

DATE: September 11, 1989
TO: Senator Coats
FROM: Tom Long
SUBJ: 9-13-89 HIMA breakfast meeting

You are addressing about 30-40 executives of HIMA companies and PACs at a breakfast that begins at 7:30 this Wednesday. NOTE: Senator Dole has agreed to stop by for a few minutes about 8:15. Dole would be comfortable with being recognized when he walks in, saying a few words to the audience about the great job you are doing, and slipping away. It would be best if he can avoid Q & A. HIMA also has invited Hatch, Durenberger, Cochran and Thurmond. All of these invitations were made without consulting us. It probably does not matter, but it makes me uncomfortable to use up so many chits -especially Dole- on this event.

At 8:00 you begin speaking. The agenda is very loose. It would be natural to begin by thanking them for their interest in your '90 race and say how pleased you are to be the first candidate they have featured during their annual meeting. You could then give an overview of the campaign and some other details about the race.

You could briefly mention either of the issues of most concern to them: user fees and medical device legislation. Enclosed is a copy of the interview you did for their newsletter. The first question is about user fees.

In regard to medical devices, as you know, HIMA will not have an easy time reaching a consensus about any legislation. Waxman and Dingell introduced the "Safe Medical Device Act of 1989" on August 2nd. HIMA has decided it opposes the bill. All of the Indiana companies, including the Cook Group, do not favor this bill. The major provisions are:

Require more extensive reporting by providers of incidents involving medical devices directly to FDA, as well as to the manufacturer.

Require user tracking for certain class III devices.

Eliminate 510(k) certification for new class III devices five years after enactment.

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Kennedy, Dodd, and perhaps Hatch are working on a bill in the Senate that may be introduced this fall. Lilly and Cook, among others, are working hard to get their point of view in this bill. Although it is possible Dingell could push his bill to the House floor, it is unlikely that the Senate will act on its version this year.

I suggest that if there is time after you thank them for featuring you in the candidate program and discussing the political situation in Indiana, you mention your opposition to user fees and conclude your remarks for Q & A. If you are asked about medical device legislation talk about your willingness to work with the industry, and the fact that you were involved with the bill that made it to conference, but was not enacted, last year.

HIMA has allotted about ten minutes for your remarks before Q & A. As I mentioned above, Dole should make an appearance, and the event will conclude at 8:30.

Also enclosed is the list of expected guests and a memo from Jay Hawkins to Dole's staff. Among the guests are Edward Bessey (CEO of Pfizer's medical device company), Joe Jenckes of Abbott, and Ronald Davis (President) and Timothy Wendt (VP) of Zimmer in Warsaw.

INTERVIEW



Sen. Dan Coats (R-Ind.) was first elected to the House of Representatives in 1980. He now serves in the U.S. Senate replacing Vice President Dan Quayle. Sen. Coats serves on the Senate Labor and Human Resources Committee, which has jurisdiction over such issues as the

medical device amendments, FDA user fees and outcomes research. Manager of Communications Laura Washington and Director of Government Affairs Jay Hawkins talked recently with Sen. Coats to learn more about his views on health policy.

HIMA: *Congress has considered requiring industry to fund FDA activities through user fees or other contribution schemes. Your committee has been one of the key forums for this issue. What are your views on industry funding FDA?*

COATS: First of all, let's acknowledge that FDA needs to be overhauled. It has old equipment, it has underpaid researchers, it is scattered in several locations and it is not nearly as efficient as it should be. FDA also must be enabled to keep pace with the rapid development of new drugs and devices that must be processed as quickly as possible. Congress needs to recognize that here is an agency in dire need of reform, new funds and new equipment. FDA can be made much more efficient than it currently is. I've been very skeptical of proposals that would impose the cost of that reform on the users of FDA, the pharmaceuticals companies, the medical device manufacturers and others. So what I have said is that I will look very suspiciously at any proposed user fee arrangement. And any user fee proposal that I will look at must be strictly dedicated to FDA and not utilized for any other purpose. The federal government has the basic responsibility to

provide the appropriation outside a user fee system and the funds ought to be dedicated to specific uses within FDA that would not in any way provide a bias toward the larger contributors. Currently we don't have legislation which accomplishes those purposes.

HIMA: *As Congress considers basing Medicare payments to physicians on a relative value scale, do you think it is important that the new system include frequent updating mechanisms to keep up with innovations?*

COATS: Absolutely. As we examine the changes taking place in medicine and the delivery of medical services, we must be aware of the fact that we are in an explosive period of technological change. In the area of delivery of medical services, we are seeing marvelous advances almost on a daily basis. Any system that locks in payment or regulates the delivery of services on the basis of what is currently in practice is going to be very quickly outmoded and inequitable. We have to build in as much flexibility as possible. We must have the ability to quickly incorporate new devices, new technology and new delivery systems into any system that we put in place to allocate payment or reimbursement for the purchase or utilization of equipment. I think we should proceed with some caution in attempting to mandate by government what the marketplace has done pretty well for more than 200 years. There are millions of individual decisions made in this country every day relative to the delivery of medical service and utilization of medical technology that no government bureaucrat, agency, board or commission can possibly keep up with. Marketplace decisions should drive the system, not some inflexible federal board or agency.

HIMA: *To what extent do you view outcomes research and medical practice guidelines as a means of holding down federal health care costs?*

COATS: I think these ideas have merit but I don't think they ought to be viewed as the only cost savings strategies that we should examine. But one danger of these notions is that the federal government could become too involved in the process and attempt to replace or overrule the expertise of the professions and qualified researchers. The federal government does have a role to play, but in no way should government dominate the field in this area.

HIMA: *Congress often talks about small business. How often does Congress really consider the impact on small business of creating new regulations such as the revised medical device amendments proposed recently and mandated health benefits?*

COATS: We do talk a lot about small business and the impact on small business. But not nearly as much as we should considering the fact that most growth, most new jobs and most new developments emanate from small business. Often our rhetoric about being aware of the importance of small business is not matched by the legislative reality of what we do. The Senate bill S. 768, Mandated Health Benefits, is a good example of legislation that largely ignores the adverse impact on small business. I think it would be a mistake for us to go down the road of mandated benefits. The labor pool is changing, the needs of business are changing. Business needs to be flexible and to be able to offer flexible benefits packages. By mandating

benefits across the board we take that flexibility away. I think it goes exactly the opposite direction of where it ought to be going.

HIMA: *What are two or three practical steps for HIMA companies to take to enable them to become better acquainted with their senators and congressman? Do you really have the time to listen?*

COATS: We had better make time to listen or we won't be in this job for very long. It's the nature of our business to listen to the people that we represent. Any senator or congressman worth his salt is going to take time to listen to the constituents that he represents—people that are providing jobs and opportunities—from his or her state. I find it can be very effective when representatives of businesses either come to Washington or send their message by letter or phone. More important, invite elected officials to come to your plant or business. There is no substitute for hands-on experience. I make it a practice to travel around the state to visit businesses and see for myself the products they're making, the people that work in the businesses and to talk to them and listen to their concerns. I would encourage those interested in contacting their senators or their congressmen to be bold. Come to Washington and arrange appointments. Pick up the phone and call or write letters. Often it takes just a little bit of initiative on the part of the constituent to gain that access which is very important. And we want to be able to give that access. ■

SCIENCE NEWS

- **EXPLORATORY MEETING ON NiCAD BATTERIES**—HIMA will hold an Exploratory Meeting Sept. 27 at HIMA headquarters to discuss federal and state regulatory activities that may restrict or ban the continued use of nickel cadmium (NiCAD) batteries. NiCADs are contained in such medical devices as defibrillators, TENS units, surgical power tools, adult monitors, apnea monitors and ophthalmic equipment. Information on the meeting, including a background paper on the issue, is available from HIMA's Maryanne Stanners. Staff contact: James Jorkasky

TAB E

Medical Device Amendments

Staff Contact: Eddie Allen

Date: September 1, 1989

Representatives Dingell (D-MI) and Waxman (D-CA) introduced legislation that would make significant changes in the medical device statute. The legislation (H.R. 3095):

1. significantly expands the reporting requirements for providers (and indirectly, manufacturers);
2. removes the 510(k) premarket notification procedure after five years for ~~most~~ **most devices**
3. removes the state-of-the-art defense under the repair, replacement, and refund provisions of the statute;
4. streamlines the process for reclassifying transitional devices; and
5. provides new flexibility in the development of controls for Class II devices by FDA.

The Medical Device Amendment Task Force and Government and Public Affairs Steering Committee will meet in early September to discuss this legislation and HIMA's response to it. Additional information about these meetings will be provided at the Board meeting.

To: Joanne Coe *JH*
From: Jay Hawkins
Date: September 7, 1989
Re: HIMA fundraising breakfast for Senator Coats

HIMA is the national trade association for domestic manufacturers of medical devices, in vitro diagnostics, and health information systems. We represent over 340 companies.

The breakfast for Senator Coats is on September 13, from 7:30 a.m. to 8:30 a.m., in the Colonial Room of the Mayflower Hotel. Tickets to the event are \$500 for PAC contributions and \$250 for individuals.

The purpose of the fundraising breakfast, which is being held in conjunction with the HIMA fall legislative conference, is twofold. First, we hope to make a significant contribution to Senator Coats' campaign. HIMA's PAC is very small and therefore can only offer token contributions to candidates. With this event, HIMA member company employees and PACs are contributing directly to Senator Coats' campaign committee rather than to HIMAPAC. The aggregate contributions will be well in excess of the amount HIMAPAC could offer independently. Second, through this event we hope to involve more of our companies in political activity. Relatively few of our 340 member companies participate in HIMAPAC. With this event we hope to encourage first time contributors by linking the supporter directly with the candidate.

I have attached a list of guests expected to date. I expect 30-40 people to be present on the 13th. In attendance will be the CEOs, presidents, and other senior managers from participating HIMA companies.

The event is a sit-down breakfast. At 8:00 Senator Coats will be introduced, he will make a few short remarks, and then take q&a. By 8:15, I would expect Senator Coats to be into the q&a segment. Senator Coats will be seated at a head table. It is from there that he will make his remarks. If Senator Dole wishes to sit down there will be a seat at the head table available. We also expect that Senator Hatch, Senator Durenberger, Senator Cochran, and Senator Thurmond may stop by.

A few remarks from Senator Dole would be most welcome. I would not expect Senator Dole to take q&a. However, for your information two key legislative issues for our industry are the proposed Medical Device Amendments (Cong. Waxman and Cong. Dingell have introduced legislation to which HIMA is opposed) and proposals to levy user fees on Food and Drug Administration activities.

Thanks again for your help. Please call if I may provide you with any additional information.

cc: *Wendy Sabar*
Tom Long

SENATOR DAN COATS FUNDRAISING BREAKFAST
SEPTEMBER 13, 1989
CONTRIBUTIONS/PLEDGES RECEIVED AS OF 9/12/89
TOTAL AMOUNT \$7,250 (NOT INCLUDING PLEDGES)

\$11,750 w/pledges

ELROY BOURGRAF - \$250
(FERNO-WASHINGTON)

CHARLES E. SAUNDERS - \$250
(MEDICAL LABORATORY AUTOMATION, INC.)

PARKER H. PETIT - \$500
(HEALTHDYNE, INC.)

RICHARD W. YOUNG - \$250
(MENTOR O&O)

EDWARD BESSEY - \$500 (PLEDGE)
(PFIZER)

JAMES A. EITING - \$250
(MIDMARK CORPORATION)

FRANK P. WILTON - \$250
(ETHOX CORPORATION)

JOSEPH JENCKES & ROBERT A. SCHOELLHORN - \$1000 (PLEDGE)
(ABBOTT LABORATORIES)

PHILIP FARIS - \$250
(DIATEK)

BRUCE GRIFFITHS - \$250
(CONCO)

JOHN W. BROWN - \$250
(STRYKER)

RAYMOND GILMARTIN - \$250
(BECTON DICKINSON)

EDWARD HARTNETT - \$250
(JOHNSON & JOHNSON)

FELIX TROILO - \$250
(BIRD PRODUCTS)

JOHN HOOVER - \$250
(W.L. GORE)

TIMOTHY WENDT - \$250
(ZIMMER)

RONALD DAVIS - \$250
(ZIMMER)

JOHN CASTELLO - \$250
(ARES-SERONO)

BURTON DOLE - \$250
(PURITAN-BENNETT)

E. GARY COOK - \$500 (PLEDGE)
(E.I. DU PONT) *

C. WILLIAM ZADEL - \$500
(CIBA CORNING) *

MAGNUS MOLITEUS - \$250
(PHARMACIA, INC.) *

JAMES R. TOBIN - \$250
(BECTON DICKINSON) *

TERENCE KERR - \$500 (BOB WEHRMEYER, MERLE SMITH)
(KINETIC CONCEPTS) *

BRANT C. STANFORD - \$250
(SUNLITE PLASTICS) *

BEN HOLMES - \$250 (PLEDGE)
(HEWLETT-PACKARD) *

TIMOTHY Y. COWART - \$250
(HEALTHDYNE) *

C. BIERGE SIGETY - \$500
(PROFESSIONAL MEDICAL PRODUCTS) *

CHARLES MCDOWELL - \$500 (PLEDGE)
(CORDIS CORPORATION) *

MONTY VICENT - \$250 (PLEDGE)
(ARBOR TECHNOLOGIES) *

LESTER ROSEN - \$250 (PLEDGE)
(MILES LABORATORIES) *

NOEL BUTTERBAUGH - \$250 (PLEDGE)
(WHITTAKER BIOPRODUCTS) *

ROBERT T. RYLEE - \$250 (PLEDGE)
(DOW CORNING) *

L.D. BEARD - \$250 (PLEDGE)
(BIOTECHNOLOGY CORP.) *

THOMAS GUNERMAN - \$250 (PLEDGE)
(DIEMOLDING) *

J. DALE SHERRATT - \$250
(THE KENDALL COMPANY)

*SEND THANK YOU LETTERS

ADVANCE: Mark Miller
543-5016 (O)
333-9083 (H)
CONTACT: Jay Hawkins
(HIMA)
452-8240

SENATOR DOLE SCHEDULE - WEDNESDAY, SEPTEMBER 13, 1989

FUNDRAISING BREAKFAST FOR SENATOR DAN COATS
MAYFLOWER HOTEL - COLONIAL ROOM
7:30 A.M. - 8:45 A.M.

8:15 A.M. Senator Dole arrives Mayflower Hotel

MET BY: Mark Miller and escorted to Colonial Room

Proceed to Head Table and
Attend FUNDRAISING BREAKFAST FOR SENATOR DAN COATS

(Event in progress since 7:30)
Senator Coats will be introduced at 8:00 A.M.
Will be doing Q&A by the time Senator Dole arrives

Sponsors: Health Industry Manufacturers Assoc.

Contact: James W. ("Jay") Hawkins
Director of Government Affairs, HIMA
452-8240

Tom Long - Senator Coats' staff
224-8726

Format: Sit-down breakfast with Head Table

Head Table: Senator Strom Thurmond
Senator Orrin Hatch
Senator Dave Durenberger
Senator Thad Cochran
Senator Dan Coats

8:20 A.M. SENATOR DOLE REMARKS

8:25 A.M. SENATOR DOLE CONCLUDES REMARKS

8:30 A.M. Depart event and proceed to Washington Court Hotel
for 9:15 speech to American Business Conference

NOTE: EVENT WILL CONCLUDE PROMPTLY AT 8:45, AS THE ROOM IS
RESERVED FOR ANOTHER FUNCTION.

*Senator Strom Thurmond
Senator Orrin G. Hatch
Senator Thad Cochran
Senator Dave Durenberger
and*

*The Health Industry
Manufacturers Association
request your presence
at breakfast
in honor of*

Senator Dan Coats

*The Mayflower Hotel
1127 Connecticut Avenue, N.W.
Washington, D.C.*

*Wednesday, September 13, 1989
7:30 a.m.*

RSP 202-452-8240

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SEPTEMBER 13, 1989
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