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Dollars and Deadlines: Rule Reforms in Short Time Frames

Toby Schonfeld,

U.S. Department of Veterans Affairs

Melinda Gormley, and

University of California Irvine

Daniel K. Nelson

U.S. Environmental Protection Agency

Abstract

In “At Last! Aye, and there’s the Rub,” (2017), Capron describes challenges related to the timing for development, adoption, and revision of the Common Rule. Capron argues that the difficulty of making changes over the ten years required before agencies adopted the original Common Rule created an “all or nothing” atmosphere. That is, because of the effort required, agencies were loath to make incremental changes and instead “take up every possible revision at once” with the process that culminated in the recently revised Rule. Here we briefly describe the efforts of one agency -- the U.S. Environmental Protection Agency (EPA) -- that made interim changes to its human subjects protections within a 180 day time frame, and the opportunities and challenges that such an ambitious goal created.

Dollars: Follow the Money

The Appropriations Act gives a federal agency its operating budget for the next fiscal year. The Appropriations Act that Congress passed on August 2, 2005 had specific stipulations that EPA was required to follow to gain access to its 2006 operating budget that supported human subject research. These stipulations included protections for vulnerable populations, adherence to a National Academy of Sciences report and the Nuremberg Code, and establishing an independent Human Studies Review Board (HSRB).

Producing a rule was the only acceptable option. Without human subjects research EPA cannot fulfill its function as a regulatory agency. If there was no budget for human subjects research, EPA employees, contractors, and grantees who perform this work would have lost their jobs and funding. EPA would have been forced to base environmental regulations on scientific studies using alternative methods and this could have resulted in less accurate data.

EPA had until early February to produce a rule. EPA staff drafted a policy and had it posted in the Federal Register in about 40 days. After the final rule was drafted and approved internally, EPA staff submitted it to the U.S. Office of Management and Budget (OMB) for

administrative review. OMB reviews and clears Executive Branch correspondence with Congress “to ensure consistency of agency legislative views and proposals with Presidential policy.” EPA staff received clearance from EPA and OMB in less than two weeks and the final rule was issued on February 6, 2006.

Deadlines: 8 years vs 6 months

In 2007, Resnik described the EPA rule-making as the “culmination of a vociferous, eight-year debate between environmental and industry groups concerning pesticide testing on human subjects” (p. 17). He was right; the 6 months that EPA had to produce a rule is only part of the history. EPA had recognized the need for additional regulatory provisions in the late 1990s, and over the five years from 1998 to 2003, EPA staff received expert advice on third-party research from two advisory committees. The Data from Testing on Human Subjects Subcommittee (DTHSS) convened two meetings to discuss the use of third-party data involving human subjects and pesticides, producing a report in September 2000. This subcommittee joined members from two of EPA’s Federal Advisory Committees, the agency-wide Science Advisory Board (SAB) and the pesticides-specific Science Advisory Panel (SAP). Among its members were physicians, toxicologists, medical ethicists and others. A useful outcome of this report was the panel’s unanimous endorsement of the statement that “bad science is always unethical” and this precept would later guide procedures of the HSRB.

In December 2001, EPA commissioned the National Academy of Sciences to deliberate on third-party research, specifically whether or not the EPA “should consider, accept, and rely on data from third-party studies that deliberately expose humans to toxicants” (National Research Council 2004). The 2004 NAS Report suggested establishing a HSRB to examine the scientific and ethical aspects of intentional exposure studies involving human subjects.

As a consequence of this cumulative history, EPA had already been working to promulgate new regulations for human research, culminating in the issuance of an Advanced Notice of Proposed Rule Making (ANPRM) in 2004. It was not until the controversial Children’s Environmental Exposure Research Study (CHEERS) became a focus in 2005 that vulnerable populations became a central element in the rule-making. Proposed and approved but never conducted, CHEERS fundamentally altered the nature of the public conversation about EPA’s proposed rule (Menikoff 2005; Resnik and Wing 2007). The issues raised by CHEERS are what ultimately led to Congress’ requirements in the 2005 Appropriations Act. Thus, while EPA’s final rule-making was compressed into 6 months as a result of the 2005 Appropriations Act, the work of the agency on this rule predated that by many years.

Similarities and Differences: the Common Rule and EPA’s Rule-Making

There are many differences between EPA’s rule and the Common Rule. First of all, EPA is a regulatory agency, which means that the concerns are different than they would be for other agencies. This difference in context arguably led to a different approach: as an organization responsible for safeguarding public health with regard to environmental matters, what are the rules that need to be in place in order to ensure that the science on which regulations are

based are both scientifically and ethically sound? In addition, because third parties submit study results to EPA as a basis for rule making, EPA's regulation had to expressly address third party research (rather than simply first and second party research, which is research conducted or funded by EPA, respectively). Finally, the scope of EPA's rule was very different: whereas the Common Rule had to take into account the very different kinds of research that is conducted by the 19 different agencies that are signatories, EPA's rule could be much more narrowly focused on research that is relevant to the agency's rule-making process.

Yet there are clear similarities in the two processes. EPA's rule also involved an ANPRM and a Notice for Proposed Rulemaking (NPRM) before finalizing the new rule, per rule-making requirements. And this is where a difference in timing can be seen. From the time that the Department of Health and Human Services issued the Common Rule ANPRM to when they released the NPRM, 50 months elapsed. EPA issued an ANPRM in May 2003 and followed that up with the NPRM 28 months later. Both rules also generated a fair amount of public comment that had to be addressed with the publication of the final rule. The Common Rule NPRM generated over 2100 comments from the 120-day comment period. Yet the EPA rule generated significantly more. Even though most comments were submitted during the 90-day comment period as part of organized campaigns, agency staff had to examine each of the 50,000 comments to determine whether or not the rule text needed to be changed as a result. HHS released its final rule one year after the comment period ended, whereas EPA did so in 2 months.

Lessons Learned

Capron (2017) argues that the community learned the wrong message from the transition of the pre-existing Human Subjects regulation into a "Common Rule;" namely, that all changes must be made at once. Yet the experience at EPA suggests that even making agency-specific, narrowly- focused rules is an exceptionally complicated and cumbersome process, especially when the public is interested in the result. All regulations will still require interpretation for implementation, and an iterative process still will not ensure that such interpretation is done consistently across all agencies or review boards (or, in our experience, even within the same agency or review board!).

Resnik argues that other agencies should learn from EPA's experience that "haste makes waste when it comes to adopting new regulations" (Resnik 2007, p. 21). He argues that there needs to be enough time for authentic conversation among experts who are equipped to consider all aspects of the issue and forecast the likely implications and implementation challenges of proposed rules – issues he alleges EPA failed to do. A review of the actual regulations that emerged from this process is outside the scope of this commentary; suffice it to say there are varying opinions on the success of the resulting product (Krimsky and Simoncelli 2007; Shrader-Frechette 2007). Whether an iterative rule-making process with small changes as Capron suggests would succeed in this realm remains an open question. One might think that the community could more quickly assess and address changes that have a more narrow scope, but the requirements for public notification and comment makes a more frequent process untenable. Particularly in an era of diminished federal resources, the

costs of revising rules more frequently may be a burden that agencies – and tax payers – cannot bear. Yet the alternative of preserving imperfect rules is also less than desirable.

It is precisely this weighing of alternatives that makes Capron's Shakespearean title so apropos. As Hamlet weighs the pros and cons of death against the alternative, so too does contemplating regulatory reform suggest multiple paths fraught with pitfalls. As with many dilemmas in research ethics, there are tensions and tradeoffs between too much and too little of anything, be it time, scope, amount of detail, or extent of protections.

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