, U.S. GOV'T ACCOUNTABILITY OFF., GAO-06-109, FOOD AND DRUG ADMINISTRATION: DECISION PROCESS TO DENY INITIAL APPLICATION FOR OVER-THE-COUNTER MARKETING OF THE EMERGENCY CONTRACEPTIVE DRUG PLAN B WAS UNUSUAL 12 (2005) [hereinafter GAO REPORT].

162. As would other contraceptives, including progesterone-containing daily oral contraceptives, as well as intrauterine devices, whether hormonal or copper. *But see* Tummino v. Hamburg (*Tummino II*), 936 F. Supp. 2d 162, 165 (E.D.N.Y. 2013) (explaining how Plan B labeling mentions the possibility of interference with implantation "without affirmative evidence" that the drug operates in this way); Pam Belluck, *No Abortion Role Seen for Morning-After Pill*, N.Y. TIMES, June 6, 2012, at A1 (citing experts explaining that it takes a long time to change the endometrium lining, and emergency contraception is a one-shot treatment).

163. *See The Human Life Bill Appendix, Hearings Before the Subcomm. on Separation of Powers of the S. Comm. on the Judiciary*, 97th Cong. 286 (1982) (statement of John D. Biggers, Professor of Physiology Harvard Medical School Laboratory of Human Reproduction & Reproductive Biology).

conclusively establish that levonorgestrel-based contraceptives do not interfere with implantation."[164]

In 1999, when the new drug application (NDA) for levonorgestrol used for the emergency contraception indication (Plan B) was first approved, it was initially approved for prescription use only.[165] Pharmaceuticals are often introduced in this way and later strategically switched to OTC status by drug sponsors to maximize the revenue generated by the drug,[166] especially since a switch involving a new clinical study can garner the sponsor an additional three-year exclusivity "after the exclusivity and patent periods for the prescription products have expired."[167]

3. *Tummino v. Hamburg*: The Case Description

In 2001, after Plan B had been on the market as an FDA-approved prescription drug for two years, outside citizens petitioned for an OTC switch.[168] Indeed, in 2003, the Plan B drug sponsors themselves also requested such a switch.[169] If initiated by someone other than the drug sponsor, such as citizens or the FDA, a switch can be conducted by means of a rulemaking.[170] If the plan sponsor initiates the switch, they generally do so through a process similar to a new drug approval application called a supplemental new drug application (SNDA).[171] Under either scenario, the standard governing such a switch is set forth in FDCA § 503B and its accompanying regulation.[172]

i. The Statutory Standard for OTC Switch

Under FDCA §503(b)(1)(a), prescription dispensation is required for a drug if "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, [it] is not *safe* for use except under the supervision of a practitioner

164. *Tummino II*, 936 F. Supp. 2d at 165 (quoting GAO REPORT, *supra* note 161, at 13). Any such post-implantation effect could also be the result of pre-conception use of birth control pills or an IUD. *See generally*, Judy Peres & Jeremy Manier, *"Morning-After Pill" Not Abortion, Scientists Say*, CHI. TRIB., June 20, 2005, at CN1.

165. *Tummino I*, 603 F. Supp. 2d at 525.

166. *See, e.g.*, Laura Mahecha, *Rx-to-OTC Switches: Trends and Factors Underlying Success*, 5 NATURE REV. DRUG DISCOVERY 380, 380 (2006).

167. RICHARD M. COOPER ET AL., FOOD AND DRUG LAW AND REGULATION 465 (David Adams et al. eds., 2d ed. 2011) [hereinafter FDLI] (referring to the regulatory exclusivities available under 21 U.S.C. § 355(c)(3)(E)(iii)–(iv)).

168. *Tummino I*, 603 F. Supp. 2d at 526. FDA had always recognized the prescription/OTC distinction under regulations promulgated in 1938 implementing FDCA § 502(f), requiring that labeling bear "adequate directions for use." HUTT ET AL., *supra* note 155, at 802. "Prescription" drugs were exempt from the requirement of adequate directions for use, but only if the product bore a label directing that the product be used only by or on the prescription of a physician. *Id.* Subsequently Congress, in the Durham-Humphrey Amendments of 1951, passed FDCA § 503B. *Id.*

169. The first SNDA submitted, unrestricted by age, was denied by FDA. *Tummino I*, 603 F. Supp. 2d at 523. The second SNDA was for women 16 and older. *Id.* The third submitted was for women 17 and older. *Id.* FDA then approved for 18 and older. *Id.*

170. Federal Food, Drug and Cosmetic Act § 503(e)(2)(B), 21 U.S.C. § 353(e)(2)(B) (2012).

171. *See Tummino I*, 603 F. Supp. 2d at 523.

172. Prescription-Exemption Procedure, 21 C.F.R. § 310.200(b) (2015).

licensed by law to administer such drug."[173] Section 503(b)(3) continues: "The Secretary may by regulation remove drugs . . . from the [prescription requirements in] paragraph (1) of this subsection when such requirements are not necessary for the protection of the *public health*."[174]

Judge Korman proceeds to quote the FDA regulation specifying that it will implement this language in such a way that:

> Any drug limited to prescription use . . . shall be exempted from prescription-dispensing requirements when the Commissioner finds such requirements are not necessary for the *protection of the public health* . . . and he finds that the drug is *safe and effective* for use in self-medication as directed in proposed labeling.[175]

Thus, public health, constituted by safety and efficacy, is understood to be the chief consideration justifying OTC switch.

ii. More Case Background

Here, the sponsor's switch request was accompanied by significant amounts of safety data; however, the FDA repeatedly hesitated to grant OTC status for Plan B.[176] The original citizen petition was filed in 2001, and the FDA did not issue a final response for over five years.[177]

In the meantime, however, the FDA was far from idle; multiple struggles played out behind the scenes. Despite the FDA's decision not to require pediatric pharmacokinetic studies for the SNDA, the FDA early in the process flagged the question of whether the OTC switch might present different risk-behavior concerns for patients of different ages.[178] The FDA thus considered the option that the switch might be undertaken only for those women above a certain age threshold. After five years of maneuvering and negotiation, including Senate obstruction of the confirmation of two successive FDA Commissioners pending progress on this issue, the FDA finally approved the switch for women eighteen and older shortly before the confirmation of Bush-appointed Commissioner Andrew Von Eschenbach.[179]

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173. 21 U.S.C. § 353(b)(1)(A) (emphasis added).

174. *Id.* § 353(b)(3) (emphasis added).

175. *Tummino I*, 603 F. Supp. 2d at 524–25 (emphasis added) (quoting Prescription-Exemption Procedure, 21 C.F.R. § 310.200(b) (2015)).

176. *Tummino I*, 603 F. Supp. 2d at 526.

177. *Id.* at 536.

178. *See id.* at 529. Federal Food, Drug and Cosmetic Act §505B(a)(4), as discussed *supra* note 154, allows FDA to waive pediatric studies for reasons like lack of feasibility. Manufacturers may still voluntarily conduct such studies. In this case, pharmacokinetic, toxicity or dosing studies would not have answered the concerns raised, which asked for actual use data.

179. *See id.* at 535.

4. Exception

This age delimitation is the feature that renders the FDA's decision an example of the phenomenon of an ex ante exception ultimately judged invalid. OTC status for Plan B was effectively approved for all women except those under eighteen.[180]

A women's health coalition sued in January 2005 to contest the rejection of their petition for full OTC availability.[181] Despite the ban on underage purchase of smoking cessation products, plaintiffs claimed that OTC status had never been conditioned upon an age threshold before.[182] Even if this were true, it is worth noting that OTC status had been conditioned upon other characteristics before, including different diagnosis, strength, route of administration, dosage form, or even sex of the patient.[183] Moreover, other types of approval, such as new drug approvals, routinely contain age exclusions, as discussed above.[184]

Judge Korman found for the plaintiffs and declared the restricted OTC switch with the age-eighteen cutoff to be "arbitrary and capricious."[185] Korman remanded to the FDA, but in the period following remand, the Obama Administration succeeded the Bush Administration, ushering in new FDA and health department leadership with ostensibly different views on sexual morality.[186]

Yet the new Administration, on December 7, 2011, once again announced a decision to age restrict the OTC availability of emergency contraception, which had by now been reformulated by the manufacturer as a one-pill version.[187] The drug would be available OTC only to wom-

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180. In a practical sense, this exception was quite difficult to implement and entailed a number of other restrictions. The FDA maintained that in order to implement the age-related exception rigorously, all Plan B products had to be carried behind the pharmacist counter, rather than on the pharmacy shelves. Tummino v. Hamburg (*Tummino II*), 936 F. Supp. 2d 162, 180 (E.D.N.Y. 2013). This unusual arrangement was dubbed the "BTC" or "behind-the-counter," regime in contrast to rather than OTC, (over-the-counter). *See id.*

181. *Id.* at 165–66.

182. The FDA has created age-based restrictions when enacting an Rx-to-OTC switch for only one other class of drugs, nicotine products (such as Nicorette gum), for which only persons 18 years and older may obtain the products OTC. *See* GAO REPORT, *supra* note 161, at 7. Nicorette gum, incidentally, was given OTC status in 1996, long before the separate tobacco product regime recognizing age distinctions was passed by Congress. *See Information for Consumers (Drugs): Now Available Without Prescription*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143547.htm (last updated Aug. 12, 2011).

183. FDLI, *supra* note 167, at 466 (citing examples including meclizine, which is available only by prescription for vertigo but OTC for nausea with motion sickness, clotrimoxazole in prescription form for certain types of candidiasis while OTC for "athlete's foot, ring worm, and jock itch," and loperamide which is prescription for chronic diarrhea, but OTC for acute diarrhea).

184. *See* HUTT ET AL., *supra* note 155, at 807 (identifying conditions on OTC availability, including gender).

185. Tummino v. Torti (*Tummino I*), 603 F. Supp. 2d 519, 523 (E.D.N.Y. 2009).

186. *See id.* at 549.

187. Tummino v. Hamburg (*Tummino II*), 936 F. Supp. 2d 162, 167 (E.D.N.Y. 2013) (referring to Plan B One-Step).

en age seventeen and above showing age verification. Among the remarkable aspects of this second OTC grant was that it was rendered not by the FDA, whose Commissioner, Margaret Hamburg, adjudged there to be "adequate and reasonable, well-supported, and science-based evidence that Plan B . . . is safe and effective and should be approved for nonprescription use for all females of child-bearing potential."[188] Instead, the decision to age restrict the OTC access was made by the supervening Secretary of Health and Human Services, Kathleen Sebelius, overriding the Commissioner and "invoking her authority under the Federal Food, Drug, and Cosmetic Act to execute its provisions."[189]

Judge Korman once again ruled the age-restricted grant to be "arbitrary" and "capricious,"[190] and instructed the FDA to grant the citizen petition "mak[ing] levonorgestrel-based emergency contraceptives available without a prescription and without point-of-sale or age restrictions within thirty days."[191]

In this case, the age-exception feature rendered the FDA's decision vulnerable as compared to blunter, less-contoured measures. Other emergency contraceptives, like ella, are prescription-only products.[192] Even the levonorgestrel birth control pill (the "mini pill") remains prescription-only, even though it is exactly the same chemical entity as Plan B.[193] The FDA is thus allowed to draw lines between one emergency contraceptive product and another, and may even distinguish preintercourse levonorgestrel from postintercourse levonorgestrel despite scant scientific support for the mini-pill's prescription status.[194] However, balancing access needs along the lines of adult and pediatric indications seemed to trigger doubt. The court seems to envision the FDA's range of action for postintercourse levonorgestrel as restricted to fully OTC or fully prescription but no ability to offer OTC access with an exception. Indeed, the judge ruled that the FDA's decision to exclude women under 18 from

188. *Id.* (quoting Statement from FDA Commissioner Margaret Hamburg, M.D., on Plan B One-Step (Dec. 7, 2011)).

189. *Id.* (quoting Statement from FDA Commissioner Margaret Hamburg, M.D., on Plan B One-Step (Dec. 7, 2011)).

190. *Id.* at 197.

191. *Id.*

192. News Release, U.S. Food & Drug Admin., FDA Approves ella™ Tablets for Prescription Emergency Contraception (Aug. 13, 2010), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm222428.htm.

193. *See* Olga Khazan, *Birth Control Without a Prescription*, ATLANTIC, Sept. 19, 2014, http://www.theatlantic.com/health/archive/2014/09/toward-a-prescription-free-birth-control-pill/380464/ (citing the vice chair of the American College of Obstetricians and Gynecologists Committee on Gynecologic Practice Bulletins saying that the mini-pill should be the first to be offered over-the-counter because of its safety profile); *see also* Scout Richters, Note & Comment, *The Moral Interception of Oral Contraception: Potential Constitutional Claims Against the FDA'S Prescription Requirement for a Progestin-Only Birth Control Pill*, 22 J.L. & POL'Y 393, 408 (2013) (saying that levonorgestrel is the substance in many progestin-only mini-pills).

194. *See id.* Indeed, the AMA has passed a resolution calling for the OTC availability of the mini-pill. *See* AM. MED. ASS'N, 2013 ANNUAL MEETING MEMORIAL RESOLUTIONS 464 (2013), http://www.ama-assn.org/assets/meeting/2013a/a13-resolutions.pdf.

OTC availability was what rendered the decision "arbitrary and capricious" as it involved improper factors.[195]

5. Value Conflict

i. No Clear Statutory Foreclosure of Offsetting Values

Korman pointed to FDCA § 503B as stating that switches had to be determined by health standards such as "protection of public health" and "safety and effectiveness."[196] But the statutory text itself does not foreclose expansive interpretations of the factors relevant to public health or safety. If the statute is open to these other interpretations, then FDA's inclusion of behavioral risk compensation effects should enjoy *Chevron* deference.[197] Indeed, if we accept Sunstein's default canons, the courts should favor readings that allow consideration of harms that might offset the health benefits of drug availability. The statute requires the Secretary to consider whether prescription status is "necessary for public health" and suggests that broader social factors should be considered as part of the assessment of safety and effectiveness.[198] Section 503B instructs consideration of factors beyond toxicity, including "other potentiality for harmful effect" and any safety problems arising because of "collateral measures necessary to [the drug's] use."[199] This language has long included consideration of harms that arise not from the drug itself but from the changes in patient behavior, such as delayed health-seeking behavior, due to the drug's availability.[200]

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195. Tummino v. Torti (*Tummino I*), 603 F. Supp. 2d 519, 542, 544, 547–48 (E.D.N.Y. 2009) (reviewing the *State Farm* articulation of the standard).

196. *Id.* at 525, 548; *see also* Tummino v. Hamburg (*Tummino II*), 936 F. Supp. 2d 162, 169 (E.D.N.Y. 2013) ("[T]he standard for determining whether contraceptives or any other drug should be available over-the-counter turns solely on the ability of the consumer to understand how to use the particular drug 'safely and effectively.' . . . I decide this case based only on my understanding of the applicable standard." (citation omitted)).

197. *See* Chevron, U.S., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 844 (1984).

198. Federal Food, Drug, and Cosmetic Act §§ 503B(b)(3), 505(d), 21 U.S.C.§§ 353(b)(3), 355(d) (2012).

199. *Id.* § 353(b)(1)(A).

200. *See* United States v. Article of Drug, Labeled Decholin, 264 F. Supp. 473, 482–84 (E.D. Mich. 1967) (refusing to grant summary judgment allowing OTC distribution, even if the drug itself is pharmacologically safe, because FDA may consider the risk behavior the drug's availability might induce, i.e., causing the patient to delay seeking professional diagnosis to discover an underlying condition that requires alternate treatment). The FDA's consideration of "risk substitution" or "risk compensation" behavior is also evident insofar as the approval of Truvada (a product for the prophylactic use of antiretrovirals among those at-risk of HIV infection) is conditioned upon postmarketing studies of whether Truvada affects behavior that might increase the chances of HIV transmission. *See* Kristen Underhill, *Risk-Taking and Rulemaking: Addressing Risk Compensation Behavior Through FDA Regulation of Prescription Drugs*, 30 YALE J. ON REG. 377, 382, 417–19 (2013). Similarly, the FDA's longstanding pre-2009 stance to apply the NDA paradigm to nicotine products that make therapeutic claims, like cessation products, but not to treat modified-risk cigarettes (like low-tar products) as therapeutic products, involves recognition that risk substitution (smoking more cigarettes, or taking longer drags to compensate) might nullify any therapeutic effects of the product. *Id.* at 395. This stance is echoed in the FDCA § 911(g) requirement that risk be measured by "actual use." 21 U.S.C.§ 387k(g).

Longtime food and drug law observers, including Peter Barton Hutt, have argued persuasively that that the statutory language thus accommodates broader societal concerns.[201] The FDA often requires "actual use studies" for OTC switches precisely to test for these broader concerns such as "compliance issues, including off-label usage . . . [and] overdose or abuse potential."[202] If the use of one drug, itself safe *in vivo*, would restrict patients' food or other medications, those considerations would be relevant.[203] None of these factors concern merely the physiological effects of the drug. They involve reasoning about value-laden human and social behavior, the dynamics of which may be more difficult to capture in a clinical study and may complicate the extrapolation of such study to a broader population.

Korman also points to the "purpose" of § 503B as proscribing the use of political values beyond public health narrowly construed to justify agency practice. But the Senate report he cites does not contemplate pure health justifications, unalloyed by other values.[204] Congress declared that its intent was "to 'relieve retail pharmacists and the public from burdensome and unnecessary restrictions on the dispensing of drugs that are safe for use without the supervision of a physician.'"[205] This statement acknowledges "burden" and a degree of "necessity" as broad factors apart from health that the FDA should consider when deciding whether to make an otherwise safe drug available OTC. None of this is to suggest that Judge Korman's requirement that the FDA extrapolate the data justifying OTC status for older women to younger age ranges is incorrect, but simply that deciding to extrapolate is a matter of judgment, indeed discretion, the scope of which, under statutory text and purpose, one can reasonably construe to encompass more than consistent technical application of health science standards.

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201. Peter Barton Hutt, *A Legal Framework for Future Decisions on Transferring Drugs from Prescription to Nonprescription Status*, 37 FOOD DRUG COSM. L.J. 427, 436 (1982). He identifies more than one statutory factor that must be considered, not just toxicity, but other potentiality for harmful effect, specifically, the "method of use or collateral measures necessary to use." *Id.* at 433. Of the last, he says, "Congress intended this factor to have the broadest possible scope. It encompasses all aspects of the circumstances under which a drug is used, including broad questions of social policy. There is perhaps no issue involving drug use that cannot properly be brought into consideration under this factor." *Id.* at 436.

202. FDLI, *supra* note 167, at 473.

203. Lars Noah, *Treat Yourself: Is Self-Medication the Prescription for What Ails American Health Care?*, 19 HARV. J.L. & TECH. 359, 366 (2006) ("Although the statute and regulations provide some general criteria for differentiating between prescription and OTC products, ultimately that determination must be made on an ad hoc basis and without clear guidance. . . Other harmful effects may include the risk of interactions with food or other drug products and the potential for abuse." (footnote omitted)).

204. Tummino v. Hamburg (*Tummino II*), 936 F. Supp. 2d 162, 173 (E.D.N.Y. 2013).

205. *Id.* (quoting S. REP. NO. 82-946, at 1 (1951)).

ii. Arbitrary and Capricious or Explained by Permissible Reasons?

Korman, in excluding these other social considerations, must rely less on text, and instead on doctrine that subjective "bad faith" will not only overcome the record rule but also support a finding of arbitrary and capricious action.[206]

What then does Korman classify as bad faith? It is not clear, and indeed other scholars have written of how this case highlights the muddled state of administrative law doctrine in this area.[207] Bad faith might be thought to consist of dissembling or duress, but what turns out to be bad faith in Korman's view is the consideration of additional "political" factors, which he defines as norms, policies, or preferences other than those of health science.[208] In other words, he manages to frame his opinion such that mere value conflict, rather than lying, is what renders an exemption "bad faith."

Whether the consideration of more than one norm is sufficient to relegate a decision to the "political" sphere is one that this Article seeks to probe more deeply, so Korman's decision to assume it here bears remark, especially when he could have based his decision on other grounds instead. Is it indeed a foregone conclusion that the agency must consider nothing other than health concerns? Surely agencies can also consider matters like priorities when it comes to enforcement.[209] Moreover, as health standards do not mechanically apply themselves, the FDA is expected to use judgment or "discretion," and one control upon discretion is political accountability.[210] The subjection of the FDA to the political processes of nomination and confirmation would suggest intention to employ this control.

Once one proves the existence of other considerations, political or otherwise, there is still some distance to go before the presence of non-health considerations constitutes decision by unreasoned and arbitrary caprice. What in Korman's decision carries us that extra distance? What administrative law doctrines do the work? Neither deceit nor falsehood

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206. Tummino v. Torti (*Tummino I*), 603 F. Supp. 2d 519, 542 (E.D.N.Y. 2009) (noting that the finding of subjective bad faith will weigh in favor of finding arbitrary and capricious action (citing Latecoere Int'l, Inc. v. U.S. Dep't of the Navy, 19 F.3d 1342, 1356 (11th Cir. 1994); James Madison Ltd. v. Ludwig, 82 F.3d 1085, 1096 (D.C. Cir. 1996))).

207. Heinzerling, *supra* note 125, at 958–59.

208. *See infra* text accompanying notes 259–66.

209. *See, e.g.*, Heckler v. Chaney, 470 U.S. 821, 831–32 (1985).

210. *See, e.g.,* Thomas O. McGarity, *Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA*, 67 GEO. L.J. 729, 732–36, 740–45, 750 (1979); *see also* David F. Cavers, *The Legal Control of the Clinical Investigation of Drugs: Some Political, Economic, and Social Questions*, 98 DAEDALUS 427, 430 (1969) ("[T]his evaluation does not call for simply a 'yes' or 'no' judgment. One dosage level may be safe, another questionable, but the safer dosage level may be of doubtful efficacy. A satisfactory answer may lie in between. Negotiation follows.").

was relied upon as the touchstone of bad faith.[211] Instead, Korman points to a series of arbitrary "departures" from prior agency practice.[212]

a) Substantive Transgression or Political Cooptation?

In condemning the first decision to age restrict, made by the Bush Administration FDA, Korman does marshal suggestions of "improper political influence . . . showing that the political pressure was intended to and did cause the agency's action to be influenced by factors not relevant under the controlling statute."[213] It is noteworthy that Korman does not go so far as to claim that any of the instances of political pressure rose to the level of procedural violations; he simply considers them as evidence that other substantive factors entered into the decision-making. Take for instance the first sign of political consideration that Korman cites, the involvement of the White House. On the day that the Plan B sponsor first submitted its SNDA requesting OTC status, then-FDA Commissioner Mark McClellan conversed with a White House domestic policy advisor about the matter and provided several status updates thereafter.[214] Korman declined to rule that these were ex parte communications: "Whether or not it was permissible for the FDA to discuss such questions with the White House, these discussions were not the norm for the FDA with respect to this type of decision."[215] In other words, the process was not the problem; the possible entry of a non-public health factor was measured, not only by the existence of a channel of external communication, but also by any departure from previous FDA practice which Korman presumes to then require justification in terms of public health to satisfy *State Farm* requirements for reasoned decision-making.[216]

The category of facts showing bad faith includes those instances throughout the process when the FDA personnel were answerable to political officers. Again, Korman slightly overstates the situation in a way that implausibly exiles conflicting values pressed by the public: the FDA leadership, subject to presidential appointment and congressional con-

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211. The magistrate judge allowed discovery beyond the record to look for just such evidence. *See* Heinzerling, *supra* note 125, at 953–54.

212. Tummino v. Hamburg (*Tummino II*), 936 F. Supp. 2d 162, 170 (E.D.N.Y. 2013).

213. Tummino v. Torti (*Tummino I*), 603 F. Supp. 2d 519, 543 (E.D.N.Y. 2009) (quoting Orangetown v. Ruckelshaus, 740 F.2d 185, 188 (2d Cir. 1984)).

214. *Id.* at 527. "Status reports" are excluded from barred ex parte communications under Administrative Procedure Act. 5 U.S.C. § 551(14) (2012).

215. *Tummino I*, 603 F. Supp. 2d at 547. Korman was presumably referring to 5 U.S.C. §§ 554(d), 557(d).

216. *See* Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43, 56–57 (1983) (explaining the arbitrary and capricious standard and requiring under such standard that NHTSA "supply a reasoned analysis" for revoking the passive restraints rules and not considering airbags or nondetachable passive belts (quoting Greater Boston Television Corp. v. FCC, 444 F.2d 841, 852 (D.C. Cir. 1970))); *Tummino I*, 603 F. Supp. 2d at 548 ("While it may have been rational for the FDA to consider adolescent cognitive development in its evaluation of Plan B as an OTC drug, plaintiffs have presented unrebutted evidence that the FDA's focus on these behavioral concerns stemmed from political pressure rather than permissible health and safety concerns.").

firmation, is expected to be politically accountable.[217] What is the political appointment and confirmation process for if not to inject a political dimension into the FDA's exercise of its discretion and interpretation of its governing law? Yet Korman disparages the role that the appointment and confirmation process played.

In the first confirmation battle over the elevation of Acting Commissioner Lester Crawford in 2005, Senators Hillary Clinton and Patty Murray put holds on his confirmation until receiving a commitment that the FDA would decide the Plan B OTC petition by a certain date.[218] However, once confirmed, Crawford backed out of the promise and missed the deadline.[219]

When the Senate next considered a nominee for Commissioner, the Senators again took a stand, demanding FDA action.[220] One day before the confirmation hearing, the FDA at long last announced the grant of OTC status, albeit restricted to women eighteen and over.[221]

Korman is unquestionably correct that politics and social considerations entered the FDA's decision-making in this case, and he hinges his decision upon the presence of those "political" considerations. What is harder to tell is if they entered in a way allowed by statute, process requirements, and permissible reasoning or not.

b) Departures Justified by the Limits of Inference from Sample?

For Korman, the chief facts showing lack of good faith reasoned decision-making lie in what he calls FDA's "[d]epartures from [i]ts [o]wn [p]olicies."[222]

The first departure he questions is the FDA's decision not to adopt the Advisory Committee's recommendations.[223] The Advisory Committee had voted unanimously that Plan B was safe for OTC use and voted 27–1 that the data from an "actual use study" (AUS) could be generalized or extrapolated to the overall population.[224] Finally, the committee voted 23–4 "to approve Plan B for over-the-counter status without age or point-of-sale restrictions."[225]

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217. *See* Paul R. Verkuil, *The Purposes and Limits of Independent Agencies*, 1988 DUKE L.J. 257, 262–63 & n.24 (noting the FDA's lack of independence and the periodic proposal that it should be made so); Adrian Vermeule, *Conventions of Agency Independence*, 113 COLUM. L. REV. 1163, 1207–09 (2013) (discussing the agencies direct accountability to HHS).
218. *Tummino I*, 603 F. Supp. 2d at 523.
219. *Id.*
220. *Id.* at 523, 546.
221. *Id.* at 546.
222. *See id.* at 547–49.
223. *Id.* at 547.
224. *Id.* at 529, 547–48.
225. *Id.* at 529.

The FDA is not required to convene advisory committees.[226] Advisory committee decisions are therefore hardly expected to be conclusive, which Korman himself concedes: "While the Advisory Committee does not have the final say regarding the OTC switch applications, the FDA has followed advisory committee recommendations in every OTC switch application in the last decade . . . ."[227] Actually, in 2001, the FDA first ignored its advisory committees on the health-insurer led petitions to switch antihistamines, such as Claritin, to OTC status.[228] Meanwhile, it is not clear that ten years worth of decisions is the right subset from which to judge FDA's practices. Nor is it clear that the OTC switch decisions are the correct category of decision from which the FDA's policy toward advisory committees should be inferred. Certainly, if one looks at the FDA's drug decisions, including NDA approvals and revocations, there are numerous instances where the FDA has acted contrary to its advisory committees.[229] Again, the portrait of the FDA's past practice as deferring consistently to advisory committee decisions is overstated by Korman—not an unreasonable stance but also not a foregone conclusion. Despite my agreement with him on the outcome in this case, my point in this Article is to show that the outcome, and the grounds recited in the opinion, were choices Korman made, leading us to ask what motivates these choices. Here, we hypothesize that his choices are guided by dependence upon the notion that the FDA, or the author of such a drug availability decision, should pursue a simple unitary value and not resolve competing norms.

Another departure Korman cites was the FDA's selection of members for the Advisory Committee. Rather than leaving it to frontline staff, the Commissioner's staff directly circulated names, allegedly to achieve

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226. HUTT ET AL., *supra* note 155, at 1013 ("FDA's use of advisory committees in the review of NDAs, BLAs, and food additive petitions is entirely discretionary . . . ." (quoting Peter Barton Hutt, *The Regulation of Drug Products by the United States Food and Drug Administration*, *in* THE TEXTBOOK OF PHARMACEUTICAL MEDICINE (John P. Griffin & John O'Grady eds., 5th ed. 2006))). The Food and Drug Administration Amendments Act of 2007 (FDAAA), Pub. L. No. 110-85, § 918, 121 Stat. 823, 960–61, recently added FDCA § 505(s), which only requires advisory committees for new chemical entities, and even then, the FDA can waive the requirement in action letter explaining why it did not do so. *See* Federal Food, Drug, and Cosmetic Act § 505(s), 21 U.S.C. § 355(s) (2012); *see also Nonprescription Drugs Advisory Committee Charter*, U.S. FOOD & DRUG ADMIN. (Aug. 27, 2015), http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/NonprescriptionDrugsAdvisoryCommittee/ucm105992.htm.

227. Tummino v. Torti (*Tummino I*), 603 F. Supp. 2d 519, 528 (E.D.N.Y. 2009).

228. Noah, *supra* note 203, at 360–61.

229. Cathryn Jakobson Ramin, *Why Did the F.D.A. Approve a New Pain Drug?*, NEW YORKER (Dec. 2, 2013), http://www.newyorker.com/business/currency/why-did-the-f-d-a-approve-a-new-pain-drug (discussing Zohydro ER, approved despite the advisory committee's opposition due to a lack of substance abuse deterrence); *see also* DIANA M. ZUCKERMAN, NATIONAL RESEARCH CENTER FOR WOMEN & FAMILIES, FDA ADVISORY COMMITTEES: DOES APPROVAL MEAN SAFETY? (2006), http://center4research.org/newsite/wp-content/uploads/2006/09/FDA-Report-v7.pdf ("The FDA also approved four (36%) of the 11 drugs that the drug advisory committees voted against, including products that were opposed by almost all the committee members. . . . [C]lose to half (43%) of the devices that were not recommended for approval obtained FDA approval anyway.").

"balance of opinion."[230] Though this procedural anomaly did not ultimately affect the decision of the advisory committee, the clash between health science criteria and other considerations is what Korman highlights as the problematic "departure."[231] Yet, balance is a statutorily inscribed consideration. The FDCA requires drug and device advisory committees to contain diverse perspectives.[232]

The level of decision-making, not just for the advisory committee selection, but also the OTC decision itself, troubled Korman. The line staff, such as the office directors within CDER, were "normally" the ones to make the decisions, but in this instance, Korman noted the involvement of the CDER Director, the Commissioner's participation, even the role of the White House, which served as a channel for the introduction of these external considerations.[233] However, the level of decision-maker was nowhere prescribed as the Office Director level, and key "Decisional Meeting[s]" have often included the CDER Director.[234] It is only since then that the statute has been modified by Congress to specify the "Division Director and Office Director's decision document" and command that "scientific review of an application is considered the work of the reviewer and shall not be altered by management or the reviewer once final."[235] Prior to 2007, the statute designated the decision to the Secretary of Health and Human Services (HHS), while the Secretary had in writing delegated to the Commissioner.[236] And because this was a licensing decision, the Administrative Procedure Act imposes fewer restrictions on the agency's choice of decision-maker.[237]

Evidence that these external considerations affected the timing of the decision was a third departure. There was deposition testimony that on January 15, 2004, the Commissioner expressed the view that the FDA would issue a non-approvable letter because of the insufficiency of data for those under sixteen, an insufficiency that was not likely to be addressed soon.[238] However, the formal office-level reviews would not be

230. *Tummino I*, 603 F. Supp. 2d at 528.

231. *Id.* at 527–28.

232. Federal Food, Drug, and Cosmetic Act §§ 505(n)(3)(B)–(C), 513(b)(2), 21 U.S.C. §§ 355(n)(3)(B)–(C), 360c(b)(2) (2012) (requiring "diversified expertise" and consumer viewpoints); *see also id.* § 360e(g)(2)(B) (requiring "diversified professional backgrounds").

233. *Tummino I*, 603 F. Supp. 2d at 546–47.

234. *See, e.g.*, U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-06-402, DRUG SAFETY: IMPROVEMENT NEEDED IN FDA'S POSTMARKET DECISION–MAKING AND OVERSIGHT PROCESS 32 (2006).

235. Federal Food, Drug, and Cosmetic Act § 505(l)(2)(C)(v), (D), 21 U.S.C. § 355(l)(2)(C)(v), (D) (2012), *amended by* Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 916 (3), 121 Stat. 823, 958–59.

236. Tummino v. Hamburg (*Tummino II*), 936 F. Supp. 2d 162, 170 (E.D.N.Y. 2013) (citing 21 U.S.C. § 393(d)(2) (2006), *amended by* Tobacco Regulation, Federal Retirement Reform, Pub. L. No. 111-31, 123 Stat. 1776 (2009); *Delegations of Authority to the Commissioner Food and Drugs*, *in* FDA STAFF MANUAL GUIDE § 1410.10 (2005).

237. Administrative Procedure Act, 5 U.S.C. §§ 557(b), 554(d)(2)(A). Alternatively, it was a petition for rulemaking, with no particular APA-defined decision maker.

238. *Tummino I*, 603 F. Supp. 2d at 530.

completed until April of that year, after which a non-approvable letter was accordingly issued in May.[239] Thus, the U.S. Government Accountability Office (GAO) and others never found conclusive evidence that earlier statements by agency superiors constituted premature decision, rather than an exchange of provisional views.[240]

And the most crucial departure—the one at the crux of whether an internal health reason could justify the other departures, or whether the decision was motivated by "bad faith" external reasons—was the FDA's reluctance to extrapolate adult clinical data to the adolescent population despite previous instances of extrapolation to pediatric subpopulations. The outcomes of the actual use study (AUS) in particular showed that at least for the population enrolled in the AUS, the "frequency of unprotected sex did not increase, condom use did not decrease, and the overall use of effective contraception did not decrease [with use of plan B]."[241]

The AUS results formed the fulcrum of the case because the design of the AUS study producing these results lacked significant inclusion of younger girls in the adolescent age range. Twenty-nine of the 585 recruited subjects were aged fourteen to sixteen, and none were younger than fourteen, giving the FDA Commissioner room to declare that he was "not convinced the studies had enough power to determine if there were behavioral differences between adults and adolescents."[242] The sponsor supplemented its own study with existing literature that also looked at the behavioral effects of emergency contraception.[243] Yet, the numbers were still low, particularly for those in the younger adolescent range. Therefore, the CDER Acting Director concluded that the failure for any differences to show up with such low numbers did not conclusively counter the worry that it is generally "'very difficult to extrapolate data on behavior from older ages to younger ages' because of the diminished capacity of adolescents to make rational decisions and the 'large developmental differences,' between [younger and older adolescents]."[244] He signed the non-approvable letter and maintained that "although he 'consulted with the Office of the Commissioner,' he himself 'made the decision,' on the basis of the scientific data."[245]

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239. *Id.* at 531–32.

240. *See* Heinzerling, *supra* note 125, at 951 (discussing how the GAO REPORT, *supra* note 161, at 21–22, found conflicting evidence on this matter).

241. *Tummino I*, 603 F. Supp. 2d at 528 (alteration in original) (quoting FDA Commissioner McClellan).

242. *Id.* at 528, 531, 547 (quoting FDA Commissioner McClellan).

243. *Id.* at 528.

244. *Id.* at 533 (quoting Dr. Galson, Acting Director of the Center for Drug Evaluation and Research).

245. Robert Steinbrook, *Waiting for Plan B—The FDA and Nonprescription Use of Emergency Contraception*, 350 NEW ENG. J. MED. 2327, 2327 (2004) (quoting Dr. Galson, Acting Director of the Center for Drug Evaluation and Research).

Korman pointed to the underlying refusal to extrapolate as an unjustified departure from a "long history" of generalizing data from older women to younger women for other contraceptives.[246]

But even Korman concedes that non-extrapolation is the shakiest ground upon which to stake a claim that the FDA's departure from past practice rendered its decision improper. Understandably, a judge would have qualms deciding that biomedical science requires inference to an under-sampled subpopulation. He allows that "[w]hile it may have been rational for the FDA to consider adolescent cognitive development in its evaluation of Plan B as an OTC drug, plaintiffs have presented unrebutted evidence that the FDA's focus on these behavioral concerns stemmed from political . . . rather than permissible health and safety concerns."[247]

Korman chooses to use this deviations analysis in a way that highlights his doctrinal focus on the agency's consideration of competing values as the central ground for rebuffing the FDA's explanation. It is notable that he does not invoke something like the *Accardi* doctrine, which holds agencies to the rules or principles they set forth themselves, even if those policies are not statutorily required.[248] Perhaps none of the "policies or practices" he cites rise to the threshold of clarity and consistency needed to bite with the force of law, though they are still background conditions that are relevant for substantive review for reasonableness and non-arbitrariness. But if they had risen to such a threshold, then the departures would be improper in and of themselves, rather than because they signal an improper consideration.

Instead, the purpose for Korman of tallying these departures is that any deviation from past practice suggests that something potentially "arbitrary" and unreasonable has entered unless such outlier action is justified by internal or statutorily permissible reasons, "supply[ing] a reasoned analysis" required by *Motor Vehicles Manufacturers Association of the United States v. State Farm Mutual Automobile Insurance Company*.[249] The defendants do in fact try to justify the deviations on that ground, saying that the key substantive considerations are the distinctive health concerns and the lack of data on those health concerns as affected by emergency contraception use in younger girls and women. As the lack of such data cannot be conclusively overcome by extrapolating the science from the older adults, the appropriateness of extrapolation becomes the decisive issue for whether deviations can be justified or not.

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246. *Tummino I*, 603 F. Supp. 2d at 533.
247. *Id.* at 548.
248. *See* United States *ex rel.* Accardi v. Shaughnessy, 347 U.S. 260, 265–66 (1954).
249. 463 U.S. 29, 42 (1983).

c) Internal Justification?

Thus, as with the soda ban, the line of scrimmage was whether the exception had an internal or external justification. Suggesting that the decision and its unique features were a response to the product's particular public health implications, an internal concern, would have then allowed the agency decision to stand. Such a position would have eliminated value clash.

How were these behavioral concerns for the adolescent population styled as internal justifications? At the outset of the FDA's process in April 2001, during review of the citizen petition, the Office of Drug Evaluation in CDER first reviewed and identified the concerns relating to younger women as follows:

- Whether availability of Plan B would crowd-out use of "more effective forms of birth control"[250]
- adolescents' comprehension of Plan B[251]
- the effect on adolescent girls' willingness to use condoms, testing, and other means of protecting against sexually transmitted diseases (STD's)[252]

Under this rubric, the concerns which arguably justified the carve-out for young women were not "pro-life" concerns or sexual morality concerns. The FDA framed these concerns as motivated by the underlying health concern over safety and contraceptive effectiveness and whether those policies should be differentially weighed for younger women and girls. These are paradigmatic "substitute risks" or "health-health tradeoffs," which Sunstein claims agencies are permitted to balance unless Congress has clearly said otherwise.[253] Cast this way, the defeasibility of the underlying health protection purpose of Plan B availability would be based not upon a competing norm but a judgment internal to the justification underlying prescription requirements for drugs.

However, the judge rejected this framing and described the concerns about the potentially different behavioral effects on younger women and girls, not strictly speaking as health concerns, but as concerns about promiscuity.[254]

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250. *Tummino I*, 603 F. Supp. 2d at 526.
251. *Id.*
252. *Id.* at 526, 533.
253. *See* Sunstein, *supra* note 4, at 1668, 1672–73.
254. *Tummino I*, 603 F. Supp. 2d at 533–34 (quoting an office-level director saying these concerns "are 'more applicable to the ability of adolescents to make reasoned decisions about engaging in sexual intercourse, not their ability to understand how to use Plan B safely and effectively as an emergency contraceptive should they engage in unprotected sexual intercourse'" (quoting Dr. Jenkins, Director of the Office of New Drugs)).

To dismiss the FDA's protests that their concerns were indeed health and safety-related, Korman again cited the AUS study results showing no change in unprotected sex or use of effective contraception.[255] Yet this response amounts to a non sequitur, as the low numbers of young adolescent subjects in the AUS study arguably offered no evidence either way for behavioral effects in that group.[256]

Thus, Korman concludes that the age-related line drawing was not justified by health reasons, but orthogonal aims, the consideration of which the judge deemed extraneous, political, and presumptively "bad faith," rendering the government's action arbitrary.

6. Assigns to Non-Legal Sphere

In contrast to the court's preference regarding NYC's soda portion cap, deferring to political decision-making is not Korman's favored answer. Indeed, Korman says the decision was illegitimate because the confirmation process politically influenced it.

Korman deplores the pressure that confirmation imposes on the FDA's Plan B actions. Is the FDA's decision therefore too political? Why isn't the erection of guidelines for the exercise of agency discretion by means of the confrontation of the President's politics with Congress's politics just exactly the degree of political that we intended?[257] Indeed, had confirmation not provided a channel for Senate pressure, the FDA might have withheld even a partial OTC grant, and the morality considerations would have prevailed utterly over health interests.

Two confirmation fights and a new Administration later, the FDA was still offering only an incrementally modified age-restricted OTC grant. With these extended battles achieving hard-won accommodations, and both political parties arriving at the same age-restricted approach, it seems quite plausible that the result represented some sort of political equipoise. The outcome was politically validated, even if not fully satisfying to any one side. Yet Korman would banish political accountability for agency decision-making.

What alternate arena does he imagine? Would he prefer that such decisions reflect private ordering, namely, the market? But market ordering entails the pure positivism of allowing the "indicated use" to be defined by the sponsor. Allowing sponsors to draw those lines is consistent with allowing the valuation of health versus other interests to be determined by the market. Thus, the age limitation would have prevailed had the sponsor decided to frame its SNDA application for OTC switch for

255. *Id.* at 532.
256. *See id.*
257. The courts recognize that agencies exist in a matrix of political accountability. *See, e.g.*, Sierra Club v. Costle, 657 F.2d 298, 405–06 (D.C. Cir. 1981).

an "age-restricted indication." Throughout the litigation, the government elected, sometimes to the limit of credulity, to present the age limitations not as conditions required by the government but as a request by the sponsor in their SNDA.[258] Even in the government's final hail-Mary attempt to stay the second invalidation granting the citizen petition, it did so by trying to grant an alternative approval to the drug sponsor's new SNDA on One-Step, limited to women and girls age fifteen and older.[259]

Korman, however, scorns the market logic of coping with the value clash in this way, at least insofar as it would implicate the FDA as a handmaiden.[260] If market incentives determined the availability of the drug, then the sponsor, through its age-restricted proposal, would earn market exclusivity for its research.[261] Korman denies any obligation to honor this incentive, calling this arrangement "a sweetheart agreement with the FDA."[262]

Instead, Korman's favored alternate arena is science. His discussion of the advisory board assumes scientific expertise, not diverse perspectives, as the requirement.[263] When he identifies the gravamen of the complaint against the FDA, he cites departure from scientifically-based review.[264] Korman approvingly cites the Pendergast Declaration, an amicus brief of sorts from a former FDA employee that stipulates the character of the FDA as "an expert scientific agency charged with making scientific and medical decisions within the boundaries set by the FDCA. Nothing in that statute suggests that scientific decisions may bend to political winds."[265] These assertions about the "character" of the FDA are presumed, rather than argued, from specific statutory text.[266]

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258. *See Tummino I*, 603 F. Supp. 2d at 523.

259. *See* Tummino v. Hamburg (*Tummino III*), No. 12–CV–763, 2013 WL 2631163, at *3 (E.D.N.Y. June 12, 2013).

260. *See id.*

261. *Id.*

262. Tummino v. Hamburg, 936 F. Supp. 2d 198, 206 (E.D.N.Y. 2013). The coda to this tussle is that in the end, the FDA complied with the order by making Plan B One-Step, Teva's product, available OTC, unrestricted by age, but continuing to age restrict OTC access to all other forms of emergency contraception. Deborah Kotz, *Teva Gets Exclusivity on Plan B Contraceptive*, BOS. GLOBE (July 24, 2013), https://www.bostonglobe.com/lifestyle/health-wellness/2013/07/23/fda-grants-exclusivity-plan-one-step-emergency-contraceptive-for-three-years/5ShlBCNplsJTGYzmkkr6MI/story.html. This exclusive arrangement was to last 3 years. *Id.*

263. *Tummino I*, 603 F. Supp. 2d at 527–28.

264. *See id.* at 523.

265. Tummino v. Hamburg (*Tummino II*), 936 F. Supp. 2d 162, 185 (E.D.N.Y. 2013) (quoting Declaration of Mary K. Pendergast, J.D., LL.M. in Support of Plaintiffs' Motion for Preliminary Injunction and Summary Judgment at ¶ 33, *Tummino II*, 936 F. Supp. 2d 162 (E.D.N.Y. 2013) (No. 12–CV–763)).

266. Dworkin says of the referee in a chess game where Tal deploys a disconcerting smile:

> The referee must select one or another of these conceptions, not to supplement the convention but to enforce it. He must *construct* the game's character by putting to himself different sets of questions. Given that chess is an intellectual game, is it, like poker, intellectual in some sense that includes ability at psychological intimidation? Or is it, like mathematics, intellectual in some sense that does not include that ability?

DWORKIN, *supra* note 10, at 103.

7. Judge Arrogates the Decision and Methodology

Yet many layers conceal Korman's answer for who should decide emergency contraception access. On the one hand, in making the drug available OTC, the result of the case stands for the proposition that the patient, not the doctor, should decide. At the same time, Korman declares that the judgment of whether health concerns should accommodate religious and sexual morality is "political," which might imply that political processes should decide the question. Yet he deplores the use of political negotiation to decide these matters. By his lights, scientific experts should control the outcome, but he is in a bind because by inserting himself, he necessarily conveys that judges, in reviewing administrative decisions, should decide.[267]

Should Korman himself apply the scientific standards, or should he enable the scientific decision-makers to do it? His choice of relief, rejecting remand, and ordering grant brings this vexed question to the fore. And what governs the judge's application of scientific standards? Korman attempts to sidestep these difficulties by proceeding as if he is engaged in methodologically familiar rule-based decision-making to conclude that science precluded the agency's decision.[268]

But to determine that the agency's decision was incompatible with science, he must define what science would require and in some sense perform his own scientific analysis.[269] Indeed, one plaintiff's lawyer noted that the judge "d[id] his own research . . . on scientific details in the case."[270] The pretense that rules are enough to decide is unconvincing.

Each "prior policy or practice" that he attempts to extend to this case turns out to fall short of a rule that would decide the case without doubling back to check the agency's work in performing the underlying "scientific" decision-making process. Rules, as we discussed before, distinctively apply pressure independently of their own justification. Something short of a rule will thus be inconclusive on the application of such prior treatment to this particular case with its particular circumstances, leaving Korman no choice but to take some position on the underlying scientific support for inference from adult to adolescent populations.

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267. *See* Memorandum in Support of Defendants' Motion for Stay Pending Appeal at 12, *Tummino III*, 2013 WL 2631163 (E.D.N.Y. May 1, 2013) (No. 12–CV–763) (voicing this very concern about the relief of granting the petition, in Korman's April 5, 2013, order invalidating the Obama Administration's age-restriction, the government argued that the public and the brand of FDA will be irreparably harmed "if a drug product that purported to be 'FDA approved' were approved instead at the direction of a court.").

268. *See Tummino I*, 603 F. Supp. 2d at 548.

269. *See* Pam Belluck, *Behind Scolding of the F.D.A., a Complex and Gentle Judge*, N.Y. TIMES (June 14, 2013), http://www.nytimes.com/2013/06/15/health/behind-scolding-of-the-fda-a-complex-and-gentle-judge.html?_r=0.

270. *Id.*

The FDA is not bound to the recommendation of advisory committees.[271] The selection of advisory committee members to represent different perspectives was not foreclosed by rule.[272] The timing of the decision was not conclusively prior to the scientific review, and the level of decision-maker was hardly clearly and irrevocably prescribed.

Fidelity to "rule-based" decision-making should lead courts to encourage and honor rules of high formal realizability, precisely the kind that contain articulated ex ante exceptions.[273] This approach is at odds with how Korman rules. The outcome he reaches instead represents a view that the rule is sufficient to decide only when backed by health science, when congruent with what Korman has constructed as the underlying purpose. The naked rule is too vulnerable.

The reasoning that he employs is less an analysis of rules, but rather a simulation of scientific analysis instead. In the central deviations analysis, it turns out he spends much of his time arguing about whether statistical findings can be extrapolated from one population to another and why inferences about a younger population can justifiably be drawn from data describing an older population.[274] The defendants point out developmental differences in younger adolescents and present information showing that they do not always extrapolate drug efficacy to pediatric populations from adult data ("in 82.5% of the drug products"[275]).[276] The factors that affect the appropriateness of extrapolation are manifold. Just in this action alone, the FDA mentions the number of younger patients enrolled;[277] other sampling features, such as whether the study enrolled subjects in a setting or manner "that would be expected to capture a representative population of women who [are potential users];"[278] the number of potential individuals to be expected in the younger age group;[279]

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271. *See* discussion *supra* Section III.B.5.ii.b.

272. *See supra* note 232 and accompanying text.

273. Duncan Kennedy, *Form and Substance in Private Law Adjudication*, 89 HARV. L. REV. 1685, 1687–88 (1976) (identifying this feature of certain rules which makes them specific and determinate as compared to standards). The portrait I paint here departs in ascribing valences to rules as opposed to standards. Adhering to rules here can be "pro-health." More open-textured, policy-inflected Dworkinian decision making can turn out to be "individualistic," in the case of the soda portion cap case, or result in less "mutual support," as in the eyeglasses benefits.

274. Korman states that the defendants' position "centers on the argument that the FDA has no set policy of extrapolating data from adults to pediatric populations." Tummino v. Hamburg (*Tummino II*), 936 F. Supp. 2d 162, 169 (E.D.N.Y. 2013). Later, he states, "The FDA's failure to extrapolate involves . . . perhaps the most significant unexplained deviation from FDA practice ordered by the Secretary." *Id.* at 175.

275. *Id.* at 176.

276. Tummino v. Torti (*Tummino I*), 603 F. Supp. 2d 519, 533 (E.D.N.Y. 2009).

277. *Id.* at 531 (explaining that FDA Commissioner Mark McClellan said he was "not convinced the studies had enough power to determine if there were behavioral differences between adults and adolescents").

278. *Tummino II*, 936 F. Supp. 2d at 177 (emphasis omitted) (quoting Dr. John K. Jenkins, Director of the Office of New Drugs).

279. *Id.* (explaining that the Acting Director of the Division of Pediatric Drug Development stated that the minimal number of individuals of pediatric age potentially using a drug could justify

the particular physiological or other differences implicated by the drug mechanism; differing metabolism; different surface-to-mass ratio; developing organs; different growth or nutritional requirements;[280] and different cognitive development.[281]

Should the norms governing justifiable inference given the data sampling constraints operate like legal norms, which may require more presumptive consistency? Is Korman, in appealing to past extrapolation and inference, piggybacking on scientific practice norms, or adhering to a legal rule requiring generalization? [282]

Korman argues that none of the FDA's past refusals to extrapolate to the pediatric population involved safety data, only efficacy findings.[283] He reasons that because the determination of OTC status for Plan B for adolescents involved consideration of whether the *safety*, as well as efficacy, of Plan B for adults could be assumed to obtain in children, the past history of extrapolating safety data justifies extrapolation here.[284] In performing his extrapolation analysis by looking to whether the FDA has deviated from its historical practices in extrapolation, he does a fair amount of violence to scientific reasoning. The FDA's protests capture this well when it says, "Notwithstanding all of these departures, the FDA argues that there is no customary agency practice and '[e]very drug presents a unique collection of issues, and no two reviews will be identical.'"[285]

Levonorgestrel is remarkably well-tolerated, has been in long-standing use, and adverse reactions have been minor and few.[286] Thus, the findings of Plan B studies may well be generalizable, even to populations that are not well-sampled. However, it is hard to imagine that judges who do not know much about the differences in physiology and drug action among different populations are the ones to best correctly identify the data and study features that would justify extrapolation. Why would Korman know whether information about a drug's safety rather than findings about its efficacy were more likely to be similar between adult and pediatric subpopulations? Why should we trust his judgment that extrapolation to adolescent populations for previous products, without

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waiving the requirement of an additional pharmacokinetic or safety study in a pediatric population, consistent with the criteria outlined in the Pediatric Research Equity Act, 21 U.S.C. § 355(c)(4)).

280. *Id.* at 173 (citing the FDA's prior decision to label an OTC diet drug, Alli, as "not . . . for use by the pediatric population" because of nutritional concerns).

281. *See* Memorandum from Kathleen Sebelius, Sec'y of Health & Human Servs. to Margaret Hamburg, Comm'r of Food & Drugs (Dec. 7, 2011) (on file with author).

282. *See Tummino I*, 603 F. Supp. 2d at 532–33 (asserting FDA's long history of extrapolating from adults).

283. *Tummino II*, 936 F. Supp. 2d at 175–76.

284. *Id.*

285. *Id.* (alteration in original) (quoting Memorandum of Law in Opposition to Plantiff's Motion for Summary Judgment and in Support of Defendant's Cross-Motion to Strike at 32, Tummino v. Eschenbach, No. 05-CV-366 (E.D.N.Y. May 26, 2007)).

286. *Id.* at 166–68.

regard to behavioral implications, should entail such extrapolation to adolescents for oral postintercourse levonorgestrel? Surely different issues can arise in different products.

C. White v. Beal*: Medicaid Eyeglasses Coverage Restrictions*

Pennsylvania, under Title XIX of the Social Security Act (SSA), administers a Medicaid program, jointly funded by the federal and state governments to provide health benefits for certain populations in need of a medical safety net.[287] Title XIX requires any Medicaid program qualifying for federal matching funds to provide certain mandatory benefits, such as inpatient hospital care, or nursing, but then allows states—at the same federal match rate—to add certain optional benefits, including eyeglasses.[288] Pennsylvania decided to furnish glasses, but not for patients with refractive error, such as near-sightedness or far-sightedness.[289] The eligible patients were those whose need for glasses stemmed from an eye disease.[290] The state's failure to provide the optional benefit to those with refractive error, when they had no obligation to provide the benefit at all, was deemed to violate the Medicaid statute's requirement of reasonableness.[291]

1. Medicaid Coverage Background

Medicaid is a joint state and federal program to cover specified populations considered in need of a safety net.[292] States are not required to establish a program following federal standards for Medicaid, but if they do so, the federal government will provide them with matching funds for such expenditures.[293] Federal standards include the coverage of certain mandatory beneficiary categories and certain mandatory benefits, as well as some crosscutting general standards.[294] Medicaid features an approach whereby federal guidelines set a baseline for what a state program must cover to qualify as a Medicaid program.[295] Failure to reach the minimum standards will cause the state to lose matching funds, but states have considerable freedom in the other direction. They are permitted to go beyond the minimum required and layer more generous eligibility or benefits on top of the federally required floor. The provision of this

287. Social Security Act (SSA) § 1901, 42 U.S.C. § 1396 (2012).
288. *See* discussion *infra* Section III.C.ii.
289. White v. Beal, 555 F.2d 1146, 1148 (3rd Cir. 1977).
290. *Id.*
291. *Id.* at 1151–52.
292. ANDY SCHNEIDER ET AL., THE MEDICAID RESOURCE BOOK 4 (2002), http://kff.org/medicaid/report/the-medicaid-resource-book/.
293. Social Security Act § 1903, 42 U.S.C. § 1396b (2012).
294. *See* discussion *infra* Section III.C.ii–iii.
295. Nicole Huberfeld, *Bizarre Love Triangle: The Spending Clause, Section 1983, and Medicaid Entitlements*, 42 U.C. DAVIS L. REV. 413, 419–20 (2008).

optional assistance garners federal matching funds if it falls within the parameters of general Medicaid requirements.[296]

i. Eligibility

Eligibility for Medicaid had historically been tethered to the old Aid to Families with Dependent Children (AFDC) and Supplemental Security Income (SSI) categories of the "deserving poor."[297] Under this paradigm, mere poverty was insufficient to qualify; the program was targeted to beneficiaries who had "reason" to be poor.[298] In addition to meeting certain means-tests, one also had to fall into one of the eligibility "categories," such as single mothers (now single parents) and their dependent children, pregnant women, the aged, blind, and disabled.[299] For states to receive federal funds, they were required to cover specified low-income individuals in these categories.[300]

Beyond these mandatory groups, states had the option to cover certain additional individuals, including those who were somewhat less indigent, but because of high medical expenses, still lacked resources for adequate medical care.[301]

ii. Benefits

The statutory benefits standards were also structured as a mandatory baseline with a state option to provide more.[302] Mandatory benefits included family planning services, inpatient hospital care, outpatient hospital services, laboratory and x-ray services, and physician and nurse practitioner services.[303]

Other items and services, such as vision, dental, and prescription drugs, were designated as optional.[304]

Just as drug indications are not susceptible to unidimensional definition, benefits can be configured along various parameters. A number of

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296. SCHNEIDER ET AL., *supra* note 292, at 95.

297. TIMOTHY STOLTZFUS JOST, DISENTITLEMENT? THE THREATS FACING OUR PUBLIC HEALTH-CARE PROGRAMS AND A RIGHTS-BASED RESPONSE 73 (2003); David A. Super, *Laboratories of Destitution: Democratic Experimentalism and the Failure of Antipoverty Law*, 157 U. PA. L. REV. 541, 585–86 (2008).

298. *See* Super, *supra* note 297, at 585.

299. *See* Nicole Huberfeld, *Federalizing Medicaid*, 14 U. PA. J. CONST. L. 431, 438–39 (2011).

300. Social Security Act § 1902, 42 U.S.C. §1396a(a)(10)(A)(i) (2012).

301. *Id.*; 42 U.S.C. § 1396b(f)(2)(B).

302. 42 U.S.C. § 1396a(a)(10) ("A State plan for medical assistance must . . . provide . . . ."); 42 U.S.C. § 1396d(a)(1)–(5), (17), (21), (28).

303. 42 U.S.C. § 1396d(a)(1)–(5), (17), (21), (28); *see also* 42 U.S.C. § 1396a(a)(10)(A).

304. *See* 42 U.S.C. §1396a(a) (excluding those services itemized in § 1396d(a)(10)(A) (citing 42 U.S.C. § 1396d(a))). A number of developments have modified this framework. Now, Medicaid is delivered largely by managed care companies, and Congress has also reduced benefit requirements to benchmark or benchmark-equivalent coverage for children, working parents, and pregnant women above 133% of the federal poverty line. *See* Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 6044 , 120 Stat. 4, 88–93 (2006) (codified as amended at Social Security Act § 1937, 42 U.S.C. § 1396u–7 (2012) (defining benchmark coverage based on certain commercial plans in the state)).

options exist for reducing benefits. Benefits could come with large co-pays.[305] Availability could be restricted to only a limited number of providers.[306] Home and community-based care could be made available for only those patients meeting certain diagnostic criteria for need.[307] Hospital days might be capped.[308] Prescription drugs might be restricted to those on a formulary.[309]

iii. Crosscutting Standards

Federal statute also imposes a few general crosscutting requirements upon state programs.[310] Title XIX contains a so-called equal access standard that stipulates that states must provide resources "sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area."[311] The so-called comparability standard derives from language that requires the provision of an equal "amount, duration, or scope" of medical assistance to any other individual in that category.[312]

The statute contains a number of other such standards,[313] but at issue in *White v. Beal*[314] was the "reasonable[ness]" requirement imposed by the statutory language that "[a] State plan for medical assistance must . . . include reasonable standards . . . for determining eligibility for and the extent of medical assistance under the plan which . . . are consistent with the objectives of this [Act]."[315]

The zone of state flexibility has been described thus: "[T]his court recognized the state's broad discretion to define the medical conditions for which treatment is 'necessary' within the meaning of the Act," but this broad discretion is not unbridled.[316] Indeed, it is bounded by the fair-

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305. *See, e.g.*, Claus v. Smith, 519 F. Supp. 829, 831 (N.D. Ind. 1981).

306. 42 U.S.C. § 1396u-2(a)(1).

307. *See generally* Sidney D. Watson, *From Almshouses to Nursing Homes and Community Care: Lessons From Medicaid's History*, 26 GA. ST. U. L. REV. 937, 961, 963–65 (2010) (providing background into availability of community-based care under Medicaid).

308. *See, e.g.*, Alexander v. Choate, 469 U.S. 287, 306 (1985).

309. 42 U.S.C. § 1396r-8(d)(4)(C).

310. For general discussion, see Huberfeld, *supra* note 295, at 418–24.

311. 42 U.S.C. § 1396a(a)(30)(A).

312. 42 U.S.C. § 1396a(a)(10)(B)–(C)(i).

313. *See, e.g.*, 42 U.S.C. § 1396a(a)(1) (requiring state medical assistance plans to be offered statewide).

314. 555 F.2d 1146 (3rd Cir. 1977).

315. 42 U.S.C. § 1396a(a)(17). For managed care, 42 U.S.C. §1396b(i)(26) requires necessary, reasonable limits. *See also* 42 U.S.C. § 1396a(a)(19). Note that advocates sometimes warn against sourcing these standards for reasonableness in amount, duration, and scope to particular statutory provisions rather than to more diffuse federal common law. *See* Stan Dorn et al., *Maximizing Coverage for Medicaid Clients ("Bridges over Troubled Waters")*, 20 CLEARINGHOUSE REV. 411, 412 & n.11 (1986) (regarding case law that "relied on 42 U.S.C. §[ ] . . . 1396a(10)(C)(i), and 45 C.F.R. § 249.10(a)(5)(i), now 42 C.F.R. § 440.230(d)").

316. White v. Beal (*White II*), 555 F.2d 1146, 1150 (3d Cir. 1977). I am grateful to Nan Hunter for pointing me to this case.

ly open-textured, non-specific norms articulated above, such as "reasonableness," "equal access," and "comparability."[317]

What we explore in *White* is the curious and arguably "extra-legal" way by which courts choose to give content to those norms.

2. Exception

The Pennsylvania Department of Public Welfare added eyeglasses, clearly an optional benefit, to its Medicaid program.[318] But state law restricted the extent of coverage provided: if the need for eyeglasses stemmed from an eye disease, Medicaid would cover it, but not if the need stemmed from refraction error, such as myopia.[319]

The court declared this exception unreasonable under the Medicaid statute, which it read to prohibit the restriction of service based on matters other than "medical need."[320] The court opined that the benefit of federal matching funds comes with a corresponding constraint to scale the benefit in accordance with the federal purpose of addressing "need":

> We conclude that when a state decides to distribute a service as part of its participation in Title XIX, its discretion to decide how the service shall be distributed, while broad, is not unfettered: the service must be distributed in a manner which bears a rational relationship to the underlying federal purpose of providing the service to those in greatest need of it.[321]

Leaving aside whether the concept of "need," even "medical need," is sufficiently well-specified to settle concrete disputes over plan design, the court seems to understand the single purpose that governs the program as no mere social policy goal to be fulfilled to the extent possible but without requirement of consistency.[322] Instead, the court applies "need fulfillment" as a Dworkinian social principle, which furnishes an individualized claim: "By permitting the state plans to provide only part of the cost, the statute must be construed to envision an evenhanded sharing of benefits and burdens among those having the same needs."[323] Even if this principle of evenhandedness for those with the "same needs" were self-evident from the Medicaid statute, the identification of the relevant dimension in which needs would be considered "same" or "different" is

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317. *See* Huberfeld, *supra* note 299, at 446.

318. *White II*, 555 F.2d at 1148. Eyeglasses, however, would not be optional for children who enjoy mandatory Early Periodic Screening Diagnostic and Treatment (EPSDT) benefits under 42 U.S.C. §1396a(a)(43)(A).

319. *White II*, 555 F.2d at 1148 & n.1.

320. *Id.* at 1151.

321. *Id.*

322. *See* DWORKIN, *supra* note 10, at 91 (describing such a goal as a "nonindividuated political aim").

323. *White II*, 555 F.2d at 1151.

so underdetermined as to be empty.[324] "This is so because any set of human beings will resemble each other in some respects and differ from each other in others and, until it is established what resemblance and differences are relevant," the principle of equal treatment for sameness cannot be determinate.[325] In fact, the parameter of the relevant medical condition along which states are obliged to provide "necessary" treatment evenhandedly proved highly manipulable: "[T]he state argues that it chose to treat the 'condition of eye disease' and not refractive error" while the court, agreeing with the beneficiary plaintiff "on the other hand contends the 'condition' is visual impairment."[326]

Does the Medicaid statute tell us, by virtue of the availability of federal financing, that exclusions, or distinctions, can only take a certain shape? Is it inherent in the legal requirement of "reasonableness" that a determination should be based on need as determined "medically" rather than "politically"? Where do these ideas come from?

Ironically, the rejection of political need for "principled" medical need was delinked from any corresponding requirement that the state actually meet patients' medical needs. Indeed, the coda was not a happy one for the plaintiff. The result of the court ruling requiring Pennsylvania to provide eyeglasses more broadly was that Pennsylvania found eyeglasses would therefore be unaffordable and withdrew the benefit altogether.[327]

This case forced the state into an all-or-nothing choice. This case would not expose the exceptions problem in such stark relief were eyeglasses a mandatory benefit. But the state is not required to provide them at all, so how can it be required to provide them to both those with eye disease and those with refractive error? For the court to read the word "reasonable" to block a state's politically accountable determination of the extent to which it wishes to provide "extra" assistance to their Medicaid population is striking.[328] What then is at work?

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324. *See, e.g.*, Peter Westen, *The Empty Idea of Equality*, 95 HARV. L. REV. 537, 560 (1982).

325. HART, *supra* note 7, at 155.

326. *White II*, 555 F.2d at 1150–51.

327. White v. Beal (*White III*), 447 F. Supp. 788, 798 (E.D. Pa. 1978).

328. This case is not entirely idiosyncratic, but part of a line of precedent where medical need is privileged and used by courts to invalidate state attempts to cut back Medicaid benefits. *See, e.g.*, Lankford v. Sherman, 451 F.3d 496, 511–12 (8th Cir. 2006) (invalidating state's decision to provide partial DME, an optional benefit, to only certain categorical populations); Weaver v. Reagen, 886 F.2d 194, 197–98 (8th Cir. 1989) (finding state's decision to limit HIV drugs violates Medicaid); Pinneke v. Preisser, 623 F.2d 546, 548–49 (8th Cir. 1980) (finding Iowa's exclusion of sex reassignment surgery was unreasonable when it was the only available medical treatment for relief of patient's condition); Phila. Welfare Rights Org. v. Shapp, 602 F.2d 1114, 1122–23 (3d Cir. 1979) (finding mandatory EPSTD benefits include orthodontia if medically necessary); Preterm, Inc. v. Dukakis, 591 F.2d 121, 126–27 (lst Cir. 1979) (holding it inconsistent with Medicaid statute for a state to limit physician's medical judgment by prohibiting medically necessary abortions except those required to save pregnant woman's life, though superseded by Congress's action in adopting the Hyde Amendment); *see also* Alexander v. Choate, 469 U.S. 287, 302–03 (1985) (holding 14-day

3. Value Conflict

As with the soda portion cap and the Plan B OTC switch, what seems to be at work is an invalidation of rules when they have, through their exceptions, accommodated conflicting values.[329] The court here forbids the tailoring of a benefit rule to strike a balance between cost and health need.[330]

Cost was behind the state's rationale for the exclusion of patients with refractive error.[331] Cost limits forced prioritization, and the state prioritized according to a social norm constructing the "normal" as opposed to "pathological," a norm that, as we will see, runs somewhat aslant to the "medical necessity" norm. The state claimed that it was simply trying to allocate limited resources and, therefore, "restrict payment for eyeglasses to those individuals it considers most in need of aid, those having pathology or disease of the eye."[332] The state articulated its criterion of need thus: "[R]ecipients whose eye pathology could be treated or cured by providing glasses were the most immediately needy group of recipients."[333]

But the court rejects this type of underinclusion: "[W]e do not believe that the state has applied a permissible method of obtaining economies in its administration of the medical assistance program."[334] Through this particular benefit rule configuration, the state has improperly assumed the prioritization of competing values.

4. Assigns to a Non-Legal Sphere: Medical Necessity

The court proposes a different prioritization instead—by the norms of medical practice. "Assuming that medical need is a valid measurement of eligibility, the state's factual premise [that they have served the needi-

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limits on hospital stays consistent with the Rehabilitation Act declaring, "Medicaid programs do not guarantee that each recipient will receive that level of health care precisely tailored to his or her particular needs"). *But see* Maher v. Roe, 432 U.S. 464, 480 (1977) (holding that Connecticut can define the procedural hurdles for first trimester abortions to be determined "medically necessary"); Dexter v. Kirschner, 972 F.2d 1113, 1116–17 (9th Cir. 1992) (holding that Arizona can choose to cover only autologous, and not allogeneic bone marrow transplants given lack of facilities); Smith v. Rasmussen, 249 F.3d 755, 760–61 (8th Cir. 2001) (finding Iowa's exclusion of gender reassignment surgery not arbitrary if done by rulemaking and if professionals disagree on the necessity); Curtis v. Taylor, 625 F.2d 645, 652–53 (5th Cir. 1980), *modified*, 648 F.2d 946 (5th Cir. 1980) (upholding caps on physician visits per month); Dodson v. Parham, 427 F. Supp. 97, 108 (N.D. Ga. 1977) (finding the state can consider cost in imposing drug formularies, as long as prior authorization process is adequate).

329. *See supra* Sections III.A.4, III.B.5.

330. *White II*, 555 F.2d at 1150.

331. *Id.* (describing the state's explanation: "First, the Commonwealth was not and is not ready to provide the large amounts of money necessary to provide glasses to every recipient needing them 'to aid or improve vision.'" (quoting White v. Beal (*White I*), 413 F. Supp. 1141, 1149 (E.D. Pa. 1976))).

332. *Id.* at 1149.

333. White v. Beal (*White I*), 413 F. Supp. 1141, 1149–50 (E.D. Pa. 1976).

334. *White II*, 555 F.2d at 1149.

est of the group], is not supported by the record."[335] The court goes on to cite affidavits from two ophthalmologists declaring that sometimes people with refractive error may be "more visually handicapped than those who have a disease of the eye."[336]

Rather than relying on state law, the court apparently prefers the concept of "medical need," citing the authority of individual clinicians to determine the degree of "medical necessity."[337]

We must therefore examine the concept of medical necessity and, once it enters into the picture, how it functions as a standard for the scope of benefits.

"Medically necessary care" is the "almost-universal contractual standard for [health insurance] coverage."[338] According to Mark Hall's empirical findings, the specificity of the insurance contract has no significant effect on whether a patient can obtain coverage in legal disputes, leaving this placeholder term, "medical necessity" to do most of the work of demarcating what is covered under the plan.[339] When interpreting medical necessity, courts and legislatures do not rest determination of the standard solely with the agency or insurer providing coverage.[340] They preserve enormous latitude for physicians to determine its application. This latitude does not mean determination by the treating physician, but rather determination by professional clinical standards,[341] a second-order analysis of what treating physicians ought to do.

The term "medical necessity" is not explicit in the Medicaid statute, but has become judicially accepted as implicit to the legislative scheme and is apparently endorsed by the Supreme Court.[342] Indeed, *White* represents a crucial early step in that process.

The courts are not alone in reading "reasonable" to imply "medically necessary." HHS states that benefits: "[M]ust be sufficient in amount, duration, and scope to reasonably achieve [their] purpose." With respect to the required services for the "categorically needy" and the "medically needy" the State "may not arbitrarily deny or reduce the amount, dura-

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335. *Id.* at 1150.

336. *Id.*

337. *Id.* at 1150–51 ("The plaintiffs submitted the affidavits of two qualified ophthalmologists stating that some persons with refractive error, but without eye pathology, may be far more visually handicapped than those who have a disease of the eye. Moreover, the physicians maintain that, while eyeglasses will correct a refractive error, they are not helpful in many cases of eye disease. The state has not controverted these affidavits." (footnote omitted)).

338. M. Gregg Bloche, *The Emergent Logic of Health Law,* 82 S. CAL. L. REV. 389, 413 (2009).

339. Mark A. Hall et al., *Judicial Protection of Managed Care Consumers: An Empirical Study of Insurance Coverage Disputes*, 26 SETON HALL L. REV. 1055, 1062–63 (1996).

340. *See id.* at 1063.

341. Timothy P. Blanchard, "*Medical Necessity" Determinations: A Continuing Healthcare Policy Problem*, 37 J. HEALTH L. 599, 619–20 (2004).

342. *See* Beal v. Doe, 432 U.S. 438, 444–45 & n.9 (1977).

tion, or scope of" such services to an otherwise eligible individual "solely because of the diagnosis, type of illness or condition. . . . [A]ppropriate limits [may be placed on] a service based on such criteria as medical necessity or [those contained in] utilization [or medical review procedures]."[343]

What does medically necessary mean, and how is the medical necessity determination made? In short, it involves significant deferral to other decision-makers, namely, to the social and institutional practice of clinical medicine. Under "medical necessity," coverage determinations depend on more than the policy terms in the contract or statute; they also involve a second query.[344] This second step asks: "[E]ven if the contemplated care is a type generally covered, is its use medically reasonable and necessary in this particular case and thus warranted?"[345] The answer to that question is determined by clinical standards, which in turn emerge from the practice of medicine. Thus, the courts' turn toward medical necessity to resolve the question of what to cover amid competing concerns is a diversion of the question away from governance by rule to another arena.

However, the concept of "medical necessity" does not determine its own domain and by no means precludes rule-governance in its entirety. The extent of coverage under public or private insurance has always included two analytical steps, the first of which identifies which categories of services are even eligible to be covered.[346] Initially, one must ascertain whether the plan covers surgically implanted artificial lenses, for instance. Only then does the "medical necessity" step determine the circumstances and patient conditions for which those services are justified.[347] For instance, just because lens implantation surgery is listed among the benefits does not mean that insurance will cover such a surgery if a patient simply wishes to correct her nearsightedness with an intraocular lens, or if her cataract is so mild that it does not yet affect the patient's vision and therefore does not yet justify the risks of surgery.

The Medicaid statute, like other health coverage schemes, lists broad categories of services to be included in or expressly excluded from benefits packages, while courts, through cases like *White*, have tasked the specification of those benefits to determination by any individual patient's clinician in accordance with her professional judgment.[348] Coverage decisions begin as a threshold matter by determining whether the type of item or service is within the policy. If physical therapy services

343. Sufficiency of Amount, Duration, and Scope, 42 C.F.R. § 440.230 (2012).
344. *See* Sara Rosenbaum et al., *Who Should Determine When Health Care is Medically Necessary?*, 340 NEW ENG. J. MED. 229, 230 (1999).
345. *Id.*
346. *See id.*
347. *Id.*
348. White v. Beal (*White II*), 555 F.2d 1146, 1150 (3d Cir. 1977).

are not within the policy, then the inquiry would end there.[349] But the *White* court glosses over the two-step character of any coverage determination and thereby represents the clinical practice step of the medical necessity inquiry as the only relevant inquiry.

The distinction between the listing of benefits and the determination of medical necessity is unquestionably fuzzy. Jessica Mantel, in considering Medicaid's sister program Medicare, observes that "[f]or example, HHS may provide that a plan's prescription drug benefits must include all drugs approved by the FDA . . . but not . . . drugs prescribed for the treatment of erectile dysfunction or infertility."[350] While such a regulation would not substitute for an individualized analysis of whether the patient's condition warrants use of a drug, it could begin to impinge upon such a determination, as the above example shows by allowing prescription drugs for some conditions but not others. A similar inclusion of therapies for some conditions and not others is arguably what Pennsylvania proposed here.

Thus, medical necessity cannot determine its own governing jurisdiction. It admits of some boundaries set by positive law. But the court aggressively redrew those boundaries.

5. Judge Arrogates Decision and Method

When the judge decides that medical necessity should govern, he is displacing another decision-maker's choice.

So how does he decide when to substitute for another's choice? Is there some legal rule distinguishing the first and second steps of the medical necessity determination? Judge Weis shows no signs of declaring such a rule. Instead, he appeals to medical norms and applies them in his own fashion.[351] Judge Weis, as we recall, "[a]ssum[es] that medical need is a valid measurement of eligibility,"[352] and he goes on to assess that need based on two ophthalmologists' affidavits. The ophthalmologists say that refractive error can be more visually handicapping and that "[eyeglasses] are not helpful in many cases of eye disease."[353] Yet Pennsylvania provides a long list of those eye diseases where glasses are helpful, such as with certain strabismuses, or asymmetries of vision, or conditions associated with lens dysfunction.[354] Is the judge really qualified to sift through medical information, especially when provided in the form

349. *See, e.g.*, DeSario v. Thomas, 139 F.3d 80, 88 (2d Cir. 1998) ("No matter how medically necessary a thing may be to a particular person . . . the state need not (and in fact cannot) provide it unless it falls within a covered medical service.").

350. Jessica Mantel, *Setting National Coverage Standards for Health Plans Under Healthcare Reform*, 58 UCLA L. REV. 221, 229–30 (2010).

351. *See White II*, 555 F.2d at 1150; *see also* Hall et al., *supra* note 339.

352. *White II*, 555 F.2d at 1150.

353. *Id.* at 1150–51.

354. *Id.* at 1148 & n.1.

of individual clinician affidavits, to aver that patients with divergent squint or faulty lenses have less medical need?

In this case, neither the legally instantiated rule, nor the underlying political prioritization, prevail; state legislatures and Medicaid agencies are thus restricted in how they can weigh economic and other considerations. Judges seem to harbor some underlying view that prompts them to deflect situations where rules alone, unsupported by what they view as the proper extralegal norms, claim to resolve value conflict.

One might respond that this case result needs no such cloak-and-dagger account. In this case, the federal statute simply prohibits such a benefit limitation. But is this conclusion unambiguously commanded by the statute?[355] An examination of the actual language reveals that the most locally controlling statutory text concerning eyeglasses as a benefit, does not prohibit the qualification of the benefit for economic considerations.[356] The court even concedes that "[s]ignificantly, the only statutory restriction on furnishing eyeglasses is that they be prescribed by a physician or an optometrist."[357] Unable to rest on the statutory language concerning eyeglasses to impose its more stringent restriction, the court points instead to the more distant crosscutting language that the state's definition of benefits must be "reasonable."[358] With such capacious terms as "reasonable" defining the restriction on state legislatures, the argument that this result was compelled, rather than chosen by the court, falters.

Why can't the state prioritize what benefits to provide rather than acceding to judge's preferences, clad in the fig leaf of medicine? Medicine, the court seems to say, is the social institution robust enough to manage this value conflict. Thus, it reroutes the matter away from settlement by pedigreed legal rule, indeed away from the political process of legitimating rules, and engages in its own ventriloquy of medical norms to do so.

CONCLUSION

So far, I have identified a pattern—courts striking down exceptions in health rules when those exceptions seek to accommodate value conflict and then assigning the matter to an extralegal, non-rule-governed arena, all the while invoking non-rule like reasoning from that extralegal realm to do so.

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355. This case predates *Chevron, U.S.A. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984).

356. Social Security Act § 1905(a)(xvii)(12), 42 U.S.C. § 1396d(a)(xvii)(12) (2012) ("[P]rescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in disease of the eye or by an optometrist, whichever the individual may select.").

357. *White II*, 555 F.2d at 1150.

358. *See id.* at 1150–51.

This pattern bespeaks a tendency in judicial reasoning to obscure value conflict, even at the expense of a most potent tool in the legal system's arsenal: rules. To strip rules of their ability to bind when even underlying reasons run out is a major sacrifice, and is it worthwhile or necessary to prop up an image of law as a realm of coherent, unitary principles? The premise of liberalism is the inevitability of disagreement.[359] People will have different policy preferences. We can agree to disagree, but we all agree to follow the rules. Why when we need clear dispositive rules the most, as the instruments of equipoise amid disagreement, are the judges loathe to allow them? Ex ante exceptions are a way to accommodate and grease social change, reducing the costs of the new rule, honoring the provisional, the plural, the incremental, acknowledging competing values, and resisting a winner-take-all form of hubris. But perhaps this tool is less available than we think.

Is the best we can hope for that law will offload these difficult settlements onto other social institutions, even as jurists engage in shadow-boxing versions of those alternate normative practices to manage the jurisdictional decisions that are necessary to maintain these arrangements?[360]

The courts in each of these cases insisted upon false unitary justifications, as though each rule should embody one principle. But justification for any rule is compound. Health care is provided to the poor to the extent financially sustainable. We allow patients direct market access to a drug if the burden of prescription control is "unnecessary." We seek to moderate unhealthful sugary drinks to the extent compatible with other aspects of our lifestyle, including some measure of choice or hedonism. Are health ends more fully respected by health policy absolutism, or by a willingness to pursue those ends despite acknowledgment of the sometimes wrenching tradeoffs?

Perhaps these judges, facing too many disparate values, yearn for absolutes that would help them maintain their self-understood role as "integrating" the law. It is true that health care exists at the intersection of a number of practices—medical, scientific, actuarial, caregiving—all of which are tangent to an otherwise closed, internal, and pedigreed set of legal rules. Does health law alone exhibit this normative overload? This pluralism and interplay of norms and practices surely characterizes other topical areas as well.

As a future line of inquiry, we might look for this phenomenon in non-health cases and test our expectation that adjudication would similarly buckle under the strain of handling the concurrency of norms. We

359. *See, e.g.*, JOHN RAWLS, A THEORY OF JUSTICE 450–51 (1971).
360. *See* DWORKIN, *supra* note 10, at 79.

would hypothesize the same desperate anxiety to restore the unitary, coherent "principle" that integrates the entire field.

One reading of these cases, or one candidate for a unifying principle, ignoring for the moment all the contrary case law, might be that health has a privileged justificatory weight. What if the implicit view that judges harbor is that health needs should prevail, that health values exert some resistance before they yield to another competing policy? What if the coherent principle that banishes the non-health values from the scene is an incipient canon privileging health, establishing what we can fairly call a "right to health?"[361]

What if a critical mass of courts is compelled by the internal logic of fairness specific to health, which I stipulate as follows: a principle that if calamity befalls a member of our community, threatening life and limb, or other existential preconditions (like pregnancy), and it is within the human arts to help, we resist limitations.[362] Perhaps we do not accept that health care needs can be weighed like any other policy. Perhaps they are in Dworkin's language, matters of principle, because the extension of health care in the face of mortality and suffering acknowledges of the individual dignity and worth of each individual.

Health interests in this regard should not differ with age, nor cede lightly to assertions of sexual morality. They obtain for those who buy their sugary drinks regardless of who vends or inspects the vendors of those drinks. They do not cleave along adventitious diagnostic distinctions, such as strabismus versus myopia. In *White*, the judge said as much: "In our view, the statute does not grant such discretion to the state. Rather, it requires an equitable distribution of the total funds available among all in need of the service, with a consequent sharing of benefit and hardship."[363]

The logic of fairness in law shies away from substantive standards of reasonableness and looks at whether the decision has authority, regardless of the content.[364] But perhaps substantive reasonability can be

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361. Such as Sunstein's non-delegation canons. *See* Sunstein, *supra* note 4, at 1668, 1683–84. Here, I am borrowing heavily from other scholars who have discussed such a canon, but primarily insofar as they lament the absence of one. *See, e.g.*, WENDY E. PARMET, POPULATIONS, PUBLIC HEALTH, AND THE LAW 267–68 (2009) (presenting a comprehensive argument for why there should be such a health norm throughout law—"*salus populi suprema lex*"—and what it might look like); *see also* Richard A. Daynard, *Regulating Tobacco: The Need for a Public Health Judicial Decision-Making Canon*, 30 J.L. MED. & ETHICS 281, 282 (2002).

362. As Mark Hall says, "the existential stakes" of death, disability, and one's personhood hang in the balance. Mark A. Hall, *The History and Future of Health Care Law: An Essentialist View*, 41 WAKE FOREST L. REV. 347, 358 (2006).

363. *White II*, 555 F.2d at 1150.

364. Waldron says this is key to Raz' positivism. JEREMY WALDRON, LAW AND DISAGREEMENT 37 (1999) ("Authority cannot exist, according to Raz, and legal authority (in whatever shape or form) cannot do its work, unless there is a basis for recognizing pronouncements as authoritative which stands apart from the content and merits of the issues that the authority addresses." (citing JOSEPH RAZ, ETHICS IN THE PUBLIC DOMAIN 203 (1994))).

supplied by health norms—norms of what we are owed and owe one another in the face of suffering, vulnerability, and mortality.[365] Health care holds out a promise of acknowledgement under those circumstances, in the form of help and care, at the level of what arts and sciences our society has accumulated by its best efforts.

The more familiar logic of substantive rationality review prohibits judges from picking and choosing among competing norms, ranking and balancing them as the judges see fit. Instead, courts claim to engage in a means-ends fit analysis. But when multiple purposes are present, other observers have argued trenchantly and persuasively that a judge actually reach his or her result by manipulating the purpose, restricting permissible ends to the unitary one that the judge has selected.[366] Thus, the courts in performing the subconstitutional forms of substantive review we have examined here are also engaged in presumptively privileging certain purposes and declaring others less weighty as against their favored values. To the extent that judges are doing so here, they may be implicitly asserting a background health right—a privileged purpose, heretofore unacknowledged.[367]

Consistent with Dworkin:

> [W]e might, for simplicity, stipulate not to call any political aim a right unless it has a certain threshold weight against collective goals in general; unless, for example, it cannot be defeated by appeal to any of the ordinary routine goals of political administration, but only by a goal of special urgency.[368]

And indeed, these cases might be understood to illustrate exactly such an attitude toward health, an attitude recognizing health as a presumptive right. Of course, Dworkin does not claim that rights inhering in background principles would override legal rules, but the courts could be viewed as acting as though these hypothesized health rights inhere in the separation of powers rules, and the arbitrary and capricious standard, and the crosscutting statutory requirement of "reasonableness." While none of these cases strike a federal statute compromising health values,[369] we

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365. This conception is broad enough that it is conceivably consistent with any one of the Health Promotion, Financial Security or Brute Luck conceptions of the purposes of health insurance articulated in Allison K. Hoffman, *Three Models of Health Insurance: The Conceptual Pluralism of the Patient Protection and Affordable Care Act*, 159 U. PA. L. REV. 1873 (2011).

366. *See* SUNSTEIN, *supra* note 31, at 127.

367. I draw from Dworkin to show the work that judges are performing to construct purpose, but this maneuver is also manifestly rooted in the Legal Process school, an important antecedent for Dworkin. Vincent A. Wellman, *Dworkin and the Legal Process Tradition: The Legacy of Hart & Sacks*, 29 ARIZ. L. REV. 413, 470–71 (1987) (drawing the connections between legal process theory and Dworkin's law as integrity).

368. DWORKIN, *supra* note 10, at 92.

369. Though the Eleventh Circuit, in the case that was appealed and would later become *National Federation of Independent Business v. Sebelius*, 132 S. Ct. 2566 (2011), did seek to declare Congress's power under the Necessary and Proper Clause invalid with respect to the mandate pre-

might still understand this privileged weight as a canon, much like Sunstein's nondelegation canons protecting special values such as federalism, or the common-law substantive canons Abbe Gluck has identified, privileging policies from taxation to international law norms.[370] But rather than default canons allowing cost-benefit analysis, we might posit instead a default canon resisting cost-benefit balancing in health care cases.[371]

I would be remiss if I implied by this view that recognizing a right to health would quell normative conflict over substance. First, the question of how much weight such a privilege exerts would move to the foreground.[372] Second, it is ironic that this health absolutist tendency is often used, as it was in the NYC soda portion cap case, to strike innovative, incremental measures to improve health.

Finally, under a "right to health," normative contest would relocate to the question of what belongs in the bundle that constitutes the "right." One final commonality these three cases all share is a demonstration that there is no underlying a priori concept called health, whose boundaries are self-evident. Health is what we construct, and it lies on a continuum. All of these cases founder on their attempts to represent health as some static identifiable principle. Judge Renwick hews to the notion that exposures are either a health hazard or not, but in the realm of food, nutrition, and obesity the questions are ones of extent. Dose-response curves need not be disjoint; some are U-shaped, and some are continuous without inflection points.[373] Meanwhile, what Judge Korman glosses over is that drug indications can be broader or narrower, and the prevailing paradigm denies that there should be any underlying "natural" category constraining what the drug sponsor posits.[374] And Judge Weis in *White* runs up against the malleability of the definition of benefits and the case law permitting states to trim benefits in myriad other ways.[375]

But that is a topic for another day. Even bracketing such complications, the task of evaluating my alternate explanation, that a right or priv-

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cisely because the mandate contained exceptions for low-income individuals. Florida *ex rel.* Att'y. Gen. v. U.S. Dep't. of Health & Human Servs., 648 F.3d 1235, 1310–11 (2011).

370. Gluck, *supra* note 17, at 765–66.

371. Sunstein, *supra* note 4, at 1692–94 (describing nondelegation canons requiring Congress to state unambiguously if it wishes a statute to be interpreted to apply extraterritorially, or to raise constitutional questions, or to implicate certain federalism concerns, etc.).

372. John F. Manning, *Lessons From a Nondelegation Canon*, 83 NOTRE DAME L. REV. 1541, 1562–65 (2008).

373. *See* Lawrence Alexander, *Scalar Properties, Binary Judgments* 7–9 (Univ. of San Diego Law Sch., Research Paper No. 07-19, 2005) (discussing how many matter subject to legal determination have this aspect of scaling according to degree, while legal determination may require the drawing of a binary line along the scale).

374. *See supra* text accompanying notes 138–59, 181–84.

375. *See, e.g.*, Dexter v. Kirschner, 972 F.2d 1113, 1118 (9th Cir. 1992); Curtis v. Taylor, 625 F.2d 645, 653 (5th Cir. 1980); Charleston Mem'l Hosp. v. Conrad, 693 F.2d 324, 332–33 (4th Cir. 1982); Va. Hosp. Ass'n v. Kenley, 427 F. Supp. 781, 786 (E.D. Va. 1977).

ilege for health might drive these cases, is somewhat outside the bounds of this piece. Perhaps one could compare this exceptions phenomenon in health-related cases to exceptions-based invalidations in other topical areas, and measure, if one could, whether the invalidations were more idiosyncratic in fields constituted by "interests" rather than "rights."

If one were to find the phenomenon sounding in other non-rights arenas, one might conclude that the condemnation of underreach in these cases has less to do with judicial concern for health and instead justifies a generalization of my proposed explanation: that this exceptions phenomenon is a late-mannerist expression of the style of adjudication along the model of Hercules, an elision of rule and principle that emerges as a function of regarding background policies as part of the law and as a direct consequence of the imperative to impose coherence over pluralism.