AMENDMENT

OFFERED BY MR. GUTHRIE OF KENTUCKY

At the end of title V, add the following:

1	SEC. 505. FACILITATING EXCHANGE OF INFORMATION
2	PRIOR TO APPROVAL.
3	Section 502(a) of the Federal Food, Drug, and Cos-
4	metic Act (21 U.S.C. 352(a)) is amended—
5	(1) in paragraph (1)—
6	(A) by striking "formulary committee" and
7	inserting "formulary or technology review com-
8	mittee";
9	(B) by striking "drugs for coverage" and
10	inserting "drugs or devices for coverage";
11	(C) by striking "approved under section
12	505 or under section 351(a) of the Public
13	Health Service Act for such drug" and insert-
14	ing "approved, cleared, or licensed pursuant to
15	section 505, 510(k), 513, or 515 of this Act or
16	pursuant to section 351 of the Public Health
17	Service Act for such drug or device";
18	(D) by striking "approved for the drug
19	under section 505 or under section 351 of the
20	Public Health Service Act" and inserting "ap-

1	proved for the drug or device pursuant to sec-
2	tion 505, 510(k), 513, or 515 of this Act or
3	pursuant to section 351 of the Public Health
4	Service Act"; and
5	(E) by striking "The requirements set
6	forth in section 505(a) or in subsections (a) and
7	(k) of section 351 of the Public Health Service
8	Act" and inserting "The requirements set forth
9	in section 505(a), 510(k), 513, or 515 of this
10	Act or section 351 of the Public Health Service
11	Act'';
12	(2) by redesignating subparagraph (2) as sub-
13	paragraph (3);
14	(3) by inserting after subparagraph (1) the fol-
15	lowing:
16	"(2)(A) Health care economic information or sci-
17	entific information provided to a payor, formulary or tech-
18	nology review committee, or other similar entity with
19	knowledge and expertise in the area of health care eco-
20	nomic analysis carrying out its responsibilities for the se-
21	lection of drugs or devices for coverage, reimbursement,
22	or other population-based health care management, shall
23	not be considered false or misleading or any other form
24	of misbranding under this paragraph, or a violation of sec-
25	tion 505, 510(k), 513, or 515 of this Act or section 351

1	of the Public Health Service Act, if it is based on com-
2	petent and reliable scientific evidence and relates to an
3	investigational use of a drug or device.
4	"(B) In order for information relating to an inves-
5	tigational use of an approved, cleared, or licensed drug
6	or device to be provided pursuant to this subparagraph—
7	"(i) the study or studies the sponsor anticipates
8	could be sufficient to support the approval, clear-
9	ance, or licensing of such use must have been con-
10	ducted;
11	"(ii) the sponsor must intend that a supple-
12	mental application will be submitted to the Secretary
13	for approval, clearance, or licensing of the use; and
14	"(iii) the information must include, where appli-
15	cable, a conspicuous and prominent statement de-
16	scribing any material differences between the infor-
17	mation provided and the labeling approved pursuant
18	to section 505, 510(k), 513, or 515 of this Act or
19	pursuant to section 351 of the Public Health Service
20	Act.
21	"(C) For purposes of this subparagraph, scientific in-
22	formation includes clinical and pre-clinical data and re-
23	sults relating to a product or use that has not been ap-
24	proved, cleared, or licensed and is being investigated or
25	developed.";

1	(4) in subparagraph (3), as redesignated—
2	(A) by striking "(A)";
3	(B) by striking clause (B); and
4	(C) by striking "drug" each place it ap-
5	pears and inserting "drug or device"; and
6	(5) by adding at the end the following:
7	"(4) Nothing in this paragraph shall be construed to
8	limit the ability of manufacturers or sponsors of drugs or
9	devices to engage in communications or activities not spec-
10	ified in subparagraph (2) or (3) that are otherwise permis-
11	sible.".

