Memorandum

To: Abstract Presenters, ENDO 2001 Annual Meeting

From: Lorraine Fitzpatrick, M.D., Chair, Media Advisory Committee
       Marisa Kessel, Manager, Public Affairs

CC: Susan Koppi, Director, Public Affairs

Date: April 9, 2001

RE: ENDO 2001 Research Summaries Book and Media Promotion

Congratulations! Your abstract has been selected from nearly 2,400 to be included in the ENDO 2001 Research Summaries Book (RSB). Each year, the Media Advisory Committee (MED) and the Public Affairs staff of The Endocrine Society identify approximately 150 newsworthy abstracts to include in the RSB. The book includes the original abstracts as well as lay translations of each abstract. The RSB is utilized as a resource by the media during ENDO and throughout the rest of the year.

Your abstract is also being considered for publicity efforts during ENDO 2001. If selected, your material may serve as the basis for a news release and/or a press conference. Furthermore, other knowledgeable scientists in the same field may be asked to comment on your work to provide perspective. Please remember that not all abstracts that are included in the RSB are used for publicity purposes—you are welcome to draft your own press release if you wish. If your institution would like to issue a press release, please contact Marisa Kessel at 301-941-0255 or mkessel@endo-society.org for permission and embargo information.

We will need your assistance in preparing a lay version of your abstract for the RSB. To help us better understand your research and findings, please complete the following faxback form, using simple English, as though you were explaining it to a high school student—without technical terms or abbreviations. Your summary should highlight the most important aspects of this study, including the following, in roughly this order:

1. What has been found? What is new about those findings?
2. Why it is NEWSWORTHY and INTERESTING? (i.e. What do you think will cause a reporter to cover this?) Is there potential impact on an average person’s daily life now or in the future? How will this change the average person’s daily life?
3. How is it important clinically or as endocrine research?
4. Provide details of the research. (Number of subjects, what was the methodology used, what was found, what are your conclusions, etc.)
5. Please provide as much background information as possible that would benefit a lay audience.
6. Who funded your research?

Please fax back the completed form to Marisa Kessel at 301-941-0259 by April 16, 2001. If you have any questions, please feel free to contact Marisa Kessel at 301-941-0255 or via e-mail at mkessel@endo-society.org
MEDIA ADVISORY COMMITTEE
ABSTRACT SUMMARY FAXBACK FORM
ENDO 2001, Denver, Colorado
June 20-23, 2001

Please fax (301-941-0259) or email (mkessel@endo-society.org) this form to Marisa Kessel by April 16, 2001.

NAME: Ritchie C. Shoemaker MD

E-MAIL: ritchieshoemaker@msn.com

TELEPHONE: 410-957-1550

ABSTRACT NUMBER: 38700

ABSTRACT TITLE: Use of rosiglitazone in treatment of hyperinsulinemic obesity in non-diabetics

1. Would you be willing to conduct media interviews on this topic? Please designate one investigator as the media contact person; and list the name, email address, and telephone number.

Ritchie C. Shoemaker MD ritchieshoemaker@msn.com 410-957-1550

2. Please list the times and phone number that the media contact person will be available one week prior to the annual meeting.

M-F 8:30-5:30 410-957-1550

3. Please list, if available, the hotel/phone number where the media contact person will be available during the annual meeting.

On site

4. Please list the contact name, phone/fax number, and email address of the public relations person from your institution.

See 1 above

5. Please present your abstract in lay language (approximately 400 words), explain why this work is important clinically, or as basic endocrine research, what has been found, details of the research, and why this is interesting or newsworthy (i.e. What do you think will make the media want to cover this?) Please include number of subjects, what was the methodology used, what was found, what are your conclusions, etc.

Obesity has reached epidemic proportions in the US. Despite a public awareness of the importance of exercise and calorie restriction, dieters seldom lose more than 30 pounds when they need to and rarely do those few successful dieters keep the weight off. Some unsuccessful dieters have a hormone problem associated with their obesity that is called “insulin resistance.” These patients don’t have diabetes, they have too much insulin in their bloodstream, but they don’t have low blood sugar. The problem comes from the fact that their insulin doesn’t work properly to take sugar out of the blood and put it into liver and muscle cells where it would normally either be stored in glycogen or immediately burned for fuel
High insulin levels are associated with other metabolic problems as well; the high insulin patient converts sugar to fat and stores it efficiently, often has blood pressure, and often has high cholesterol and triglycerides. High insulin patients also are more likely to have heart disease and gout among other illnesses.

A new group of FDA approved medications, used to help treatment of diabetes, called thiazolidinediones, shows great promise in the treatment of insulin resistance. These medicines, including rosiglitazone (Avandia), is safe for patient use. Unlike the first FDA approved medication in this class, Rezulin, they don’t cause liver problems and, unlike sulfonylurea medications or patient administered insulin, they don’t create the risk of low blood sugar reactions. They work by actually turning on a group of genes that help the body move sugar into the cells more efficiently.

In this study, the authors used a special diet and rosiglitazone to treat 40 of the most refractory obese patients attending a weight loss clinic. These patients had all failed multiple attempts to lose weight and keep it off. With explicit, FDA and IRB approved informed consent, these patients eliminated a particular starchy carbohydrate, amylose, from their diet. They ate 8 ounces of protein a day, and 3 servings each of fresh fruit and vegetables that grow above the ground. They did not count calories, portion size was not restricted and fat grams were not counted.

The results were astounding. With the diet alone, the patients lost only one half pound per week. With the diet and medication, women lost 1.5 pounds per week in the 12-week study and men lost 1.7 pounds per week. Even more impressive was where the weight loss occurred. Women lost 2.4 inches around their hips and 1.6 inches off their waist. There were no adverse events.

This study will need to be verified in larger clinical trials, done with in multiple sites, but if the results are confirmed, rosiglitazone and the special no-amylose diet has the promise of defeating the rising problem of obesity by activating the body’s own metabolic machinery to burn fat. Lose your hips, ladies!

6. Was this research or any part of it ever publicized to the press before?

No, this is the first time the study has been presented in its entirety.

7. Please provide as much background information as would benefit a lay audience. Please include your funding source.
Dr. Shoemaker is a Family Practice physician in Pocomoke, MD. He has written two books on treatment of obesity and remains interested in developing new approaches to problems in contemporary Medicine. He has written two other books on the emergence of new illnesses associated with pollution and alteration of the environment. He was named Maryland's Family Doctor of the Year 2000. Dr. Cobitz is an endocrinologist and biochemist working for GlaxoSmithKline, the company that funded the study. The research interests of Dr. Cobitz include diabetes, obesity and insulin resistance. The unique collaborative effort shown in this study underscores the importance of joining primary care, observational based medicine with the most sophisticated laboratory research.

Thank you for your cooperation. If you would like to receive another copy of this form, please feel free to contact Marisa Kessel at 301-941-0255 or via e-mail: mkessel@endo-society.org.