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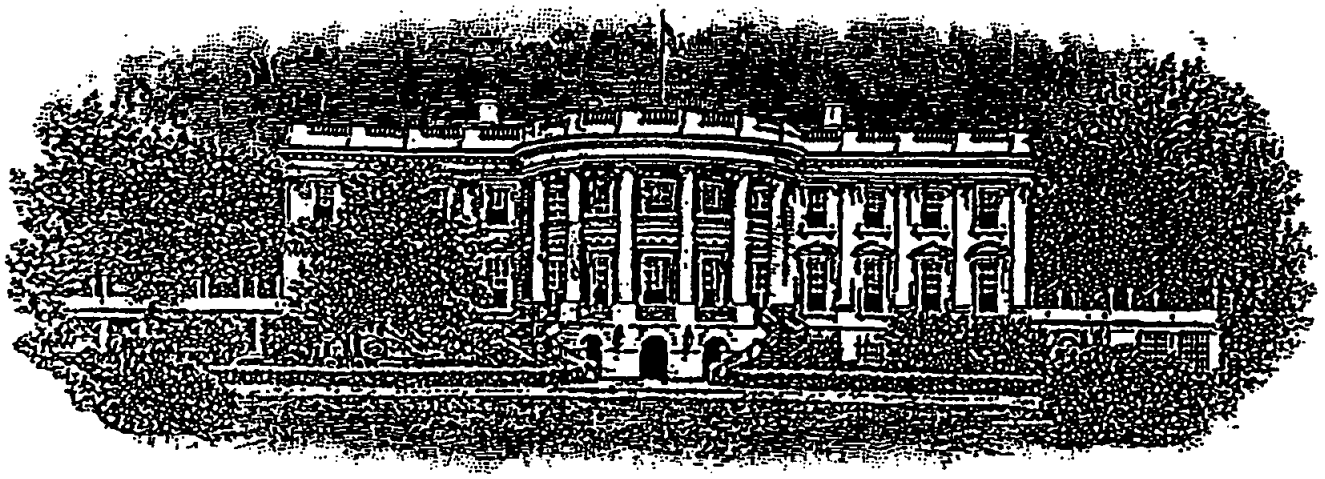
Medical Liability

Elena

The White House



DOMESTIC POLICY

FACSIMILE TRANSMISSION COVER SHEET

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PAGES (INCLUDING COVER): 3

COMMENTS: New med. liab. reform sheet

MEDICAL LIABILITY REFORM

Background: H.R. 3103 contains several provisions that would limit the liability of providers and manufacturers responsible for medical injuries. These provisions would apply to all health care liability actions except those arising from vaccine-related injuries and those under ERISA. Our major concern is that, under principles of Federalism, this does not appear to be a proper subject for Federal legislation. In the area of medical malpractice, each state should be permitted to apply the legal principles it believes represent the policy for proceedings affecting its citizens and residents. While this Federalism concern is overriding, we are also object to particular limitations in the bill including: the proposed caps on punitive and noneconomic damages; the restrictive nature of the statute of limitation provision; the elimination of joint and several liability for noneconomic damages; and the elimination of punitive damages in cases against a drug or device manufacturer or seller if the product had been approved by the FDA.

Issues:

1. **Federalism.** We do not believe that the proponents of this bill have met their burden of demonstrating the need for comprehensive Federal legislation that would override critical features of the medical malpractice laws of the states. To the extent there ever was evidence of a widespread medical malpractice "crisis," that trend has subsided either on its own accord or as the result of state medical malpractice reforms. Since the delivery of most medical services occurs within state borders, any problems concerning medical malpractice laws do not directly implicate Federal interstate commerce concerns and should be left to state legislatures to solve, to the extent a solution is necessary.

2. **Cap on Punitive and Noneconomic Damages.** The Administration opposes arbitrary ceilings on the amount of punitive and noneconomic damages that may be awarded in medical malpractice suit, because they endanger the safety of the consuming public. Capping punitive damages invites companies willing to put economic gain above else to weight the costs of wrongdoing against potential profits. Caps on noneconomic damages ignore the fact that such damages are as real and as important to victims as economic damages. It also discriminates against those individuals who disproportionately receive these damages – the poor, the elderly and nonworking women.

3. **Statute of Limitations.** While having a national statute of limitations might make sense in some areas involving interstate commerce , it makes no sense to have such a statute in instances where a plaintiff is likely to sue only in the state in which the malpractice occurred. Moreover, the statute of limitations is so broadly framed as to seemingly cover actions for breach of contract and other suits not normally subsumed under the heading of medical malpractice.

4. **Elimination of Joint and Several Liability for Noneconomic Damages.** The Administration opposes the elimination of joint and several liability for noneconomic damages for the same reasons it opposes capping those damages. Simply put, noneconomic damages should not be relegated to second class status.

5. **Regulatory Defense.** Most courts that have addressed the question whether FDA approval should constitute a defense to punitive damages have viewed that agency's regulations and procedures as establishing only minimum standards of safety, not equivalent to the higher standards required by tort law. The proposed regulatory defense rests on the questionable assumption that the responsible agencies will be adequately staffed and will be permitted to regulate effectively by the Administration then in office. The widespread injuries that thousands of women suffered as a consequence of using the Dalkon Shield, DES or breast implants -- all of which received FDA approval during prior Administrations -- suggest the potential danger in assuming that regulatory agencies will always function effectively.

care, nursing home care, home health care, or community-based care and that coordinates against or excludes items and services available or paid for under this title and (for policies sold or issued on or after 90 days after the date of enactment of this clause) that discloses such coordination or exclusion in the policy's outline of coverage, is not considered to 'duplicate' health benefits under this title.

"(II) For purposes of this subparagraph, a health insurance policy (which may be a contract with a health maintenance organization) that is a replacement product for another health insurance policy that is being terminated by the issuer, that is being provided to an individual entitled to benefits under part A on the basis of section 226(b), and that coordinates against or excludes items and services available or paid for under this title is not considered to 'duplicate' health benefits under this title.

"(III) For purposes of this clause, the terms 'coordinates' and 'coordination' mean, with respect to a policy in relation to health benefits under this title, that the policy under its terms is secondary to, or excludes from payment, items and services to the extent available or paid for under this title.

"(vi) Notwithstanding any other provision of law, no criminal or civil penalty may be imposed at any time under this subparagraph and no legal action may be brought or continued at any time in any Federal or State court if the penalty or action is based on an act or omission that occurred after November 5, 1991, and before the date of the enactment of this clause, and relates to the sale, issuance, or renewal of any health insurance policy or rider during such period, if such policy or rider meets the nonduplication requirements of clause (iv) or (v).

"(vii) A State may not impose, in the case of the sale, issuance, or renewal of a health insurance policy (other than a medicare supplemental policy) or rider to an insurance contract which is not a health insurance policy, that meets the nonduplication requirements of this section pursuant to clause (iv) or (v) to an individual entitled to benefits under part A or en-

rolled under part B, any requirement relating to any duplication (or nonduplication) of health benefits under such policy or rider with health benefits to which the individual is otherwise entitled to under this title.".

(b) CONFORMING AMENDMENTS.—Section 1882(d)(3) (42 U.S.C. 1395ss(d)(3)) is amended—

(1) in subparagraph (C)—

(A) by striking "with respect to (i)" and inserting "with respect to", and

(B) by striking ", (ii) the sale" and all that follows up to the period at the end; and

(2) by striking subparagraph (D).

Subtitle H—Medical Liability Reform

PART 1—GENERAL PROVISIONS

SEC. 271. FEDERAL REFORM OF HEALTH CARE LIABILITY ACTIONS.

(a) APPLICABILITY.—This subtitle shall apply with respect to any health care liability action brought in any State or Federal court, except that this subtitle shall not apply to—

(1) an action for damages arising from a vaccine-related injury or death to the extent that title XXI of the Public Health Service Act applies to the action, or

(2) an action under the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1001 et seq.).

(b) PREEMPTION.—This subtitle shall preempt any State law to the extent such law is inconsistent with the limitations contained in this subtitle. This subtitle shall not preempt any State law that provides for defenses or places limitations on a person's liability in addition to those contained in this subtitle or otherwise imposes greater restrictions than those provided in this subtitle.

(c) EFFECT ON SOVEREIGN IMMUNITY AND CHOICE OF LAW OR VENUE.—Nothing in subsection (b) shall be construed to—

(1) waive or affect any defense of sovereign immunity asserted by any State under any provision of law;

(2) waive or affect any defense of sovereign immunity asserted by the United States;

(3) affect the applicability of any provision of the Foreign Sovereign Immunities Act of 1976;

(4) preempt State choice-of-law rules with respect to claims brought by a foreign nation or a citizen of a foreign nation; or

(5) affect the right of any court to transfer venue or to apply the law of a foreign nation or to dismiss a claim of a foreign nation or of a citizen of a foreign nation on the ground of inconvenient forum.

(d) AMOUNT IN CONTROVERSY.—In an action to which this subtitle applies and which is brought under section 1332 of title 28, United States Code, the amount of noneconomic damages or punitive damages, and attorneys' fees or costs, shall not be included in determining whether the matter in controversy exceeds the sum or value of $50,000.

(e) FEDERAL COURT JURISDICTION NOT ESTABLISHED ON FEDERAL QUESTION GROUNDS.—Nothing in this subtitle shall be construed to establish any jurisdiction in the district courts of the United States over health care liability actions on the basis of section 1331 or 1337 of title 28, United States Code.

SEC. 272. DEFINITIONS.

As used in this subtitle:

(1) ACTUAL DAMAGES.—The term "actual damages" means damages awarded to pay for economic loss.

(2) ALTERNATIVE DISPUTE RESOLUTION SYSTEM; ADR.—The term "alternative dispute resolution system" or "ADR" means a system established under Federal or State law that provides for the resolution of health care liability claims in a manner other than through health care liability actions.

(3) CLAIMANT.—The term "claimant" means any person who brings a health care liability action and any person on whose behalf such an action is brought. If such action is brought through or on behalf of an estate, the term in-

cludes the claimant's decedent. If such action is brought through or on behalf of a minor or incompetent, the term includes the claimant's legal guardian.

(4) CLEAR AND CONVINCING EVIDENCE.—The term "clear and convincing evidence" is that measure or degree of proof that will produce in the mind of the trier of fact a firm belief or conviction as to the truth of the allegations sought to be established. Such measure or degree of proof is more than that required under preponderance of the evidence but less than that required for proof beyond a reasonable doubt.

(5) COLLATERAL SOURCE PAYMENTS.—The term "collateral source payments" means any amount paid or reasonably likely to be paid in the future to or on behalf of a claimant, or any service, product, or other benefit provided or reasonably likely to be provided in the future to or on behalf of a claimant, as a result of an injury or wrongful death, pursuant to—

(A) any State or Federal health, sickness, income-disability, accident or workers' compensation Act;

(B) any health, sickness, income-disability, or accident insurance that provides health benefits or income-disability coverage;

(C) any contract or agreement of any group, organization, partnership, or corporation to provide, pay for, or reimburse the cost of medical, hospital, dental, or income disability benefits; and

(D) any other publicly or privately funded program.

(6) DRUG.—The term "drug" has the meaning given such term in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)).

(7) ECONOMIC LOSS.—The term "economic loss" means any pecuniary loss resulting from injury (including the loss of earnings or other benefits related to employment, medical expense loss, replacement services loss, loss due to death, burial costs, and loss of business or employ-

ment opportunities), to the extent recovery for such loss is allowed under applicable State law.

(8) HARM.—The term "harm" means any legally cognizable wrong or injury for which punitive damages may be imposed.

(9) HEALTH BENEFIT PLAN.—The term "health benefit plan" means—

(A) a hospital or medical expense incurred policy or certificate,

(B) a hospital or medical service plan contract,

(C) a health maintenance subscriber contract,

(D) a multiple employer welfare arrangement or employee benefit plan (as defined under the Employee Retirement Income Security Act of 1974), or

(E) a MedicarePlus product (offered under part C of title XVIII of the Social Security Act),

that provides benefits with respect to health care services.

(10) HEALTH CARE LIABILITY ACTION.—The term "health care liability action" means a civil action brought in a State or Federal court against a health care provider, an entity which is obligated to provide or pay for health benefits under any health benefit plan (including any person or entity acting under a contract or arrangement to provide or administer any health benefit), or the manufacturer, distributor, supplier, marketer, promoter, or seller of a medical product, in which the claimant alleges a claim (including third party claims, cross claims, counter claims, or distribution claims) based upon the provision of (or the failure to provide or pay for) health care services or the use of a medical product, regardless of the theory of liability on which the claim is based or the number of plaintiffs, defendants, or causes of action.

(11) HEALTH CARE LIABILITY CLAIM.—The term "health care liability claim" means a claim in which the claimant alleges that injury was caused by the provision of (or the failure to provide) health care services.

(12) HEALTH CARE PROVIDER.—The term "health care provider" means any person that is engaged in the delivery of health care services in a State and that is required by the laws or regulations of the State to be licensed or certified by the State to engage in the delivery of such services in the State.

(13) HEALTH CARE SERVICE.—The term "health care service" means any service for which payment may be made under a health benefit plan including services related to the delivery or administration of such service.

(14) MEDICAL DEVICE.—The term "medical device" has the meaning given such term in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)).

(15) NONECONOMIC DAMAGES.—The term "noneconomic damages" means damages paid to an individual for pain and suffering, inconvenience, emotional distress, mental anguish, loss of consortium, injury to reputation, humiliation, and other nonpecuniary losses.

(16) PERSON.—The term "person" means any individual, corporation, company, association, firm, partnership, society, joint stock company, or any other entity, including any governmental entity.

(17) PRODUCT SELLER.—The term "product seller" means a person who, in the course of a business conducted for that purpose, sells, distributes, rents, leases, prepares, blends, packages, labels a product, is otherwise involved in placing a product in the stream of commerce, or installs, repairs, or maintains the harm-causing aspect of a product. The term does not include—

(A) a seller or lessor of real property;

(B) a provider of professional services in any case in which the sale or use of a product is incidental to the transaction and the essence of the transaction is the furnishing of judgment, skill, or services; or

(C) any person who—

(i) acts in only a financial capacity with respect to the sale of a product; or

(ii) leases a product under a lease arrangement in which the selection, possession, maintenance, and operation of the product are controlled by a person other than the lessor.

(18) PUNITIVE DAMAGES.—The term "punitive damages" means damages awarded against any person not to compensate for actual injury suffered, but to punish or deter such person or others from engaging in similar behavior in the future.

(19) STATE.—The term "State" means each of the several States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, and any other territory or possession of the United States.

SEC. 273. EFFECTIVE DATE.

This subtitle will apply to any health care liability action brought in a Federal or State court and to any health care liability claim subject to an alternative dispute resolution system, that is initiated on or after the date of enactment of this subtitle, except that any health care liability claim or action arising from an injury occurring prior to the date of enactment of this subtitle shall be governed by the applicable statute of limitations provisions in effect at the time the injury occurred.

PART 2—UNIFORM STANDARDS FOR HEALTH CARE LIABILITY ACTIONS

SEC. 281. STATUTE OF LIMITATIONS.

A health care liability action may not be brought after the expiration of the 2-year period that begins on the date on which the alleged injury that is the subject of the action was discovered or should reasonably have been discovered, but in no case after the expiration of the 5-year period that begins on the date the alleged injury occurred.

SEC. 282. CALCULATION AND PAYMENT OF DAMAGES.

(a) TREATMENT OF NONECONOMIC DAMAGES.—

(1) LIMITATION ON NONECONOMIC DAMAGES.—The total amount of noneconomic damages that may be awarded to a claimant for losses resulting from the injury which

(4) BIFURCATION.—At the request of any party, the trier of fact shall consider in a separate proceeding whether punitive damages are to be awarded and the amount of such award. If a separate proceeding is requested, evidence relevant only to the claim of punitive damages, as determined by applicable State law, shall be inadmissible in any proceeding to determine whether actual damages are to be awarded.

(5) DRUGS AND DEVICES.—

(A) IN GENERAL.—(i) Punitive damages shall not be awarded against a manufacturer or product seller of a drug or medical device which caused the claimant's harm where—

(I) such drug or device was subject to premarket approval by the Food and Drug Administration with respect to the safety of the formulation or performance of the aspect of such drug or device which caused the claimant's harm, or the adequacy of the packaging or labeling of such drug or device which caused the harm, and such drug, device, packaging, or labeling was approved by the Food and Drug Administration; or

(II) the drug is generally recognized as safe and effective pursuant to conditions established by the Food and Drug Administration and applicable regulations, including packaging and labeling regulations.

(ii) Clause (i) shall not apply in any case in which the defendant, before or after premarket approval of a drug or device—

(I) intentionally and wrongfully withheld from or misrepresented to the Food and Drug Administration information concerning such drug or device required to be submitted under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or section 351 of the Public Health Service Act (42

is the subject of a health care liability action may not exceed $250,000, regardless of the number of parties against whom the action is brought or the number of actions brought with respect to the injury.

(2) JOINT AND SEVERAL LIABILITY.—In any health care liability action brought in State or Federal court, a defendant shall be liable only for the amount of noneconomic damages attributable to such defendant in direct proportion to such defendant's share of fault or responsibility for the claimant's actual damages, as determined by the trier of fact. In all such cases, the liability of a defendant for noneconomic damages shall be several and not joint.

(b) TREATMENT OF PUNITIVE DAMAGES.—

(1) GENERAL RULE.—Punitive damages may, to the extent permitted by applicable State law, be awarded in any health care liability action for harm in any Federal or State court against a defendant if the claimant establishes by clear and convincing evidence that the harm suffered was the result of conduct—

(A) specifically intended to cause harm, or

(B) conduct manifesting a conscious, flagrant indifference to the rights or safety of others.

(2) PROPORTIONAL AWARDS.—The amount of punitive damages that may be awarded in any health care liability action subject to this subtitle shall not exceed 3 times the amount of damages awarded to the claimant for economic loss, or $250,000, whichever is greater. This paragraph shall be applied by the court and shall not be disclosed to the jury.

(3) APPLICABILITY.—This subsection shall apply to any health care liability action brought in any Federal or State court on any theory where punitive damages are sought. This subsection does not create a cause of action for punitive damages. This subsection does not preempt or supersede any State or Federal law to the extent that such law would further limit the award of punitive damages.

U.S.C. 262) that is material and relevant to the harm suffered by the claimant, or

(II) made an illegal payment to an official or employee of the Food and Drug Administration for the purpose of securing or maintaining approval of such drug or device.

(B) PACKAGING.—In a health care liability action for harm which is alleged to relate to the adequacy of the packaging or labeling of a drug which is required to have tamper-resistant packaging under regulations of the Secretary of Health and Human Services (including labeling regulations related to such packaging), the manufacturer or product seller of the drug shall not be held liable for punitive damages unless such packaging or labeling is found by the court by clear and convincing evidence to be substantially out of compliance with such regulations.

(c) PERIODIC PAYMENTS FOR FUTURE LOSSES.—

(1) GENERAL RULE.—In any health care liability action in which the damages awarded for future economic and noneconomic loss exceeds $50,000, a person shall not be required to pay such damages in a single, lump-sum payment, but shall be permitted to make such payments periodically based on when the damages are found likely to occur, as such payments are determined by the court.

(2) FINALITY OF JUDGMENT.—The judgment of the court awarding periodic payments under this subsection may not, in the absence of fraud, be reopened at any time to contest, amend, or modify the schedule or amount of the payments.

(3) LUMP-SUM SETTLEMENTS.—This subsection shall not be construed to preclude a settlement providing for a single, lump-sum payment.

(d) TREATMENT OF COLLATERAL SOURCE PAYMENTS.—

(1) INTRODUCTION INTO EVIDENCE.—In any health care liability action, any defendant may introduce evidence of collateral source payments. If any defendant elects to in-

troduce such evidence, the claimant may introduce evidence of any amount paid or contributed or reasonably likely to be paid or contributed in the future by or on behalf of the claimant to secure the right to such collateral source payments.

(2) NO SUBROGATION.—No provider of collateral source payments shall recover any amount against the claimant or receive any lien or credit against the claimant's recovery or be equitably or legally subrogated the right of the claimant in a health care liability action.

(3) APPLICATION TO SETTLEMENTS.—This subsection shall apply to an action that is settled as well as an action that is resolved by a fact finder.

SEC. 283. ALTERNATIVE DISPUTE RESOLUTION.

Any ADR used to resolve a health care liability action or claim shall contain provisions relating to statute of limitations, non-economic damages, joint and several liability, punitive damages, collateral source rule, and periodic payments which are identical to the provisions relating to such matters in this subtitle.

TITLE III—TAX-RELATED HEALTH PROVISIONS

SEC. 300. AMENDMENT OF 1986 CODE.

Except as otherwise expressly provided, whenever in this title an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Internal Revenue Code of 1986.

Subtitle A—Medical Savings Accounts

SEC. 301. MEDICAL SAVINGS ACCOUNTS.

(a) IN GENERAL.—Part VII of subchapter B of chapter 1 (relating to additional itemized deductions for individuals) is amended by redesignating section 220 as section 221 and by inserting after section 219 the following new section:

"SEC. 220. MEDICAL SAVINGS ACCOUNTS.

"(a) DEDUCTION ALLOWED.—In the case of an individual who is an eligible individual for any month during the taxable year, there shall be allowed as a deduction for the taxable year an amount equal to the aggregate amount paid in cash during such taxable year by such individual to a medical savings account of such individual.

"(b) LIMITATIONS.—

"(1) IN GENERAL.—Except as otherwise provided in this subsection, the amount allowable as a deduction under subsection (a) to an individual for the taxable year shall not exceed—

"(A) except as provided in subparagraph (B), the lesser of—

"(i) $2,000, or

"(ii) the annual deductible limit for any individual covered under the high deductible health plan, or

"(B) in the case of a high deductible health plan covering the taxpayer and any other eligible individual who is the spouse or any dependent (as defined in section 152) of the taxpayer, the lesser of—

"(i) $4,000, or

"(ii) the annual limit under the plan on the aggregate amount of deductibles required to be paid by all individuals.

The preceding sentence shall not apply if the spouse of such individual is covered under any other high deductible health plan.

"(2) SPECIAL RULE FOR MARRIED INDIVIDUALS.—

"(A) IN GENERAL.—This subsection shall be applied separately for each married individual.

"(B) SPECIAL RULE.—If individuals who are married to each other are covered under the same high deductible health plan, then the amounts applicable under paragraph (1)(B) shall be divided equally between them unless they agree on a different division.