How Litigation Imports Foreign Regulation

Guest Post by Diego A. Zambrano, Assistant Professor of Law, Stanford Law School

For years now, the concept of a "Brussels Effect" on global companies has become widely accepted. A simple version of the story goes as follows: the European Union sets global standards across a range of areas simply by virtue of its large market size and willingness to construct systematic regulatory regimes. That is true, for instance, in technology where European privacy regulations force American companies (including Facebook, Google, and Apple) to comply worldwide, lest they segment their markets. As Anu Bradford has expertly argued, it is also true in environmental protection, food safety, antitrust, and other areas. When companies decide to comply with European regulations across markets, the European Union effectively "exports" its regulatory regimes abroad, even to the United States.

In a forthcoming article, How Litigation Imports Foreign Regulation, I argue that foreign regulators not only shape the behavior of American companies—they also influence American litigation. From the French Ministry of Health to the Japanese Fair Trade Commission and the European Commission, I uncover how foreign agencies can have a profound impact on U.S. litigation. In this sense, the "Brussels Effect" is a subset of broader foreign regulatory influence on the American legal system.

The intersections are rich and varied. For instance, plaintiffs in dozens of pharmaceutical cases in U.S. court are requesting that multinational defendants disclose documents previously produced to foreign regulators. These plaintiffs base their legal cases around findings by, say, the French Ministry of Health rather than the American Food and Drug Administration (FDA). Similarly, plaintiffs in antitrust cases keep close tabs on enforcement actions by the European Commission, piggybacking on the work of foreign regulators, borrowing foreign theories and documents, and even arguing that foreign regulatory action should bolster cases in U.S. courts. And foreign regulators even submit letters to U.S. district courts, advocating for a particular outcome or objecting to the

production of confidential documents.

Take a recent case, *In re Zofran*, involving allegations that GlaxoSmithKline (GSK) sold the drug Zofran while knowing it caused severe birth defects. GSK argued that "plaintiffs could offer no evidence that the drug caused birth defects" and that "even the FDA had rejected similar claims." Plaintiffs' case was headed for an adverse summary judgment until a key piece of evidence emerged—documents that GSK had produced to the "Japanese Ministry of Health and Welfare, including a series of studies showing potential birth defects that defendants had 'performed specifically to satisfy Japanese regulatory requirements.'" These documents allowed plaintiffs to dodge FDA findings and defeat a motion for summary judgment.

Or take another example, antitrust cases that piggyback on the foreign agencies. In a recent case alleging a conspiracy by American and foreign banks to fix prices for European sovereign bonds, plaintiffs left no doubt that "they remained ignorant of the conspiracy's existence until the European Commission's Statement of Objections put them on notice." In other words, a European Commission report triggered a large antitrust case in U.S. court.

Sometimes, plaintiffs draw on foreign regulators precisely because those foreign agencies disagree with U.S. regulators. In one pharmaceutical case, plaintiffs blamed a company for failing to warn of cancer risks, "citing reports from Health Canada, which they argued uncovered 'new safety information' that the FDA failed to consider."

I argue in my article that this phenomenon of private litigation that borrows foreign regulation is widespread and needs more attention. The trend comes, of course, with costs and benefits. On the one hand, drawing on foreign regulators can serve as a "failsafe" when domestic regulators are incompetent or captured. This could audit the work of our underperforming agencies, allowing litigators to compare the FDA with the Taiwanese health agency or the Environmental Protection Agency against European environmental regulators. Moreover, importing regulation can give litigants and courts access to increased expertise and information gathering. And it may even harmonize U.S. and foreign regulations, promoting coherence and regulatory convergence.

Recent litigation involving the Boeing 737 Max crashes demonstrates the promise

of imported foreign regulation. Many sources have reported a cozy relationship between Boeing and the Federal Aviation Administration, suggesting a classic case of regulatory capture. Private plaintiffs suing Boeing may thus have difficulty relying on reports from the FAA to support their cases. But Boeing does not wield similar influence over the European Aviation Safety Agency. So, plaintiffs could rely on EASA investigations to establish basic facts against Boeing, allowing the court to leverage the work of a relatively unbiased regulator.

While these benefits seem clear, costs also abound. We may worry, for instance, about empowering foreign regulators that have their own political agendas. Europeans, for one, may be protectionist against American tech companies. This could promote inefficient overregulation of activity that U.S. regulators have deemed appropriate. Foreign regulation could also chill essential domestic innovation. What if the FDA approves a COVID vaccine but private plaintiffs sue the manufacturer based on adverse reports in Japan? In a nightmare scenario, companies in the United States would worry not only about complying with America's sprawling regulations, but also about litigants trawling foreign countries for regulatory support.

Because it shows both promise but also risks, I recommend a better way to control the use of foreign regulations: Whenever a plaintiff proposes to use a foreign regulatory finding, courts should solicit the opinions of our domestic regulators. These opinions would help courts determine whether foreign regulations are compatible with America's regulatory regimes. However, agency opinions would not bind courts. Indeed, judges should take these opinions with a grain of salt and be wary of domestic regulatory capture. Even if agencies are unwilling to offer opinions, asking plaintiffs to give notice of their intent to use a foreign regulatory finding would alert domestic regulators of areas where they may be underperforming.

As traditional channels of transnational coordination die out, private parties, courts, and regulators are searching for new ways to promote transnational convergence. Both the Brussels Effect and the phenomenon of regulatory importation are examples of where the legal international order is heading.