REGULATORY REFORM/Timely Protection of Human Health & Safety

SUBJECT: **Comprehensive Regulatory Reform Act of 1995 . . . S. 343. Hatch amendment No. 1531 to the Dole/Johnston substitute amendment No. 1487.**

ACTION: AMENDMENT AGREED TO, 99-0

SYNOPSIS: As reported, S. 343 will make changes to reform the regulatory process.The Dole/Johnston substitute amendment would modify the bill in accordance with suggestions made by Senate Democrats, the Administration, and the American Bar Association. The amendment would: recodify and modify the Administrative Procedures Act (APA); impose judicially reviewable obligations on Federal agencies to craft rules in which the benefits justify the costs and to use peer reviewed, standardized risk assessments; expand the Regulatory Flexibility Act; reform the Delaney Clause; and strengthen congressional oversight.

The Hatch amendment would express the sense of the Senate that "nothing in this Act is intended to delay the timely promulgation of any regulations that would meet a human health or safety threat, including any rules that would reduce illness or mortality from the following: heart disease, cancer, stroke, chronic influenza, diabetes mellitus, human immunodeficiency virus infection, or water or food borne pathogens, polio, tuberculosis, measles, viral hepatitis, syphilis, or all other infectious and parasitic diseases."

NOTE: See vote No. 305 for related debate.

Those favoring the amendment contended:

We have reluctantly agreed to consider the Hatch amendment as a free-standing amendment instead of as a substitute to the Boxer amendment. We have done so in order to allow an up-or-down vote on the Boxer amendment, which would provide a totally unneeded exemption from this Act for the Mammography Quality Standards Act. Though the Boxer amendment is without merit, an up-or-down vote is now needed in order to reassure the public after some of the wildly inaccurate rhetoric that has been engaged in by certain Senators over the past several hours. This bill does not need a special exemption to deal with breast cancer rules, with

(See other side)

YEAS (99)				NAYS (0)		NOT VOTING (1)	
Republican (54 or 100%)		Democrats (45 or 100%)		Republicans (0 or 0%)	Democrats (0 or 0%)	Republicans (0)	Democrats (1)
Abraham	Hutchison	Akaka	Inouye				Bingaman-[2]
Ashcroft	Inhofe	Baucus	Johnston				
Bennett	Jeffords	Biden	Kennedy				
Bond	Kassebaum	Boxer	Kerrey				
Brown	Kempthorne	Bradley	Kerry				
Burns	Kyl	Breaux	Kohl				
Campbell	Lott	Bryan	Lautenberg				
Chafee	Lugar	Bumpers	Leahy				
Coats	Mack	Byrd	Levin				
Cochran	McCain	Conrad	Lieberman				
Cohen	McConnell	Daschle	Mikulski				
Coverdell	Murkowski	Dodd	Moseley-Braun				
Craig	Nickles	Dorgan	Moynihan				
D'Amato	Packwood	Exon	Murray				
DeWine	Pressler	Feingold	Nunn				
Dole	Roth	Feinstein	Pell				
Domenici	Santorum	Ford	Pryor				
Faircloth	Shelby	Glenn	Reid				
Frist	Simpson	Graham	Robb				
Gorton	Smith	Harkin	Rockefeller				
Gramm	Snowe	Heflin	Sarbanes				
Grams	Specter	Hollings	Simon				
Grassley	Stevens		Wellstone				
Gregg	Thomas						
Hatch	Thompson						
Hatfield	Thurmond						
Helms	Warner						

EXPLANATION OF ABSENCE:
1—Official Buisiness
2—Necessarily Absent
3—Illness
4—Other

SYMBOLS:
AY—Announced Yea
AN—Announced Nay
PY—Paired Yea
PN—Paired Nay

E. coli rules, with cryptosporidium rules, or with any other rules dealing with any other disease or health problem, because a general exemption is already in the bill. Debating these amendments is a waste of time, unless one has some reason for mischaracterizing this legislation.

In 1992, Congress adopted the Mammography Quality Standards Act (MQSA), which was co-authored by Senator Hatch. In December, 1993, an interim final rule was issued to implement the Act. Interim rules have the full force and effect of law. Once an interim final rule is passed, no further action is necessary, though it may follow. On May 8, 1995, the Clinton Administration outlined its regulatory agenda for the year in the FEDERAL REGISTER. It listed its priorities and set target dates for regulatory actions it expected to take. No target date was set for a proposed final rule for the MQSA, and in fact no such contemplation of proposing a rule was even mentioned. Ten short weeks ago, all the Administration had to say about the Act is that the regulations to implement it would cost the Federal Government and private parties an average of only $33 million per year. That statement was the last that was heard from the Clinton Administration on the rules to implement the MQSA, which was passed in 1992, right before he took office. For most of his term this Act has been on the books, but until this particular debate began we did not hear any speeches from him (or from our colleagues) on the urgency of passing final regulations, nor did we hear of any concerns from the FDA. All of that changed as soon as this bill was proposed.

The FDA is violently opposed to having to consider the costs of its regulations. It is an affront to the bureaucrats at the FDA that anyone would have the authority to question their right to impose any costly regulation they desire on businesses, without any assessment as to whether they are even regulating a real risk. The FDA, as soon as this bill came under consideration, announced that it was going to issue a final rule on the MQSA in October, and that its expected annual cost would be $97 million, which is "coincidentally" close to the $100 million threshold. The FDA has not given us an explanation for why it never mentioned it was considering a final rule before, nor has it explained why the expected costs have tripled in 2.5 months. Our colleagues go on and on about how many years it takes to develop a final rule--if the FDA is being honest, and really was considering this final rule for some time, then surely it would have considered the cost of this final rule well before now. These two facts--that a proposed final rule is supposedly slated to go into final effect in October, and that the supposed cost of this rule has tripled in less than 3 months, are suspiciously inconsistent.

When negotiations were ongoing on this bill before it reached the floor, we never heard word one from our colleagues on mammography standards either. As recently as a couple of days ago we were given a list of their major concerns and no mention was made of the MQSA. Now, though, Senators are proudly proclaiming that this issue is of such monumental importance that they are willing to stand on the floor and filibuster this bill for months to get their way. Though we certainly would not doubt our colleagues, it is rather surprising that they just now thought to mention this issue. In sum, the sequence of events on the MQSA standards has left us with the impression that this entire issue was manufactured by opponents of this reform bill who wanted an emotional issue with which they could attack it.

The Hatch amendment is a reasonable response to the Boxer amendment. It would express the sense of the Senate that nothing in this Act is intended to delay the timely promulgation of any regulations that would meet a human health or safety threat. This amendment is absolutely accurate. If it were not necessary to give reassurance to the public after they have listened to some of the rhetoric of certain of our colleagues, we would insist on voting for it as a substitute to the Boxer amendment. Unfortunately, we must ask our colleagues to vote in favor of both amendments.

While favoring the amendment, some Senators expressed the following reservations:

The Hatch amendment makes a fine sense-of-the-Senate statement that this bill is not intended to hinder the promulgation of any regulations on a variety of very urgent health topics, including cancer. Such statements are fine, but they do not have the force of law. We can talk about what we intend, but if the substantive provisions of the bill have the opposite effect, our intentions are for naught. This amendment was originally intended to serve as a substitute for the Boxer amendment on mammography standards. That amendment is necessary to make sure that a rule that is scheduled to soon go into effect will not be delayed. We will vote for this amendment, but if Senators care about women's health, after this vote they will vote for the Boxer amendment, which will do more than just make a statement about the Senate's intent.