TECHNICAL ATTACHMENT

AMENDMENT 1

Add the following new section 315(d)(2):

(a) The head of a Federal agency may deviate on a class basis from the single patent rights clause normally used provided that such deviation is necessary to expedite resolution of an imminent public health problem.

Change present section 315(d)(2) to 315(d)(3).

Change present section 315(d)(3) to 315(d)(4).

Discussion: Such authority is necessary to enable the Department to properly manage its research and development program on a timely basis. The need for this authority was evidenced by public reaction to the possibility of the swine flu epidemic.

In any future cases similar to the swine flu situation, it is anticipated that research and development contracts will need to be negotiated with a number of pharmaceutical companies in order to accomplish expeditious delivery of the necessary therapeutic agent. The Department may need to control ownership of any invention made by such a company in performance of its contract in order to assure its availability to all the other companies in the delivery program.

Health, safety, or welfare are the only purposes identified as affecting allocation of invention rights in the bill. Thus, section 313(a)(2)(D)(i) requires licensing of an invention if necessary to resolve a health, safety, or welfare problem. Further, section 315(b)(7) lists public health, safety, or welfare as factors to be considered by the agency in determining whether licensing should be required after the expiration of the normal 7 and 10 year exclusive control period.

If the Department can regain control of an invention after it has been made on the basis of public health considerations, it should also have the ability to deny ownership prior to the making of an invention if it has identified an imminent public health problem.

AMENDMENT 2

It is suggested that the Act's coverage of grant-sponsored research (by defining contracts as including grants) be given more visibility by including definitions near the beginning of the bill.

AMENDMENT 3

Section 313(a)(2)(D)(i) - In lines 12 and 13 of page 10 substitute the words "health or safety" for the words "health, safety, or welfare."

Discussion: The Government has historically retained march-in rights only for "health or safety needs." Reasonable people can agree when a contractor is not satisfying health or safety needs. However, to expand the "march-in" to "welfare needs" appears to overly broaden the march-in to the point of making it undefinable.

AMENDMENT 4

Section 313(a)(2)(E) - Substitute, in lines 4 and 5 of page 11, the words "of the patent application covering the subject invention" for the words "the subject invention was made."

Discussion: Determining when an invention was "made" is probably impossible and certainly subject to varying interpretation. By using the date of filing of the patent application, the beginning of the period will be a time certain not subject to debate.

AMENDMENT 5

Section 313(a)(2)(E) - Add after the word "apply" in line 18 of page 11 the words "to non-profit institutions, their agents, or".

Discussion: Universities and other non-profit organizations do not manufacture and deliver inventions to the public. Accordingly, they should be treated more like small business in the bill, rather than industry subject to the 7 and 10 year limitations of ownership. The only basis for a university to acquire rights to an invention is to promote its utilization through licensing industry. Such licensing has been traditionally on a limited term exclusive basis when necessary and on a non-exclusive basis otherwise. Therefore, the added flexibility will unlikely be abused. The purpose of referral to "agents" is to assure that universities may continue to utilize related non-profit organizations such as Research Corporation and Wisconsin Alumni Research Foundation as their licensing agents.

AMENDMENT 6

Section 313 - After line 9 on page 12 add the following new subsections (c) and (d):

"(c) In any case, determinations made under section 313(a)(2)(C), (D), or (E) shall only be made after the contractor is advised in advance that the Federal agency is considering taking such an action, and only after an opportunity for hearing if so requested by the contractor, its assignee, or a licensee of either."

"(d) Any hearing conducted pursuant to paragraphs (b) and (c) of this section 313 shall not be subject to the provisions of 5 U.S.C. 554, 555 or 556; however, all interested parties shall have the right to present either written or oral testimony and to provide rebuttal testimony. The agency's determination shall be accompanied by a written statement of findings and conclusions."

Section 316 - On page 15 revise line 23 to read as follows:

"Sec. 316(a) Any contractor, its assignee, or a licensee of either adversely affected by a Federal".

Section 316 - On line 25 of page 15 delete "or undersubsection (a), (b)" and on line 1 of page 16 delete "or (c) of section 315". In line 5 of page 16 change the word "determination" to "action".

Section 316 - On page 16 after line 5 add the following new subparagraph (b):

"(b) Other Federal agencies or other persons adversely affected by an agency determination under section 313(a)(2)(D) or (E) may at any time within sixty days after the determination is issued, file a petition to the United States Court of Claims requesting review, and the Court of Claims may hold unlawful and set aside agency action, findings, and conclusions which are found to be as set forth in 5 U.S.C. 706(a)(A)-(E)".

Discussion: These are a related set of changes pertaining to hearing and appeals procedures under the "march-in" provisions of the bill. As now written these provisions may inhibit investment in Government supported inventions because potential licensees, especially smaller concerns, may be open to excessive harassment by competitors when they perceive that a successful subject invention will bring

competitors into the marketplace. As presently drafted, inventing organizations may shy away from investing in the further development of such inventions. For the same reasons the procedural rights of the contractor vis-a-vis the Government need clarification.

For example, the bill is silent on when contractors are entitled to a hearing in section 313(a)(2)(C) cases and only makes this optional in section 313(a)(2)(D) and (E) cases. Also, while H.R. 6249 does not appear to require a full APA type hearing, it does allow "any person adversely affected" to obtain a de novo hearing in the Court of Claims. It seems that this language would likely be construed to allow competitors or others who initiated or participated in the hearing to bring a de novo appeal, especially in Section 313(a)(2)(D) and (E) cases. Such a procedure effectively removes the decision-making power from the agency and places it in a court. The agency proceeding will largely be meaningless, and competitors or other persons who purport to represent the public interest will be in a position to force the contractor and his licensee to go through a lengthy and expensive process. This costly process would be an especially easy means for dominant members of the industry to harass smaller competitors. The only party that should have standing to appeal an agency's decision on a de novo basis is the contractor, his licensees, or assignees. Moroever, the right of appeal by parties other than the contractor should be limited to Section 313(a)(2)(D) and (E) cases, and no appeal should be permitted of Section 313(a)(2)(C) determinations. The latter creates a rather sweeping march-in right with no time set on its exercise. Because of this, its use should be left to the discretion of the agency with a right of appeal by an adversely affected contractor. Other parties will be able to force judicial review at a later date under Section 313(a)(2)(E), but to allow competitors the means to attack a competitor immediately will discourage the development of Government supported inventions, especially by smaller companies.

In line with the above, the purposes of the recommended changes are to:

(i) Make it clear that a contractor is always entitled to advance notification and a hearing if he requests, before any Government action is taken under sections 313(a)(2)(C)-(E);

(ii) To allow the contractor the right to a de novo review of any agency decision under section 313(a)(2)(C)-(E);

(iii) To eliminate any right of appeal by parties other than the contractor in section 313(a)(2)(C) cases;

(iv) To limit judicial review under section 313(a)(2)(D) and (E) cases, when the appeal is by a contractor's competitor or other person adversely affected by the agencies' decisions, to a review on the agency record rather than de novo; and

(v) To make it clear that agency hearings are not required to comply with all the requirements of the Administrative Procedures Act, but at the same time require certain minimum requirements, including a requirement that the agency prepare findings of fact and conclusions, so as to provide a suitable record for judicial review of appeals that are not de novo.

Limiting section 316 to use of contractors, its assignees or a licensee of either eliminates any right of appeal by any party of section 315(a)-(c) matters. Section 315(b) and (c) actually are subsumed as part of section 313(a)(2)(C)-(E) cases, and the change of the word "determination" on page 16, line 5, to "action" is intended to show that the appeal is to the entire decision and remedy prescribed by the agency and not just the "determination". Deletion of the reference to section 315(a) is related to amendment 8 discussed below.

AMENDMENT 7

Page 7, line 24, delete the word "promptly" and add the word "prompt" before the word "disclosure" on page 7, line 25. On page 8, line 2, add "within a prescribed time thereafter or such longer periods as may be agreed to by the Federal agency" after the word "election".

Discussion: As now written section 312 could be interpreted in a way that might force premature elections prior to the time a contractor has had an opportunity to evaluate the commercial potential of the invention. The proposed amendment makes it clear that the implementing clauses could provide for a flexible system of electing rights.

AMENDMENTS 8 AND 9

Section 315 - At the end of line 15 on page 13 add the following:

"Such determination shall be final and not subject to any form of judicial review."

Section 315 - On page 13 line 6 delete the words "of the contractor's exclusive commercial rights".

Discussion: Amendment 9 is merely an attempt to correct an inaccurate description of what the period in section 313(a)(2)(E) is. It is not the period "of the contractor's exclusive commercial rights" as now stated. Rather, it is the period after which march-in under section 313(a)(2)(E) may be exercised. Amendment 8 ties in with Amendment 6 and is intended to make it clear that an agency's decision either to extend the section 313(a)(2)(e) period or to refuse to extend it are not subject to appeal or judicial review. In some instances, such extensions may be necessary to allow the successful licensing of an invention. A right of appeal coupled with the public notice requirement would be a sure invitation to litigation by dominant competitors of the proposed licensee.