

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 201
(I-08)

Introduced by: Texas Delegation

Subject: Equality of Civil Liability Preemption for Physicians

Referred to: Reference Committee B
(Ralph J. Coppola, MD, Chair)

1 Whereas, The physicians of America rely on the US Food and Drug Administration (FDA) to
2 perform the vital role of ensuring the reasonable safety of pharmaceuticals and devices used in
3 the diagnosis and treatment of their patients; and
4

5 Whereas, The FDA Pre-Market Approval (PMA), 510k (substantial equivalence), and New Drug
6 Application (NDA) processes are designed to ensure that physicians can prescribe, implant, and
7 apply the devices and pharmaceuticals that are FDA-approved with reasonable assurance of
8 their safety for patients; and
9

10 Whereas, Despite the methods and standards that the FDA employs, manufacturers from time
11 to time withdraw drugs and devices, reveal significant new safety information concerning such
12 products, or make labeling changes such as the addition of a black box warning; and
13

14 Whereas, Patients do, from time to time, have adverse events from appropriately prescribed
15 FDA-approved pharmaceuticals and medical devices; and
16

17 Whereas, The current FDA administrator has opined in court proceedings that FDA approval
18 preempts the drug or device manufacturer from civil liability in state courts, but these
19 proceedings do not address preemption for physicians who prescribe or utilize these same
20 FDA-approved drugs and devices; and
21

22 Whereas, The Supreme Court of the United States (SCOTUS) ruling in February 2008 in *Riegel*
23 *v. Medtronic* upheld preemption of the defendant medical device manufacturer from civil liability,
24 yet did not address the protection for physicians who use or implant said devices; and
25

26 Whereas, The *Wyeth v. Levine* case now before SCOTUS involves similar issues of preemption
27 for the manufacturer of an FDA-approved pharmaceutical, without addressing the preemption
28 status of the prescribing physician; and
29

30 Whereas, If manufacturers of FDA-approved products are unilaterally granted preemption
31 protection in all contexts (including reasonable but non-FDA-approved uses of drugs and
32 devices), physicians may become not simply the “deep pocket,” but quite likely the “only pocket”
33 against whom patients who are injured by said drugs or devices may seek redress;
34 therefore be it
35

36 RESOLVED, The our American Medical Association oppose efforts to grant greater levels of
37 liability protection for manufacturers than for physicians, whether by court decision or statute
38 (New HOD Policy); and be it further
39

1 RESOLVED, That our AMA support state and federal legislation that addresses the civil liability
2 of physicians who use FDA-approved devices and pharmaceuticals in a reasonable and prudent
3 manner, so that physicians have no less than the level of protection offered the manufacturer for
4 adverse events resulting from the use of said products (New HOD Policy); and be it further
5
6 RESOLVED, That our AMA report on AMA activities in support of this policy to the House of
7 Delegates at the 2009 Annual Meeting. (Directive to Take Action).

Fiscal Note: Implement accordingly at estimated staff cost of \$3,047.

Received: 09/11/08

RELEVANT AMA POLICY

H-435.960 Physician Relief from Product Class Actions

Our AMA: (1) asks Congress to pass legislation which prevents naming the treating physician as a party to product liability lawsuits when the treating physician has used a Food and Drug Administration-approved drug or device; and (2) promotes the introduction of legislation which would exempt physicians who have properly prescribed usage of Food and Drug Administration-approved medications from liability in class action suits against pharmaceutical companies. (Res. 208 & 225, A-01; Reaffirmed in lieu of Res. 905, I-06)

H-435.967 Report of the Special Task Force and the Advisory Panel on Professional Liability

... (3) Our AMA supports medical product liability reform, applicable to the producers of pharmaceuticals and medical devices, as an important state and federal legislative reform objective... (BOT Rep. 53, I-93; Reaffirmation A-00; Reaffirmation I-03; Reaffirmed: Sub. Res. 910, I-03; Reaffirmation A-04)

H-435.983 Impact of Product Liability on the Development of New Medical Technologies

The AMA (1) urges the continuation of efforts at the state and federal level to reform product liability laws, (2) supports creative solutions to prevent product liability suits from slowing the development and utilization of medical technologies in this country. Effective medical liability reform, based on the California Medical Injury Compensation Reform Act (MICRA) model, is integral to health system reform; and (3) continues to support efforts to alleviate the growing health crisis caused by decreasing availability or provision of biomaterials to manufacturers of medical devices and implants and to support legislative efforts to provide legal protection to biomaterial suppliers to ensure that all Americans have access to medical devices. (BOT Rep. BB, A-88; Reaffirmed: BOT Rep. O, I-91; BOT Rep. I-93-53; Appended by Res. 518, A-98)