

This bill supports responsible hunting, while curbing something so out-of-bounds with hunting norms that hunters and animal advocates alike view it as unfair and inhumane.

TRIBUTE TO SHOALS
ELEMENTARY

HON. SHELLEY MOORE CAPITO

OF WEST VIRGINIA

IN THE HOUSE OF REPRESENTATIVES

Wednesday, December 12, 2001

Mrs. CAPITO. Mr. Speaker, I rise today in honor of Shoals Elementary in recognition of their achievement as an "exemplary" school.

Shoals Elementary has been selected as one of the top 50 schools of West Virginia. "Exemplary" status is based on Stanford Achievement Test results, attendance, drop out rates, and writing exam scores.

I commend the leadership and faculty on their dedication to the children that walk through their doors each day. They have set an incredible example for the other 817 schools in West Virginia.

I equally commend the students and parents of Shoals Elementary for their commitment to a quality education and a bright future.

Efforts to bring superior education to all of West Virginia and America are among our top priorities. Mr. Speaker, I urge my colleagues to join me in honoring Shoals Elementary.

ANALYSIS OF SECTION II OF H.R.
2887

HON. SHEILA JACKSON-LEE

OF TEXAS

IN THE HOUSE OF REPRESENTATIVES

Wednesday, December 12, 2001

Ms. JACKSON-LEE of Texas. Mr. Speaker, on October 11, 2001, the Committee on Energy and Commerce favorably reported H.R. 2887, the "Best Pharmaceuticals for Children Act." I commend the Committee for its great work to reauthorize legislation to promote labeling of prescription drugs for use in children. However, I am concerned that a section of this legislation may violate the Takings Clause of the United States Constitution. As a member of the Committee on the Judiciary, I have vigorously sought to protect private property rights and to pursue just compensation for those whose property rights are violated. My analysis of section 11 of H.R. 2887, brings me to the conclusion that it would violate current exclusive rights of manufacturers and in turn expose the U.S. government to substantial claims for just compensation. Attached are legal memoranda by Professor Laurence Tribe of Harvard University that validate my concerns:

MEMORANDUM TO THE UNITED STATES CONGRESS—CONSTITUTIONAL ANALYSIS OF H.R. 2887'S PROPOSED AMENDMENT TO HATCH-WAXMAN ACT ELIMINATING THREE-YEAR CLINICAL STUDIES EXCLUSIVITY PERIOD

(By Laurence H. Tribe)

I have been asked to address the implications under the Fifth Amendment Just Compensation Clause (sometimes called the

Takings Clause) of H.R. 2887, which proposes to eliminate the three-year clinical studies exclusivity period under the Hatch-Waxman Act. Section 11(a) of the reported version of H.R. 2887 provides that a generic drug may be approved under the Federal Food, Drug and Cosmetic Act ("FDCA") even when its labeling omits a pediatric use that is protected by patent or marketing exclusivity under Section 505(j)(5)(D)(iii) and (iv). Section 11(b) of H.R. 2887 implies that Section 11(a) applies to already running three-year exclusivity periods.

The FDCA establishes a quid pro quo that H.R. 2887 would retroactively abrogate. In order to gain regulatory approval from the FDA, a pharmaceutical company must invest enormous time, money, and human resources to develop extensive clinical data regarding its drug. At the end of a three-year period, the protected data is opened to the public and may be used by competitors. In exchange, Section 505(j)(5)(D)(iii) and (iv) provide that the FDA "may not make the approval of [a competitor application]... for three years." H.R. 2887 now proposes to undo the bargain struck by current law.

Under the Supreme Court's decision in *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984), and related precedent, the retroactive elimination of the exclusivity period qualifies as a taking of private property for public use and therefore triggers the right to just compensation.

ANALYSIS

1. The *Ruckelshaus* Decision.

Fifth Amendment analysis must begin with the text of the Clause: "nor shall private property be taken for public use, without just compensation." The meaning of that text as most authoritatively set forth in the Supreme Court's decision in *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984), which held that the government's use of private proprietary research data for public regulatory purposes constituted a compensable taking. *Ruckelshaus* is highly instructive because the statutory change at issue in that case was the elimination of an exclusive pesticide marketing scheme, closely analogous to the change effected by H.R. 2887. The fact that *Ruckelshaus* concerned pesticides, while the instant controversy involves pharmaceuticals, obviously is not material to the constitutional analysis.

The Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") at issue in *Ruckelshaus* originally limited an agency's use of studies submitted by an initial applicant to support later applicants' efforts to obtain approval of similar formulations. In 1978, FIFRA was amended to weaken that restriction. The 1978 amendments were then challenged in court, and the Supreme Court held in *Ruckelshaus* that they worked a taking and triggered the right to just compensation.

The Supreme Court noted that, with respect to trade secrets submitted by Monsanto under FIFRA between 1972 and 1978, "the Federal Government had explicitly guaranteed to Monsanto and other registration applicants an extensive measure of confidentiality and exclusive use. This explicit governmental guarantee formed the basis of a reasonable investment-backed expectation." 467 U.S. at 1011 (emphasis added). The Court then explained that "[i]f EPA, consistent with the authority granted it by the 1978 FIFRA amendments, were now... to consider those data in evaluating the application of a subsequent applicant in a manner not authorized by the version of FIFRA in effect between 1972 and 1978, EPA's actions

would frustrate Monsanto's reasonable investment-backed expectation with respect to its control over the use and dissemination of the data it had submitted." *Id.*

Plainly, the Supreme Court's decision in *Ruckelshaus* provides strong support for the conclusion that the elimination of the three-year clinical studies exclusivity period would effect a compensable taking.

2. There is a Protectable Property Right.

I understand that proponents of H.R. 2887 take the position that the elimination of the three-year clinical studies exclusivity period does not work a taking because it does not implicate any property rights at all. I find this surprising, to say the least, because the Government did not even dispute in the *Ruckelshaus* case that "Monsanto has certain property rights in its information, research and test data that it has submitted under FIFRA to EPA and its predecessor agencies which may be protected by the Fifth Amendment to the Constitution." 467 U.S. at 1001.

Indeed, in *Tri-Bio Laboratories, Inc. v. United States*, 836 F.2d 135 (3d Cir. 1987), the court upheld the refusal of the FDA to allow a generic animal drug manufacturer to incorporate in its application the research and testing data submitted by another manufacturer which had earlier obtained approval to market the predecessor brand name drug. The FDA insisted that such testing data was proprietary and confidential and that its use "to review generic drug applications would constitute expropriation." *Id.* at 138. The court agreed that the FDA's rules "provided pioneer animal drug manufacturers with [a] reasonable investment-backed expectation that the FDA would refrain from nonconsensual use of research material." *Id.* at 140-41. "Use of that material in processing the [competitor's] application, therefore, would constitute a Fifth Amendment taking, requiring payment of compensation by the government." *Id.* at 141.

The Supreme Court has long held that intangible property rights are protected under the Fifth Amendment's Just Compensation Clause. See, e.g., *Armstrong v. United States*, 364 U.S. 40, 44 (1960) (materialman's lien protected); *Louisville Joint Stock Land Bank v. Radford*, 295 U.S. 555, 596-602 (1935) (real estate lien protected); *Lynch v. United States*, 292 U.S. 571, 579 (1934) (contracts protected). See also Laurence H. Tribe, *AMERICAN CONSTITUTIONAL LAW* §9-2, p. 591 n.11 (2d ed. 1988) (observing that the Supreme Court has tended toward "a broadened conception of 'property' in takings analysis," "incorporating wholly intangible forms of property").

By the same token, the Court has also opened that the retroactive alteration of the terms on which a patent is granted would work a compensable taking of private property. See, e.g., *Richmond Screw Anchor Co. v. United States*, 275 U.S.C 331, 345 (1928) (elimination of patent infringement action "is an attempt to take away from a private citizen his lawful claim for damage to his property by another private person, which but for this act he would have against the private wrongdoer. This result... would seem to raise a serious question... under the fifth Amendment to the Federal Constitution."); *William Cramp & Sons Ship & Engine Bldg Co. v. International Curtis Marine Turbine Co.*, 246 U.S. 28, 39-40 (1918) ("rights secured under the grant of letters patent by the United States [are] property and protected by the guarantees of the Constitution and not subject therefore to be appropriated even for public use without adequate compensation").