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Uncovering Agencies' Hidden Unrules

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The prevailing understanding of regulation in the United States is myopic. It focuses mainly on administrative agencies' power to impose obligations, while too often overlooking their power to alleviate obligations.

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Lawyers are very familiar with rules—*i.e.*, legal obligations—but often are not sufficiently attentive to their opposite: what we call "unrules." *See* Cary Coglianese, Gabriel Scheffler, & Daniel E. Walters, *Unrules*, 73 Stan. L. Rev. 885 (2021). An unrule comes into play whenever a regulator circumscribes an obligation contained in a regulation by carving out exceptions or letting some actors or activities slip through the cracks. Unrules can also be issued after the adoption of a regulation, when administrative officials grant specific waivers or exemptions to individuals or businesses from the duties imposed by an otherwise applicable legal obligation.

Obligation alleviation can be used for good. Unrules can, for instance, help to tailor legal obligations to just those entities or circumstances where they are needed. Without this ability, legislators and agencies might sometimes decide not to regulate at all.

But unrules can also be misused. They can be applied in ways that negate or forgo regulatory benefits, foster favoritism for certain interest groups, and even undercut the rule of law. Given these important potential consequences, their use deserves much the same transparency and oversight that govern regulatory agencies' exercise of their authority to impose obligations.

Consider one highly consequential unrule that affects the safety of medical devices: the Food and Drug Administration's 510(k) clearance process. This fast-track process allows devices deemed "substantially equivalent" to devices already on the market to escape the more rigorous premarket approval process that aims to ensure safety and efficacy. According to one study, about 70% of all high-risk recalls of medical devices from 2005 to 2009 involved products that were cleared through the 501(k) unrule. Diana M. Zuckerman, Paul Brown, & Steven E. Nissen, *Medical Device Recalls and the FDA Approval Process*, 171 Archiv. Intern. Med. 1006 (2011). This rate is especially concerning, given that medical devices have been linked to an estimated 1.7 million injuries and more than 80,000 deaths over the past decade. *See 80,000 Deaths. 2 Million Injuries. It's Time for a Reckoning on Medical Devices*, N.Y. Times (May 4, 2019).

Or consider a loophole established by the Environmental Protection Agency (EPA) that carved out an important source of water pollution from the normally applicable regulatory standards. In applying Clean Water Act regulations, the EPA early on allowed international tankers and other ships to escape from complying with certain requirements when they enter the Great Lakes and other major inland bodies of water. *See* 38 Fed. Reg. 13,528, (May 22, 1973). Shipping companies have used this loophole to discharge pollutants, contaminating the water of other rivers and lakes throughout the United States with invasive species, thereby damaging fisheries and creating up to an estimated $17 billion in annual economic costs—not to mention an unquantified risk to human health from the discharges. *See* Off. of Wastewater Mgmt., U.S. EPA, Economic and Benefits Analysis of the Proposed 2013 Vessel General Permit (VGP) 129-30, 134 (2011).

Unrules Are Everywhere

Although unrules are clearly important, they have largely escaped systematic empirical study. The dominant emphasis in both regulatory rhetoric and scholarly inquiry is on rules—that is, the imposition of legal obligations—whereas unrules are often less visible.

The relatively hidden nature of unrules has contributed to a misleading impression that the regulatory system is more onerous and inflexible than it truly is. Our empirical research, recently published in greater detail in the *Stanford Law Review*, finds that unrules are a substantial and widespread feature of federal regulatory law in the United States.

Our research followed an approach used first by researchers at the Mercatus Center who developed a quantitative dataset they call

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RegData. This dataset contains the results of computerized word searches that quantify the number of obligation-related terms used in regulations: *shall, must, may not, prohibited,* and *required*. The Mercatus team uses their finding of a nearly 20% increase in obligation-related words since 1997 to caution against adopting further regulations, claiming that "regulatory accumulation will continue to stifle economic growth." Patrick A. Mclaughlin, Nita Ghei & Michael Wilt, Mercatus Ctr., Policy Brief: Regulatory Accumulation and its Costs—An Overview 1 (2018).

But *RegData* does not account for unrules. We replicated the Mercatus methods and adapted them to measure unrules based on a dictionary of five comparable obligation-alleviating terms: *waive, exclude, except, exempt,* and *variance*. We used computerized techniques to search for and validate both obligation-imposing and obligation-alleviating terms throughout the *Federal Register* and the Code of Federal Regulations (CFR)—as well as in the United States Code because, by our definition, Congress can also alleviate obligations or adopt legislation authorizing administrators to alleviate them.

We began with the *Federal Register*, as it has been the source most widely cited to support conventional wisdom about the growth of obligation imposition in the United States. Agencies are required to publish all new regulations in the *Federal Register* before they can go into effect. Looking at 2016, the most recent year in the data, we found a ratio of 1.0 obligation-alleviating term to every 5.1 obligation-imposing terms.

We then turned to the source of regulatory law that is thought to best capture the slate of obligations that agencies impose—the CFR—and here too we found that unrules were ubiquitous. In 2017, the ratio of obligation-alleviating words to obligation-imposing words in the CFR was 1.0 for every 5.9. Here, the word *except* and its variants accounted for nearly 50% of all occurrences of obligation-alleviating words.

Turning to the legislative arena, we found that the United States Code exhibited a comparable level of obligation-alleviating language to regulations. Across the entire legislative corpus, we found a ratio of 1.0 obligation-alleviating term for every 6.5 obligation-imposing terms.

Across all three sources, then, there exists one obligation-alleviating word for approximately every five to six obligation-imposing words.

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This ratio almost certainly understates the prevalence and impact of unrules. After all, one unrule can wipe out several dozen or even hundreds of rules that might otherwise apply. A single provision within federal law, for example, contains just one word from our unrule dictionary but nevertheless authorizes the Secretary of Homeland Security to "waive all legal requirements . . . [as] necessary to ensure expeditious construction" of security measures along the border of the United States. *See* Pub. L. No. 109-13, § 102, 119 Stat. 231, 306 (codified as amended at 8 U.S.C. § 1103 note (Improvement of Barriers at Border)). The Trump Administration invoked this provision to waive a series of environmental laws that would otherwise have applied to the construction of wall sections along the U.S-Mexico border.

Our findings demonstrate that an "unrulemaking" authority is omnipresent in the federal regulatory corpus, and they imply that government regulation is far less onerous—and far more flexible—than previously imagined. Indeed, based on our findings, it seems clear that previous critiques of regulatory burdens that count only the restrictive dimensions of regulations overstate the true size, scope, and intrusiveness of federal regulation. The true extent to which regulation burdens business can be understood only by taking into account the net effects of both rules and unrules.

Classifying Unrules and Identifying Risks

The power to alleviate obligations takes one of two forms. The first type of unrule we call "dispensations." These are the actions by which regulatory agencies grant waivers, exemptions, or variances to individual people or businesses after a regulation has become effective. Dispensations arise frequently in response to unusual circumstances or emergency situations. Think of the outbreak of COVID-19 and the FDA's subsequent issuance of "emergency use authorizations" for vaccines.

Other times, agencies use dispensations to adapt regulations to changed conditions or new technologies. For instance, the Securities and Exchange Commission recently issued several no-action letters for digital-coin offerings, promising not to enforce securities laws for companies seeking to offer a new cryptocurrency. Sometimes, agencies do not even announce that they are not going to enforce a rule; dispensations include countless deliberate nonenforcement decisions made at the discretion of agency officials.

A second type of unrule we call a "carveout." Carveouts comprise exceptions and other limitations embedded within law, such as when an existing business is "grandfathered" and exempted from the obligations of a new regulation.

Or, to use another example, when the Affordable Care Act imposed a mandate that businesses with fifty or more full-time employees provide health insurance for their employees, it necessarily carved out businesses with fewer than fifty full-time employees from the statute's obligation.

Carveouts and dispensations are distinguishable in terms of their scope and timing, but these two types of unrules are part of the same phenomenon because both have at their core the *sine qua non* of obligation alleviation. And both types can be found within every source and domain of law, including health care, securities, environmental protection, transportation, and campaign finance.

As we noted above, unrules can sometimes be essential for a fair, flexible, and dynamic system of rules. Yet, if used unthinkingly or injudiciously, unrules can undermine the purpose of a regulation or statute, or they can advantage special interests over the broader public good. In some cases, unrules can even threaten the rule of law: If carveouts are indiscriminate and dispensations frequent and secret, the law may no longer come to provide the predictability, notice, and fairness that it needs to operate effectively. And when regulatory agencies dole out dispensations or carve out firms from the scope of regulations, they might be acting at the behest of interest groups and at the expense of the general public.

Such concerns might be easy to overlook if unrules were only an exceptional or infrequent part of the regulatory system, or if administrative discretion to use unrules were sufficiently constrained by adequate procedures and oversight. But unrules are pervasive, and they are not subject to the same force of administrative law as are actions that impose obligations.

Reorienting Administrative Law

Throughout the last century, administrative law's focus has been protecting individual and economic liberty from state intrusion. Unrules, meanwhile, have remained largely in the background—hiding in what we refer to as administrative law's "blind spot." Administrative law's requirements for transparency, benefit-cost analysis, and judicial review tend to impose greater constraints on government agencies' ability to impose obligations than on their ability to alleviate the application, scope, or stringency of obligations.

Our empirical findings about the ubiquity of unrules suggest a need to reorient thinking about administrative power and discretion. The risks of unrules are real, and they become even more disquieting once it is clear how pervasive unrules truly are.

Unfortunately, that pervasiveness has not always been evident based on the materials that agencies produce under existing procedural law. One glaring problem with dispensations, in particular, is that many of them never need to be disclosed to the public. To make unrules more transparent, Congress or the president could consider requiring agencies to maintain online lists of granted dispensations. Similar publication requirements have been imposed on agencies with respect to their guidance documents. Cary Coglianese, *Illuminating Regulatory Guidance*, 9 Mich. J. Envtl. & Admin. L. 243, 275-276 (2020). Transparency would help reduce the barriers that regulatory beneficiaries face to pursuing judicial review of unrules. Such review may reduce the level of arbitrariness and abuse of power that can exist in the granting of dispensations.

When it comes to reforming administrative law's approach to carveouts, we offer two suggestions. First, when agencies publish notices of their proposed and final regulations, they could be expected to provide notice to the public of the classes or categories of potential regulatory targets that have been carved out of the regulation, along with a justification for these carveouts.

Second, regulatory impact analysis—and its review by the Office of Information and Regulatory Affairs—could more evenly focus on obligation imposition and alleviation. Right now, agencies focus more on the obligations that new regulations will impose than on the roads that agencies have not traveled: that is, the carveouts contained within those regulations or the options they provide for dispensations.

In the end, the most crucial step to protect against the abuses of unrules is to recognize their relative ubiquity, current opacity, and potential for abuse. Only then can lawyers, judges, and legislators begin to develop more systematic reforms that will level the playing field between obligation imposition and alleviation.