Preeminent Work on Health Reform and Preemption

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Elizabeth Y. McCuskey, *Agency Imprimatur & Health Reform Preemption*, 78 **Ohio St. L.J.** 1099 (2017), available at SSRN.

With the future of health law and policy shifting on a nearly daily basis, producing clear and stable health law scholarship has become a daunting task, risking leaving the field adrift during a period of vexing uncertainty. Evocatively handling this challenge, one piece of esteemed scholarship that has boldly filled a gap—and, I would submit, one of the best articles of health law scholarship over the last year—is *Agency Imprimatur & Health Reform Preemption* by Elizabeth Y. McCuskey. The article was a pleasure to read and review for this Jot.

No matter the future of specific features of the Affordable Care Act (ACA)—as many truly hang in the balance—McCuskey's piece takes on a core principle and likely enduring feature of health care reform: the federal statute's waiver mechanism. Her piece places the ACA's "big" state innovation waiver (housed in Section 1332 of the Act) in the larger context of murky preemption doctrine and highlights its ultimate impact on judicial review, substantive policy expertise, and communicative federalism. McCuskey's masterful treatment of a complicated topic is valuable not only given the instability in federal health reform, but given the fact that the ACA's state-empowering waiver process is likely to only *increase* in importance and focus under the Trump administration. In short, her topic is likely to become only more significant, and her analysis more indispensable.

Starting by painting the picture of preemption doctrine as it relates to health law and policy, Professor McCuskey begins by describing a "particularly complicated" landscape of health law regulation and an "enormously complex preemption picture." Preemption doctrine—clouded by Congress's statements (or non-statements)—has undoubtedly been impacted by inconsistent treatment in the courts, and, consequently, a muddled understanding of preemption doctrine has impacted health law and regulation. Citing ERISA as one example, McCuskey captures the complexity in health and policy as it relates to preemption, noting that the "regulatory landscape before the ACA was … littered with various preemptions that established some uniformity, but which also under-enforced important initiatives, undermined experimentation, and stymied coherent health care regulation." Preemption has obstructed a substantial portion of health law and policy for decades.

Into this fragmented landscape entered the massive ACA, seeking to expand access and improve insurance policies "by making law incrementally in nearly every sphere of health care regulation," as she notes. Here, Professor McCuskey's article does a nice of job of providing a quick summary of various types of preemption, and she notes that the ACA contemplates these issues with an express but "muddled" preemption statement. The remainder of the article focuses on the major feature of the ACA in this space, its "State Flexibility to Establish Alternative Programs" under section 1332.

This "big waiver," also known as the state innovation waiver, allows states to suspend a number of components of the ACA's most notable reforms that govern the private insurance marketplace—from the individual and employer mandates, to essential health benefits requirements, to the calculation and structure of tax subsidies under the law. The Centers for Medicare and Medicaid Services (CMS) is vested with the power to approve state waivers, and states must show that their proposed programs are

similar to the ACA in coverage and affordability.

McCuskey calls the waiver a "giant" waiver because it "has enormous potential to undo the statute's seminal provisions based on speculative evidence." Indeed, the waiver operates to allow CMS to suspend the application of major parts of the ACA—not just those provisions based on the Spending Clause, but also those based on Commerce and Taxation powers—and "preapprove" proposed state legislation. Professor McCuskey also briefly discusses recent proposed reforms that would have expanded the waiver mechanism even further.

The most interesting part of Professor McCuskey's contribution is her analysis of how, exactly, this "big waiver" within the ACA radically changes the operation of health law and policy. Most notably, she argues that due to the ACA's structure, which is reliant on "preemptive federal health insurance law, coupled with the big-waiver power to officially sanction state-law variations," it "creates a preemption-diffusion mechanism favoring agency expertise regarding whether state variations serve federal purposes and objectives." To this end, she presents the agency imprimatur model, which she illustratively notes, "pushes state law out of the regulatory space with preemption, then invites state law into that space if the agency determines state law will serve federal objectives."

Indeed, CMS retains discretion and supervision over the waiver approval process, which, in theory, eliminates the necessity of employing the judiciary to determine difficult and thorny preemption questions in court. This evinces a major shift from "*post hoc* judicial application of preemption doctrine to an *ex ante* federal agency approval of potentially conflicting state law," as she notes. And, CMS must adhere to the waiver requirements under the ACA, ensuring that "federal regulatory infrastructure and priorities" retain power. McCuskey calls this "*pre*-preemption."

The article then evaluates the structure of the ACA's big waiver, and its shift "from judicial preemption doctrine to agency imprimatur," addressing the waiver's delegation and discretion, as well as looking at agency institutional competence as compared to judicial expertise. While noting that empowering the agency makes for a potentially more "fresh" and "nimble" executive body, Professor McCuskey also looks at three relevant metrics—preemption analysis, substantive health law issues, and federalism—to evaluate the shift.

McCuskey leaves the reader with fascinating points on reviewability and review. First, the agency imprimatur model may diffuse and divert preemption litigation in the first place, and, second, where challenged, the agency imprimatur model likely requires courts to defer to CMS's decision-making authority unless the agency determination was arbitrary and capricious, a major shift from the now utilized *de novo* review on preemption questions. Third, the agency imprimatur model here theoretically invites additional transparency (given the notice and comment period for wavier applications) and communicative federalism (insofar as the structure of the waiver makes the federalism debate more "engaged" and perhaps, more informed).

In sum, Professor McCuskey's work is measured and incisive. It addresses a complicated topic with skillful ease. And given the pervasive uncertainty facing health law and policy in this era, it is an appreciated respite of clarity on an increasingly important topic.

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