

11808 WOLF RUN LANE CLIFTON, VA 20124

3210 S. GILBERT ROAD SUITE 4 CHANDLER, AZ 85286 (602) 388-8899 | FAX (602) 393-4361

1050 SEVENTEENTH STREET, N.W. SUITE 600 WASHINGTON, D.C. 20036 (202) 466-6937 | FAX (202) 466-6938

PRESS RELEASE

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PRESS CONTACT: Jonathan Emord (703-755-8202)

## RON PAUL INTRODUCES THE "COMPASSIONATE FREEDOM OF CHOICE ACT" (H.R. 6342)

WASHINGTON, D.C.—On August 2, 2012, Rep. Ron Paul (R-TX14) introduced the "Compassionate Freedom of Choice Act," H.R. 6342, a Bill designed to "allow the importation, distribution, and sale of investigational drugs and devices intended for use by terminally ill patients who execute an informed consent document." Rep. Paul Broun (R-GA10) and Rep. Richard Hanna (R-NY24) joined as cosponsors. The legislation follows a concerted effort by industry members, interest groups, victims, and patients to raise awareness of FDA's overbroad authority over "compassionate use" of drugs for terminally ill patients. On Wednesday, July 25th, Emord & Associates joined Donna Navarro (mother of cancer victim Thomas Navarro), actress Dianne Ladd, renowned oncologist Dr. Charles Simone, Frank Burroughs (Founder of the Abigail Alliance for Better Access to Developmental Drugs), producers of the film "Cut, Poison, Burn," and others in a briefing at the Rayburn House Office Building to discuss the need for legislative intervention.

Terminally ill patients often have few treatment alternatives. So-called "FDA-approved" therapies (e.g., chemotherapy) may cause more harm and dramatically reduce quality of life. *See* "Cut, Poison, Burn" (Nehst Out Productions, 2012). Yet the FDA exercises broad discretion to deny or delay approval of compassionate use requests for those most in need. All too often FDA has approved requests for experimental therapies only after the illness progressed to where those therapies were no longer effective. FDA can request that patients complete FDA-approved therapies before it will "allow" experimental treatments, even when treating physicians give little chance that those therapies are efficacious.

Speaking on the House floor August 2, 2012, Ron Paul explained that H.R. 6342 "allows terminally ill patients to use drugs, treatments and devices that have not yet been approved by the Food and Drug Administration if their physicians certify: (i) such patients have no other treatment options; and (ii) the patient executes written, informed consent that they are aware of any potential risks from the drug, device, or treatment." A full copy of Rep. Paul's statement is

available <u>here</u>. The Bill would substantially limit FDA's ability to second-guess treating physicians' decisions concerning the standard and methods of care available to terminally ill patients. H.R. 6342 puts medical decisions back in the hands of treating physicians by limiting FDA authority over compassionate use. The Bill preserves FDA's ability to oversee large scale treatment INDs, and limits compassionate use data in the drug approval process—providing important safeguards for drug companies that, in turn, encourage drug sponsors' participation in compassionate use protocols.

Please help us support the Compassionate Freedom of Choice Act by encouraging your politicians to vote in favor of H.R. 6342. Do not hesitate to contact Emord & Associates with questions, or for more information about how to further this cause.

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