112TH CONGRESS
1st Session
HOUSE OF REPRESENTATIVES
REPT. 112–39
Part 2

HELP EFFICIENT, ACCESSIBLE, LOW-COST, TIMELY HEALTHCARE (HEALTH) ACT OF 2011

MAY 23, 2011.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. UPTON, from the Committee on Energy and Commerce, submitted the following

R E P O R T

together with

DISSENTING VIEWS

[To accompany H.R. 5]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 5) to improve patient access to health care services and provide improved medical care by reducing the excessive burden the liability system places on the health care delivery system, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

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99–006

The amendments (stated in terms of the page and line numbers of the introduced bill) are as follows:

Page 14, line 21, strike "or".

Page 15, line 2, strike the period at the end and insert "; or".

Page 15, insert after line 2 the following:

> (C) the defendant caused the medical product which caused the claimant's harm to be misbranded or adulterated (as such terms are used in chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.)).

PURPOSE AND SUMMARY

H.R. 5 seeks to improve patient access to quality health care while reducing the overall cost of health in America.

BACKGROUND AND NEED FOR LEGISLATION

Introduction

The nation's medical liability system imperils patient access and imposes tremendous costs on our nation. It has forced doctors out of practicing in certain specialties; it has caused trauma centers to close; it has forced pregnant women to drive hours to find an obstetrician. This badly broken system also imposes tremendous financial burdens: Americans spend over $200 billion every year in unnecessary "health care" costs; [1] the Congressional Budget Office has reported to the Committee that comprehensive medical liability reform will save American taxpayers $62 billion over 10 years.[2]

President Obama has repeatedly cited the importance of medical tort reform, but nothing meaningful in this area was included in his signature Patient Protection and Affordable Care Act (PPACA), enacted on March 23, 2010.

In sharp contrast, states like California and Texas, as well as others, have already enacted comprehensive medical liability reforms. As discussed below, enacting these reforms nationally will decrease the costs of defensive medicine, reduce medical liability fears that inhibit quality of care improvement, end years of Washington inaction on this recurring crisis, and, as shown by the states, increase patient access to quality care while reducing costs, including liability premiums.

The Costs of Defensive Medicine

Doctors are sued at an alarming rate (by the age of 55, 61% of doctors have been sued) [3] and forced to practice defensive medicine. In fact, a 2005 survey published in the Journal of the American Medical Association revealed that 93% of doctors said they have practiced defensive medicine and 92% said they made referrals to specialists and/or ordered tests or procedures in part to insulate themselves from medical liability.[4]

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[2] The Congressional Budget Office document is available at the following link: *http://www.cbo.gov/ftpdocs/1200xx/doc12085/03-10-ReducingTheDeficit.pdf.*

[3] AMA's "Medical Liability: By late career, 61% of doctors have been sued": *http://www.ama-assn.org/amednews/2010/08/16/pr120816.htm.*

[4] David M. Studdert, Michelle M. Mello, William N. Sage, Catherine M. DesRoches, Jordan Peugh, Kinga Zapert, Troyen A. Brennan, *Defensive Medicine: Among High-Risk Specialist Physicians in a Volatile Malpractice Environment,* 293 J. AM. MED. ASS'N 2609 (2005).

Part of defensive medicine is called assurance behavior where a monetary value assigned. This occurs when a doctor orders a test or procedure where at least some of the motivation is to avoid being second-guessed in retrospect and possibly named in a medical liability suit. This is not fraud. Medicine is not an exact science. No doctor can tell whether the patient in front of them is the one who may have the rare clinical condition that may have been detected with an additional test. Faced with the possibility of a professionally devastating malpractice suit, many physicians will order the extra test. Sixty percent of malpractice cases are dropped or dismissed and never go to court, but it costs a doctor an average of $18,000 to defend against a lawsuit. Doctors are found *not* negligent in 90% of the cases that *do* go to trial, but each of these cases costs an average of $100,000 to defend.[5]

Defensive medicine is not done to increase income. If an internist orders a CAT scan, the radiologist gets paid, not the internist.

Medical malpractice premiums written in 2009 totaled approximately $10.8 billion.[6] Indirect costs, particularly increased use of tests and procedures by providers to protect against future lawsuits ("defensive medicine"), have been estimated to be much higher than direct premiums.

The Pacific Institute puts the cost of defensive medicine at some $200 billion and estimates that these additional liability-based medical care costs add at least 3.4 million Americans to the rolls of the uninsured.[7] Nearly half of all medical malpractice claims do not involve injury or medical error. Less than 15 cents of every litigation-related dollar goes to those injured from medical negligence. Likewise, the Manhattan Institute concluded that about ten cents of every dollar paid for health care services goes to cover malpractice premiums, defensive medicine, and other costs associated with excessive litigation.

Medical Liability Fears Inhibit Quality of Care Improvements

Fear of medical liability makes it more difficult to improve systems by making doctors reluctant to discuss and study errors and "near misses" or participate in morbidity and mortality conferences if the findings are "discoverable" in a malpractice claim.

Another common myth claims that it is a small group of bad doctors who are responsible for most malpractice cases and the current medical tort system is needed or they will be free to repeatedly harm patients through their negligence. According to a 2007 analysis of National Practitioner Data Bank (NPDB) files by Public Citizen, "The vast majority of doctors—82 percent—have never had a medical malpractice *payment* since the NPDB was created in 1990. Just 5.9 percent of doctors were responsible for 57.8 percent of all malpractice payments since 1991, according to data from September 1990 through 2005. Just 2.3 percent of doctors, having three or more malpractice payments, were responsible for 32.8 percent of all payments. Only 1.1 percent of doctors, having four or

[5] See note 5.

[6] NAIC, "Countrywide Summary of Medical Malpractice Insurance, Calendar Years 1991–2009," provided to CRS on December 16, 2010.

[7] Lawrence I. McQuillan, Hovannes Ahramyan and Anthony P. Archie, *Jackpot Justice: The True Cost of America's Tort System,* Pacific Research Institute (Mar. 2007).

more malpractice payments, were responsible for 20.2 percent of all payments."[8]

However, Public Citizen's own report highlights the problem. According to the AMA Physician Practice Information Survey, 75.4% of cardiothoracic surgeons, 68.3% of general surgeons, 79.1% of neurosurgeons, 70.3% of orthopedic surgeons and 69.6% of OB/GYNs have been sued.[9] The numbers don't add up. Either there are a lot of frivolous lawsuits or almost all doctors are really bad doctors. The truth is that most claims are meritless and do not result in a payment, yet most doctors have to defend themselves from these unnecessary claims at a substantial cost to themselves and the nation's health care system.

The medical liability tort system does not improve quality. A number of studies have failed to show that the current system of medical liability deters medical errors or promotes patient safety.[10] This has been most extensively studied in the specialty of obstetrics where the fear of medical liability has not been shown to result in fewer complications or cesarean sections.[11] There is evidence, however, that fears of medical liability deter doctors from treating high risk patients, performing high risk procedures, entering high risk specialties and practicing in states without liability reform.

H.R. 5 will make it easier to promote efforts at improving patient safety and quality of care by allowing doctors and hospitals to examine the causes of medical errors and make systemic improvements without the fear of litigation that exists in states without liability reform.

A Recurring Crisis, Yet Washington Has Failed To Act

Medical malpractice reform has surfaced as a national issue repeatedly over recent decades during periods of "crisis". A 2004 survey found that three out of four emergency rooms had to divert ambulances because of a shortage of specialists due to medical liability issues.[12] The evidence from states like California that medical liability reform works has been available for over three decades. Unnecessary costs and defensive medicine exact a negative effect on the federal health care programs of Medicare and Medicaid.[13]

President Obama has repeatedly expressed his support for meaningful medical liability reform. In a 2009 speech before the American Medical Association, the President acknowledged that defensive medicine leads to more tests and needless costs because doctors must protect themselves from frivolous lawsuits.[14] Again, during a speech to a Joint Session of Congress in September 2009, President Obama said "I don't believe malpractice reform is a silver

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[8] Public Citizen, Congress Watch, *The Great Medical Malpractice Hoax: NPDB Data Continue to Show Medical Liability System Produces Rational Outcomes,* (January 2007). *http://www.citizen.org/publications/publicationredirect.cfm?ID=.*

[9] AMA 2007–2008 Physician Practice Information survey.

[10] *Mello MM, Brennan TA. Deterrence of medical errors: theory and evidence for malpractice reform. Texas Law Review. 2002;* 80:1595–638.

[11] A. Russell Localio, JD, MPH, MS; Ann G. Lawthers, ScD; Joan M. Bengtson, MD; Liesi E. Hebert, ScD; Susan L. Weaver; Troyen A. Brennan, MD, JD; J. Richard Landis, PhD, Relationship Between Malpractice Claims and Cesarean Delivery, JAMA. 1993;269(3):366–373.

[12] Hospital Emergency Department Administration Survey, "Federal Medical Liability Reform," 2004, the Schumacher Group, *Alliance of Specialty Medicine,* July 2005.

[13] Under Medicare, the federal government pays a percentage of doctors' liability premiums through the practice expense component of the physician fee schedule. The federal government also incurs costs because of defensive medicine.

[14] The text of the June 2009 speech can be found here: *http://www.whitehouse.gov/the-press-office/remarks-president-annual-conference-american-medical-association.*

bullet, but I've talked to enough doctors to know that defensive medicine may be contributing to unnecessary costs."[15] In his most recent State of the Union address, President Obama again included medical liability reform as part of his agenda.[16]

A common question from the American people is why there were no meaningful medical liability reform provisions in the health reform law. An October 2009 survey conducted by the Health Coalition on Liability and Access found that 69% of Americans wanted medical liability reform included in health care reform legislation.[17] One of the most truthful answers came from Governor Howard Dean when he commented as follows on the House bill (H.R. 3200):

> This is the answer from a doctor and a politician: "Here's why tort reform is not in the bill. When you go to pass a really enormous bill like that, the more stuff you put in it, the more enemies you make, right? And the reason that tort reform is not in the bill is because the people who wrote it did not want to take on the trial lawyers in addition to everyone else they were taking on. And that is the plain and simple truth."[18]

As Shown by the States, Comprehensive Reform Will Increase Patient Access to Quality Care While Reducing Costs

States that adopted caps saw tremendous benefits. Patients who are harmed are still compensated 100% for economic losses (anything to which a receipt can be attached), suffered as the result of a health care injury. California's landmark legislation, the Medical Injury Compensation Reform Act of 1975 (MICRA) signed into law by Governor Jerry Brown (D), helped to stabilize the California medical liability insurance market. From 1976 through 2009, California's medical liability insurance premiums increased by 261% compared to a total increase of 945% for the other 49 states.[19]

Additionally, Texas adopted comprehensive medical malpractice reform, including caps on non-economic damages, in 2003, and these reforms have yielded remarkable outcomes, including an increase in new physicians, additional obstetricians, and reduced medical liability premiums. From 2003 through 2009, the Texas Medical Board saw an increase of roughly 60% in their new physician licensure applications.[20] While other states were losing obstetricians, Texas actually gained obstetricians. The number of obstetricians in Texas increased by 218 between 2002 and 2009 to a

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[15] The text of this address can be found here: *http://www.whitehouse.gov/the-press-office/remarks-president-a-joint-session-congress-health-care.*

[16] In his January 25, 2011, State of the Union address, President Obama specifically called for "medical malpractice reform to rein in frivolous lawsuits." On January 27, Republicans on the Committee wrote directly to the President seeking his leadership in crafting such legislation. There has been no response from the Administration.

[17] 112th Congress Committee on the Judiciary Report on the "Help Efficient, Accessible, Low-Cost, Timely Healthcare Act of 2011."

[18] *http://washingtonexaminer.com/blogs/beltway-confidential/2009/08/dean-says-obamacare-authors-dont-want-challenge-trial-lawyers.*

[19] The American Medical Association's written testimony for January 20, 2011, House Judiciary Committee hearing: *http://www.ama-assn.org/ama1/pub/upload/mm/399/ama-statement-medical-liability-reform-2011.pdf.*

[20] Texas Medical Association's "Proposition 12 Produces Healthy Benefits": *http://www.texmed.org/Template.aspx?id=5238.*

total of 2,444.[21] Finally, all major physician liability carriers in Texas have reduced their rates resulting in nearly all Texas physicians having their premiums lowered by at least 30% and some by well over 40% since 2004.[22]

Caps on non-economic damages do not deny injured patients the ability to have their cases heard. States that have enacted caps have not seen a significant reduction in the *number* of claims, only in the number of unpredictable and unreasonably large awards for pain and suffering.[23] States that have not enacted reform continue to allow a few patients and their attorneys unlimited awards while everyone else is burdened with limited health care and rising costs.

Twenty-eight states have enacted meaningful medical liability reform that includes, among other provisions, a cap on non-economic damages, while twenty-two states continue to operate within the national health care system without meaningful liability reform.[24] In states with caps on non-economic damages, liability premiums are 17% lower than they are in states without such caps.[25]

In those states that have enacted meaningful reform, malpractice premiums are affordable, defensive medicine costs are lower and patients have greater access to care when and where they need it. For example, two thorough studies that used national data on Medicare populations concluded that states with medical litigation reforms saw an average reduction of 4.3% in hospital costs for patients in managed care programs.[26] This is not the case in states that have refused to enact meaningful reform.

In states without liability reform, the system does not serve anyone except trial lawyers. Injured patients are not compensated in a timely or equitable way. They are forced to wade through several years of litigation and receive, on average, only 46 cents of every dollar awarded while the remaining 54 cents goes to their lawyers and other administrative fees.[27]

State reforms show that comprehensive medical liability reform, like H.R. 5, will improve patients' access to quality care while reducing the overall cost of health care in America.

HEARINGS

On April 6, 2011, the Subcommittee on Health held a hearing entitled, "The Cost of the Medical Liability System and Proposals for Reform, including H.R. 5, the Help Efficient, Accessible, Low-cost, Timely Healthcare (HEALTH) Act of 2011." At the hearing, the Subcommittee examined the nation's medical liability system and approaches for reform. The Subcommittee received testimony from: Lisa M. Hollier, MD, MPH, Fellow, American College of Obstetri-

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[21] The chart detailing *obstetricians in Texas can be found here: http://www.tapa.info/Downloads/Improving_Access/2010_Charts/06_TAPA_Obstetricians.pdf.*

[22] Texas Medical Association "Professional Liability Insurance Reform": *http://www.texmed.org/Template.aspx?id=780.*

[23] In July 2007, a Los Angeles County Court awarded a plaintiff over $96 million in damages while abiding by MICRA's $250,000 cap on non-economic damages. *www.micra.org.*

[24] AANS/CNS PowerPoint Presentation "The State of Medical Liability Reform: Successes and Challenges for the Future", February 19, 2010.

[25] "The Medical Malpractice Crisis': Trends and the Impact of State Tort Reforms," Kenneth E. Thorpe, (January 21, 2004) at 20–30.

[26] Daniel P. Kessler and Mark B. McClellan, "Medical Liability, Managed Care, and Defensive Medicine," National Bureau of Economic Research (NBER) Working Paper 7537 (February 2000) at 16.

[27] NEJM "Claims, Errors, and Compensation Payments in Medical Malpractice Litigation.": *http://www.nejm.org/doi/full/10.1056/NEJMsa054479.*

cians and Gynecologists; Allen B. Kachalia, MD, JD, Harvard Medical School; Troy M. Tippett, MD, Past President, American Association of Neurological Surgeons; Joanne Doroshow, Executive Director, The Center for Justice and Democracy; and, Brian Wolfman, JD, Visiting Professor, Georgetown University Law Center.

COMMITTEE CONSIDERATION

On May 10–11, 2011, the Full Committee met in open markup session and favorably ordered H.R. 5 reported to the House, as amended, by a roll call vote, a quorum being present. The Committee received only a time-limited, additional referral on this legislation.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. The following are the recorded votes taken on amendments offered to the measure, including the names of those Members voting for and against. A motion by Mr. Upton to order H.R. 5 reported to the House, as amended, was agreed to by a roll call vote.

COMMITTEE ON ENERGY AND COMMERCE -- 112TH CONGRESS
ROLL CALL VOTE #26

BILL: **H.R. 5**, the "Help Efficient, Accessible, Low-cost, Timely Healthcare (HEALTH) Act of 2011"

AMENDMENT: An amendment by Ms. Baldwin, No. 1, to prevent the modification, preemption or impairment of state laws or state authority governing medical malpractice or medical liability.

DISPOSITION: **NOT AGREED TO**, by a roll call vote of 20 yeas to 29 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Upton		X		Mr. Waxman	X		
Mr. Barton		X		Mr. Dingell			
Mr. Stearns		X		Mr. Markey	X		
Mr. Whitfield		X		Mr. Towns	X		
Mr. Shimkus		X		Mr. Pallone	X		
Mr. Pitts		X		Mr. Rush			
Mrs. Bono Mack		X		Ms. Eshoo	X		
Mr. Walden		X		Mr. Engel	X		
Mr. Terry	X			Mr. Green	X		
Mr. Rogers		X		Ms. DeGette	X		
Mrs. Myrick		X		Mrs. Capps			
Mr. Sullivan				Mr. Doyle	X		
Mr. Murphy		X		Ms. Schakowsky	X		
Mr. Burgess		X		Mr. Gonzalez			
Mrs. Blackburn		X		Mr. Inslee	X		
Mr. Bilbray		X		Ms. Baldwin	X		
Mr. Bass		X		Mr. Ross	X		
Mr. Gingrey		X		Mr. Weiner	X		
Mr. Scalise		X		Mr. Matheson		X	
Mr. Latta		X		Mr. Butterfield	X		
Mrs. McMorris Rodgers		X		Mr. Barrow	X		
Mr. Harper		X		Ms. Matsui	X		
Mr. Lance		X		Ms. Christensen	X		
Mr. Cassidy		X					
Mr. Guthrie		X					
Mr. Olson		X					
Mr. McKinley		X					
Mr. Gardner		X					
Mr. Pompeo		X					
Mr. Kinzinger		X					
Mr. Griffith	X						

Current as of 03/14/2011

COMMITTEE ON ENERGY AND COMMERCE -- 112TH CONGRESS
ROLL CALL VOTE #27

BILL: H.R. 5, the "Help Efficient, Accessible, Low-cost, Timely Healthcare (HEALTH) Act of 2011"

AMENDMENT: An amendment by Mr. Barrow, No. 2, to prevent the preemption of state constitutions.

DISPOSITION: NOT AGREED TO, by a roll call vote of 20 yeas to 30 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Upton		X		Mr. Waxman	X		
Mr. Barton		X		Mr. Dingell			
Mr. Stearns		X		Mr. Markey			
Mr. Whitfield		X		Mr. Towns	X		
Mr. Shimkus		X		Mr. Pallone	X		
Mr. Pitts		X		Mr. Rush			
Mrs. Bono Mack		X		Ms. Eshoo	X		
Mr. Walden		X		Mr. Engel	X		
Mr. Terry	X			Mr. Green	X		
Mr. Rogers		X		Ms. DeGette	X		
Mrs. Myrick		X		Mrs. Capps	X		
Mr. Sullivan		X		Mr. Doyle	X		
Mr. Murphy		X		Ms. Schakowsky	X		
Mr. Burgess		X		Mr. Gonzalez			
Mrs. Blackburn		X		Mr. Inslee	X		
Mr. Bilbray		X		Ms. Baldwin	X		
Mr. Bass		X		Mr. Ross	X		
Mr. Gingrey		X		Mr. Weiner	X		
Mr. Scalise		X		Mr. Matheson		X	
Mr. Latta		X		Mr. Butterfield	X		
Mrs. McMorris Rodgers		X		Mr. Barrow	X		
Mr. Harper		X		Ms. Matsui	X		
Mr. Lance		X		Ms. Christensen	X		
Mr. Cassidy		X					
Mr. Guthrie		X					
Mr. Olson		X					
Mr. McKinley		X					
Mr. Gardner		X					
Mr. Pompeo		X					
Mr. Kinzinger		X					
Mr. Griffith	X						

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COMMITTEE ON ENERGY AND COMMERCE -- 112TH CONGRESS
ROLL CALL VOTE #28

BILL: **H.R. 5**, the "Help Efficient, Accessible, Low-cost, Timely Healthcare (HEALTH) Act of 2011"

AMENDMENT: An amendment by Mr. Waxman, No. 6, to strike medical product manufacturers, distributors, suppliers, marketers, promoters and sellers from the legislation.

DISPOSITION: **NOT AGREED TO**, by a roll call vote of 17 yeas to 29 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Upton		X		Mr. Waxman	X		
Mr. Barton		X		Mr. Dingell	X		
Mr. Stearns		X		Mr. Markey			
Mr. Whitfield		X		Mr. Towns			
Mr. Shimkus		X		Mr. Pallone	X		
Mr. Pitts		X		Mr. Rush	X		
Mrs. Bono Mack		X		Ms. Eshoo	X		
Mr. Walden		X		Mr. Engel	X		
Mr. Terry		X		Mr. Green	X		
Mr. Rogers				Ms. DeGette	X		
Mrs. Myrick				Mrs. Capps			
Mr. Sullivan				Mr. Doyle	X		
Mr. Murphy		X		Ms. Schakowsky			
Mr. Burgess		X		Mr. Gonzalez			
Mrs. Blackburn		X		Mr. Inslee	X		
Mr. Bilbray		X		Ms. Baldwin	X		
Mr. Bass		X		Mr. Ross	X		
Mr. Gingrey		X		Mr. Weiner	X		
Mr. Scalise		X		Mr. Matheson		X	
Mr. Latta		X		Mr. Butterfield	X		
Mrs. McMorris Rodgers		X		Mr. Barrow	X		
Mr. Harper		X		Ms. Matsui	X		
Mr. Lance		X		Ms. Christensen	X		
Mr. Cassidy		X					
Mr. Guthrie		X					
Mr. Olson		X					
Mr. McKinley		X					
Mr. Gardner		X					
Mr. Pompeo		X					
Mr. Kinzinger		X					
Mr. Griffith		X					

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COMMITTEE ON ENERGY AND COMMERCE -- 112TH CONGRESS
ROLL CALL VOTE #29

BILL: **H.R. 5**, the "Help Efficient, Accessible, Low-cost, Timely Healthcare (HEALTH) Act of 2011"

AMENDMENT: An amendment by Mr. Pallone, No. 7, to raise the cap on non-economic damages to $1,000,000 million and adjust annually on the basis of the Consumer Price Index.

DISPOSITION: **NOT AGREED TO**, by a roll call vote of 16 yeas to 30 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Upton		X		Mr. Waxman	X		
Mr. Barton		X		Mr. Dingell	X		
Mr. Stearns		X		Mr. Markey			
Mr. Whitfield		X		Mr. Towns	X		
Mr. Shimkus		X		Mr. Pallone	X		
Mr. Pitts		X		Mr. Rush			
Mrs. Bono Mack		X		Ms. Eshoo	X		
Mr. Walden		X		Mr. Engel	X		
Mr. Terry		X		Mr. Green		X	
Mr. Rogers		X		Ms. DeGette			
Mrs. Myrick				Mrs. Capps			
Mr. Sullivan				Mr. Doyle	X		
Mr. Murphy		X		Ms. Schakowsky	X		
Mr. Burgess		X		Mr. Gonzalez			
Mrs. Blackburn		X		Mr. Inslee	X		
Mr. Bilbray		X		Ms. Baldwin	X		
Mr. Bass		X		Mr. Ross	X		
Mr. Gingrey		X		Mr. Weiner	X		
Mr. Scalise		X		Mr. Matheson		X	
Mr. Latta		X		Mr. Butterfield	X		
Mrs. McMorris Rodgers		X		Mr. Barrow	X		
Mr. Harper		X		Ms. Matsui	X		
Mr. Lance		X		Ms. Christensen	X		
Mr. Cassidy		X					
Mr. Guthrie		X					
Mr. Olson		X					
Mr. McKinley		X					
Mr. Gardner		X					
Mr. Pompeo		X					
Mr. Kinzinger							
Mr. Griffith		X					

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COMMITTEE ON ENERGY AND COMMERCE -- 112TH CONGRESS
ROLL CALL VOTE #30

BILL: **H.R. 5**, the "Help Efficient, Accessible, Low-cost, Timely Healthcare (HEALTH) Act of 2011"

AMENDMENT: An amendment by Mr. Pallone, No. 10, to strike the cap on punitive damages.

DISPOSITION: **NOT AGREED TO**, by a roll call vote of 15 yeas to 27 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Upton		X		Mr. Waxman	X		
Mr. Barton		X		Mr. Dingell	X		
Mr. Stearns		X		Mr. Markey			
Mr. Whitfield		X		Mr. Towns	X		
Mr. Shimkus		X		Mr. Pallone	X		
Mr. Pitts				Mr. Rush			
Mrs. Bono Mack		X		Ms. Eshoo	X		
Mr. Walden		X		Mr. Engel			
Mr. Terry		X		Mr. Green	X		
Mr. Rogers		X		Ms. DeGette	X		
Mrs. Myrick		X		Mrs. Capps			
Mr. Sullivan				Mr. Doyle	X		
Mr. Murphy		X		Ms. Schakowsky			
Mr. Burgess		X		Mr. Gonzalez			
Mrs. Blackburn		X		Mr. Inslee	X		
Mr. Bilbray				Ms. Baldwin	X		
Mr. Bass		X		Mr. Ross			
Mr. Gingrey		X		Mr. Weiner	X		
Mr. Scalise		X		Mr. Matheson		X	
Mr. Latta		X		Mr. Butterfield	X		
Mrs. McMorris Rodgers				Mr. Barrow	X		
Mr. Harper		X		Ms. Matsui	X		
Mr. Lance		X		Ms. Christensen	X		
Mr. Cassidy		X					
Mr. Guthrie		X					
Mr. Olson		X					
Mr. McKinley		X					
Mr. Gardner		X					
Mr. Pompeo							
Mr. Kinzinger		X					
Mr. Griffith		X					

Current as of 03/14/2011

COMMITTEE ON ENERGY AND COMMERCE -- 112TH CONGRESS
ROLL CALL VOTE #31

BILL: **H.R. 5**, the "Help Efficient, Accessible, Low-cost, Timely Healthcare (HEALTH) Act of 2011"

AMENDMENT: An amendment by Mr. Waxman, No. 11, to eliminate intentional torts from the bill.

DISPOSITION: **NOT AGREED TO**, by a roll call vote of 18 yeas to 29 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Upton		X		Mr. Waxman	X		
Mr. Barton		X		Mr. Dingell	X		
Mr. Stearns		X		Mr. Markey	X		
Mr. Whitfield		X		Mr. Towns	X		
Mr. Shimkus		X		Mr. Pallone	X		
Mr. Pitts		X		Mr. Rush			
Mrs. Bono Mack		X		Ms. Eshoo			
Mr. Walden		X		Mr. Engel	X		
Mr. Terry		X		Mr. Green	X		
Mr. Rogers				Ms. DeGette	X		
Mrs. Myrick		X		Mrs. Capps	X		
Mr. Sullivan				Mr. Doyle			
Mr. Murphy		X		Ms. Schakowsky	X		
Mr. Burgess		X		Mr. Gonzalez			
Mrs. Blackburn		X		Mr. Inslee	X		
Mr. Bilbray		X		Ms. Baldwin	X		
Mr. Bass		X		Mr. Ross	X		
Mr. Gingrey		X		Mr. Weiner	X		
Mr. Scalise		X		Mr. Matheson		X	
Mr. Latta		X		Mr. Butterfield	X		
Mrs. McMorris Rodgers		X		Mr. Barrow	X		
Mr. Harper		X		Ms. Matsui			
Mr. Lance		X		Ms. Christensen	X		
Mr. Cassidy		X					
Mr. Guthrie		X					
Mr. Olson		X					
Mr. McKinley		X					
Mr. Gardner		X					
Mr. Pompeo		X					
Mr. Kinzinger		X					
Mr. Griffith	X						

Current as of 03/14/2011

COMMITTEE ON ENERGY AND COMMERCE -- 112TH CONGRESS
ROLL CALL VOTE #32

BILL: **H.R. 5**, the "Help Efficient, Accessible, Low-cost, Timely Healthcare (HEALTH) Act of 2011"

AMENDMENT: An amendment by Mr. Towns, No. 12, to delay the implementation of the bill until the Secretary of HHS certifies that the medical liability programs and report authorized by the Patient Protection and Affordable Care Act were funded or issued and that the bill will accomplish the purposesset forth in Section 2 better than the PPACA programs.

DISPOSITION: **NOT AGREED TO**, by a roll call vote of 18 yeas to 31 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Upton		X		Mr. Waxman	X		
Mr. Barton		X		Mr. Dingell	X		
Mr. Stearns		X		Mr. Markey	X		
Mr. Whitfield		X		Mr. Towns	X		
Mr. Shimkus		X		Mr. Pallone	X		
Mr. Pitts		X		Mr. Rush	X		
Mrs. Bono Mack		X		Ms. Eshoo			
Mr. Walden		X		Mr. Engel	X		
Mr. Terry		X		Mr. Green	X		
Mr. Rogers				Ms. DeGette	X		
Mrs. Myrick		X		Mrs. Capps	X		
Mr. Sullivan		X		Mr. Doyle			
Mr. Murphy		X		Ms. Schakowsky	X		
Mr. Burgess		X		Mr. Gonzalez			
Mrs. Blackburn		X		Mr. Inslee	X		
Mr. Bilbray		X		Ms. Baldwin	X		
Mr. Bass		X		Mr. Ross	X		
Mr. Gingrey		X		Mr. Weiner	X		
Mr. Scalise		X		Mr. Matheson		X	
Mr. Latta		X		Mr. Butterfield	X		
Mrs. McMorris Rodgers		X		Mr. Barrow	X		
Mr. Harper		X		Ms. Matsui			
Mr. Lance		X		Ms. Christensen	X		
Mr. Cassidy		X					
Mr. Guthrie		X					
Mr. Olson		X					
Mr. McKinley		X					
Mr. Gardner		X					
Mr. Pompeo		X					
Mr. Kinzinger		X					
Mr. Griffith		X					

Current as of 03/14/2011

COMMITTEE ON ENERGY AND COMMERCE -- 112TH CONGRESS
ROLL CALL VOTE #33

BILL: **H.R. 5**, the "Help Efficient, Accessible, Low-cost, Timely Healthcare (HEALTH) Act of 2011"

AMENDMENT: An amendment by Mr. Markey, No. 13, to require that damages awarded above the caps on non-economic and punitive damages go toward reducing premiums of health care providers.

DISPOSITION: **NOT AGREED TO**, by a roll call vote of 18 yeas to 31 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Upton		X		Mr. Waxman	X		
Mr. Barton		X		Mr. Dingell	X		
Mr. Stearns		X		Mr. Markey	X		
Mr. Whitfield		X		Mr. Towns	X		
Mr. Shimkus		X		Mr. Pallone	X		
Mr. Pitts		X		Mr. Rush	X		
Mrs. Bono Mack		X		Ms. Eshoo			
Mr. Walden		X		Mr. Engel	X		
Mr. Terry		X		Mr. Green	X		
Mr. Rogers				Ms. DeGette	X		
Mrs. Myrick		X		Mrs. Capps	X		
Mr. Sullivan		X		Mr. Doyle			
Mr. Murphy		X		Ms. Schakowsky	X		
Mr. Burgess		X		Mr. Gonzalez			
Mrs. Blackburn		X		Mr. Inslee	X		
Mr. Bilbray		X		Ms. Baldwin	X		
Mr. Bass		X		Mr. Ross	X		
Mr. Gingrey		X		Mr. Weiner	X		
Mr. Scalise		X		Mr. Matheson		X	
Mr. Latta		X		Mr. Butterfield	X		
Mrs. McMorris Rodgers		X		Mr. Barrow	X		
Mr. Harper		X		Ms. Matsui			
Mr. Lance		X		Ms. Christensen	X		
Mr. Cassidy		X					
Mr. Guthrie		X					
Mr. Olson		X					
Mr. McKinley		X					
Mr. Gardner		X					
Mr. Pompeo		X					
Mr. Kinzinger		X					
Mr. Griffith		X					

Current as of 03/14/2011

COMMITTEE ON ENERGY AND COMMERCE -- 112TH CONGRESS
ROLL CALL VOTE #34

BILL: **H.R. 5**, the "Help Efficient, Accessible, Low-cost, Timely Healthcare (HEALTH) Act of 2011"

AMENDMENT: An amendment by Mr. Waxman, No. 14, to prevent courts from approving settlements restricting disclosure of information or approving orders restricting access to court records unless certain requirements are met.

DISPOSITION: **NOT AGREED TO**, by a roll call vote of 18 yeas to 32 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Upton		X		Mr. Waxman	X		
Mr. Barton		X		Mr. Dingell	X		
Mr. Stearns		X		Mr. Markey	X		
Mr. Whitfield		X		Mr. Towns	X		
Mr. Shimkus		X		Mr. Pallone	X		
Mr. Pitts		X		Mr. Rush	X		
Mrs. Bono Mack		X		Ms. Eshoo			
Mr. Walden		X		Mr. Engel	X		
Mr. Terry		X		Mr. Green	X		
Mr. Rogers		X		Ms. DeGette	X		
Mrs. Myrick		X		Mrs. Capps	X		
Mr. Sullivan		X		Mr. Doyle			
Mr. Murphy		X		Ms. Schakowsky	X		
Mr. Burgess		X		Mr. Gonzalez			
Mrs. Blackburn		X		Mr. Inslee	X		
Mr. Bilbray		X		Ms. Baldwin	X		
Mr. Bass		X		Mr. Ross	X		
Mr. Gingrey		X		Mr. Weiner	X		
Mr. Scalise		X		Mr. Matheson		X	
Mr. Latta		X		Mr. Butterfield	X		
Mrs. McMorris Rodgers		X		Mr. Barrow	X		
Mr. Harper		X		Ms. Matsui			
Mr. Lance		X		Ms. Christensen	X		
Mr. Cassidy		X					
Mr. Guthrie		X					
Mr. Olson		X					
Mr. McKinley		X					
Mr. Gardner		X					
Mr. Pompeo		X					
Mr. Kinzinger		X					
Mr. Griffith		X					

Current as of 03/14/2011

COMMITTEE ON ENERGY AND COMMERCE -- 112TH CONGRESS
ROLL CALL VOTE #35

BILL: **H.R. 5**, the "Help Efficient, Accessible, Low-cost, Timely Healthcare (HEALTH) Act of 2011"

AMENDMENT: A motion by Mr. Upton to order H.R. 5 favorably reported to the House, amended. (Final Passage)

DISPOSITION: **AGREED TO**, by a roll call vote of 30 yeas to 20 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Upton	X			Mr. Waxman		X	
Mr. Barton	X			Mr. Dingell		X	
Mr. Stearns	X			Mr. Markey		X	
Mr. Whitfield	X			Mr. Towns		X	
Mr. Shimkus	X			Mr. Pallone		X	
Mr. Pitts	X			Mr. Rush		X	
Mrs. Bono Mack	X			Ms. Eshoo			
Mr. Walden	X			Mr. Engel		X	
Mr. Terry		X		Mr. Green		X	
Mr. Rogers	X			Ms. DeGette		X	
Mrs. Myrick	X			Mrs. Capps		X	
Mr. Sullivan	X			Mr. Doyle			
Mr. Murphy	X			Ms. Schakowsky		X	
Mr. Burgess	X			Mr. Gonzalez			
Mrs. Blackburn	X			Mr. Inslee		X	
Mr. Bilbray	X			Ms. Baldwin		X	
Mr. Bass	X			Mr. Ross		X	
Mr. Gingrey	X			Mr. Weiner		X	
Mr. Scalise	X			Mr. Matheson	X		
Mr. Latta	X			Mr. Butterfield		X	
Mrs. McMorris Rodgers	X			Mr. Barrow		X	
Mr. Harper	X			Ms. Matsui			
Mr. Lance	X			Ms. Christensen		X	
Mr. Cassidy	X						
Mr. Guthrie	X						
Mr. Olson	X						
Mr. McKinley	X						
Mr. Gardner	X						
Mr. Pompeo	X						
Mr. Kinzinger	X						
Mr. Griffith		X					

Current as of 03/14/2011

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The goal of H.R. 5 is to improve patient access to quality health care by reducing the excessive burdens the medical liability system places on the health care delivery system.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 5, the Help Efficient, Accessible, Low-Cost, Timely Healthcare (HEALTH) Act of 2011, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

EARMARK

In compliance with clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 5 contains no earmarks, limited tax benefits, or limited tariff benefits.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, May 23, 2011.

Hon. FRED UPTON,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 5, the Help Efficient, Accessible, Low-cost, Timely Healthcare (HEALTH) Act of 2011.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Tom Bradley.

Sincerely,

DOUGLAS W. ELMENDORF.

Enclosure.

H.R. 5—Help Efficient, Accessible, Low-cost, Timely Healthcare (HEALTH) Act of 2011

Summary: H.R. 5 would impose limits on medical malpractice litigation in state and federal courts by capping awards and attorney fees, modifying the statute of limitations and the "collateral source" rule, and eliminating joint and several liability.

CBO expects that those changes would, on balance, lower costs for health care both directly and indirectly: directly, by lowering premiums for medical liability insurance; and indirectly, by reducing the use of health care services prescribed by providers when

faced with less pressure from potential malpractice suits. Those reductions in costs would, in turn, lead to lower spending in federal health programs and to lower private health insurance premiums.

Because employers would pay less for health insurance for employees, more of their employees' compensation would be in the form of taxable wages and other fringe benefits. As discussed below, the bill also would increase revenues because it would result in lower subsidies for health insurance. In total, CBO and the staff of the Joint Committee on Taxation (JCT) estimate that enacting H.R. 5 would increase federal revenues by almost $10 billion over the 2012–2021 period.

Enacting H.R. 5 would reduce federal direct spending for Medicare, Medicaid, the government's share of premiums for annuitants under the Federal Employees Health Benefits (FEHB) program, and other federal health benefits programs. CBO estimates that direct spending would decline by about $48 billion over the 2012–2021 period.

Because enacting the legislation would affect direct spending and revenue, pay-as-you-go procedures apply. In total, CBO estimates that enacting H.R. 5 would reduce deficits by almost $14 billion over the 2011–2016 period and by about $57 billion over the 2012–2021 period.

Federal spending for active workers participating in the FEHB program is included in the appropriations for federal agencies, and is therefore discretionary. H.R. 5 would also affect discretionary spending for health care services paid by the Departments of Defense (DoD) and Veterans Affairs (VA). CBO estimates that implementing H.R. 5 would reduce discretionary spending by about $2 billion over the 2012–2021 period, assuming appropriations actions consistent with the legislation.

H.R. 5 contains an intergovernmental mandate as defined in the Unfunded Mandates Reform Act (UMRA) because it would preempt state laws that provide less protection for health care providers and organizations from liability, loss, or damages (other than caps on awards for damages). CBO estimates the cost of complying with the mandate would be small and would fall well below the threshold established in UMRA for intergovernmental mandates ($71 million in 2011, adjusted annually for inflation).

H.R. 5 contains several mandates on the private sector, including caps on damages and on attorney fees, a more restrictive statute of limitations, and the fair share rule. The cost of those mandates would exceed the threshold established in UMRA for private-sector mandates ($142 million in 2011, adjusted annually for inflation) in four of the first five years in which the mandates were effective, rising to $1.4 billion per year in 2016, and totaling $3.3 billion over the 2012–2016 period.

Estimated cost to the Federal Government: The estimated budgetary impact of H.R. 5 is shown in the following table. The costs of this legislation fall with multiple budget functions, primarily 550 (health) and 570 (Medicare).

	By fiscal year, in billions of dollars—											
	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2012–2016	2012–2021
CHANGES IN REVENUES												
Estimated Revenues:												
On-budget	*	0.1	0.3	0.6	0.8	0.9	1.0	1.0	1.1	1.2	1.8	7.0
Off-budget	*	*	0.1	0.2	0.3	0.3	0.3	0.4	0.4	0.4	0.7	2.5
Total	*	0.1	0.4	0.8	1.1	1.2	1.3	1.4	1.5	1.6	2.5	9.6
CHANGES IN DIRECT SPENDING												
Estimated Budget Authority	−0.1	−0.5	−1.8	−3.6	−5.3	−6.2	−6.7	−7.3	−7.9	−8.4	−11.3	−47.8
Estimated Outlays	−0.1	−0.5	−1.8	−3.6	−5.3	−6.2	−6.7	−7.3	−7.9	−8.4	−11.3	−47.8
NET INCREASE OR DECREASE (−) IN THE DEFICIT FROM CHANGES IN REVENUES AND DIRECT SPENDING												
Impact on the Deficit:												
On-budget	−0.1	−0.6	−2.1	−4.2	−6.1	−7.1	−7.7	−8.3	−9.0	−9.6	−13.1	−54.8
Off-budget	*	*	−0.1	−0.2	−0.3	−0.3	−0.3	−0.4	−0.4	−0.4	−0.7	−2.5
Total	−0.1	−0.6	−2.2	−4.4	−6.4	−7.4	−8.0	−8.7	−9.4	−10.0	−13.8	−57.4
CHANGES IN SPENDING SUBJECT TO APPROPRIATION												
Estimated Authorization Level	0	*	−0.1	−0.1	−0.2	−0.2	−0.2	−0.3	−0.3	−0.3	−0.4	−1.6
Estimated Outlays	0	*	−0.1	−0.1	−0.2	−0.2	−0.2	−0.3	−0.3	−0.3	−0.4	−1.6

Notes: Components may not add to totals because of rounding.
* = increase in revenues, reduction in spending, or reduction in deficits of less than $50 million.

Basis of estimate: H.R. 5 would establish:

- A three-year statute of limitations for medical malpractice claims, with certain exceptions, from the date of discovery of an injury;
- A cap of $250,000 on awards for noneconomic damages;
- A cap on awards for punitive damages that would be the larger of $250,000 or twice the economic damages, and restrictions on when punitive damages may be awarded;
- Replacement of joint-and-several liability with a fair-share rule, under which a defendant in a lawsuit would be liable only for the percentage of the final award that was equal to his or her share of responsibility for the injury;
- Sliding-scale limits on the contingency fees that lawyers can charge;
- A safe harbor from punitive damages for products that meet applicable FDA safety requirements; and
- Permission to introduce evidence of income from collateral sources (such as life insurance payouts and health insurance) at trial.

Over the 2012–2021 period, CBO and the staff of the Joint Committee on Taxation estimate that enacting H.R. 5 would reduce direct spending by about $48 billion and increase federal revenues by almost $10 billion. The combined effect of those changes in direct spending and revenues would reduce federal deficits by $57 billion over that period, with changes in off-budget revenues accounting for about $3 billion of that reduction in deficits. (Because those estimates assume enactment of H.R. 5 near the end of fiscal year 2011, no budgetary effects are expected in that year.)

In addition, CBO estimates that implementing H.R. 5 would reduce discretionary spending for the FEHB program, DoD, and VA by about $2 billion over the 2012–2021 period.

Effects on National Spending for Health Care

CBO reviewed recent research on the effects of proposals to limit costs related to medical malpractice ("tort reform"), and estimates that enacting H.R. 5 would reduce national health spending by about 0.5 percent.[1] That figure comprises a direct reduction in spending for medical liability premiums and an additional indirect reduction from slightly less utilization of health care services. CBO's estimate takes into account the fact that, because many States have already implemented some elements of H.R. 5, a significant fraction of the potential cost savings has already been realized. Moreover, the estimate assumes that the reduction of about 0.5 percent would be realized over a period of four years, as providers gradually change their practice patterns.

Revenues

CBO estimates that private health spending would be reduced by about 0.5 percent. Much of private-sector health care is paid for through employment-based insurance that represents nontaxable compensation. In addition, beginning in 2014, refundable tax credits will be available to certain individuals and families to subsidize health insurance purchased through new health insurance exchanges. (The portion of those tax credits that exceed taxpayers' liabilities are classified as outlays, while the portions that reduce taxpayers' liabilities are recorded as reductions in revenues.)

Lower costs for health care arising from enactment of H.R. 5 would lead to an increase in taxable compensation and a reduction in subsidies for health insurance purchased through an exchange. Those changes would increase federal tax revenues by an estimated $9.6 billion over the 2012–2021 period, according to estimates by JCT. Social Security payroll taxes, which are off-budget, account for $2.5 billion of that increase in federal revenues.

Direct Spending

CBO estimates that enacting H.R. 5 would reduce direct spending for Medicare, Medicaid, the Children's Health Insurance Program, the Federal Employees Health Benefits program, the Defense Department's TRICARE for Life program, and subsidies for enrollees in health insurance exchanges by roughly $48 billion over the 2012–2021 period.

For programs other than Parts A and B of Medicare, the estimate assumes that federal spending for acute care services would be reduced by about 0.5 percent, in line with the estimated reductions in the private sector.

CBO estimates that the reduction in federal spending for services covered under Parts A and B of Medicare would be larger—about 0.7 percent—than in the other programs or in national health spending in general. That estimate is based on empirical evidence showing that the impact of tort reform on the utilization of health

[1] See Congressional Budget Office, letter to the Honorable Orrin G. Hatch regarding CBO's Analysis of the Effects of Proposals to Limit Costs Related to Medical Malpractice, (October 9, 2009). *http://www.cbo.gov/ftpdocs/106xx/doc10641/10-09-Tort_Reform.pdf.*

care services is greater for Medicare than for the rest of the health care system.[2]

Spending Subject to Appropriation

CBO estimates that implementing H.R. 5 would reduce federal spending for health insurance for federal employees covered through the FEHB program by about 0.5 percent—in line with the estimated reductions in the private sector—and would reduce spending for health insurance and health care services paid for by the Departments of Defense and Veterans Affairs by lesser amounts. CBO expects that the impact on those agencies would be proportionally smaller than the impact on overall health spending because medical malpractice costs are already lower than average for entities covered by the Federal Tort Claims Act. In CBO's estimation, the cost of health insurance and health care services funded through appropriation acts would be reduced by $1.6 billion over the 2012–2021 period.

Pay-As-You-Go considerations: The Statutory Pay-As-You-Go Act of 2010 establishes budget reporting and enforcement procedures for legislation affecting direct spending or revenues. The net changes in outlays and revenues that are subject to those pay-as-you-go procedures are shown in the following table. Only on-budget changes to outlays or revenues are subject to pay-as-you-go procedures.

[2] One possible explanation for that disparity is that the bulk of Medicare's spending is on a fee-for-service basis, whereas most private health care spending occurs through plans that manage care to some degree. Such plans limit the use of services that have marginal or no benefit to patients (some of which might otherwise be provided as "defensive" medicine), thus leaving less potential for savings from the reduction of utilization in those plans than in fee-for-service systems.

CBO ESTIMATE OF PAY-AS-YOU-GO EFFECTS FOR H.R. 5, AS ORDERED REPORTED BY THE HOUSE COMMITTEE ON ENERGY AND COMMERCE ON MAY 11, 2011

	By fiscal year, in millions of dollars—												
	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2011–2016	2011–2021
NET INCREASE OR DECREASE (−) IN THE ON-BUDGET DEFICIT													
Statutory Pay-As-You-Go Impact	0	−108	−593	−2,112	−4,186	−6,131	−7,105	−7,672	−8,331	−9,002	−9,574	−13,129	−54,814
Memorandum:													
Direct spending	0	−100	−500	−1,800	−3,600	−5,300	−6,200	−6,700	−7,300	−7,900	−8,400	−11,300	−47,800
Revenues	0	8	93	312	586	831	905	972	1,031	1,102	1,174	1,829	7,014

Estimated impact on State, local, and tribal governments:

Intergovernmental Mandates

The bill contains an intergovernmental mandate because it would preempt state laws that would prevent the application of any provision of the bill; however, it would not preempt any State law that provides greater protections for health care providers and organizations from liability, loss, or damages. While the preemption would limit the application of State and local laws, CBO estimates that it would not impose significant costs and would fall well below the threshold established in the Unfunded Mandates Reform Act for intergovernmental mandates ($71 million in 2011, adjusted annually for inflation).

Other Impacts

A decline in health care spending is expected to result in a decrease in rates for health insurance premiums. State, local, and tribal governments, as employers, would save money as a result of lower health insurance premiums precipitated by the bill. State, local, and tribal governments that collect income taxes also would realize increased tax revenues as a result of increases in workers' taxable income. State spending in Medicaid would decrease by over $4 billion over the 2012–2016 period, with additional savings in the subsequent years.

Estimated impact on the private sector: H.R. 5 contains several mandates on the private sector, because it would limit the amount of compensatory damages that a plaintiff can receive.

Compensatory damages are paid to compensate a claimant for loss, injury, or harm suffered by a defendant's breach of duty. Laws that directly limit the right of plaintiffs to be compensated for losses that they incurred as a result of a defendant's wrongful acts impose a mandate.

Applying this standard, the cap on non-economic damages, the statute of limitations, and the fair-share rule included in H.R. 5 would be considered mandates on the private sector, as defined by UMRA, because they would limit the ability of some claimants to recover the entire amount of compensatory damages that could be collected under current law. In addition, the cap on attorney fees is a mandate because it limits the fees that attorneys might otherwise be able to collect from their clients. The cost of those mandates would exceed the threshold established in UMRA for private-sector mandates ($142 million in 2011, adjusted annually for inflation) in four of the first five years in which the mandates were effective, rising to $1.4 billion per year in 2016, and totaling $3.3 billion over the 2012–2016 period.

Previous CBO estimate: On March 10, 2011, CBO transmitted a cost estimate for the HEALTH Act as ordered reported by the House Committee on the Judiciary on February 16, 2011. The version of H.R. 5 approved by the Committee on Energy and Commerce would permit the introduction of evidence of income from collateral sources at trial. The version approved by the Committee on the Judiciary did not contain that provision. Differences in the CBO cost estimates primarily reflect that difference in the bills.

Estimate prepared by: Federal Costs: Tom Bradley, Stuart Hagen, and Kirstin Nelson; Impact on State, Local, and Tribal Gov-

ernments: Lisa Ramirez-Branum; Impact on the Private Sector: Stuart Hagen.

Estimate approved by: Holly Harvey, Deputy Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Authority Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 establishes the short title of the bill as the "Help Efficient, Accessible, Low Cost, Timely Healthcare (HEALTH) Act of 2011."

Section 2. Findings and purpose

Section 2 states the findings and purpose of the bill.

Section 3. Encouraging speedy resolution of claims

Section 3 states that a health care lawsuit shall be commenced 3 years after the date of manifestation of injury or 1 year after the claimant discovers, or through the use of reasonable diligence should have discovered, the injury, whichever occurs first. In no event shall the time for commencement of a health care lawsuit exceed 3 years after the manifestation of injury unless tolled for any of the following: (1) upon proof of fraud; (2) intentional concealment; or (3) the presence of a foreign body, which has no therapeutic or diagnostic purpose or effect, in the person of the injured person. There is an exception for alleged injuries sustained by a minor before the age of 6, in which case a health care lawsuit may be commenced by or on behalf of the minor until the later of 3 years from the date of manifestation of injury, or the date on which the minor attains the age of 8. This time period is tolled for minors for any period during which a parent or guardian and a health care provider or health care organization have committed fraud or collusion in the failure to bring an action on behalf of the injured minor. The Committee does not intend the term injury to include business injuries. The manifestation of injury occurs when the damaging effect becomes known. The discovery of injury occurs when the damaging effect becomes known and the claimant suspects it was caused by wrongdoing.

Section 4. Compensating patient injury

Section 4 sets forth new guidelines regarding patients' ability to recover for certain types of damages. Subsection 4(a) provides that in any health care lawsuit, nothing in this Act shall limit a claimant's recovery for the full amount of available economic damages, notwithstanding the limitation in subsection (b). Under subsection 4(b), there can be no more than $250,000 in non-economic damages with respect to the same injury.

The cap in this section can apply separately to each party with a direct personal injury. For example, if there is a single class-action lawsuit where a drug manufacturer sold drugs that were taken by several individuals and those individuals suffered adverse events, each of those individuals could receive up to $250,000 in non-economic damages. Similarly, if a pregnant mother and her baby sustain physical injuries during an operation and a health care provider is found liable, then the mother and the baby could each recover damages up to the cap permitted in subsection 4(b).

Subsection 4(c) makes clear that courts should apply the $250,000 cap for non-economic damages without calculations that include discounting to present value. Whether a given award below the cap involves discounting, however, remains a function of separate state and Federal law. Juries will not be informed about the maximum award for non-economic damages.

Subsection 4(d) provides that each party shall be liable for the amount of damages allocated to such party. This allocation shall be determined in direct proportion to such party's percentage of responsibility for the damages. The Committee notes that this subsection does not override principles of vicarious liability. Furthermore, the "fair share" rule only applies when a judgment of liability is rendered.

Section 5. Maximizing patient recovery

Section 5 requires that courts supervise the arrangements for payment of damages to protect against conflicts of interests. This section also establishes a sliding fee schedule for the payment of attorneys' contingency fees. Payments are allocated as follows: 40 percent of the first $50,000 recovered by the claimant; 33⅓ percent of the next $50,000 recovered by the claimant; 25 percent of the next $500,000 recovered by the claimant; and 15 percent of any amount by which the recovery by the claimant(s) is in excess of $600,000.

The requirements for court supervision in the first paragraph do not apply outside of judicial proceedings. Thus, disputes settled prior to filing a lawsuit would not necessitate court supervision. The sliding fee schedule, by contrast, applies in all cases.

Section 6. Additional health benefits

Section 6 ensures that, in any health care lawsuit involving injury or wrongful death, a party may introduce evidence of collateral source benefits received, or reasonably likely to be received, from other parties. This section also restricts a provider of collateral source benefits from subrogating a claimant's recovery or obtaining any lien or credit against the claimant's damage award.

Section 7. Punitive damages

Section 7 specifies guidelines for awarding punitive damages. Under this section, punitive damages may be awarded, if otherwise permitted by applicable state or Federal law, against any person in a health care lawsuit. The amount of punitive damages awarded may be as high as two times the amount of economic damages awarded or $250,000, whichever amount is greater.

This section does not permit juries to be informed of the formula for calculating punitive damages. Moreover, punitive damages may only be awarded if it is first proven by clear and convincing evidence that a defendant acted with malicious intent to injure the claimant, or that such person deliberately failed to avoid unnecessary injury that such person knew the claimant was substantially certain to suffer. This section states that no demand for punitive damages shall be included in a health care lawsuit as initially filed. Further, punitive damages in healthcare lawsuits may not be awarded if compensatory damages are not awarded.

Paragraph 7(c)(1) shields manufacturers and distributors of medical products from punitive damages in certain instances. The provision is intended to shield those companies that are fully compliant with all Federal Food, Drug, and Cosmetic Act (FFDCA) laws and regulations (in the case of biological medical products, full compliance with the FFDCA and section 351 of the Public Health Service Act (PHSA) is required)). The FFDCA ensures the safety and effectiveness of drugs, devices, and biological products, all of which are covered by this section. Unless a claimant can demonstrate by clear and convincing evidence a lack of compliance with any FFDCA or PHSA section 351 law or regulation, then a manufacturer, distributor or supplier is shielded from punitive damages. All other damages, if proven, are still available to the claimant.

Under paragraph 7(c)(1), if a claimant can prove by clear and convincing evidence that a manufacturer, distributor or supplier has not complied with the FFDCA or section 351 of the PHSA, the claimant must then further prove that the harm attributed to the medical product resulted from the proven compliance failure. A technical violation of the Act that is wholly unrelated to the harm will not remove the shield provided for in this section. Rather, punitive damages will only be available to claimants who prove both a violation of the Act or regulations, and then draw the nexus between failed compliance and harm.

Paragraph 7(c)(1) applies to medical products, as defined in section 9. Included in this definition are nonprescription, over-the-counter (OTC) drugs. Some OTC drugs are marketed after approval of a new drug application (NDA) or abbreviated new drug application (ANDA). Some OTC drugs are also marketed pursuant to monographs or tentative final monographs promulgated by the Agency. While a final monograph is a regulation, a tentative final monograph represents the Agency's current position on the requirements for safe and effective labeling, formulation and marketing of the OTC drug product. In some instances, tentative final monographs have been in existence for decades, yet have never been finalized. Companies follow these so-called "tentative" monographs and deliver safe and effective drug products. The Committee believes that the mere fact that the FDA has not taken the last step to finalize monographs in existence for decades should not preclude

a manufacturer, distributor or supplier of such products from claiming the protections afforded by section 7(c).

Subsection 7(c) does not create an affirmative obligation on the part of the FDA to demonstrate compliance or noncompliance for the purposes of private litigation. The section also revokes the shield for persons: (1) who knowingly misrepresent information to the FDA or withhold information from the FDA; or (2) who bribe government officials for the purpose of obtaining approval of medical products. At the markup, the Committee adopted an amendment by Mr. Dingell that provides another exception to this shield. Under the amendment, a defendant could be liable for punitive damages if the defendant caused the medical product, which caused the claimant's harm, to be misbranded or adulterated. The Committee notes that term "misbranding" includes mislabeling and the term "adulterated" includes storing medical products at the incorrect temperature. The Committee also notes that a court or trier of fact may make the determination as to whether a product is misbranded or adulterated. There need not be an FDA determination.

Paragraph 7(c)(2) prohibits a health care provider who prescribes, or who dispenses pursuant to a prescription, a medical product that is approved by the FDA from being named as a party in a product liability lawsuit. Nothing in the paragraph prevents a court from consolidating cases involving health care providers and cases involving products liability claims.

Section 8. Authorization of payment of future damages to claimants in health care lawsuits

Section 8 requires the court, at the request of any party, to order that the award of future damages equaling or exceeding $50,000 be paid by periodic payments.

Section 9. Definitions

Section 9 defines many of the terms included in the legislation. The term "health care lawsuit" does not include a claim or action which is based on criminal liability; which seeks civil fines or penalties paid to Federal, State or local government; which is grounded in antitrust; or in which the dispute is over the price of health care goods or services. The latter exclusion addresses cases concerning price-fixing or over charging, not cases involving personal injury. Finally, the Committee intends the term "health care goods and services" to include those involving "the assessment or care of the health of human beings." Such terms include the monitoring, supervision, and provision of direct assistance to claimants.

Section 10. Effect on other laws

Section 10 states that this legislation does not apply to civil actions brought for a vaccine-related injury or death which is covered under provisions of the Public Health Service Act. It also states that nothing in the Act should affect any defense available to a defendant in a health care lawsuit or action under any other provision of federal law.

Section 11. State flexibility and protection of state's rights

Section 11 specifies many of the rules governing the relationship between the HEALTH Act and state and Federal laws. Specifically,

subsection 11(a) provides that provisions governing health care lawsuits outlined in the legislation preempt state law to the extent that state law prevents the application of these provisions. The legislation also supersedes the Federal Tort Claims Act (FTCA) to the extent that the FTCA provides for a greater amount of damages or contingent fees, a longer period in which a health care lawsuit may be commenced, or a reduced application of periodic payments of future damages. The FTCA is also superseded if it prohibits the introduction of evidence regarding collateral source benefits, or mandates or permits subrogation or a lien on collateral source benefits.

Under subsection 11(b), if an issue is not addressed by a provision of law established by this legislation, it shall be governed by otherwise applicable state or Federal law. The subsection further states that the Act does not preempt or supersede any law that imposes greater procedural or substantive protections for health care providers and health care organizations from liability, loss, or damages.

Subsection 11(c) states that this legislation does not preempt any state law (enacted before, on, or after the date of enactment of H.R. 5) that specifies a particular amount of compensatory or punitive damages (or the total amount of damages) that may be awarded in a health care lawsuit. The subsection also provides that the Act does not preempt any defense available to a party in a health care lawsuit under any other provision of state or Federal law.

Finally, the Committee notes the interrelationship of a number of provisions of H.R. 5. H.R. 5 does not create a cause of action or provide for a remedy or recovery that is not available or permitted under other provisions of applicable law. Moreover, any protections, defenses, or restrictions that are legally enforceable or available under contracts would still apply. Before applying the provisions of H.R. 5, courts should first review the law applicable to the appropriate claim or cause of action without reference to H.R. 5. Courts should then apply the limitations of H.R. 5 where appropriate.

Section 12. Applicability; effective date

Section 12 states that the provisions of the legislation apply to any health care lawsuit brought in Federal or state court, or subject to alternative dispute resolutions system, that is initiated on or after the date of the enactment of the Act, except that any health care lawsuit arising from an injury occurring prior to the date of the enactment of the Act is governed by the applicable statute of limitations provision in effect at the time the injury occurred.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

This legislation does not amend any existing Federal statute.

DISSENTING VIEWS

We, the undersigned members of the Committee on Energy and Commerce, oppose the passage of H.R. 5, the *Help Efficient, Accessible Low-cost Timely Healthcare (HEALTH) Act of 2011,* a bill to reform the nation's medical malpractice liability system. Accordingly, we submit the following comments to express our concerns about this profoundly flawed and deeply divisive legislation.

INTRODUCTION

H.R. 5, the *Help Efficient, Accessible, Low-cost, Timely Healthcare (HEALTH) Act of 2011,*[1] should not and will not become law. And for good reason. It is one-sided. It will not "fix" the problems it purports to address. And in one-fell swoop, it completely upends literally centuries of state law. Pure and simple—and contrary to the argument put forth by the bill's leading sponsor, H.R. 5 is not "meaningful [medical malpractice] reform.[2]

This is not to suggest that medical malpractic not a problem in this country. It is. On this point members on all sides of the issue agree.[3] But it is also complex and complicated and therefore, deserving of a very thoughtful and measured response. H.R. 5 is anything but that.

Congresses of the past share this belief. Indeed, since the 107th Congress, legislation identical or similar to H.R. 5 has repeatedly failed to reach the president's desk.[4] Most recently, the text of H.R. 5 was rejected in the form of the motion to recomit[5] offered by the Republicans at the conclusion of the House debate on the Affordable Care Act (ACA).[6] Its failure to become law under Democratic or Republican congresses and presidents alike is itself a verdict on its merits and efficacy.

We do not believe the case has been made for this House, for this Congress or for this President to follow a different course of action. While the current state-based system for dealing with medical malpractice is far from perfect, in our view, it is the framework through which appropriate modifications and improvements should be developed and implemented. A "one-size-fits-all" approach—the very vision of H.R. 5—not only tears this system down; it also im-

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[1] Hereinafter cited as the HEALTH Act.

[2] Rep. Phil Gingrey, *The HEALTH Act: A Real Reform Option* (online at: *http://gingrey.house.gov/News/DocumentSingle.aspx?DocumentID-240791* (accessed on May 19, 2011).

[3] See, *e.g.*, remarks of Rep. Frank Pallone (p. 12); Rep. Joe Pitts (p. 18); and Rep. Michael Burgess (p. 29) during the full Committee markup of H.R. 5 (House Committee on Energy and Commerce, *Markup on H.R. 5, HEALTH Act of 2011,* 112th Cong. (May 10, 2011) (transcript of the proceeding) and Ranking Member Henry Waxman (House Committee on Energy and Commerce, *Markup on H.R. 5, HEALTH Act of 2011*, 112th Cong., p. 21 (May 11, 2011) (transcript of the proceeding).

[4] House Committee on the Judiciary, *HEALTH Act of 2011*, Dissenting Views, 112th Cong., p. 88 (Mar. 17, 2011) (H. Rept. No. 112–39, Part 1).

[5] *Common Sense Health Care Reform and Affordability Act*, H. Amdt. 510, 111th Cong. (2009) (offered by Minority Leader John Boehner as a substitute amendment to H.R. 3963, the *Affordable Health Care for America Act).*

[6] The ACA is comprised of two public laws, P.L. 111–148 and P.L. 111–152.

poses upon the states, a new, unified, and untested legal structure with little regard for the potential consequences.

There are many particulars in the bill and the arguments of its advocates to which we object. The views expressed here focus only on those specifics that received extensive attention during the Committee's consideration of the legislation:

- the mis-representation of the California law upon which H.R. 5 is supposedly based;
- the bill's wholesale preemption of state medical malpractice law;
- its broad and expansive scope that goes beyond traditional medical malpractice; and
- its unparalleled protections for manufacturers of drugs and medical devices approved by the Food and Drug Administration (FDA).

As such, and in recognition of both the thorough and thoughtful analysis of all aspects of the legislation by the Committee on the Judiciary minority members and our shared jurisdiction over H.R. 5, we incorporate by reference herein the dissenting views included in the report filed by the Corrittee on the Judiciary on H.R. 5 by members of that Committee who oppose the bill.[7] We concur in those views and stand with these colleagues in wholly rejecting this legislation.

BACKGROUND AND OVERVIEW

A medical malpractice claim is an allegation of harm or injury caused by a health care provider. A medical malpractice lawsuit is a civil (i.e., non-criminal) action in which an individual making such an allegation seeks damages against those health care providers the individual believes is legally responsible or liable for the harm or injury that has occurred. Medical malpractice liability arises when a health care provider engages in negligence or an intentional wrongdoing.[8] "The general difference between an action based in negligence and one based in intentional tort [wrongdoing] is that a 'medical procedure poorly performed might constitute negligence, while a medical proced correctly performed that was not consented to might constitute an intentional tort.'"[9]

Traditionally, the principals of medical malpractice liability and the procedures for the conduct of medical malpractice lawsuits have been governed by state law.[10] In fact, it has always been that way.

Periodically, however, Congress has engaged in a debate about various aspects of medical malpractice, generally in response to sharply rising medical malpractice insurance premiums for physicians as well as reports of activities strongly associated with such increases—the difficulty of doctors in some specialties obtaining any malpractice coverage at all and the decision of many physi-

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[7] House Committee on the Judiciary, *HEALTH Act of 2011,* Dissenting Views, 112th Cong., pp. 88–120 (Mar. 17, 2011) (H. Rept. No. 112–39, Part 1).

[8] See Garner, BA (editor-in-chief), *Black's Law Dictionary* (9th ed. 2009), ("malpractice: medical malpractice") (available online at: *http://www.westlaw.com*); and Keeton, WP, Dobbs, DB, Keeton, RE, and Owen, DG, *Prosser and Keeton on Torts* (5th ed. 2004), pp. 185–187 (West Group, Hornbook Series).

[9] Congressional Research Service, *Medical Malpractice Liability Reform: Legal Issues and 50-State Surveys on Tort Reform Proposals,* Rept. No. R411661, P. 2 (Mar. 28, 2011).

[10] *Id.* at Summary.

cians to leave the practice of medicine altogether because the insurance they could secure was too expensive.[11] Reform the system and premium charges will subsequently fall, resulting in good things for doctors, for their patients, and for the nation's health care bill—so the argument has gone. This flawed logic apparently failed to sway past Congresses, which chose not to act upon it.

Sponsors of the HEALTH Act have put forth the same defective reasoning, stating that H.R. 5 "will . . . bring down the cost of medical malpractice insurance which will reduce the overall cost of health care in this country,"[12] and making lower malpractice insurance premiums one of the driving forces behind the legislation.[13] Yet, data indicate that today, the overall medical liability insurance market is not in crisis.[14] They also show it is the direct regulation of insurance companies—and not a cap on non-economic damages (one of the core elements of H.R. 5)—that is responsible for the reductions in insurance premiums that have been seen.[15]

Nor is there compelling evidence that the HEALTH Act will achieve the other major goals articulated by its advocates[16]—to eliminate the practice of so-called defensive medicine;[17] to "put the focus back on patients";[18] and to significantly reduce health care costs.[19]

Despite the poor prognosis for success of the approach taken by H.R. 5, and as previously acknowledged, we believe medical malpractice is a very real and significant concern that requires appropriate attention. Malpractice insurance premiums remain high in

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[11] Congressional Research Service, *Medical Malpractice: Background and Legislation in the 112th Congress,* Rept. No. R41693, p. 1 (Apr. 26, 2011).

[12] Remarks of Rep. Phil Gingrey, House Committee on Energy and Commerce, *Markup on H.R. 5, HEALTH Act of 2011,* 112th Cong., p. 151 (May 11, 2011) (transcript of the proceeding).

[13] HEALTH Act, Section (2)(b)(2).

[14] Congressional Research Service, *Medical Malpractice: Background and Legislation in the 112th Congress,* Rept. No. R41693, p. 1 (Apr. 26, 2011); Testimony of Joanne Doroshow, Executive Director, Center for Justice & Democracy, House Committee on Energy and Commerce, *Hearing on the Cost of the Medical Liability System Proposals for Reform, Including H.R. 5, HEALTH Act of 2011,* 112th Cong., p. 25 (Apr. 6, 2011) (transcript of the proceeding).

[15] This is precisely what happened in the state of California. After the state's cap on non-economic damages for medical malpractice cases was enacted in 1975 as part of MICRA, malpractice premium rates rose by some 450%. They only dropped in 1988 when state Proposition 103 was passed, setting up a state regulatory process for insurance rates. (Testimony of Joanne Doroshow, Executive Director, Center for Justice & Democracy, House Committee on Energy and Commerce, *Hearing on the Cost of the Medical Liability System Proposals for Reform, Including H.R. 5, HEALTH Act of 2011,* 112th Cong., p. 51 (Apr. 6, 2011) (transcript of the proceeding)).

[16] HEALTH Act, Section (2)(b).

[17] Congressional Research Service, *Medical Malpractice: Background and Legislation in the 112th Congress,* Rept. No. R41693, pp. 4–5; 7 (Apr. 26, 2011); Testimony of Allen B. Kachalia, MD, JD, Medical Director, Brigham and Women's Hospital (p. 34) and Joanne Doroshow, Executive Director, Center for Justice & Democracy (p. 70), House Committee on Energy and Commerce, *Hearing on the Cost of the Medical Liability System Proposals for Reform, Including H.R. 5, HEALTH Act of 2011,* 112th Cong., (Apr. 6, 2011) (transcript of the proceeding).

[18] Rep. Phil Gingrey, *The HEALTH Act: A Real Reform Option* (online at: *http://gingrey.house.gov/News/DocumentSingle.aspx?DocumentID=240791* (assessed on May 19, 2011). See Testimony of Allen B. Kachalia, MD, JD, Medical Director, Brigham and Women's Hospital, House Committee on Energy and Commerce, *Hearing on the Cost of the Medical Liability System Proposals for Reform, Including H.R. 5, HEALTH Act of 2011,* 112th Cong., p. 34 (Apr. 6, 2011) (transcript of the proceeding). See also the 2009 letter to Senator Orrin Hatch from the Congressional Budget Office (CBO) on the effects of medical malpractice reform in which CBO stated that ". . . imposing limits on [the right to sue for damages that result from negligent health care] might be expected to have a negative impact on health outcomes." (Letter from Douglas W. Elmendorf, Director, Congressional Budget Office to Senator Orrin G. Hatch, p. 5 (Oct. 9, 2009) (online at: *http:cbo.gov/ftpdocs/106xx/doc10641/10-09-Tort_Reform.pdf*)

[19] Congressional Research Service, *Medical Malpractice: Background and Legislation in the 112th Congress,* Rept. No. R41693, pp. 4–5 (Apr. 26, 2011).

some parts of the country.[20] And the justice system does not always work as it should. Many legitimate malpractice cases are never filed and when they are, in some instances, severely injured individuals do not receive just compensation; in others, damages appear to be excessive.[21] These issues can and should be addressed in the proper forum.

But beyond all this lies the root problem of medical malpractice—medical errors. As summarized succinctly by Congressional Research Service experts, "medical errors can lead to injury, and injury is the medical basis on which a malpractice claim is made."[22] Such mistakes appear to be at an all-time high. For example, a recent study from the leading journal Health Affairs indicates that the number of confirmed serious, adverse events occurring in hospitalized patients is at least ten times higher than previously reported, with such events taking place in one-third of hospital admissions.[23]

H.R. 5 makes no attempt to address this fundamental issue. Shockingly, other than improving the exchange of information, reducing medical errors and improving patient care is not even listed among the purposes of the legislation.[24] Moreover, proponents of the HEALTH Act specifically rejected an amendment to the bill offered at the full Committee markup that would have included the achievement of these goals in that section of the bill.[25] This makes no sense given that experts on all sides of the malpractice issue agree: We must address medical mismanagement as part of any fundamental reform of our health care system.[26]

The Affordable Care Act takes on this challenge. It includes several provisions designed to improve patient safety and reduce unnecessary medical errors.[27] The Administration has already begun

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[20] See *e.g.,* Testimony of Troy M. Tippetts, MD, Past President, American Association of Neurological Surgeons, House Committee on Energy and Commerce, *Hearing on the Cost of the Medical Liability System Proposals for Reform, Including H.R. 5, HEALTH Act of 2011,* 112th Cong., p. 115–116 (Apr. 6, 2011) (transcript of the proceeeding); and comments of Rep. Tim Murphy during the full Committee markup of H.R. 5 (Remarks of Rep. Tim Murphy, House Committee on Energy and Commerce, *Markup on H.R. 5, HEALTH Act of 2011,* 112th Cong., p. 43 (May 11, 2011) (transcript of the proceeding)).

[21] Testimony of Allen B. Kachalia, MD, JD, Medical Director of Quality and Safety, Brigham and Women's Hospital, House Committee on Energy and Commerce, *Hearing on the Cost of the Medical Liability System Proposals for Reform, Including H.R. 5, HEALTH Act of 2011,* 112th Cong., p. 32 (Apr. 6, 2011) (transcript of the proceeding).

[22] Congressional Research Service, *Medical Malpractice: Background and Legislation in the 112th Congress,* Rept. No. R41693, p. 6 (Apr. 26, 2011).

[23] Classen DC, Resar R, Griffin F, Federico F, Frankel T, Kimmel N, Whittington JC, Frankel A, Seger A and James BC, *'Global Trigger Tool' Shows That Adverse Events in Hospitals May Be Ten Times Greater Than Previously Measured,* Health Affairs, 30, No. 4 (2011):581–589.

[24] HEALTH Act, Section 2(b).

[25] House Committee on Energy and Commerce, *Markup on H.R. 5, HEALTH Act of 2011,* 112th Cong., pp. 201–207; 229–237 (amendment offered by Rep. Ed Towns) (May 11, 2011) (transcript of the proceeding).

[26] "Reform should address how well the malpractice system improves the quality of care that we provide. After all, this is one of the system's main goals." (Testimony of Allen B. Kachalia, MD, JD, Medical Director of Quality and Safety, Brigham and Women's Hospital, House Committee on Energy and Commerce, *Hearing on the Cost of the Medical Liability System Proposals for Reform, Including H.R. 5, HEALTH Act of 2011,* 112th Cong., p. 33 (Apr. 6, 2011) (transcript of the proceeding)).

[27] See, *e.g.,* ACA Section 2702 (Medicaid payment adjustment for Health care-acquired conditions); Section 3001 (hospital value-based purchasing program); Section 3008 (Medicare payment adjustment for conditions acquierd in hospitals; Section 3011 (national strategy to improve health care quality); Section 3012 (interagency working group on health care quality); Section 3013 (quality measure development); Section 3014 (quality measurement); Section 3015 (quality data collection, public reporting); Section 3021 (Center for Medicare and Medicaid Innovation); Section 3025 (hospital readmissions reduction program); Section 3026 (community-based care

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to use these authorities to address patient safety in a significant fashion.[28] When fully implemented and evaluated, theses types of measures are expected to have a positive impact on the medical malpractice situation as it exists today.

In the meantime and in recognition of the immediate desire to address a number of medical malpractice concerns, the ACA also provides $50 million for demonstration projects to allow states to develop, implement and evaluate alternatives to current malpractice litigation practices and procedures.[29] The Department of Health and Human Services (HHS) is now in process of awarding those grants. In addition, the President's budget proposal for FY 2012 calls for $100 million in state medical malpractice demonstration projects (followed by $50 million for each of FY 2013 through FY 2015) to be administered by the Department of Justice in consultation with HHS.[30] This demonstration project approach to malpractice reform has also been endorsed by a recent study on behalf of the Medicare Payment Advisory Commission (MedPAC).[31]

We believe these efforts, combined with those designed to improve patient outcomes, form the basis for real and truly meaningful medical malpractice reform that can have a substantial impact on health care costs. They should be given every opportunity to proceed and succeed. As currently structured, H.R. 5 cannot produce same results. In our view, then, once again, the legislation should be turned back and aside.

H.R. 5 IS NOT MICRA

Since its introduction, proponents of the HEALTH Act have suggested that it is modeled on the Medical Injury Compensation Reform Act (MICRA),[32] medical malpractice legislation that was enacted in California in 1975.[33] At best, this is an unintentional misreading of the California law; at worse, it is an attempt to mislead members into believing that a vote for H.R. 5 is a vote for MICRA. As the plain language of H.R. 5 makes clear, this is simply not true.

The differences between MICRA and H.R. 5 on a number of key issues are stark and important:

• *MICRA applies only to cases involving a doctor, a nurse, or a hospital (and similar health care providers).*

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transitions program); Section 3501 (health care delivery system research; quality improvement technical assistance); Section 3503 (medication management services in treatment of chronic disease); and Section 3508 (demonstration program to integrate quality improvement and patient safety training into clinical eduction of health professionals).

[28] For a description of these initiatives, see HHS, *Partnership for Patients: Better Care, Lower Costs* (Apr. 12, 2011) (online at: *http://www.healthcare.gov/news/factsheets/partnership04122011a.html*).

[29] ACA, Section 10607.

[30] Office of Management and Budget, Exc. Office of the President, Budget of the United States Government, Fiscal Year 2012, p. 191 (online at: *http://www.whitehouse.gov/omb/budget/Overview/*).

[31] Mello MM, Kachalia A, *Evaluation of Options for Medical Malpractice System Reform, MedPAC, No. 10–2 (Apr. 2010).*

[32] MICRA is codified at different sections within the California Code. See Cal. Business and Professions Code, Section 6146; Cal. Civil Code, Sections 3333.1 and 3333.2; and Cal. Code of Civil Procedure, Section 667.7.

[33] See e.g., Internal Memorandum from Committee Staff to Members of the House Committee on Energy and Commerce, *Full Committee Markup on May 10–11, 2011*, p. 5., in which Committee staff state: "H.R. 5 mirrors the provisions of MICRA . . ." and comments of Rep. Joe Pitts during the full Committee markup of H.R. 5. (Remarks of Rep. Joe Pitts, House Committee on Energy and Commerce, *Markup on H.R. 5, HEALTH Act of 2011,* 112th Cong., pp. 18–19 (May 10, 2011) (transcript of the proceeding).

The Health Act is breathtaking in its scope. Its provisions—including caps on non-economic and punitive damages—cover all "healthcare lawsuits," providing protections not only for physicians and hospitals, but also for nursing homes, insurance companies, health maintenance organizations, medical device manufacturers, and pharmaceutical companies.[34] This approach goes far beyond what is typically contemplated as a medical malpractice case.

• *MICRA applies only to cases of professional negligence and not other causes of action.*

H.R. 5 takes in all "health care liability actions . . . regardless of the theory of liability" on which a lawsuit is based.[35] This includes cases of intentional wrongdoing—cases in which a patient does not consent to a medical or health care service—as well as negligence.

• *MICRA does not include any limitations on claims brought against pharmaceutical and medical device companies.*

Except in rare instances, the HEALTH Act provides complete immunity from punitive damages to manufacturers of drugs and devices that have been approved by the FDA or that are generally recognized as being safe and effective in accordance with FDA standards.[36] Such blanket immunity is virtually unprecedented.[37]

• *MICRA does not cap punitive damages or require special action before punitive damages can be awarded.*

H.R. 5 includes a cap on punitive damages—$250,000 or twice the amount of non-economic damages, whichever is greater.[38] Moreover, H.R. 5 establishes special procedures and conditions that must be met before punitive damages can be sought in a lawsuit,[39] making it far more difficult for such damages to be awarded.

• *MICRA restricts its limitations on attorney contingency fees only to cases brought against health care providers.*

The HEALTH Act imposes limits on contingency fees for attorneys involved in a much broader spectrum cases, including those in which a claim is brought against a pharmaceutical or medical device manufacturer.[40] Such limits, in effect, create hurdles for an injured party to obtain the best possible legal representation.

These dramatic differences between the two pieces of legislation—along with others—illustrate just how misguided and deceptive it is to assert that H.R. 5 is a MICRA look-alike. Moreover, these distinctions highlight the extreme nature of H.R. 5. Indeed, the HEALTH Act not only goes far beyond what is covered and considered by MICRA; it is, in fact, a constellation of reforms that when taken together in a single package, constitutes a radical transformation of the nation's tort system and not simply medical malpractice reform. Such transformation is neither necessary nor warranted and certainly is not what MICRA stands for.

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[34] HEALTH Act, Section 9(9).
[35] HEALTH Act, Section 9(8).
[36] HEALTH Act, Section 7(c).
[37] Generally speaking, punitive damages cannot be assessed against vaccine manufacturers under the National Vaccine Injury Compensation Program (established in Title 21 of the Public Health Service Act) in those vaccine injury cases in which an injured person rejects compensation and elects to file a lawsuit in court. However, as discussed in these views on the issue of states' rights, we believe the Compensation Program is a unique and special initiative, completely distinguishable from the HEALTH Act.
[38] HEALTH Act, Section 7(b)(2).
[39] HEALTH Act, Section 7(a).
[40] HEALTH Act, Section 5.

H.R. 5 IS AN ASSAULT ON STATES' RIGHTS

At its core, H.R. 5 is a wholesale refutation of the federalist approach to medical malpractice liability under which states have traditionally developed their own law and established their own rules to govern these kinds of cases.[41] Every state is affected by the legislation and, despite suggestions to the contrary, no state will be able to keep its current malpractice law intact.[42]

Such action is troubling on many fronts. Of greatest concern perhaps—beyond the bill's direct and unjustified attack on states' rights—is the magnitude of what is contemplated under the legislation.

In one form or another, all 50 states have addressed the issue of medical malpractice liability and no two states have come out in exactly the same place. Instead, each has developed a process and set of procedures for medical malpractice cases that best meet the needs of its citizens and own legal system. Thus, for example, some states have enacted caps on damages in malpractice cases; other states have laws or even constitutional provisions that specifically prohibit them. The same can be said for many of the other reforms included in the HEALTH Act such as those related to joint and several liability, statutes of limitations, attorney contingency fees, and periodic payments for awards.[43]

No state, however, has attempted to capture every action against "a health care provider, a health care organization, or the manufacturer, distributor, supplier, marketer, promoter, or seller of a medical product, regardless of the theory of liability on which the claim is based"[44] under the umbrella of a single medical malpractice reform initiative. No state, then—not a single one—has in place the "new world" malpractice order set out in H.R. 5.

The sweep of H.R. 5 is simply stunning. In short, advocates of the HEALTH Act would have the federal government strike down the medical malpractice law of all 50 states[45] and replace it with their own, uniform, first-of-a-kind version of what that law should be. It comes as no surprise, then, that the bi-partisan National Conference of State Legislatures strongly opposes the legislation and concludes that "federal malpractice legislation is unnecessary."[46]

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[41] States have traditionally set their own rules and procedures for dealing with other health-related matters, e.g., licensure of medical professionals and the regulation of health insurance.

[42] "I have heard or been briefed that Section 11 [state flexibility] of H.R. 5 does protect the states' rights, but if you read it, it is extremely restrictive, and most states that have medical liability or medical malpractice reform laws will have this federal law supersede it. Read Section 11. It is a one size fits all." (Remarks of Rep. Lee Terry, House Committee on Energy and Commerce, *Markup on H.R. 5, HEALTH Act of 2011,* 112th Cong., p. 26 (May 10, 2011) (transcript of the proceeding)).

[43] Congressional Research Service, *Medical Malpractice Liability Reform: Legal Issues and 50-State Surveys on Tort Reform Proposals.* Rept. No. R41661 (Mar. 29, 2011).

[44] HEALTH Act, Section 9(7).

[45] The HEALTH Act allows for only two exceptions under which state law would not be preempted: (a) state law that provides greater procedural or substantive protections for health care providers and organizations than those found in H.R. 5 (HEALTH Act, Section 11(b)(2)); and (b) state law that specifies an exact dollar figure for a cap on either non-economic or punitive damages; such figures would remain untouched, regardless of their amount (HEALTH Act, Section 11(c)). The former demonstrates the one-sided approach of the HEALTH Act—state laws that protect health care providers and organizations are preserved while state laws that protect patients and consumers are tossed out.

[46] Letter from Assemblyman William Home (NV) and Rep. Jerry Madden (TX), National Conference of State Legislatures, to Rep. Joe Pitts and Rep. Frank Pallone (Apr. 4, 2011) (online at: *http://www.ncsl.orgdefault.aspx?tabid=22497*).

The inconsistency of this vision cannot go unmentioned. By and large, proponents of H.R. 5 are the very same members who have staunchly spoken out in favor of states rights—at times even with respect to medical malpractice law.[47] Yet, in this instance, they have squarely turned their backs on this principle. This reincarnation is stunning as well.[48]

HEALTH Act proponents cite two statutes in support of their federalist approach to medical malpractice reform[49]—the Federal

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[47] See, e.g., the debate over the amendment offered by Rep. Tammy Baldwin during the full Committee mark up of H.R. 5. The text of that amendment reads: "Nothing in this Act shall be construed to modify or preempt any substantive or procedural state law governing medical malpractice or medical liability cases or to impair state authority regarding legal standards or procedures used in medical malpractice or medical product liability cases." This language is identical to that found in Section 2(c) of H.R. 816, *Provider Shield Act of 2011,* introduced by Rep. Phil Gingrey, the primary sponsor of H.R. 5, in February 2011. Yet Rep. Gingrey, along with two other co-sponsors of H.R. 816, Reps. Tim Murphy and Michael Burgess—as well as all other proponents of the HEALTH Act—voted against the Baldwin amendment. (House Committee on Energy and Commerce, *Markup on H.R. 5, HEALTH Act of 2011*, 112th Cong., pp. 6–65 (amendment offered by Rep. Tammy Baldwin) (May 11, 2011) (transcript of the proceeding)). All of these members went on to reject a narrower amendment to carve out and preserve only state constitutional provisions that address medical malpractice liability. (House Committee on Energy and Commerce, *Markup on H.R. 5, HEALTH Act of 2011,* 112th Cong., pp. 66–88 (amendment offered by Rep. John Barrow) (May 11, 2011) (transcript of the proceeding)). During the markup, Rep. Lee Terry emphasized how support for H.R. 5 is inconsistent with support for states rights: "It seems ironic to me that as someone who passionately opposed the nationalization of our health care based on the fact that this was extreme federalism and usurps states' rights that now, because it is politically expedient for us on this side of the aisle, that we are now engaging in that same philosophical conduct." (Remarks of Rep. Lee Terry, House Committee on Energy and Commerce, *Markup on H.R. 5, HEALTH Act of 2011,* 112th Cong., p. 26 (May 10, 2011) (transcript of the proceeding)). Rep. Terry's point is underscored in an op-ed piece against H.R. 5, penned by Professor Randy Barnett of Georgetown University Law Center at the very time this Committee report is being filed. Professor Barnett is a well-known and ardent opponent of the ACA who has twice this year testified against the law before Congress, co-authored the National Federation of Independent Business's amicus brief on the constitutionality of the Act for the 11th Circuit Court of Appeals, and has appeared with Republicans to promote its repeal. In his op-ed piece, Professor Barnett states:

> But tort law—the body of rules by which persons seek damages for injuries to their person and property—has always been regulated by the states, not the federal government. Tort law is at the heart of what is called the 'police power' of states . . . Indeed, if Congress can now regulate tort law, which has always been at the core of state powers, then Congress, and not the states, has a general police power. . . . While I strongly support reforming our malpractice laws to protect honest doctors from false claims and out-of-control state juries, this reform must come at the state level, as it has in recent years. Constitutional law professors have long cynically ridiculed a 'fair-weather federalism' that is abandoned whenever it is inconvenient to someone's policy preferences. If House Republicans ignore their pledge to America to assess the Constitution themselves, and invade the powers 'reserved for the states' affirmed by the Tenth Amendment, they will prove my colleagues right.

Barnett, R. *Tort Reform and the GOP's Fair-Weather Federalism,* Washington Examiner (May 21, 2011). It is also noteworthy that during Committee consideration of H.R. 5, one proponent of the bill pointed to the efforts of Mississippi Governor Haley Barbour in enacting a "comprehensive tort reform law that has significantly reshaped our [Mississippi] medical liability system" as a model Congress should "emulate." (Remarks of Rep. Gregg Harper, House Committee on Energy and Commerce, *Markup on H.R. 5, HEALTH Act of 2011,* 112th Cong., p. 47 (May 10, 2011) (transcript of the proceeding)). Yet Governor Barbour is on record before the Committee in opposing federal legislation that would preempt state medical malpractice law. (Committee on Energy and Commerce, *Hearing on the Consequences of Obamacare: Impact on Medicaid and State Health Care Reform,* 112th Cong., p. 111 (Mar. 1, 2011) (transcript of the proceeding)).

[48] We are compelled to comment as well on the inconsistency concerning the assertions of H.R. 5 advocates regarding the bill's constitutional authority. They cite Article I, Section 8, Clause 3 of the Constitution as the basis for the bill, stating that "health-care related lawsuits are activities that affect interstate commerce" and argue that such lawsuits contribute to the high costs of health care. (Statement of Rep. Phil Gingrey, Congressional Record, H434 (Jan. 24, 2011)). Yet, for the past two years, supporters of the HEALTH Act have argued precisely the opposite with respect to the ACA—that its provisions violate the Constitution's Commerce Clause even though, they too, are designed to address the high costs of health care.

[49] See, e.g., the comments of Rep. Brian Bilbray (pp. 23–24); Rep. Phil Gingrey (p. 25); and Rep. Bill Cassidy (pp. 31–32) on this point during the full Committee markup. (House Committee on Energy and Commerce, *Markup on H.R. 5, HEALTH Act of 2011,* 112th Cong., (May 11, 2011) (transcript of the proceeding)).

Torts Claim Act (FTCA)[50] and the National Childhood Vaccine Injury Act[51]—as examples of congressional intervention in medical malpractice liability. We submit at neither law is on point.

Enacted in 1946, the FTCA was established to provide a mechanism through which the federal government could be sued and held liable for damages in civil or tort actions. (Until then, under our traditional common law borrowed from the British, the government enjoyed sovereign immunity, meaning that it could never be held liable for claims, regardless of its degree of culpability.) The FTCA partially waives the government's sovereign immunity by authorizing civil suits (with some exceptions) to be brought against the United States and making federal employees acting within the scope of their employment immune from liability—that is, it makes the United States liable for torts of its employees to the extent private employers are liable under state law for the torts of their employees.

In contrast to the HEALTH Act, the FTCA does not create federal tort law; it simply makes the federal government subject to state tort law. The law of the state in which the misconduct occurs governs both the substantive and procedural aspects of FTCA cases.

Congress can, however, place limitations on its waiver of sovereign immunity. It has, for example, not waived sovereign immunity for punitive damages so no individual can collect such damages from the federal government. Under the FTCA specifically, Congress has capped attorney fees and requires that individuals seeking redress against the federal government first file an administrative claim with the appropriate federal agency before bringing a lawsuit in federal court. But once that lawsuit is initiated, state law will fully apply, including state law regarding the award of non-economic damages.[52] Under H.R. 5, a completely different set of rules—those established under the legislation—would be used instead.[53]

The National Childhood Vaccine Injury Act does not work either as a justification for H.R. 5. Created in 1986, this statute established a new "no-fault" system to compensate individuals who have been injured by vaccines routinely administered to children. Unlike H.R. 5, the scope of this law is quite narrow and targeted. It was enacted to address two very specific and overriding concerns with which the federal government has a direct interest: "(a) the inadequacy—from both the perspective of vaccine-injured persons as well as vaccine manufacturers—of the [then current] approach to

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[50] United States Code, Title 28, Chapter 171.

[51] Public Health Service Act, Title 21, Subtitle 2.

[52] The following example illustrates how the FTCA interacts with state law. A doctor employed by a federally-qualified health center in Delaware commits medical malpractice on one of the center's patients. Since the doctor is a federal employee, the patient cannot sue either the health center or the doctor directly, but can file a claim against the federal government under the procedures set forth in the FTCA. Under those procedures, the patient must first file an administrative claim with HHS. If the patient is not satisfied with the determination made by HHS, she may then file a medical malpractice cause of action against the government in the U.S. District Court of Delaware. That action will be based on Delaware state law which does not cap non-economic damages.

[53] See HEALTH Act, Section 9(8), which defines "health care liability action" to include malpractice cases brought in federal as well as state court. Moreover, the HEALTH Act specifically supersedes provisions of the FTCA related to damages, attorney contingency fees, statutes of limitations, and periodic payments of awards. (HEALTH Act, Section 11(a).)

compensating those who have been damaged by a vaccine; and (b) the instability and unpredictability of the childhood vaccine market.[54] As discussed in our Introduction to these dissenting views, we do not believe supporters of H.R. 5 have made the same kind of compelling argument to rationalize direct federal intervention into the issue of medical malpractice liability. Nor do we believe that the legislation is designed to adequately address that problem.

But beyond their differences in purpose and scope is the primary substantive distinction between H.R. 5 and the vaccine compensation law. Under the National Childhood Vaccine Injury Act, injured patients who meet the relevant and relatively generous eligibility criteria are awarded compensation from a fund supported by a federal tax on specified vaccines. Those who are dissatisfied with their awards may take their claim to court.

It is true that such claims are litigated under special rules and limitations that, like the HEALTH Act, affect state tort law. But those rules and limitations must be understood in the context of the larger National Childhood Vaccine Injury Program which, as previously noted, makes federally supported compensation—including economic and non-economic damages—available to injured persons. H.R. 5 does not, of course, include a compensation component; it merely changes the rules under which compensation can be awarded, making it far more difficult for justice to be best served. The difference between the two pieces of legislation in this regard could not be more profound.

In sum, H.R. 5 is unprecedented in its approach to, and in its reach and impact on, state medical malpractice liability law—for no justified end. And there is no relevant federal statute which legitimately serves as its prototype. In our view, then, this legislation—on these grounds alone—should be rejected.

H.R. 5 Reaches Too Far and Protects Too Many

As described in our Background and Overview to these dissenting views, medical malpractice typically refers to negligent wrongdoing by health professionals, resulting in harm to a patient. As we also discussed, H.R. 5 goes well beyond this understanding to include all health care liability actions involving "a health care provider, a health care organization, or the manufacturer, distributor, supplier, marketer, promoter, or sellers of a medical product, regardless of the theory of liability on which the claim is based."[55] Such a broad, expansive and sweeping perspective of medical malpractice is not to be found in the law books of any of the 50 states. H.R. 5 simply goes too far.

Three areas that H.R. 5 touches directly received considerable attention during the Committee's deliberations over the HEALTH Act:

- the HEALTH Act's inclusion of intentional torts;
- its protections for nursing homes; and
- the inclusion of lawsuits involving FDA-approved drugs and medical devices.

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[54] House Committee on Energy and Commerce, *National Childhood Vaccine Injury Act of 1986*, 99th Cong., p. 7 (Sept. 26, 1986) (H. Rept. 99–908, Part 1).

[55] HEALTH Act, Section 9(7).

Here we address the first two issues; the last is discussed separately in the section, *H.R. 5 Is An Unwarranted Windfall for Pharmaceutical and Medical Companies*.

INTENTIONAL HARMS

In the context of medical malpractice, an intentional tort or wrongdoing occurs when a patient does not consent to a procedure or service—even if it is performed or provided correctly. In such cases, the health care provider is "generally alleged to have intentionally acted in a fashion that ultimately caused harm to the patient."[56] Intentional torts include claims such as assault, sexual assault and rape, battery, false imprisonment (unlawfully holding someone against their will), invasion of privacy, conversion (theft), misrepresentation, and fraud.[57]

Except in those instances in which a claim is based upon criminal liability,[58] the HEALTH Act affords its liability protections to those who have committed these and similar kinds of acts, including conduct that results in egregious injury or even death to patients. Nothing in the Committee's deliberations over H.R. 5—not a shred of testimony presented at the Health Subcommittee hearing or any point of debate made during the full Committee markup—documents or justifies this position. This is yet another example of how extreme H.R. 5 is in its approach to medical malpractice reform.

Consider these real world examples:

• Dr. Ben D. Ramaley, a Connecticut obstetrician/gynecologist, substituted his own sperm for that of a patient's husband during an artificial insemination procedure. The couple went on to have a set of twins, only to learn after their birth and a subsequent paternity test that the treating physician (and not the husband) was the biological father. The state's Department of Public Health fined the doctor $10,000 for "using the wrong man's sperm" in the procedure, but allowed him to keep an unrestricted license to practice medicine. The couple's medical malpractice lawsuit against the physician was settled, but there is no record of Dr. Ramaley's ever facing criminal charges.[59]

• Dr. Kermit Gosnell, a Pennsylvania physician, performed late term abortions on minority and low-income women—many of whom were pregnant for the first time—without informing the mothers he was doing so. He falsified ultrasounds used to determine the duration of the pregnancy and taught his staff to hold the probe in such a way that the fetuses looked smaller. Few, if any, of the women who were sedated during the procedure knew that their babies had been delivered alive. And because they were misled about the length of their pregnancies, none of them was given the opportunity to make an informed choice about what to do about their

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[56] Congressional Research Service, *Medical Malpractice Liability Reform: Legal Issues and 50-State Surveys on Tort Reform Proposals*, Rept. No. R41661, p. 2 (Mar. 28, 2011).

[57] See Gamer, BA (editor-in-chief), *Black's Law Dictionary)* (9th ed. 2009) ("battery: tort"); ("tort: intentional tort") (available online at: *http://www.westlaw.com*); and Keeton, WP, Dobbs, DB, Keeton, RE, and Owen, DG, *Prosser and Keeton on Torts* (5th ed. 2004), pp. 33–54 (West Group, Hornbook Series).

[58] HEALTH Act, Section 9(7).

[59] Greenwich Times, *Doctor Uses Wrong Man's Sperm to Produce Twins* (Nov. 12, 2009) (online at: http://www.ctpost.com/default/article/Doctor-uses-wrong-man-s-sperm-to-produce-twins-215345.php).

pregnancy. Dr. Gosnell is now facing criminal charges, but has not yet been found guilty of any crime. At least 46 lawsuits have been filed against him in the past.[60]

• Mildred Taylor, who suffered from Alzheimer's disease, but was otherwise healthy, was a resident at the Prestige Assisted Living facility in Marysville, California. On June 24, 2004, the wheelchair-bound, 98-year old was falsely imprisoned when she was left outside overnight by facility staff. No one made any attempt to find her, even though staff knew she was not in her room. No one called Ms. Taylor's family and no one contacted the police to report her missing. She was not found until the next morning when her body temperature had dropped to 93 degrees and her right leg had become severely swollen. Ms. Taylor remained bed-ridden and debilitated until her death less than one month later. The California Department of Social Services cited Prestige for violating Ms. Taylor's rights, but did not even fine the company.[61]

In each of these cases, a "health good or service"—as that term is defined in H.R. 5[62]—was provided, arguably bringing them within the purview of H.R. 5. In the instance of Mildred Taylor, we think our position is made even stronger by the comments found in the majority views of this Committee report that the term "health care goods and services" is intended to include those "involving the assessment or care of the health of human beings" as well as the "monitoring, supervision, and provision of direct assistance to claimants."

Supporters of the HEALTH Act point to the bill's exclusion of actions constituting criminal liability as the basis for arguing that examples such as these and those discussed during the full Committee markup[63] would fall outside the reach of H.R. 5. But intentional tort is not the same as criminal liability. In criminal cases, individuals must be selected for prosecution, tried in a court of law, and successfully convicted using a standard of proof that is appropriately high—proof beyond a reasonable doubt. In contrast, many incidents of intentional tort—even if they meet the elements of a crime—are never reported, let alone prosecuted.[64] Indeed, Dr. Ramaley does not appear to ever have faced criminal charges; Dr. Gosnell has not yet been convicted of anything. And it is unclear how an entity such as a nursing home could be charged with a crime in a case like Mildred Taylor's. We submit that under H.R. 5, these health care providers could escape significant civil liability as well.[65]

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[60] MSNBC, *'House of Horrors' Alleged at Abortion Clinic* (Jan. 19, 2011) (online at: http:www.msnbc.msn.com/id41154527/ns/us__news-crime__and__courts/t/house-horrors-alleged-abortion-clinic/); *ABC News, Alleged Victim Calls Philadelphia Abortion Doc Kermit Gosnell a 'Monster'* (Jan. 25, 2011) (online at: *http://abcnews.go.com/US/alleged-victim-calls-philadelphia-abortion-doctor-kermit-gosnell/storsyid=12731387*).

[61] Appeal Democrat, *Suit Filed in Death of Patient* (June 9, 2005) (online at: http://www.appeal-democrat.com/news/prestige-15049-taylor-lawsuit.html).

[62] HEALTH Act, Section 9(12).

[63] House Committee on Energy and Commerce, *Markup on H.R. 5, HEALTH Act of 2011,* 112th Cong., pp. 103–106 (May 11, 2011) (transcript of the proceeding).

[64] This is especially true with regard to sexual assaults. See U.S. Department of Justice, Bureau of Justice Statistics, *Rape and Sexual Assault: Reporting to the Police and Medical Attention, 1992–2000* (Aug. 2002) (online at: *http://bjs.ojp.usdoj.gov/content/pub/pdf/rsarp00.pdf*).

[65] This argument made by H.R. 5 advocates is undercut further by the very language of the bill which lists among the factors to be considered in determining punitive damages "any criminal penalties imposed on [a party] as a result of the conduct complained of. . . ." (HEALTH

Continued

Advocates of H.R. 5 also maintain that even in the absence of criminal activity, cases like these are not protected under the bill because they are extreme and non-therapeutic in nature and thus do not meet the definition of a health care good or service.[66] We struggle to find text in the legislation that supports this argument. At the very least, the language is ambiguous on the point. Regardless, there is no bright line here. Consider, for example, the situation in which a psychiatrist has consensual sex with a patient because he believes—and convinces the patient—that this is the best way to "treat" her emotional problems. Do the protections of H.W. 5 apply in any subsequent malpractice lawsuit brought by the patient? Again, based upon the text of the legislation, we believe the answer is unclear at best.

Supporters of the HEALTH Act argue further that the availability of punitive damages in cases in which "malicious intent to injure"[67] occur should address any concerns we have about the inclusion of intentional torts in this legislation because, in their view, such actions are *de facto,* ones of this character.[68] We are not comforted at all by this assertion; indeed, we believe it is Orwellian.

The purpose of H.R. 5's provisions on punitive damages is to limit them or cut them out altogether. Although "malicious intent to injure" is one ground upon which an injured person may seek punitive damages, the punitive damages procedural hurdles[69] and monetary limits in the bill—$250,000 or two times the amount of economic damages awarded[70]—still apply. Moreover, this argument ignores other features of the legislation that may adversely affect an individual who has experienced an intentional tort and seeks compensation for the wrong that has occurred.[71] In sum, we believe it is unconscionable for the federal government to place these kinds of restrictions on anyone—such as those individuals described in the cases above—who has been injured as a result of an intentional tort.

We find these provisions of the bill particularly troublesome because during the debate over the issue of intentional torts, there appeared to be consensus among the members who participated that these activities are not the stuff of traditional medical malpractice cases. And so it was especially disappointing that an amendment to clarify and resolve the matter was not adopted. Under that amendment, intentional torts would be removed from the scope of the bill.[72] Much to our amazement and consternation, the amendment was resoundly defeated, keeping intact liability protections for actions that—regardless of one's position on medical

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Act, Section 7(b)(E)). If criminal acts are outside the scope of H.R. 5, how can such acts be taken into account in determining punitive damages under the legislation?

[66] House Committee on Energy and commerce, *Markup of HR. 5, HEALTH Act of 2011,* 112th Cong., pp. 196–199 (May 11, 2011) (transcript of the proceeding).

[67] HEALTH Act, Section 7(a).

[68] House Committee on Energy and Commerce, *Markup on H.R. 5, HEALTH Act of 2011*, 112th Cong., pp. 193–194 (May 11, 2011) (transcript of the proceeding).

[69] HEALTH Act Section 7(a).

[70] HEALTH Act Section 7(b)(2).

[71] Such an example is the elimination of the legal standard of joint and several liability which allows injured persons to sue all responsible parties and recover from each one in proportion to the degree of fault, or to sue any one party and recover the entire amount of damages. (HEALTH Act Section 4(d)).

[72] House Committee on Energy and Commerce, *Markup on H.R. 5, HEALTH Act of 2011,* 112th Cong., pp. 190–200; 222–229 (amendment offered by Ranking Member Henry Waxman) (May 11, 2011) (transcript of the proceeding).

malpractice reform—never should have been a part of the HEALTH Act in the first place.

NURSING HOMES AND OTHER HEALTH CARE ENTITIES

H.R. 5 covers lawsuits brought against not only providers such as physicians or hospitals—the typical medical malpractice situation—but also cases involving "health care organizations," including nursing homes, health maintenance organizations (HMOs), and health insurance companies.[73] As such, these entities are entitled to the liability protections afforded under the bill, including the caps on non-economic and punitive damages.

We have found no credible evidence to support the inclusion of these entities within the range of the HEALTH Act. Nursing homes, HMOs, and insurance companies were not even discussed during the Health Subcommittee hearing on the legislation. And the debate in the full Committee markup did nothing to persuade us to see the need to include these organizations within the realm of "medical malpractice reform."

In fact, our concern over H.R. 5's inclusion of these businesses has only grown. This is especially true with respect to nursing homes which continue to be the subject of countless cases of negligence and even intentional wrongdoing. According to a Government Accountability Office (GAO) report on this topic, the proportion of nursing homes with serious quality problems remains unacceptably high, despite a decline in the incidence of such reported problems. Actual harm or more serious deficiencies were cited for 20% or some 3500 nursing homes during an 18-month period.[74] A more recent GAO report concludes that serious care problems in nursing homes continue to be of concern.[75] These findings were reinforced by the several examples provided during the debate over this issue in the full Committee markup.[76]

Supporters of the legislation contend that liability protections are necessary for nursing homes to decrease their liability costs and increase access to liability insurance coverage.[77] But a recent study conducted by the same firm whose work was cited in support of this argument suggests that these issues have been largely resolved. In fact, according to this study, the average annual loss (i.e., expenses related to liability insurance claims) per nursing home bed *decreased* from $1,710 in 2001 to $1,270 in 2009.[78] And an article in Insurance Journal on the study concluded that "liability insurance pricing and availability for long term care providers

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[73] HEALTH Act, Sections 9(7) and 9(10).

[74] GAO, *Nursing Home Quality: Prevalence of Serious Problems, While Declining, Reinforces Importance of Enhanced Oversight,* pp. 3–4, GAO–03–561 (July 2003).

[75] GAO, *High-Risk Series: An Update,* p. 159, GAO–11–278 (Feb. 2011).

[76] House Committee on Energy and Commerce, *Markup on H.R. 5, HEALTH Act of 2011,* 112th Cong., pp. 103–105 (May 11, 2011) (transcript of the proceeding).

[77] See, e.g., the comments of Rep. Pete Olson on this point. (Remarks of Rep. Pete Olson, House Committee on Energy and Commerce, *Markup of H.R. 5, HEALTH Act on 2011,* 112th Cong., pp. 106–108; 110–113 (May 11, 2011) (transcript of the proceeding)).

[78] Aon Risk Solutions, *2010 Long Term Care General Liability and Professional Liability Actuarial Analysis* (Aug. 2010) (online at: http://img.en25.com/Web/AON/LTC%20Benchmark%20Study__2010__FINAL.pdf).

are good and getting better" and attributed this trend to a newfound emphasis on quality of care.[79]

With regard to the impact of tort reform on these promising results, study documents observe that "while long term care liability costs are stable across much of the nation, Arkansas, Tennessee and West Virginia are experiencing high expenses—known as loss costs—related to insurance claims."[80] In the context of the HEALTH Act, it is worth noting that two of these states—Arkansas and West Virginia—have both enacted some form of tort reform;[81] yet, according to this study, the insurance market in these states remains turbulent. This suggests that such reform is not the cure-all advocates of H.R. 5 would have us believe.

Thus we remain unconvinced that nursing homes (or any other health care organization)[82] should receive the unprecedented protections provided to them under the HEALTH Act. In this respect, too, the legislation is unnecessarily and inappropriately broad in its scope and therefore, should be rejected.

H.R. 5 Is an Unwarranted Windfall for Pharmaceutical and Medical Device Companies

H.R. 5 sweeps so-called "medical products," or FDA-approved drugs, biologics, and devices into its overly broad span. Lawsuits involving drugs and medical devices are not the kind of cases that are traditionally considered medical malpractice cases, which are ostensibly the subject of the legislation. A typical "medical malpractice" lawsuit is one filed by an injured patient against his or her treating physician. In contrast, cases involving medical products are filed by patients who are injured—and often killed—by defective drugs and medical devices against large, extremely well-resourced pharmaceutical or medical device companies.[83]

The primary rationales advanced by supporters of H.R. 5 for the legislation[84] simply do not apply to lawsuits relating to FDA-approved drugs and medical devices. For instance, proponents of the HEALTH Act argue that it is necessary to curtail the practice of defensive medicine.[85] They claim the legislation will bring down

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[79] Insurance Journal, *Growth, Stability and Changes in Store for Long Term Care Market* (Nov. 14, 2010) (online at: http://www.insurancejournal.com/magazines/mag-features/2010/11/14/160493.htm).

[80] Aon Risk Solutions, *Highest Long Term Care Liability Costs in Arkansas, Tennessee and West Virginia: Aon Study Costs Across the Rest of the Nation Remain Stable* (Aug. 5, 2010) (online at: http://ir.aon.com/phoenix.zhtml?c=105697&p=irol-newsArticle&ID=1457169&highlight=).

[81] Insurance Journal, *Growth, Stability and Changes in Store or Long Term Care Market* (Nov. 14, 2010) (online at: http://www.insurancejournal.com/magazines/mag-features/2010/11/14/160493.htm)).

[82] Physician groups now supporting H.R. 5 have in the past argued fervently in favor of ensuring that HMOs are held fully accountable for injuries that occur to their patients. (See, *e.g.,* the position of the American Medical Association on this issue. (American Medical News, *Both Sides Ready for HMO Liability Fight* (Feb. 2004) (on line at: http://www.ama-assn.org/amednews/2004/02/16/gvsb0216.htm)).

[83] Testimony of Brian Wolfman, JD, Visiting Professor of Law, Georgetown University Law Center, House Committee on Energy and Commerce, Subcommittee on Health, *Hearing on The Cost of Medical Liability System Proposals for Reform. Including H.R. 5, HEALTH Act 2011,* 112th Cong., p. 5 (Apr. 6, 2011).

[84] As discussed in the Background and Overview section of these dissenting views, we do not believe H.R. 5 will achieve any of the primary goals set forth by its supporters.

[85] *See e.g.,* the comments of Rep. Joe Pitts during the full Committee markup of H.R. 5. (Remarks of Rep. Joe Pitts, House Committee on Energy and Commerce, *Markup on H.R. 5, HEALTH Act of 2011,* 112th Cong., p. 18 (May 9, 2011) (transcript of the proceeding)).

the cost of medical malpractice insurance[86] and also fix doctor shortages caused by liability exposure.[87]

Absolutely no justification has been asserted during the Committee's deliberations on the legislation for H.R. 5's inclusion of medical products. To the contrary, there was much debate about the danger and inappropriateness of covering drugs and devices, particularly during the testimony of Professor Brian Wolfman at the Health Subcommittee's hearing on the bill.[88]

In our view, the HEALTH Act will have an especially devastating impact on patients injured by defective or inadequately labeled drugs and devices. For instance, in addition to failing to fully compensate victims of dangerous drugs and devices for their non-economic damages, H.R. 5's $250,000 cap on non-economic damages would make it very difficult for these individuals to retain competent counsel who would be willing to take on the typical large, and well endowed pharmaceutical or medical device company.[89] Most individuals who are injured by these products cannot begin to pay for the out-of-pocket expenses necessary to finance a potentially massive lawsuit against a drug or device manufacturer.[90] Instead, they rely upon a contingency system in which an attorney is willing to represent them in exchange for a certain percentage of any final recovery in the case.[91] Particularly in cases that are complex and difficult or include very well-financed defendants, a limit of $250,000 in non-economic damages would be insufficient to enable most attorneys to afford the protracted litigation process such cases involve.[92]

In his testimony at the Health Subcommittee hearing on H.R. 5, Professor Wolfman provided a disturbing illustration of this concern.[93] He described a conversation he had with the attorney who represented Diana Levine, the injured party (plaintiff) in the recent U.S. Supreme Court case, *Wyeth* v. *Levine.*[94] Ms. Levine brought a lawsuit against Wyeth, one of the country's largest pharmaceutical companies, having lost her arm by amputation after receiving an inadequately labeled Wyeth drug.[95] After years of litigation, Ms. Levine's case was eventually heard by the Supreme Court, which affirmed that persons injured by an inadequately labeled FDA-approved drug can sue the manufacturer of that product.[96]

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[86] *See e.g.,* the comments of Rep. Phil Gingrey during the full Committee markup of H.R. 5. (Remarks of Rep. Phil Gingrey, House Committee on Energy and Commerce, *Markup on H.R. 5, HEALTH Act of 2011,* 112th Cong., p. 151 (May 10, 2011) (transcript of the proceeding)).

[87] *See e.g.,* comments of Rep. Tim Murphy during the Health Subcommittee hearing on H.R. 5. (House Committee on Energy and Commerce, Subcommittee on Health, *Hearing on The Cost of Medical Liability System Proposals for Reform, Including H.R. 5, HEALTH Act 2011,* 112th Cong., pp. 101; 104 (Apr. 6, 2011) (transcript of the proceeding)).

[88] House Committee on Energy and Commerce, Subcommittee on Health, *Hearing on The Cost of Medical Liability System Proposals for Reform, Including H.R. 5, HEALTH Act 2011,* 112th Cong., pp. 51–52; 104–107; 117–121 (Apr. 6, 2011) (transcript of the proceeding).

[89] Testimony of Brian Wolfman, JD, Visiting Professor of Law, Georgetown University Law Center, House Committee on Energy and Commerce, Subcommittee on Health, *Hearing on The Cost of Medical Liability System Proposals for Reform, Including H.R. 5, HEALTH Act 2011,* 112th Cong., p. 5 (Apr. 6, 2011).

[90] *Id.*

[91] *Id.*

[92] *Id.*

[93] *Id.* at 12.

[94] *Wyeth* v. *Levine,* 129 S.Ct. 1178 (2009).

[95] *Id.*

[96] *Id.*

Subsequent to the Court's decision, Professor Wolfman spoke with Ms. Levine's lawyer. Professor Wolfman asked the attorney if he would have taken the *Levin* case if there had been a $250,000 limit on non-economic damages; after a long pause, the attorney hesitantly responded "no."[97] Unquestionably, then, had the provisions of H.R. 5 been in place during the litigation, Ms. Levine might well have lost out in securing the stellar and long-term representation she was able to obtain under current law. Thus, as the *Levine* case clearly demonstrates, the adverse effects of the kinds of caps found in the HEALTH Act go beyond simply imposing an artificial dollar amount on damages.

The limits H.R. 5 puts on attorney contingency fees would only exacerbate this problem. With draconian caps on the amount that an attorney could collect through his or her contingency contracts in place, most plaintiffs' attorneys would financially unable to take on complex product liability cases involving drugs and devices.[98] Mr. Wolfman's testimony about his conversation with the attorney in the *Levine* case underscores this point as well.

H.R. 5 would also abolish punitive damages in cases pertaining to FDA-approved drugs and devices, except in the most limited circumstances.[99] Specifically, H.R. 5 would prohibit punitive damages in cases in which a drug or device either received FDA approval or is "generally recognized among qualified experts as safe and effective."[100]

Because much information is gained about the safety and effectiveness of drugs and devices after they are on the market and in use by a broad population of people, it is misguided to tie the availability of punitive damages to these products' initial FDA approval. Indeed, most product liability lawsuits regarding drug safety relate information that was not presented to the FDA at the time of the drug's approval.[101] But under the HEALTH Act, even a manufacturer that fails to exercise due diligence and investigate reports of a safety problem could be immunized from punitive damages.

Although an amendment was adopted during the full Committee markup of the bill that would permit an award of punitive damages in cases in which the defendant caused the drug or device to be misbranded or adulterated,[102] H.R. 5 would still have the effect of

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[97] Testimony of Brian Wolfman, JD, Visiting Professor of Law, Georgetown University Law Center, House Committee on Energy and Commerce, Subcommittee on Health, *Hearing on the Cost of Medical Liability System Proposals for Reform, Including H.R. 5 HEALTH Act 2011,* 112th Cong., p. 12 (Apr. 6, 2011).

[98] *Id.* at 19.

[99] Under Section 7(c)(4) of the HEALTH Act, punitive damages may be awarded in such cases only when a person: (a) before or after premarket approval, clearance, or licensure of the medical product at issue, knowingly misrepresented to or withheld from the FDA information that is required to be submitted under the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act (regulation of biological products) that is material and is causally related to the harm which the injured party allegedly suffered; or (b) made an illegal payment to an official of the FDA for the purpose of either securing or maintaining approval, clearance, or licensure of such medical product.

[100] H.R. 5, Section 7(c).

[101] Testimony of Brian Wolfman, JD, Visiting Professor of Law, Georgetown University Law Center, House Committee on Energy and Commerce, Subcommittee on Health, *Hearing on The Cost of Medical Liability System Proposals for Reform, Including H.R. 5, HEALTH Act 2011,* 112th Cong., p. 20 (Apr. 6, 2011).

[102] House Committee on Energy and Commerce, *Markup of H.R. 5. HEALTH Act of 2011,* 112th Cong., pp. 162–164 (amendment offered by Rep. John Dingell) (May 11, 2011) (transcript of the proceeding).

severely restricting the availability of punitive damages in lawsuits involving medical products.

Punitive damages have a unique and specific function: They serve to punish exceptionally outrageous, deliberate or harmful misconduct, and to deter both the wrongdoer and others from engaging in similar misconduct in the future.[103] By severely limiting punitive damages in drug and device cases, H.R. 5 places all of us in danger because in effect, it removes the most potent and effective means of deterring bad actors. There is simply no justification for this drastic action.

This is especially true in light of FDA's recognition of the valuable role state-based litigation plays in complementing the agency's regulation of drugs and medical devices.[104] FDA is on record in finding that drug and device lawsuits help to uncover post-market safety risks that are unknown to the agency at the time of approval. Indeed, as a former FDA chief counsel has stated: "FDA regulation of a device cannot anticipate and protect against all safety risks to individual consumers. Even the most thorough regulation of a product such as an important medical device may fail to identify potential problems presented by the product. Regulation cannot protect against all possible injuries that might result over time." [105]

Drug and medical device manufacturers will always be better positioned and better equipped than the FDA to know the safety profile of their products, since they develop and manufacture the products, typically receive safety reports about the products first, and are required to alert the FDA to any product-related risks they uncover. FDA, on the other hand, is responsible for overseeing the safety of hundreds of thousands of drugs and medical devices. The U.S. Supreme Court recently recognized this reality in *Wyeth* v. *Levine,* in which it found: "The FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access information about their drugs, especially in the post-marketing phase as new risks emerge." [106]

Simply put: H.R. 5 would weaken the tort system's critically important layer of consumer protection at the very time when FDA's ability to assure the safety of our drugs and medical devices is in great peril. The Republican FY 2012 budget resolution calls for a return to FY 2008 funding levels for discretionary funding across all government agencies.[107] For FDA, this translates into a funding cut of over $600 million—almost 20% of the agency's entire budget. Reductions of this magnitude will only exacerbate FDA's inherent difficulty both in monitoring the post-market safety of the tens of thousands of FDA-approved products on the market and in sending timely safety information to physicians and patients.

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[103] Testimony of Joanne Doroshow, Executive Director, Center for Justice & Democracy, House Committee on Energy and Commerce, Subcommittee on Health, *Hearing on The Cost of Medical Liability System Proposals for Reform, Including H.R. 5, HEALTH Act 2011,* 112th Cong., p. 32 (Apr. 6, 2011).

[104] Kessler, D and Vladeck D, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims,* Georgetown Law Journal, 96:461, 463 (Jan. 2008) (online at *http://www.georgetownlawjounalorg/issues/pdf/96-2/Kessler&Vladeck.PDF*).

[105] Porter, MJ, *The Lohr Decision: FDA Perspective and Position,* Food & Drug Law Journal, 52:7, 11 (Jan. 1997).

[106] *Wyeth* v. *Levine,* 129 S. Ct. 1187 (2009).

[107] H. Con. Res. 34 (adopted by the House of Representatives on Apr. 15, 2011).

For these reasons and more, it is irresponsible—even dangerous—to sweep drug and medical device cases within the scope of the HEALTH Act. In our view, such lawsuits should continue to stand on their own—subject to the substantive and procedural law that now governs them—so as to help ensure that these products remain as safe as possible while at the same time, providing the opportunity for adequate compensation for those individuals who have been harmed.

CONCLUSION

Our colleagues on the Committee on the Judiciary who have also filed dissenting views on the HEALTH Act have summed up our own views quite well:

> Collectively, the 'reforms' proposed by H.R. 5 would limit a patient's ability to recover compensation for damages caused by medical negligence, defective products, and irresponsible insurance practices. In addition to raising core issues of fairness, H.R. 5 preempts the law in all 50 states, with little regard for the consequences. The legislation was designed more than 20 years ago to resolve an insurance 'crisis', but all available evidence shows that the insurance market is not in crisis today. H.R. 5 does not make insurance more available, does not cut spending to any appreciable degree, and does not address issues of access to justice or patient safety. Because H.R. 5 solves few problems facing Americans and exacerbates many real ones, we believe the Congress should reject this bill.[108]

We concur in this assessment of the HEALTH Act and join with these colleagues in opposing H.R. 5.

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CHARLES A. GONZALEZ.
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EDWARD J. MARKEY.
EDOLPHUS TOWNS.
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JOHN D. DINGELL.
DIANA DEGETTE.
GENE GREEN.

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[108] House Committee on the Judiciary, *HEALTH Act of 2011,* Dissenting Views, 112th Cong., p. 118 (Mar. 17, 2011) (H. Rept. No. 112–39, Part 1.)