

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").

Under these principles, the exclusivity guaranteed by Section 505(j)(5)(D) (iii) and (iv), which is mirrored in FDA regulations, see 21 CFR §314.127(a)(7), is a prototypical property right. As the Supreme Court has explained, the right to exclude "is central to the very definition of the property interest," *Ruckelshaus*, 467 U.S. at 1011, for it is "one of the most essential sticks in the bundle of rights that are commonly characterized as property." *Kaiser Aetna v. United States*, 444 U.S. 164, 176 (1979); see also *Nollan v. California Coastal Comm'n.*, 483 U.S. 825, 830-32 (1987) (same); *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 435 (1982) ("The power to exclude has traditionally been considered one of the most treasured strands in an owner's bundle of property rights."). See generally *Thomas W. Merrill & Henry E. Smith, What Happened to Property in Law & Economics?*, 111 *Yale L.J.* 357, 360 (Nov. 2001) ("property rights attach to persons insofar as they have a particular relationship to some thing and confer on those persons the right to exclude a large and indefinite class of other persons ('the world' from the thing)").

As the Court explained in *Ruckelshaus*, "[W]ith respect to a trade secret, the right to exclude others is central to the very definition of the property interest. Once . . . others are allowed to use those data, the holder of the trade secret has lost his property interest in the data." 467 U.S. at 1011. "[T]he value of a trade secret lies in the competitive advantage it gives its owner over competitors. Thus, it is the fact that operation of the [statutory change] will allow a competitor to register more easily its product or to use the disclosed data to improve its own technology that may constitute a taking." *Id.* at 1011 n.15.

The three-year exclusivity period is enforceable by means of a suit against the FDA under 21 C.F.R. §§ 10.30, 10.35. It is also transferable. See 59 *Fed. Reg.* 50338, 50339 (Oct. 3, 1994) ("an applicant may purchase an application or rights of data and information in an application (i.e., exclusive rights to a new clinical investigation), from which exclusivity would flow").

Thus, the three-year exclusivity period—acquired at great expense and heretofore protected by law—is the very essence of an "investment-backed expectation" that is fully protected by the Fifth Amendment from any taking without just compensation. *Penn Central Transp. Co. v. City of New York*, 438 U.S. 104, 124 (1978).

Moreover, the confidential and proprietary research submitted by drug manufacturers—which under H.R. 2887 would be used by the FDA in order to approve generic versions of the same pharmaceuticals—also qualifies as a "trade secret" under applicable state law. "A trade secret is any information that can be used in the operation of a business or other enterprise and that is sufficiently valuable and secret to afford an actual or potential economic advantage over others." *Restatement (Third) of Unfair Competition* § 39 (1995). The *Uniform Trade Secrets Act*, § 1(4), promulgated in 1979 by the National Conference of Commissioners on Uniform State Laws, contains the equivalent definition of "trade secret." Tellingly, confidential information regarding the production of pharmaceuticals is the very first illustrative example of a trade secret provided by the *Restatement*. See *Restatement (Third) of Unfair Competition* at § 39, *Illustration 1*. See also *MILGRIM ON TRADE SECRETS* § 1.09 (2001) (providing numerous examples where pharmaceutical information has been classified as a trade secret).

CONCLUSION

The retroactive elimination of the three-year clinical studies exclusivity period would undoubtedly effect a "taking" of "private property" within the meaning of the Fifth Amendment. Any public purposes that may be advanced in favor of H.R. 2887 bear only on whether the taking is altogether void—which it is if the property is not put to a "public use," equated by the Supreme Court with "public purpose." See *Hawaii Housing Auth. v. Midkiff*, 465 U.S. 229, 239-41 (1984). If property is taken for a "private use"—i.e., a purely private purpose—then the taking violates substantive due process and cannot be saved by an amount of compensation. See, e.g., *Thompson v. Consolidated Gas Utilities Corp.*, 300 U.S. 55, 77-79 (1937).

A "purpose purpose," however compelling, has no bearing whatsoever on whether just compensation is required in order to make the taking valid. Compensation for a taking of private property is invariably required precisely when that taking is for a public purpose or use. See, e.g., *Jed Rubinfeld, Usings*, 102 *Yale L.J.* 1077 (1993). The Just Compensation Clause is concerned not with the question whether a given taking was substantially justifiable but solely with the question of who should pay for presumptively justifiable takings. As the Supreme Court has often put it, one of the principal purposes of the Just Compensation Clause is "to bar Government from forcing some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole." *Dolan v. City of Tigard*, 512 U.S. 374, 384 (1994) (quoting *Armstrong v. United States*, 364 U.S. 40, 49 (1960)).

From the fact that just compensation would be required, and the further fact that the Just Compensation Clause is self-executing, see *First English Evangelical Lutheran Church of Glendale v. County of Los Angeles*, 482 U.S. 304, 315, 316 n.9 (1987), it follows that H.R. 2887 would represent an enormous tax lien automatically levied by the measure's proponents upon the rest of the nation. It would, despite protestations of its proponents that no tax expenditure would be required and thus that no added appropriation or tax levy would be needed, have to be funded either by new or higher taxes or by an equivalent cut in spending on military or other discretionary budget items. H.R. 2887, therefore, cannot be evaluated as though it would provide some sort of pharmaceutical free lunch. Someone's ox, to mix metaphors just a bit, would plainly have to be gored to pay for whatever public benefits the measure might provide. That the cost could quietly and painlessly be laid at the feet of private investors in pharmaceutical companies is a pure mirage. Those investors know their rights, and they know the address of the U.S. Court of Federal Claims.

DIETARY SUPPLEMENT TAX
FAIRNESS ACT

HON. DAN BURTON

OF INDIANA

IN THE HOUSE OF REPRESENTATIVES

Wednesday, December 12, 2001

Mr. BURTON of Indiana. Mr. Speaker, I am pleased to be reintroducing this legislation in the Congress. It represents an important and critical step forward to improving our healthcare system. Throughout my career in

Congress, I have always led efforts to examine and support complementary and alternative healthcare. In chairing the House Committee on Government Reform, we have learned a great deal about healthcare that represents a marketplace of over \$30 billion dollars and is utilized by one out of every four Americans.

One critical item we have discovered is the inequities that exist within the Internal Revenue Code that discourage good health and wellness. For example, many consumers often ask why there are no insurance benefits for dietary supplements, which are used primarily to maintain good health and wellness. Some dietary supplements, like Folic Acid, can help prevent disease or disease risks like birth defects. Many insurance companies would like to offer coverage to their beneficiaries who continually demand this type of coverage. Unfortunately, the tax code does not allow an insurer to offer this coverage without incurring tax liabilities to consumers and higher administration costs. This powerful disincentive needs to be removed so health insurers can begin developing meaningful and cost effective benefits for their beneficiaries and assist them in maintaining good health longer.

I am pleased to be joined by five of my colleagues on the reintroduction of this bill. I am pleased that Mr. CANNON of Utah, Mr. ISTOOK of Oklahoma, Mr. PAUL of Texas, and Mr. HORN of California have joined as cosponsors in this bill. I am also pleased to be joined by the Gentleman from New Jersey, Mr. PALLONE in reintroducing this legislation. It emphasizes two other important things for my colleagues. This legislation is bipartisan and should be supported by members on both sides of the aisle.

I also note last week the White House Commission on Complementary and Alternative Medicine Policy convened for one of its final meetings. This Commission will be issuing an important report and recommendations for the Congress and the Administration in March 2002. One of the several key recommendations that is likely to be made by the Commission is that the Congress begin reforming the Internal Revenue Code to support and encourage health insurance coverage for complementary health care. The federal government should be actively working to remove barriers to coverage and access to complementary health care. I look forward to reviewing that report when it is released next year and work with the Administration to implement the recommendations.

COMMENDING MR. JAMES D.
RUTH, CITY MANAGER OF ANAHEIM,
CALIFORNIA

HON. CHRISTOPHER COX

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Wednesday, December 12, 2001

Mr. COX of California. Mr. Speaker, I rise today to commend Mr. James D. Ruth, City Manager of Anaheim, California, who is ending his 45 year career in public service at the end of this year.

After serving in several California municipalities, Jim came to Orange County in 1976 to