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105TH CONGRESS
1ST SESSION

H. R. 1060

To amend the Federal Food, Drug, and Cosmetic Act to authorize compounding of drugs and devices under certain circumstances.

IN THE HOUSE OF REPRESENTATIVES

MARCH 13, 1997

Mr. BURR of North Carolina (for himself, Mr. CONDIT, Mr. DELAY, Mr. MCCOLLUM, Mr. NETHERCUTT, Mr. CANADY of Florida, Mr. ANDREWS, Mr. DEAL of Georgia, Mr. HOLDEN, Mr. HASTERT, Mr. WATTS of Oklahoma, Mr. DEFAZIO, Mr. KLUG, Mr. LIVINGSTON, Mr. SPRATT, Mr. MCINTOSH, Ms. FURSE, Mr. SAXTON, Mr. COBURN, Mr. PETERSON of Minnesota, Mr. LAHOOD, Mr. EHLERS, Mr. BARTON of Texas, Mr. NORWOOD, and Mr. MILLER of Florida) introduced the following bill; which was referred to the Committee on Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to authorize compounding of drugs and devices under certain circumstances.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Pharmacy Compounding Act''.

SEC. 2. APPLICATION OF FEDERAL LAW TO THE PRACTICE OF PHARMACY COMPOUNDING.

(a) IN GENERAL.—Section 503 (21 U.S.C. 353) is amended by adding at the end the following:

''(h)(1) Sections 501(a)(2)(B), 501(f), 501(h), 502(f)(1), 502(l), 502(o), 502(s), 502(t), 505, and sections 510 through 520 shall not apply to a drug or device that is compounded by a licensed pharmacist or licensed physician or other licensed practitioner authorized by State law to prescribe drugs or devices or both—

''(A) on the order of such a licensed physician or other licensed practitioner for an individual patient; or

''(B) in limited quantities, as determined by the principal State agency of jurisdiction which regulates the practice of pharmacy for that pharmacist, before receiving a valid order for an individual patient if the compounding of the drug or device is based on a history of receiving valid orders that have been generated solely within an established relationship between the pharmacist, and (i) the patient for whom the order will be given, or (ii) the physician or other licensed practitioner who will write such order.

Such sections shall not apply to a drug or device if such pharmacist or physician or other licensed practitioner does

no more than advertise or otherwise promote the compounding service and does not advertise or otherwise promote the compounding of a particular drug or device.

''(2) None of the provisions of this Act referred to in paragraph (1) shall apply to a bulk drug product or other drug, including an imported drug, that is intended for use by a licensed pharmacist or licensed physician or other licensed practitioner in compounding a drug or device on the order of a licensed physician or other licensed practitioner for an individual patient, except to the extent that the provision relates directly to the quality, purity, potency, or identity of such drug.''.

(b) WITHDRAWAL OF PROPOSED RULE AND GUIDELINE.—The proposed rule of the Secretary of Health and Human Services concerning exceptions to the current good manufacturing practices for makers of positron emission tomography drug products and the draft guideline on the manufacture of positron emission tomography drug products published in the Federal Register of February 27, 1995 (at 60 FR 10517-10520 and 60 FR 10593-10594) are null and void and the Secretary of Health and Human Services may not propose another proposed regulation or guideline respecting the same matters covered by the pro-

posed regulation and guideline described in this subsection.

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