

880. In contrast, information compelled by the government would continue to be considered under the two prongs enunciated in *National Parks*.

The Exemption 4 jurisprudence in the aftermath of *Critical Mass* makes clear that the determination of whether information should be protected under Exemption 4 may include additional considerations, but only to the extent that those considerations relate to the government functions for which the information is sought. Underpinning the jurisprudence surrounding Exemption 4 has been the acknowledgement that "it is intended to protect the interests of both the Government and the individual," including advancing the efficiency of government operations. *National Parks*, 498 F.2d at 767. The concern that disclosure policy should not impair government programs remains strong whether the information is compelled (and its disclosure governed by the two prongs of *National Parks*) or voluntarily submitted (and its disclosure governed by the *Critical Mass* test). See *CAS v. NHTSA*, 244 F.3d at 148 (D.C. Cir. 2001) (explaining that "[w]hen the Government obtains the information as part of a mandatory submission, the Government's access to the information normally is not seriously threatened by disclosure; the private interest is the principal factor tending against disclosure, and the harm to the private interest must be significant to prevent public access to information") (emphasis added).

For example, the government may withhold information that, if disclosed, would diminish the effectiveness of a licensing program even when the basis for disclosure would arguably advance an underlying public interest. See *Public Citizen Health Research Group v. National Institutes of Health (PCHRG v. NIH)*, 209 F. Supp. 2d 37, 46 (D.D.C. 2002) (finding certain royalty information confidential under Exemption 4 because "disclosure of the royalty information would impair the efficient and effective performance of [the government's] licensing program").

It is not sufficient, therefore, to argue that some public need unrelated to the government's function warrants the disclosure of information under Exemption 4. *Public Citizen Health Research Group v. Food & Drug Administration (PCHRG v. FDA)*, 185 F.3d 898 (D.C. Cir. 1999) (rejecting the argument that a company's clinical studies, which were required to be submitted to the FDA, should be disclosed because disclosure would allow the public to learn from the company's experience). As the D.C. Circuit stated in *PCHRG v. FDA*:

It is not open to Public Citizen, however, to bolster the case for disclosure by claiming an additional public benefit in that, if the information is disclosed, then other drug companies will not conduct risky clinical trials of the drugs that Schering has abandoned. That is not related to "what the [] government is up to" and the Court has clearly stated "whether disclosure of a * * * document * * * is warranted must turn on the nature of the requested document and its relationship to the basic purpose of the Freedom of Information Act to open agency action to the light of public scrutiny * * * rather than on the particular purpose for which the document is being requested. In other words, the public interest side of the balance is not a function of the identity of the requester * * * or of any potential negative consequences disclosure may have for the public * * * nor likewise of any collateral benefits of disclosure. *Id.* at 904 (citations omitted).

In most of the cases discussing the *National Parks* test, the courts were considering the kind of commercial information that would be created independent of any government mandate, and thus the courts have generally considered the inquiry under the impairment prong to focus on the reliability, rather than the availability, of the data. Yet, the courts have carefully maintained the vitality of the impairment prong as applied to compelled submissions and, in doing so, have maintained an analytic framework within which to ensure that the disclosure of information does not unduly impair the government's functions by reducing both qualitatively and quantitatively the data available to the government. Thus, as in *CAS v. NHTSA*, the Court was careful to state that "when the Government obtains the information as part of a mandatory submission, the Government's access to information normally is not seriously threatened by disclosure," and in *PCHRG v. NIH*, the impairment of the government's program served as an independent basis for the court's refusal to require disclosure.

IX. Regulatory Analyses and Notices

A. Executive Order 12866 and DOT Regulatory Policies and Procedures

NHTSA has considered the impact of this rulemaking action under Executive Order 12866 and the Department of Transportation's regulatory policies and procedures. This rulemaking document is not economically significant. It was, however, reviewed by the Office of Management and Budget under E.O. 12866, "Regulatory Planning and Review." The rulemaking action has been determined to be significant under the Department's regulatory policies and procedures, given the degree of public

interest in the treatment of the early warning reporting information.

This final rule simplifies and clarifies the agency's regulation on confidential information and updates specific sections of the regulation to reflect legal developments. In addition, this final rule creates a series of class determinations applicable to those portions of the data to be submitted pursuant to the early warning reporting regulation that are determined to be entitled to confidential treatment under the procedures set forth in this final rule.

The procedural aspects of this final rule impose no new, significant burdens on submitters of information. The treatment of the early warning reporting information addresses the manner in which the agency will handle the data, and also imposes no new, significant burdens on submitters of information. Because no additional burdens are imposed, there are no costs requiring the development of a full cost/benefit evaluation.

B. Regulatory Flexibility Act

We have considered the effects of this rulemaking action under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) This rule does not have a significant economic impact on a substantial number of small entities. Therefore, a regulatory flexibility analysis is not required for this action. This final rule imposes no additional obligations on the submitters of information to NHTSA beyond those otherwise required by the Vehicle Safety Act and the early warning reporting regulation. This final rule addresses the agency's treatment of early warning reporting data and simplifies procedures for all submitters, including small entities, when submitting information to the agency. The rule protects from disclosure early warning reporting information found likely to cause competitive harm. It permits the disclosure of that early warning information determined neither to cause competitive harm if released nor to impair the ability of the government to obtain the information in the future.

C. National Environmental Policy Act

NHTSA has analyzed this rule for the purposes of the National Environmental Policy Act and determined that it does not have any significant impact on the quality of the human environment.

D. Executive Order 13132 (Federalism)

The agency has analyzed this rulemaking action in accordance with the principles and criteria set forth in Executive Order 13132 and has