

The easiest way to gut regulations is simply to stop enforcing them. That tried and true technique has been enthusiastically embraced by the Trump Administration. That's been long suspected in terms of environmental law. Shockingly, the Administration has also mostly given up on enforcing the standards for conducting clinical drug trials.

The breakdown in FDA enforcement is detailed in an October 2 article in *Science*, the flagship U.S. research journal. To be fair, some of the problems with clinical drug trials predate the Trump Administration, but it has now gotten much worse. We can only hope that these flawed trials haven't resulted in approval for unsafe or ineffective drugs.

The article opens with the tale of one egregious violator of clinical trial requirements, an osteopath running a private firm in Utah with many drug evaluation contracts. The Utah operation sounds like something of a shambles. FDA found "serious lapses" in obtaining informed consent, medical assessment by unqualified staff members, failure to report abnormal lab tests, disorganized records, and backdated entries that called into question the credibility of the data. This went on for a decade, with no resulting enforcement action.

There is clear evidence of a decline of enforcement under Trump. The article reports that "the agency issued 99 'warning letters' for serious clinical trial transgressions during Obama's first 3 years in office, 36 in his last 3 years, and just 12 during the first 3 years under Trump." The lack of warning letters was not an isolated problem. There was also a fall in Official Action Indicated (OAI) decisions, that flag investigator practices as faulty:

"Under Trump, the number of FDA inspections per year has increased significantly, yet enforcement actions have nosedived. About 6% of FDA inspections were classified as OAI during the Obama administration, although the proportion began to decline in his second term. During Trump's first 3 years, however, OAI reports fell to less than 1% of the total."

But wait, it gets worse. Besides formal enforcement, investigations can be closed if an investigator voluntarily agrees to correct problems. Or there can be a "no action" resolution, in which nothing is done about a violation. Even the voluntary resolutions "declined sharply under Trump, whereas 'no action' inspections spiked." The upshot is that very few cases got to the point of actually disbaring investigators from running future clinical trials: "The agency disqualified an average of three investigators per year under Obama but just two total during Trump's first 3 years."

Please don't jump to conclusions about the current vaccine trials. Those trials are taking place in the full glare of publicity, and the drug companies themselves have strong

incentives to ensure the validity of the research. A bungled clinical trial would be a publicity disasters for the company, if nothing else. But more routine drug trials may be a different story.

There are chronic problems here, such as lack of enforcement resources and cumbersome enforcement procedures. Moreover, FDA doesn't want to close off too many avenues for conducting clinical trials, because doing so might deter drug companies from trying to bring useful new drugs to market. FDA may be reluctant to be too stringent, for fear of diminishing future opportunities for clinical trials. Quite apart from the chronic problems, however, the Trump Administration seems to have almost entirely given up on enforcement efforts.

Something very similar has happened with environmental enforcement. By 2019, the [Washington Post](#) reported, enforcement was spiraling downward:

“The sharp drop in inspections and evaluations last fiscal year — to roughly 10,600 — is only half the number EPA conducted at its peak in 2010, and continues a downward trend that began in 2012. Other enforcement activities at the agency experienced similar declines, according to EPA figures: The number of civil cases the division started and completed in 2018 hit a 10-year low, and the \$69 million in civil penalties it leveled represents the lowest level in nearly a quarter-century.”

A news report in September from the [LA Times](#) indicated that these trends have continued at EPA and other agencies. “The Environmental Protection Agency’s penalties for polluters are down, there are fewer inspectors working for the Occupational Safety and Health Administration, and financial penalties against corporations and banks accused of wrongdoing have declined.”

Apparently not content with the existing decline in enforcement, the White House issued [guidance](#) that month imposing additional hurdles for agencies in enforcing the laws. That was in addition to the EPA’s general forgiveness for environmental violations during the earlier part of the coronavirus outbreak.

Give its druthers, the Trump Administration would probably be happy to dispense with any regulation of pollution and drug safety. Since that’s politically impossible, giving up on enforcement is the next best thing. Apparently “taking care that the laws be faithfully executed” is no longer part of the presidential job description.

