

To: Senator

From: Joe

Re: Patent Extension bill

May 14, 1980

cc: Kefin, Mary, Linda, Tom, Eve, David B., Press, Bob, Ann M., Leg, Ind

Bernie Nash has been talking with Tom and me about the possibility of your introducing a bill to extend the life of a patent to compensate for the time that the patent is held before a regulatory agency before the product is allowed to enter the market.

The problem is that many times a drug takes as much as ten years to clear the Food and Drug Administration before it can be marketed. This leaves only 7 years for the company to develop a market and recoup their investment. The draft bill would be limited to these pharmaceutical cases and would grant a maximum 7 year extension of the patent in these cases.

The small businesses and universities are interested in including medical devices in the coverage of the bill. This is an area of small business interest (more so than pharmaceuticals which are largely big companies) and the supporters of the bill are now working on a draft that is agreeable to everyone.

This concept is a popular one with the business interests and even the regulatory agencies are giving positive signals to the idea. Bernie has said that he has received indications of support from Mathias, Thurmond, Kennedy and Kastenmeier in the House side. He would like for you to introduce this in the Senate because of your leadership in the patent area.

There will probably be a negative reaction from some of the public interest groups who might view this as an attempt to strengthen the control of the pharmaceutical companies in the marketing of drugs. This could be overcome as long as the small businesses and universities are brought on board the bill.

Bernie expects to have a final draft ready next week. I told him that even if you agree to introduce it your schedule precludes any effort to pass it or hold hearings on it this year, but we could circulate it so that next

session you could get it started. Apparently Kastermeier is indicating that he might want to move it this year.

I recommend that you introduce this bill if the small businesses and universities agree to support it. This concept fits in with your previous efforts to strengthen the patent system and the experts that I have discussed this with agree that it is basically unfair for the government to grant a 17 year patent with one hand and to take away most of its life before regulatory agencies. No one is questioning the need for premarket clearance of drugs; the question is over the equity of losing valuable years on the patent when you are prevented by the government from marketing the invention.

Senator - I agree with Joe -
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