

IN THE MATTER OF

NME HOSPITALS, INC.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket C-3397. Complaint, Aug. 24, 1992--Decision, Aug. 24, 1992*

This consent order prohibits, among other things, the California-based hospital chain from misrepresenting the comparative efficacy, permanence, or likely complications of any reconstructive surgical procedure, and requires that the respondent base future claims about the efficacy, permanence, or likely complications of any surgical procedure used in the treatment of bowel-related diseases on competent and reliable scientific evidence that substantiates any such representation.

Appearances

For the Commission: *Michael A. Katz* and *Matthew Daynard*.

For the respondent: *John A. Meyers*, in-house counsel, Santa Monica, CA.

COMPLAINT

The Federal Trade Commission, having reason to believe that NME Hospitals, Inc., d/b/a Continent Ostomy Center ("NME Hospitals"), a corporation, hereinafter referred to as respondent or proposed respondent, has violated Section 5(a) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. 45(a), and that an action by it is in the public interest, issues this complaint and alleges that:

PARAGRAPH 1. Respondent NME Hospitals is a Delaware corporation with its principal office and place of business located at 2700 Colorado Avenue, Santa Monica, California. NME Hospitals owns and operates numerous hospitals, the following five of which contain individual Continent Ostomy Centers:

1. Century City Hospital, 2070 Century Park East, Los Angeles, California.
2. RHD Memorial Center, 7 Medical Parkway, Dallas, Texas.
3. Lutheran Medical Center, 2639 Miami Street, St. Louis, Missouri.
4. Palms of Pasadena Hospital, 1501 Pasadena Avenue South, St. Petersburg, Florida.
5. San Ramon Regional Medical Center, 6001 Norris Canyon Road, San Ramon, California.

PAR. 2. Respondent is engaged in offering for sale and the sale of services in connection with the treatment of ulcerative colitis and other bowel-related diseases. The services are made available to the public under the trade name, "Continent Ostomy Center."

PAR. 3. Since at least 1989, NME Hospitals has placed, or caused to be placed, advertisements in various periodicals that are in general circulation to the public, has mailed promotional materials to potential patients and has provided on site promotional materials regarding services offered by the Continent Ostomy Center.

PAR. 4. The acts and practices of respondent alleged in this complaint have been and are in or affecting commerce, as "commerce" is defined in the FTC Act.

PAR. 5. Respondent has disseminated or caused to be disseminated advertisements and promotional materials in the offering for sale of services in connection with the treatment of ulcerative colitis and other bowel-related diseases, including, but not necessarily limited to, the attached Exhibits A through D. These advertisements and promotional materials contain one or more of the following statements:

1. "The Barnett procedure is recognized as the most successful alternative to the conventional ileostomy." (Exhibit A)
2. "[The Barnett ileostomy has] [n]o slippage or leakage." (Exhibit B)
3. "Generally [with an ileoanal anastomosis] there is over a 50% chance that patients will require additional surgery." (Exhibit C)
4. "Indeed, our initial experience with the Kock pouch was attended by an operative revision rate of 40%." (Exhibit D)

5. "A review of 71 consecutive cases where [the Barnett] technique was employed revealed a valve slippage incidence of 2.8% and overall revision rate of 7%." (Exhibit D)

6. "[With the Barnett ileostomy] [t]he incidence of valve slippage has been reduced to approximately 3%." (Exhibit D)

7. "[With the Barnett ileostomy] [t]he necessity for reoperation has progressively declined." (Exhibit D)

PAR. 6. By and through the use of the statements referred to in paragraph five, and others of similar import and meaning not specifically set forth herein, respondent has represented, directly or by implication, that:

1. Respondent's surgical procedure -- the Barnett ileostomy -- for the treatment of ulcerative colitis and other bowel-related diseases is superior to other surgical procedures used as alternatives to a conventional ileostomy.

2. No patients who have received a Barnett ileostomy have experienced slippage or leakage problems.

3. For patients who receive an ileoanal anastomosis, there is over a 50 percent chance that they will need corrective surgery.

4. Respondent's clinical experience shows that the incidence of valve slippage and reoperation for the Barnett ileostomy is substantially less than that for the Kock procedure.

PAR 7. In truth and in fact:

1. Respondent's surgical procedure--the Barnett ileostomy--for the treatment of ulcerative colitis and other bowel-related diseases is not superior to other surgical procedures used as alternatives to a conventional ileostomy.

2. Some patients who have received a Barnett ileostomy have experienced slippage and leakage problems.

3. For patients who receive an ileoanal anastomosis, there is significantly less than a 50 percent chance that they will need corrective surgery.

4. Respondent's clinical experience does not show that the incidence of valve slippage and reoperation for the Barnett ileostomy is substantially less than that for the Kock procedure.

Therefore, the representations as set forth in paragraph six were and are false and misleading.

PAR. 8. Through the use of the statements in paragraph five, and others not specifically set forth herein of similar import and meaning, respondent has represented, directly or by implication, that at the time respondent made the representations set forth in paragraph six, respondent possessed and relied upon a reasonable basis for such representations.

PAR. 9. In truth and in fact, at the time respondent made the representations set forth in paragraph six, respondent did not possess and rely upon a reasonable basis for such representations. Therefore, the representation set forth in paragraph eight was and is false and misleading.

PAR. 10. The acts and practices of respondent alleged in this complaint constitute deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the FTC Act, 15 U.S.C. 45(a).

EXHIBIT A

CONTINENT OSTOMY CENTER

AT PALMS OF PASADENA HOSPITAL

April 26, 1990

Mr. Ros Percy
30-70 34th St, 3-B
Astoria, NY 11103

Dear Mr. Percy:

Enclosed is information on the BCIR, the appliance-free ileostomy.

Due to tremendous success of the Barnett Continent Ileostomy, our experience has taken us beyond the original cases written about in the enclosed materials. Now, over 500 patients are experiencing an improved quality of life with the Barnett procedure. Today, several distinguished surgeons perform the Barnett procedure at Continent Ostomy Centers throughout the United States. Dr. Barnett has assumed the responsibility of the National Medical Directorship of these centers.

The Barnett procedure is recognized as the most successful alternative to the conventional ileostomy. In a recent article in the Journal of the American College of Surgeons, it was stated that 98% of the patients that converted to the Barnett procedure "had experienced a significant improvement in the quality of their lives." In the last year, Barnett was honored for his continent ileostomy with awards of recognition from the American College of Surgeons, United Ostomy Association, Southern Medical Association, and the National Foundation for Ileitis and Colitis.

The Continent Ostomy Centers are dedicated to providing inflammatory bowel disease patients information about this renowned procedure for surgical treatment. If, after reviewing the enclosed information, you have any questions or comments, please feel free to call us at 1-800-262-5051.

Sincerely,

Melanie Krapf
Counselor

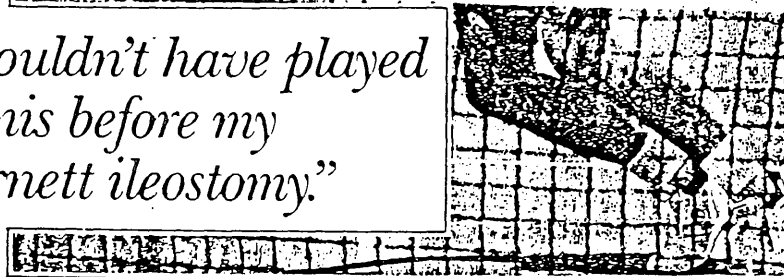
Enclosures

EXHIBIT B



EXHIBIT B

"I wouldn't have played tennis before my Barnett ileostomy."



A few years ago, I had the Brooke ileostomy. You know what that means. I had to wear an external pouch. It was difficult. Unsightly. Cumbersome. And at certain personal moments, more embarrassing than I could ever tell you.

I felt cut off from the rest of the world. I couldn't wear the clothes I wanted, or play sports the way I wanted. And, of course, it was nearly impossible to have the kind of personal relationships I wanted. The problems were mortifying—the terrible appearance, leakage and odors. I had never known that kind of depression before.

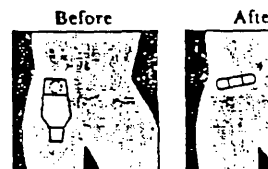
At The Century City Hospital Continent Ostomy Center, I learned about a new operation called the Barnett ileostomy. It completely replaced my earlier Brooke ileostomy. It can even replace the Kock Pouch, with its leakage and valve slippage problems.

Now I have a new internal pouch using essentially my own body. No external pouch. No slippage or leakage.

No odor. All I wear now is a small Band-Aid® to hide, because there is practically nothing to

It's changed my life so drastically I feel as if I've been reborn. I wear what I want and do what I want. And you won't believe what it's done for my personal life!

Find out about the new Barnett Continent Ostomy. It will change your life. Forever.



THE CONTINENT OSTOMY CENTER

Century City Hospital
2070 Century Park East

LOS ANGELES TIMES

EXHIBIT C

EXHIBIT C

Alternative Procedures After Coloproctectomy

JEFFREY W. CLARKE, B.A., M.A., Ostomy Center Administrator

ABSTRACT: After removal of the colon, surgical options include: the conventional ileostomy, the ileoanal anastomosis, and the continent intestinal reservoir. Patients should be informed of their options and be allowed to make a knowledgeable decision. The conventional ileostomy is a comparatively elementary procedure which insures removal of the disease. A 18% rate of re-operation is associated with the conventional ileostomy. The ileoanal anastomosis is an unpredictable procedure. Approximately 43% of these patients remain incontinent. Its re-operative rate is about 50%. Recent technical improvements with the continent intestinal reservoir have made it a viable option. It insures removal of the disease. A 7% re-operative rate is identified with the continent intestinal reservoir.

INTRODUCTION

In patients with bowel disease such as ulcerative colitis, Crohn's colitis, or familial polyposis three possible alternatives exist for treatment after removal of the diseased colon. They are: the conventional ileostomy, the ileoanal anastomosis (with or without a pouch), and the continent intestinal reservoir. Each procedure has its benefits and disadvantages. The operation which is best for one patient may not be suitable for another.¹

Thus, individual evaluation of each procedure allows one to choose the appropriate procedure on a case by case basis.

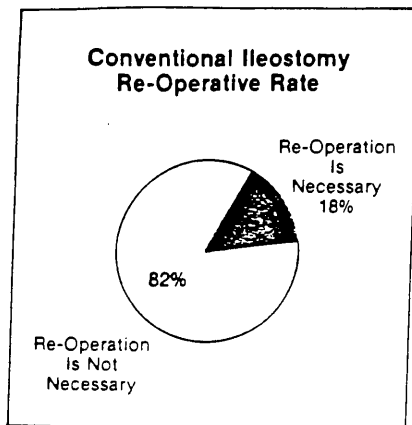
THE CONVENTIONAL ILEOSTOMY

Until recently proctocolectomy with the conventional ileostomy was the preferred procedure for patients with inflammatory bowel disease.^{2,3} The procedure involves removal of the entire colon and rectum and construction of a protruding stoma on the abdominal wall. An external appliance is then needed to collect fecal discharge.

The major advantage of the conventional ileostomy is that it is a comparatively elementary procedure which is readily available from a multiplicity of surgeons. Also, with this method usually all of the disease can be completely removed. A

The Conventional Ileostomy
(With Appliance)

patient with a conventional ileostomy loses control of his feces and is reliant upon an external appliance; this is considered a major disadvantage because of the various physical and psychological problems associated with it.⁴



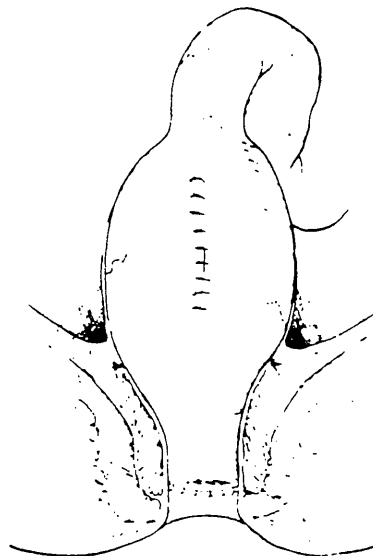
One indication of a successful procedure is the necessity for additional operations. Some individuals are under the misconception that the conventional ileostomy is without problems when in fact a substantial amount of these patients require additional surgery. The conventional ileostomy necessitates additional operations in approximately 18% of patients.⁵

THE ILEOANAL ANASTOMOSIS

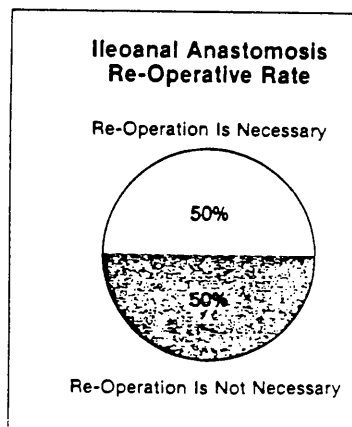
A person must approach the ileoanal anastomosis very carefully because the results are unpredictable.⁶ The surgery consists of removal of the colon with preservation of the rectum's outer wall. A temporary conventional ileostomy is created and then, if the blood supply permits, the ileum is attached (preferably with an ileal pouch) to the anus. Weeks later, during a second surgery the conventional ileostomy is removed. Thus, patients without a rectum, patients with rectal cancer, perianal fistulas, poor sphincter function, or occupations that prohibit very frequent visits to the toilet are not candidates for this procedure.⁷ Patients with Crohn's disease are not candidates for this procedure.⁸

The obvious advantage to this procedure is that continence may be restored and somewhat normal defecation is permitted. Unfortunately, 43% of these patients experience incontinence.⁹ The continent patients initially have averaged about

The Ileoanal Anastomosis



ten (10) fecal discharges per twenty four h period.¹⁰ After about a year, they report five nine (5-9) stools per day.¹¹ Thus, medication required to slow the intestine and to relieve perianal and anal pain. Because the outer rectus



retained there is always an increased chance for recurrence of the disease.¹² Also, because of nerve damage due to this surgery urinary incontinence and sexual dysfunction (impotence) are more common.^{13, 14}

Re-operations are fairly common with the ileoanal anastomosis. Although results vary considerably, none are exceptional. Generally there is over a 50% chance that patients will require additional surgery.¹⁵ However, because of the appeal of defecation from the anus some patients may acquiesce to these poor results and should be informed of this procedure.

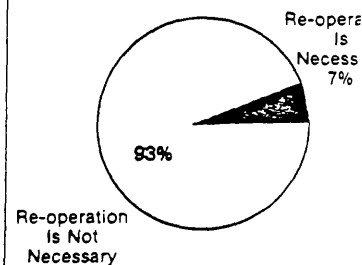
THE CONTINENT INTESTINAL RESERVOIR

Recent technical advancements have made the continent intestinal reservoir a plausible procedure for most patients that must undergo a colectomy.^{16, 17} Additionally, this procedure enables patients with a conventional ileostomy the possibility to convert to a continent arrangement. Most authorities on the continent intestinal reservoir recognize that a select group of Crohn's

patients are candidates for this procedure.¹⁸ The procedure involves the removal of the cecum and rectum and the formation of a self-sealing internal ileal pouch (preferably with an isoperistaltic valve and intestinal collar). A flush stoma is placed just above the pubis.

The advantages to this procedure are aesthetic and psychological benefits of the ileal procedure without the physiological difficulties of a conventional ileostomy. Continence is restored. The disease is remitted and medication is no longer required.²¹ To remove the stool the patient induces a 30 Fr. intubation catheter into the stoma about two or three times per day.²²

Continent Intestinal Reservoir Re-Operative Rate



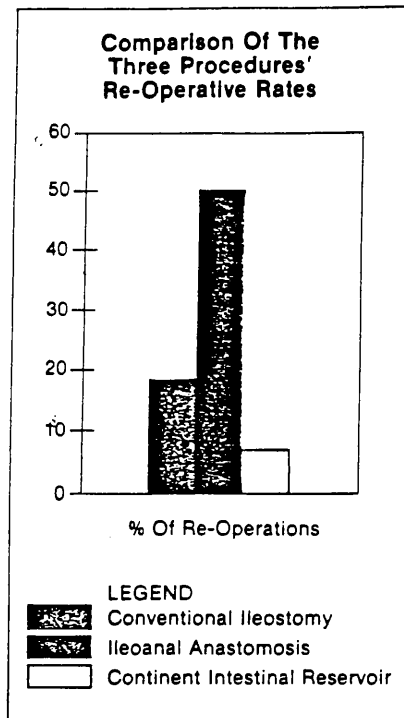
The Continent Intestinal Reservoir



The re-operative rate for this procedure is about 7%.^{23, 24} The re-operations may be more intensive than those associated with conventional ileostomy. This procedure is a good alternative because of its wide spectrum of candidate patients, low re-operative rate and continent design; patients should also be informed of this alternative.

SUMMARY

In conclusion, if it is necessary to undergo surgery for the removal of the colon, alternatives to the conventional ileostomy are available. Factors such as the extent and type of the disease, rectal musculature, social and professional life-styles may eliminate some of the alternatives. Thus, patients should be informed of their options and be allowed to make a knowledgeable decision.



(Jeffrey W. Clarke is the Administrator of the Continent Ostomy Center at Palms of Pasadena Hospital in St. Petersburg, Florida. The Center acts as a gastroenterologic educational institution and specializes in the treatment of bowel disease. Author of numerous papers, Clarke is an active member of both the United Ostomy Association and the National Foundation of Ileitis and Colitis.)

Notes

1. Lavery, IC. "Alternative Procedures" *Ostomy Quarterly* 24, 16-18.
2. Brooke BN. "The Management of an Ileostomy" *Lancet* 195 102-104.
3. Emblem, R., et al. "Operative Treatment of Ulcerative Colitis: Conventional Proctectomy with Brooke Ileostomy versus Mucosal Proctectomy with Ileoanal Anastomosis" *Scand J Gastroenterol* 1988, 23, 493-500.
4. Barnett WO. "Current Experiences with the Continent Intestinal Reservoir" *Surgery, Gynecology and Obstetrics*, 1989, 168.
5. Dozios, RR. Alternatives to Conventional Ileostomy; Book Medical Publishers, Inc. 1985, 42.
6. Cohen, Z. "Current Status of the Continent Ileostomy" *Can J Surg* 1987, 30, 358.
7. Fazio, VW. "Complications and Function of the Continent Ileostomy" *World Journal of Surgery*, 1988, 12, 148.
8. Mortensen, N. "Spout or Pouch? Alternatives for patients with ileostomies" *British Medical Journal*, 1988, 296, 154.
9. Pemberton, et al. "Quality of Life After Brooke Ileostomy and Pouch-Anal Anastomosis" *Annals of Surgery*, 1989, 205.
10. Emblem, R., et al. "Operative Treatment of Ulcerative Colitis: Conventional Proctectomy with Brooke Ileostomy versus Mucosal Proctectomy with Ileoanal Anastomosis" *Scand J Gastroenterol* 1988, 23, 497.
11. Pemberton, JH, et al. "Quality of Life After Brooke Ileostomy and Pouch-Anal Anastomosis" *Annals of Surgery*, 1985, 620-628.
12. Lavery, IC. "Alternative Procedures" *Ostomy Quarterly* 24, 85.
13. Pemberton, JH. "Quality of Life After Brooke Ileostomy and Pouch-Anal Anastomosis" *Annals of Surgery*, 1989, 205.
14. Dozios, R. Alternatives to Conventional Ileostomy; Book Medical Publishers, Inc. 1985, 348.
15. Emblem, R., et al. "Operative Treatment of Ulcerative Colitis: Conventional Proctectomy with Brooke Ileostomy versus Mucosal Proctectomy with Ileoanal Anastomosis" *Scand J Gastroenterol* 1988, 23, 493-500.
16. Barnett WO. "Modified Techniques for Improving the Continent Ileostomy" *American Surg.*, 1984, 49, 66-69.
17. Zane C. "Current Status of the Continent Ileostomy" *Can J Surg* 1987, 30, 30.
18. Bloom, RJ. "A Reappraisal of the Kock Continent Ileostomy: Patients with Crohn's Disease" *Surgery, Gyn. and Ob* 1986, 162, 105.
19. Barnett, WO. "Continent Intestinal Reservoir" *Southern Medical Journal*, 1987, 80, 1263.
20. Fazio, VW. "Complications and Functions of the Continent Ileostomy at the Cleveland Clinic" *World Journal of Surgery*, 1988, 12, 152.
21. Lavery, IC. "Alternative Procedures" *Ostomy Quarterly* 24, 16-18.
22. Barnett, WO. "Continent Intestinal Reservoirs: Ten Years Experience" currently unpublished, 1-8.
23. Barnett, WO. "Current Experiences with the Continent Intestinal Reservoir" *Surgery, Gyn. and Obstetrics*, 1989, 168, 1.
24. Cohen, Z. "Current Status of the Continent Ileostomy" *Can J Surg* 1987, 30, 358.

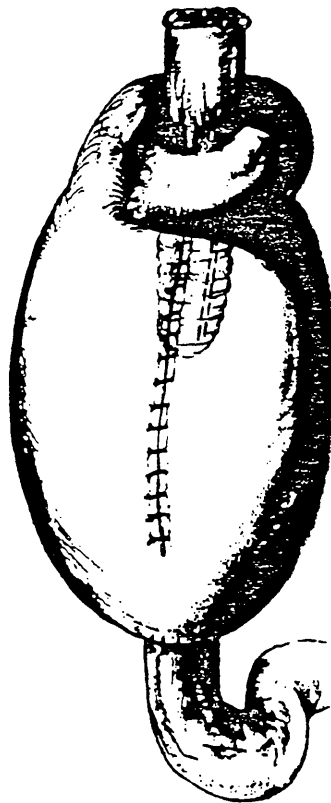
EXHIBIT D

EXHIBIT D

Continent Intestinal Reservoirs

A TEN YEAR EXPERIENCE

WILLIAM O. BARNETT, M.D., F.A.C.S.



CONTINENT OSTOMY CENTER
AT PALMS OF PALMDENA HOSPITAL

- I. INTRODUCTION
- II. CLINICAL MATERIAL - 351 CASES
- III. EVOLUTION OF SURGICAL TECHNIQUES - BCIR I
- IV. EVOLUTION OF SURGICAL TECHNIQUES - BCIR II
- V. EVOLUTION OF SURGICAL TECHNIQUES - BCIR III
- VI. CONCLUSIONS

I. INTRODUCTION

It was in 1969 that Dr. Niles Kock introduced the concept of the continent intestinal reservoir (CIR). Initial enthusiasm was high and many conventional ileostomy patients were thrilled by the prospect of a restored capacity to store intestinal waste and to control its discharge from the body. There is little question of the conclusion that a smoothly functioning CIR provides a better quality of life for most ileostomy patients. As experience with the procedure increased and larger series were reported, physicians became increasingly aware of the large number of CIR malfunctions requiring additional operative intervention. Valve slippage was probably the complication of greatest concern, being reported as 22% in one large series. Indeed, our initial experience with the Kock pouch was attended by an operative revision rate of 40%. Over the last 10 years we have maintained an effort to alter, correct and improve various technical details in CIR construction which held promise of improving results. An accumulated experience with 351 cases, all operated upon by a single surgeon, forms the basis of the subsequently detailed techniques, results and conclusions.

II. CLINICAL MATERIAL - 351 CASES

1. CONTINENT INTESTINAL RESERVOIR
A TEN YEAR EXPERIENCE

<u>CIR TYPE</u>	<u>NO. CASES</u>
KOCK	5
BCIR I	188
BCIR II	130
BCIR III	28
Total	351

2. SEX DISTRIBUTION

	<u>NO. CASES</u>
MALES	140 (40%)
FEMALES	211 (60%)
Total	351

3. AGE RANGE

<u>AGE</u>	<u>NO. CASES</u>
10 - 19	9
20 - 29	77
30 - 39	137
40 - 49	47
50 - 59	71
60 - 69	10
Total	351

4. CIR CONSTRUCTION

	<u>NO. CASES</u>
AT TIME OF COLOPROCTECTOMY	70 (20%)
CONVERTED FROM CONVENTIONAL ILEOSTOMY	281 (80%)
Total	351

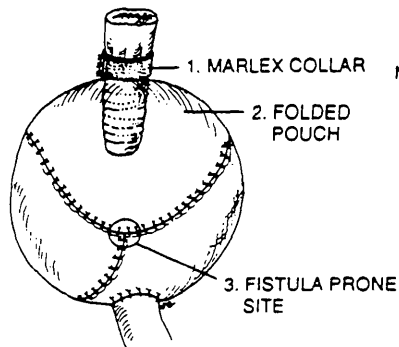
5. INDICATIONS FOR COLOPROCTECTOMY

	<u>NO. CASES</u>
ULCERATIVE COLITIS	279 (79%)
FAMILIAL POLYPOSIS	30 (9%)
CROHN'S COLITIS	32 (10%)
OTHERS	10 (2%)
Total	351

III. EVOLUTION OF SURGICAL TECHNIQUES - BCIR I

BCIR I

1980-1986



NO. CASES	RE OPERATIONS	
	SLIPPED VALVE	POUCH AND VALVE PROBLEMS
170	3.5%	15%

DISADVANTAGES

1. VALVE FISTULA
2. POUCH FISTULA

In 1980 we began the use of a valve which incorporated an isoperistaltic direction, a Marlex collar, stapling of the valve and irrigation of the serosal surface of the valve with the electrocautery. The valve slippage rate was reduced to 3.5% and the overall operative revision rate was 15%. Among the 26 cases requiring revision it was found that valve fistula, valve slippage and pouch fistula were responsible for 80% of these cases.

IV. EVOLUTION OF SURGICAL TECHNIQUES - BCIR II

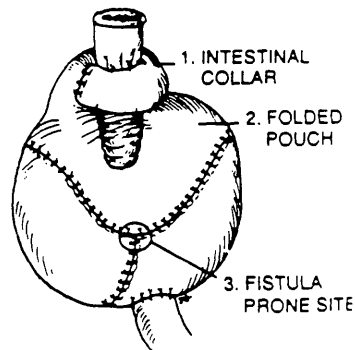
BCIR II

1986-1988

NO. CASES	RE OPERATIONS	
	SLIPPED VALVE	POUCH AND VALVE PROBLEMS
71	2.8%	7%

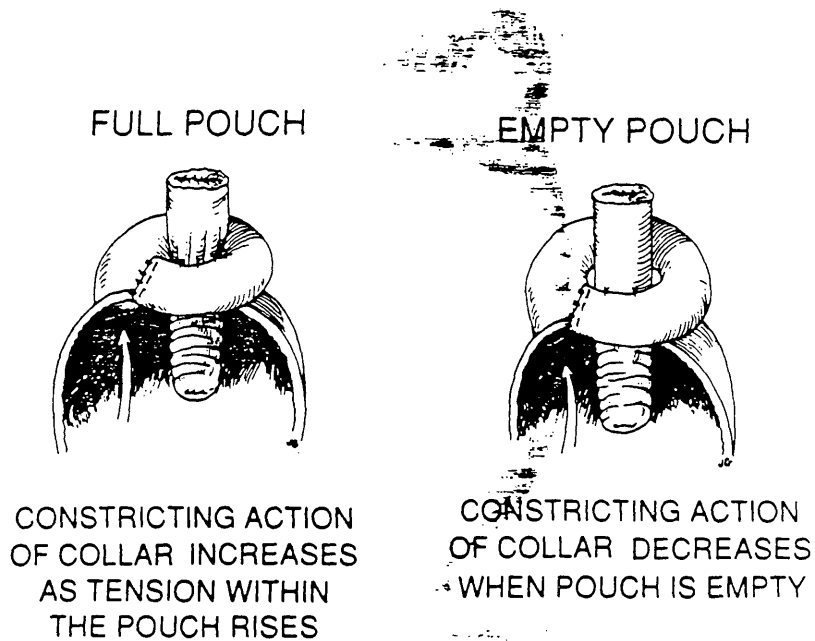
DISADVANTAGES

1. POUCH FISTULA



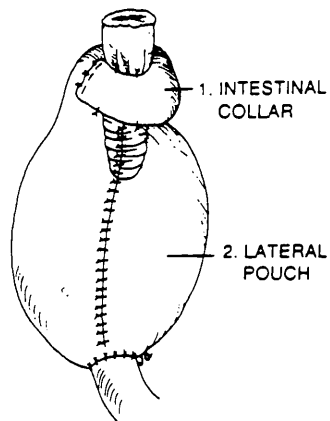
IV. EVOLUTION OF SURGICAL TECHNIQUES - BCIR II (cont'd.)

In order to eliminate valve erosion resulting from the Marlex collar we began using an intestinal collar in April of 1986. The intestinal collar provides a buttressing effect exerted against the mesenteric side of the valve where dessusception is usually initiated. This beneficial support is similar to that provided by the Marlex collar in lowering the incidence of valve slippage, but without the threat of erosion. In addition, the lumen of the intestinal collar communicates with the reservoir and allows gas and liquid to flow freely into the collar when pressure within the reservoir increases. Thus, the constricting action of the collar progressively increases as the tension within the reservoir rises. Fig (full pouch - empty pouch) The dynamics of these functions simulate the actions of the Nissen fundoplication in controlling reflux of gastric content into the esophagus. A review of 71 consecutive cases where this technique was employed revealed a valve slippage incidence of 2.8% and overall revision rate of 7%.



V. EVOLUTION OF SURGICAL TECHNIQUES - BCIR III

BCIR III



NO. CASES	RE OPERATIONS	
	SLIPPED VALVE	POUCH AND VALVE PROBLEMS
27	0%	3%

ADVANTAGES

1. NO VALVE EROSION FROM MARLEX
2. NO FISTULA PRONE SITE

The Kock pouch is characterized by the intersection of 3 suture lines at a point near the base of the valve. This is the usual site for pouch fistula formation, apparently because of poor healing at the suture line trifurcation. In January of 1988, we initiated the use of a lateral pouch which utilizes one straight suture line that completely encircles the pouch. The resulting pouch is longer and more narrow than the Kock pouch but has the same volume. Twenty seven such pouches have been fashioned over a 6 month period. One patient (3%) has required operative revision for valve malfunction. The follow up period is relatively short but results to date are encouraging.

VI. CONCLUSIONS

1. *The Continent Ileostomy was introduced by Kock in 1969 and represents a tremendous contribution to the quality of life for many ileostomy patients.*
2. *Storage capacity for intestinal waste and control of its discharge from the body are restored.*
3. *There is no need to wear a bag.*
4. *Skin problems are virtually non-existent.*
5. *There are no restrictions upon clothing (no bag bulge).*
6. *The ileal reservoir is emptied 2 to 3 times per 24 hours and this may be done with no difficulty in a public restroom.*
7. *The incidence of valve slippage has been reduced to approximately 3%.*
8. *Valve fistula has been controlled by the use of an intestinal collar rather than a Marlex collar.*
9. *Pouch fistula has been virtually eliminated by utilization of the lateral pouch.*
10. *The necessity for reoperation has progressively declined.*



CONTINENT OSTOMY CENTER
AT PALMS OF PASADENA HOSPITAL

1809 Pasadena Ave. South • 2A
St. Petersburg, FL 33707
1-813-282-5051
WILLIAM G. BARNETT, M.D., F.A.C.S., Director

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft of complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondent with violation of the Federal Trade Commission Act; and

The respondent, its attorney, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondent of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondent that the law has been violated as alleged in such complaint, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondent has violated the said Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such an agreement on the public record for a period of sixty (60) days, now in further conformity with the procedure prescribed in Section 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent NME Hospitals, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 2700 Colorado Boulevard, Santa Monica, California.
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

ORDER

For purposes of this order, the following definition shall apply:

"*Competent and reliable scientific evidence*" shall mean tests, analysis, research, studies or other evidence conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted by others in the profession or science to yield accurate and reliable results.

I.

It is ordered, That respondent NME Hospitals, Inc., a corporation, its successors and assigns, and its officers, and respondent's agents, representatives, and employees, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, promotion, offering for sale or sale of services relating to the treatment of ulcerative colitis and other bowel-related diseases, do forthwith cease and desist from:

A. Representing in any manner, directly or by implication, that respondent's surgical procedure -- the Barnett ileostomy -- for the treatment of ulcerative colitis and other bowel-related diseases is superior to other surgical procedures used as alternatives to a conventional ileostomy, unless such is the case, or otherwise misrepresenting the efficacy of the Barnett ileostomy as compared to any other surgical procedure used in the treatment of bowel-related diseases.

B. Misrepresenting in any manner, directly or by implication, that patients who had received a Barnett ileostomy have not experienced slippage or leakage problems, or otherwise misrepresenting complications following the Barnett ileostomy procedure, or any other surgical procedure used in the treatment of bowel-related diseases.

C. Representing in any manner, directly or by implication, that there is over a 50 percent chance that patients who receive an ileoanal anastomosis will need corrective surgery, or otherwise misrepresenting

senting the need for corrective surgery for any procedure used in the treatment of bowel-related diseases.

D. Misrepresenting in any manner, directly or by implication, that respondent's clinical experience shows that the incidence of valve slippage and reoperation for the Barnett ileostomy is substantially less than that for the surgical procedure commonly referred to as the "Kock procedure," or otherwise misrepresenting its clinical experience with complications following any other surgical procedure used in the treatment of bowel-related diseases.

E. Making any representation, directly or by implication, about the efficacy, permanence, or likely complications of any surgical procedure used in the treatment of bowel-related diseases unless, at the time of making any such representation, respondent possesses and relies upon competent and reliable scientific evidence that substantiates any such representation.

II.

It is ordered, That respondent NME Hospitals, Inc., a corporation, its successors and assigns, and its officers, and respondent's agents, representatives, and employees, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, promotion, offering for sale or sale of services relating to "reconstructive surgery," cease and desist from misrepresenting, directly or by implication, the efficacy, permanence, or likely complications of any of respondent's "reconstructive surgical procedures" as compared to the efficacy, permanence, or likely complications of any other surgical procedure. For purposes of this order provision, "reconstructive surgery" or "reconstructive surgical procedures" are those surgical procedures listed on Attachment A which is appended to this order.

III.

It is further ordered, That respondent shall maintain for a period of five (5) years after the date the representation was last made, and make available to the Federal Trade Commission upon request for inspection and copying, all materials possessed and relied upon to

substantiate any representation covered by this order, and all test reports, studies, or information in their possession or control that contradict, qualify or call into question any such representation.

IV.

It is further ordered, That, for a period of five (5) years after the date of entry of this order, respondent shall notify the Commission at least thirty (30) days prior to any proposed change in respondent such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in respondent which may affect compliance obligations arising out of this order.

V.

It is further ordered, That respondent NME Hospitals, Inc., a corporation, and its successors or assigns, shall forthwith distribute a copy of this order to each of its officers, agents, representatives, independent contractors and employees who are engaged in the preparation and placement of advertisements or promotional materials, who communicate with patients or prospective patients, or who have any responsibilities with respect to the subject matter of this order; and, for a period of five (5) years from the date of entry of this order distribute same to all of respondent's future officers, agents, representatives, independent contractors and employees having said responsibilities.

VI.

It is further ordered, That respondent shall, within sixty (60) days after service of this order, file with the Commission a report, in writing, setting forth in detail the manner and form in which it has complied with all requirements of this order.

ATTACHMENT A

RECONSTRUCTIVE SURGICAL PROCEDURES

ICD-9-CM

PROCEDURE CODES

PROCEDURE

NERVOUS SYSTEM

0204	BONE GRAFT TO SKULL
0205	INSERTION OF SKULL PLATE
0212	REPAIR OF CEREBAL MENINGES (INCLUDES GRAFT)
022	VENTRICULOSTOMY (INCLUDES VALVE/SHUNT INSERTION)
0231	VENTRICULAR SHUNT TO STRUCTURE IN HEAD AND NECK
0232	VENTRICULAR SHUNT TO CIRCULATORY SYSTEM
0233	VENTRICULAR SHUNT TO THORACIC CAVITY
0234	VENTRICULAR SHUNT TO ABDOMINAL CAVITY AND ORGANS
0235	VENTRICULAR SHUNT TO URINARY SYSTEM
0239	OPERATION TO ESTABLISH DRAINAGE OF VENTRICLE
0242	REPLACEMENT OF VENTRICULAR SHUNT
0293	IMPLANTATION OF INTRACRANIAL NEUROSTIMULATOR
0294	INSERTION/REPLACEMENT OF SKULL TONGS/HALO TRACTION DEVICE
0371	SPINAL SUBARACHNOID-PERITONEAL SHUNT
0372	SPINAL SUBARACHNOID-URETERAL SHUNT
0379	SHUNT OF SPINAL THECA
0390	INSERTION OF CATHETER INTO SPINAL CANAL FOR INFUSION OF THERAPEUTIC/PALLIATIVE SUBSTANCES
0393	INSERTION OR REPLACEMENT OF SPINAL NEUROSTIMULATOR
0395	SPINAL BLOOD PATCH
045	CRANIAL/PERIPHERAL NERVE GRAFT
0492	IMPLANTATION/REPLACEMENT OF PERIPHERAL NEUROSTIMULATOR

ENDOCRINE SYSTEM

0694	THYROID TISSUE REIMPLANTATION
0695	PERATHYROID TISSUE REIMPLANTATION
0745	REIMPLANTATION OF ADRENAL TISSUE
0794	TRANSPLANTATION OF THYMUS

EYE

0861	RECONSTRUCTION OF EYELID WITH SKIN FLAP/GRAFT
0862	RECONSTRUCTION OF EYELID WITH MUCOUS MEMBRANE FLAP/GRAFT
0863	RECONSTRUCTION OF EYELID WITH HAIR FOLLICLE GRAFT

0869	RECONSTRUCTION OF EYELID WITH FLAP/GRAFT
0944	INTUBATION OF NASOLACRIMAL DUCT
0983	CONJUNCTIVORHINDSTOMY WITH INSERTION OF TUBE/STENT
1041	REPAIR OF SYMBLEPHARON WITH FREE GRAFT
1042	RECONSTRUCTION OF CONJUNCTIVAL CUL-DE-SAC WITH FREE GRAFT
1044	FREE GRAFT TO CONJUNCTIVA
1132	EXCISION OF PTERYGIUM WITH CORNEAL GRAFT
1153	REPAIR OF CORNEAL LACERATION/WOUND WITH CONJUNCTIVAL FLAP
1160	CORNEAL TRANSPLANT, NOT OTHERWISE SPECIFIED
1162	LAMELLAR KERATOPLASTY
1164	PENETRATING KERATOPLASTY
1169	CORNEAL TRANSPLANT
1172	KERATOPHAKIA
1173	KERATOPROSTHESIS
1176	EPIKERATOPHAKIA
1285	REPAIR OF SCLERAL STAPHYLOMA WITH GRAFT
1287	SCLERAL REINFORCEMENT WITH GRAFT
1292	INJECTION INTO ANTERIOR CHAMBER
1371	INSERTION OF INTRAOCULAR LENS PROSTHESIS AT TIME OF CATARACT EXTRACTION (ONE-STAGE)
1370	INSERTION OF PSEUDOPHAKOS, UNSPECIFIED
1372	SECONDARY INSERTION OF INTRAOCULAR LENS PROSTHESIS
1441	SCLERAL BUCKLING WITH IMPLANT
1449	SCLERAL BUCKLING (with vitrectomy)
1475	INJECTION OF VITREOUS SUBSTITUTE
1631	REMOVAL OF OCULAR CONTENTS WITH SYNCHRONOUS IMPLANT
1641	EYEBALL ENUCLEATION WITH SYNCHRONOUS IMPLANT INTO TENON'S CAPSULE; ATTACHMENT OF MUSCLES
1642	EYEBALL ENUCLEATION WITH SYNCHRONOUS IMPLANT
1661	SECONDARY INSERTION OF OCULAR IMPLANT
1662	REVISION & REINSERTION OF OCULAR IMPLANT
1663	REVISION OF ENUCLEATION SOCKET WITH GRAFT
1665	SECONDARY GRAFT TO EXENTERATION CAVITY

EAR

186	RECONSTRUCTION OF EXTERNAL AUDITORY CANAL
1871	CONSTRUCTION OF AURICLE OF EAR
1911	STAPEDECTOMY WITH INCUS REPLACEMENT
1921	REVISION OF STAPEDECTOMY WITH INCUS REPLACEMENT
1952	TYPE II TYMPANOPLASTY
1953	TYPE III TYMPANOPLASTY
1954	TYPE IV TYMPANOPLASTY
1955	TYPE V TYMPANOPLASTY

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- 2001 MYRINGOTOMY WITH INSERTION OF TUBE
- 2061 FENESTRATION OF INNER EAR (INITIAL)
- 2071 ENDOLYMPHATIC SHUNT
- 208 OPERATIONS ON EUSTACHIAN TUBE (INCLUDES INSERTION
OF CATHETER OR TUBE)
- 2095 IMPLANTATION OF ELECTROMAGNETIC HEARING DEVICE
- 2096 IMPLANTATION OF COCHLEAR PROSTHETIC DEVICE, NOT
OTHERWISE SPECIFIED
- 2097 IMPLANTATION OR REPLACEMENT OF COCHLEAR
PROSTHETIC DEVICE, SINGLE CHANNEL
- 2098 IMPLANTATION OR REPLACEMENT OF COCHLEAR
PROSTHETIC DEVICE, MULTIPLE CHANNEL

NOSE, MOUTH, PHARYNX (1)

- 2107 CONTROL OF EPISTAXIS BY EXCISION OF NASAL MUCOSA &
SKIN GRAFT OF SEPTUM/LATERAL NASAL WALL
- 2185 AUGMENTATION RHINOPLASTY
- 242 GINIVOPLASTY
- 245 ALVEOLOPLASTY
- 247 APPLICATION OF ORTHODONTIC APPLIANCE
- 2755 FULL-THICKNESS SKIN GRAFT TO LIP & MOUTH
- 2756 SKIN GRAFT TO LIP & MOUTH

(1) Excludes dental procedures

RESPIRATORY SYSTEM

- 3175 RECONSTRUCTION OF TRACHEA & CONSTRUCTION OF
ARTIFICIAL LARYNX
- 3193 REPLACEMENT OF LARYNGEAL/TRACHEAL STENT
- 3485 IMPLANTATION OF DIAPHRAGMATIC PACEMAKER,

CARDIOVASCULAR (2)

- 3520 REPLACEMENT OF UNSPECIFIED HEART VALVE
- 3521 REPLACEMENT OF AORTIC VALVE WITH TISSUE GRAFT
- 3522 REPLACEMENT OF AORTIC VALVE
- 3523 REPLACEMENT OF MITRAL VALVE WITH TISSUE GRAFT
- 3524 REPLACEMENT OF MITRAL VALVE
- 3525 REPLACEMENT OF PULMONARY VALVE WITH TISSUE GRAFT
- 3526 REPLACEMENT OF PULMONARY VALVE
- 3527 REPLACEMENT OF TRICUSPID VALVE WITH TISSUE GRAFT
- 3528 REPLACEMENT OF TRICUSPID VALVE
- 3550 REPAIR OF UNSPECIFIED SEPTAL DEFECT OF HEART WITH
PROSTHESIS

- 3551 REPAIR OF ATRIAL SEPTAL DEFECT WITH PROSTHESIS, OPEN
TECHNIQUE
- 3552 REPAIR OF ATRIAL SEPTAT DEFECT WITH PROSTHESIS,
CLOSED TECHNIQUE
- 3553 REPAIR OF VENTRICULAR SEPTAL DEFECT WITH PROSTHESIS
- 3554 REPAIR OF ENDOCARDIAL CUSHION DEFECT WITH
PROSTHESIS
- 3560 REPAIR OF UNSPECIFIED SEPTAL DEFECT OF HEART WITH
TISSUE GRAFT
- 3561 REPAIR OF ATRIAL SEPTAL DEFECT WITH TISSUE GRAFT
- 3562 REPAIR OF VENTRICULAR SEPTAL DEFECT WITH TISSUE
GRAFT
- 3563 REPAIR OF ENDOCRAREAL CUSHION DEFECT WITH TISSUE
GRAFT
- 3595 REVISION OF CORRECTIVE PROCEDURE ON HEART (INCLUDES
REPLACEMENT OF HEART VALVE)
- 3603 OPEN CHEST CORONARY ANGIOPLASTY (WITH PATCH GRAFT)
- 3610 AORTOCORONARY BYPASS FOR HEART
REVASCULARIZATION, NOT OTHERWISE SPECIFIED
- 3611 AORTOCORONRRY BYPASS OF ONE CORONARY ARTERY
- 3612 AORTOCORONARY BYPASS OF TWO CORONARY ARTERIES
- 3613 AORTOCORONARY BYPASS OF THREE CORONARY ARTERIES
- 3614 AORTOCORONARY BYPASS OF FOUR OR MORE CORONARY
ARTERIES
- 3615 SINGLE INTERNAL MAMMARY-CORONARY ARTERY BYPASS
- 3616 DOUBLE INTERNAL MAMMARY-CORONARY ARTERY BYPASS
- 3619 OTHER BYPASS ANASTOMOSIS FOR HEART
REVASCULARIZATION
- 362 HEART REVASCULARIZATION BY ARTERIAL IMPLANT
- 375 HEART TRANSPLANTATION
- 3761 IMPLANT OF PULSATION BALLOON
- 3762 IMPLANT OF HEART ASSIST SYSTEM
- 3763 REPLACEMENT AND REPAIR OF HEART ASSIST SYSTEM
- 3770 INITIAL INSERTION OF PACEMAKER LEAD (ELECTRODE),
UNSPECIFIED
- 3771 INITIAL INSERTION OF TRANSVENOUS LEAD (ELECTRODE)
INTO VENTRICLE
- 3772 INITIAL INSERTION OF TRANSVENOUS LEADS (ELECTRODES)
INTO ATRIUM AND VENTRICLE
- 3773 INITIAL INSERTION OF TRANS VENOUS LEAD (ELECTRODE)
INTO ATRIUM
- 3774 INSERTION OF REPLACEMENT OF EPICARDIAL LEAD
(ELECTRODE) INTO EPICARDIUM
- 3776 REPLACEMENT OF TRANS VENOUS ATRIAL/VENTRICULAR
LEAD(S) (ELECTRODE)
- 3778 INSERTION OF TEMPORARY TRANSVENOUS PACEMAKER
SYSTEM

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- 3780 INSERTION OF PERMANENT PACEMAKER, INITIAL OR
REPLACEMENT, TYPE OF DEVICE UNSPECIFIED
- 3781 INITIAL INSERTION OF SINGLE-CHAMBER DEVICE, NOT
SPECIFIED AS RATE RESPONSIVE (TO PHYSIOLOGIC STIMULI)
- 3782 INITIAL INSERTION OF SINGLE-CHAMBER DEVICE, RATE
RESPONSIVE
- 3783 INITIAL INSERTION OF DUAL-CHAMBER DEVICE
- 3785 REPLACEMENT OF ANY TYPE OF PACEMAKER DEVICE WITH
SINGLE-CHAMBER DEVICE, NOT SPECIFIED AS RATE
RESPONSIVE
- 3786 REPLACEMENT OF ANY TYPE OF PACEMAKER DEVICE WITH
SINGLE-CHAMBER DEVICE, RATE RESPONSIVE
- 3787 REPLACEMENT OF ANY TYPE PACEMAKER DEVICE WITH
DUAL-CHAMBER DEVICE
- 3794 IMPLANTATION/REPLACEMENT OF AUTOMATIC
CARDIOVERTER/DEFIBRILLATOR, TOTAL SYSTEM (AICD)
- 3795 IMPLANTATION OF AUTOMATIC
CARDIOVERTER/DEFIBRILLATOR LEAD(S) ONLY
- 3796 IMPLANTATION OF AUTOMATIC
CARDIOVERTER/DEFIBRILLATOR PULSE GENERATOR ONLY
- 3797 REPLACEMENT OF AUTOMATIC
CARDIOVERTER/DEFIBRILLATOR LEAD(S) ONLY
- 3798 REPLACEMENT OF AUTOMATIC
CARDIOVERTER/DEFIBRILLATOR PULSE GENERATOR ONLY
- 3840 RESECTION OF VESSEL WITH REPLACEMENT, UNSPECIFIED
SITE
- 3841 RESECTION OF VESSEL WITH REPLACEMENT, INTRACRANIAL
VESSEL
- 3842 RESECTION OF VESSEL WITH REPLACEMENT, VESSEL OF
HEAD & NECK
- 3843 RESECTION OF VESSEL WITH REPLACEMENT, UPPER LIMB
VESSEL
- 3844 RESECTION OF VESSEL WITH REPLACEMENT, ABDOMINAL
AORTA
- 3845 RESECTION OF VESSEL WITH REPLACEMENT, THORACIC
VESSEL (AORTA)
- 3846 RESECTION OF VESSEL WITH REPLACEMENT, ABDOMINAL
ARTERY
- 3847 RESECTION OF VESSEL WITH REPLACEMENT, ABDOMINAL
VEIN
- 3848 RESECTION OF VESSEL WITH REPLACEMENT, LOWER LIMB
ARTERY
- 3849 RESECTION OF VESSEL WITH REPLACEMENT, LOWER LIMB
VEIN
- 387 INTERRUPTION OF THE VENA CAVA (INCLUDES WITH
IMPLANT OR SIEVE)
- 3895 VENOUS CATHETERIZATION FOR RENAL DIALYSIS

- 3956 REPAIR OF BLOOD VESSEL WITH TISSUE PATCH GRAFT
- 3957 REPAIR OF BLOOD VESSEL WITH SYNTHETIC PATCH GRAFT
- 3958 REPAIR OF BLOOD VESSEL WITH UNSPECIFIED TYPE OF
PATCH GRAFT
- 3964 INTRAOPERATIVE CARDIAC PACEMAKER
- 398 OPERATIONS OF CARTOD BODY AND OTHER VASCULAR
BODIES
- 3993 INSERTION OF VESSEL-TO-VESSEL CANNULA

(2) Does not include specialized pediatric cardiovascular procedures (not performed at any hospital owned by NME Hospitals, Inc.)

HEMIC/LYMPHATIC SYSTEM

- 4061 CANNULATION OF THORACIC DUCT
- 4100 BONE MARROW TRANSPLANT, NOT OTHERWISE SPECIFIED
- 4101 AUTOLOGOUS BONE MARROW TRANSPLANT
- 4102 ALLOGENEIC BONE MARROW TRANSPLANT WITH PURGING
- 4103 ALLOGENEIC PONE MARROW TRANSPLANT WITHOUT
PURGING
- 4194 TRANSPLANTATION OF SPLEEN

DIGESTIVE SYSTEM (3)

- 4281 INSERTION - PERMANENT TUBE INTO ESOPHAGUS
- 4287 GRAFT OF ESOPHAGUS
- 4311 PERCUTANEOUS (ENDOSCOPIC) GASTROSTOMY (PEG)
- 4493 INSERTION OF GASTRIC BUBBLE (BALLOON)
- 4522 CONTINENT ILEOSTOMY
- 4532 PERCUTAEIOUS (ENDOSCOPIC) JEJUNOSTOMY (PEJ)
- 4610 COLOSTOMY, UNSPECIFIED
- 4612 PERMANENT MAGNETIC COLOSTOMY
- 4613 PERMANENT COLOSTOMY
- 4620 ILEOSTOMY, UNSPECIFIED
- 4621 TEMPORARY ILEOSTOMY
- 4992 INSERTION OF SUBCUTANEOUS ELECTRICAL ANAL
STIMULATOR
- 5051 AUXILIARY LIVER TRANSPLANT
- 5059 LIVER TRANSPLANT
- 5143 INSERTION OF CHOLEDO CHOHEPATIC TUBE FOR
DECOMPRESSION
- 5186 ENDOSCOPIC INSERTION OF NASOBILIARY DRAINAGE TUBE
- 5187 ENDOSCOPIC INSERTION OF STENT (TUBE) INTO BILE DUCT
- 5280 PANCREATIC TRANSPLANT, UNSPECIFIED
- 5281 REIMPLANTATION OF PANCREATIC TISSUE
- 5282 HOMOTRANSPLANT OF PANCREAS
- 5283 HETEROTRANSPLANT OF PANCREAS

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- 5292 CANJULATION OF PANCREATIC DUCT
- 5297 ENDOSCOPIC INSERTION OF NASOPANCREATIC DRAINAGE
TUBE
- 5303 UNILATERAL REPAIR OF DIRECT INGUINAL HERNIA WITH
GRAFT/PROSTHESIS
- 5304 UNILATERAL REPAIR OF INDIRECT INGUINAL HERHIA WITH
GRAFT/PROSTHESIS
- 5305 UNILATERAL REPAIR OF INGUINAL HERNIA WITH
GRAFT/PROSTHESIS, UNSPECIFIED
- 5314 BILATERAL REPAIR OF DIRECT INGUINAL HERNIA WITH
GRAFT/PROSTHESIS
- 5315 BILATERAL REPAIR OF INDIRECT INGUINAL HERHIA WITH
GRAFT/PROSTHESIS
- 5316 BILATERAL REPAIR OF INGUINAL HERNIA, DIRECT&INDIRECT,
WITH GRAFT/PROSTHESIS
- 5317 BILATERAL REPAIR OF INGUINAL HERNIA, WITH
GRAFT/PROSTHESIS, UNSPECIFIED
- 5321 UNILATERAL REPAIR OF FEMORAL HERHIA WITH
GRAFT/PROSTHESIS
- 5331 BILATERAL REPAIR OF FEMORAL HERHIA WITH
GRAFT/PROSTHESIS
- 5341 REPAIR UMBILICAL HERNIA WITH PROSTHESIS
- 5361 INCISIONAL HERNIA REPAIR WITH PROSTHESIS
- 5369 REPAIR OF HERNIA OF ANTERIOR ABDOMINAL WALL WITH
GRAFT/PROSTHESIS

(3) Excludes bilroths, bypasses, and anastomoses

URINARY SYSTEM

- 5561 RENAL AUTOTRANSPLANTATION
- 5569 KIDNEY TRANSPLANTATION
- 5597 IMPLANTATION/REPLACEMENT OF MECHANICAL KIDNEY
- 5692 IMPLANTATION OF ELECTRONIC URETERAL STIMULATOR
- 5693 REPLACEMENT OF ELECTRONIC URETERAL STIMULATOR
- 5794 INSERTION OF INDWELLING URINARY CATHETER
- 5795 REPLACEMENT OF INDWELLING URINARY CATHETER
- 5796 IMPLANTATION OF ELECTRONIC BLADDER STIMULATOR
- 5797 REPLACEMENT OF ELECTRONIC BLADDER STIMULATOR
- 5893 IMPLANTATION OF ARTIFICIAL URINARY SPHINCTER (AUS)
- 598 URETERAL CATHETERIZATION
- 5993 REPLACEMENT OF URETEROSTOMY TUBE
- 5994 REPLACEMENT OF CYSTOSTOMY TUBE

MALE GENITAL ORGANS

- 627 INSERTION OF TESTICULAR PROSTHESIS

- 6395 INSERTION OF VALVE IN VAS DEFERENS
- 6443 CONSTRUCTION OF PENIS
- 6494 FITTING OF EXTERNAL PROSTHESIS OF PENIS
- 6495 INSERTION OR REPLACEMENT OF INTERNAL
NON-INFLATABLE PROSTHESIS OF PENIS
- 6497 INSERTION OR REPLACEMENT OF INTERNAL INFLATABLE
PROSTHESIS OF PENIS

FEMALE GENITAL ORGANS

- 6693 IMPLANTATION/REPLACEMENT OF PROSTHESIS OF
FALLOPIAN TUBE
- 697 INSERTION OF INTRAUTERINE CONTRACEPTIVE DEVICE
- 6991 INSERTION OF THERAPEUTIC DEVICE INTO UTERUS
- 6992 ARTIFICIAL INSEMINATION (INCLUDES INVITRO
FERTILIZATION)

MUSCULOSKELETAL

- 7691 BONE GRAFT TO FACIAL BONE
- 7692 INSERTION SYNTHETIC IMPLANT IN FACIAL BONE
- 7800 BONE GRAFT TO UNSPECIFIED BONE
- 7801 BONE GRAFT TO SCAPULA/CLAVICLE/THORAX
(RIBS/STERNUM)
- 7802 BONE GRAFT TO HUMERUS
- 7803 BONE GRAFT TO RADIUS/ULNA
- 7804 BONE GRAFT TO CARPALS/METACARPALS
- 7805 BONE GRAFT TO FEMUR
- 7806 BONE GRAFT TO PATELLA
- 7807 BONE GRAFT TO TIBIA/FIBULA
- 7808 BONE GRAFT TO TARSALS/METATARSALS
- 7809 BONE GRAFT TO SPECIFIED BONE, EXCEPT FACIAL BONE
- 7810 APPLICATION OF EXTERNAL FIXATION DEVICE, UNSPECIFIED
BONE
- 7811 APPLICATION OF EXTERNAL FIXATION DEVICE,
SCAPULA/CLAVICLE/THORAX (RIBS/STERNUM)
- 7812 APPLICATION OF EXTERNAL FIXATION DEVICE HUMERUS
- 7813 APPLICATION OF EXTERNAL FIXATION DEVICE, RADIUS/ULNA
- 7814 APPLICATION OF EXTERNAL FIXATION DEVICE,
CARPALS/METACARPALS
- 7815 APPLICATION OF EXTERNAL FIXATION DEVICE, FEMUR
- 7816 APPLICATION OF EXTERNAL FIXATION DEVICE, PATELLA
- 7817 APPLICATION OF EXTERNAL FIXATION DEVICE, TIBIA/FIBULA
- 7818 APPLICATION OF EXTERNAL FIXATION DEVICE,
TARSALS/METATARSALS
- 7819 APPLICATION OF EXTERNAL FIXATION DEVICE
- 7830 LIMB LENGTHENING, UNSPECIFIED BONE

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- 7832 LIMB LENGTHENING, HUMERUS
- 7833 LIMB LENGTHENING, RADIUS/ULNA
- 7834 LIMB LENGTHENING, CARPALS/METACARPALS
- 7835 LIMB LENGTHENING, FEMUR
- 7837 LIMB LENGTHENING, TIBIA/FIBULA
- 7838 LIMB LENGTHENING, TARSALS/METATARSALS
- 7839 LIMB LENGTHENING
- 7850 INTERNAL FIXATION OF BONE WITHOUT FRACTURE
REDUCTION, UNSPECIFIED SITE
- 7851 INTERNAL FIXATION OF BONE WITHOUT FRACTURE
REDUCTION, SCAPULA/CLAVICLE/THORAX (RIBS/STERNUM)
- 7852 INTERNAL FIXATION OF BONE WITHOUT FRACTURE
REDUCTION, HUMERUS
- 7853 INTERNAL FIXATION OF BONE WITHOUT FRACTURE
REDUCTION, RADIUS/ULNA
- 7854 INTERNAL FIXATION OF BONE WITHOUT FRACTURE
REDUCTION, CARPALS/METACARPALS
- 7855 INTERNAL FIXATION OF BONE WITHOUT FRACTURE
REDUCTION, FEMUR
- 7856 INTERNAL FIXATION OF BONE WITHOUT FRACTURE
REDUCTION, PATELLA
- 7857 INTERNAL FIXATION OF BONE WITHOUT FRACTURE
REDUCTION, TIBIA/FIBULA
- 7858 INTERNAL FIXATION OF BONE WITHOUT FRACTURE
REDUCTION, TARSALS/METATARSALS
- 7859 INTERNAL FIXATION OF BONE WITHOUT FRACTURE
REDUCTION, SPECIFIC BONE, EXCEPT FACIAL BONE
- 7890 INSERTION OF BONE GROWTH STIMULATOR INTO UNSPECIED
BONE
- 7891 INSERTION OF BONE GROWTH STIMULATOR INTO
SCAPULA/CLAVICLE/THORAX (RIBS/STERNUM)
- 7892 INSERTION OF BONE GROWTH STIMULATOR INTO HUMERUS
- 7893 INSERTION OF BONE GROWTH STIMULATOR INTO
RADIUS/ULNA
- 7894 INSERTION OF BONE GROWTH STIMULATOR INTO
CARPALS/METACARPALS
- 7895 INSERTION OF BONE GROWTH STIMULATOR INTO FEMUR
- 7896 INSERTION OF BONE GROWTH STIMULATOR INTO PATELLA
- 7897 INSERTION OF BONE GROWTH STIMULATOR INTO
TIBIA/FIBULA
- 7898 INSERTION OF BONE GROWTH STIMULATOR INTO
TARSALS/METATARSALS
- 7899 INSERTION OF BONE GROWTH STIMULATOR INTO SPECIFIED
BONE, EXCEPT FACIAL BONE
- 7910 CLOSED REDUCTION OF FRACTURE WITH INTERNAL
FIXATION OF UNSPECIFIED SITE

- 7911 CLOSED REDUCTION OF FRACTURE WITH INTERNAL
FIXATION OF HUMERUS
- 7912 CLOSED REDUCTION OF FRACTURE WITH INTERNAL
FIXATION OF RADIUS/ULNA
- 7913 CLOSED REDUCTION OF FRACTURE WITH INTERNAL
FIXATION OF CARPALS/METACARPALS
- 7914 CLOSED REDUCTION OF FRACTURE WITH INTERNAL
FIXATION OF PHALANGES OF HAND
- 7915 CLOSED REDUCTION OF FRACTURE WITH INTERNAL
FIXATION OF FEMUR
- 7916 CLOSED REDUCTION OF FRACTURE WITH INTERNAL
FIXATION OF TIBIA/FIBULA
- 7917 CLOSED REDUCTION OF FRACTURE WITH INTERNAL
FIXATION OF TARSALS/METATARSALS
- 7918 CLOSED REDUCTION OF FRACTURE WITH INTERNAL
FIXATION OF PHALANGES OF FOOT
- 7919 CLOSED REDUCTION OF FRACTURE WITH INTERNAL
FIXATION OF SPECIFIED BONE
- 7930 OPEN REDUCTION OF FRACTURE WITH INTERNAL FIXATION
OF UNSPECIFIED SITE
- 7931 OPEN REDUCTION OF FRACTURE WITH INTERNAL FIXATION
OF HUMERUS
- 7932 OPEN REDUCTION OF FRACTURE WITH INTERNAL FIXATION
OF RADIUS/ULNA
- 7934 OPEN REDUCTION OF FRACTURE WITH INTERNAL FIXATION
OF PHALANGES OF HAND
- 7935 OPEN REDUCTION OF FRACTURE WITH INTERNAL FIXATION
OF FEMUR
- 7936 OPEN REDUCTION OF FRACTURE WITH INTERNAL FIXATION
OF TIBIA/FIBULA
- 7937 OPEN REDUCTION OF FRACTURE WITH INTERNAL FIXATION
OF TARSALS/METATARSALS
- 7938 OPEN REDUCTION OF FRACTURE WITH INTERNAL FIXATION
OF PHALANGES OF FOOT
- 7939 OPEN REDUCTION OF FRACTURE WITH INTERNAL FIXATION
OF SPECIFIED BONE
- 8100 SPINAL FUSION, UNSPECIFIED
- 8101 ATLAS-AXIS SPINAL FUSION
- 8102 CERVICAL FUSION, ANTERIOR TECHNIQUE
- 8103 CERVICAL FUSION, POSTERIOR TECHNIQUE
- 8104 DORSAL/DORSOLUMBAR FUSION, ANTERIOR TECHNIQUE
- 8105 DORSAL/DORSOLUMBAR FUSION, POSTERIOR TECHNIQUE
- 8106 LUMBAR/LUMBOSACRAL FUSION, ANTERIOR TECHNIQUE
- 8107 LUMBAR/LUMBOSACRAL FUSION, LATERAL TRANSVERSE
PROCESS TECHNIQUE
- 8108 LUMBAR/LUMBOSACRAL FUSION, POSTERIOR TECHNIQUE
- 8109 REFUSION OF SPINE, ANY LEVEL OR TECHNIQUE

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- 8111 ANKLE FUSION
- 8112 TRIPLE ARTHRODESIS
- 8113 SUBTALAR FUSION
- 8114 MIDTARSAL FUSION
- 8115 TARSO/METATARSAL FUSION
- 8116 METATARSOPHALANGEAL FUSION
- 8117 FUSION OF FOOT
- 8120 ARTHRODESIS OF UNSPECIFIC JOINT
- 8121 ARTHRODESIS OF HIP
- 8122 ARTHRODESIS OF KNEE
- 8123 ARTHRODESIS OF SHOULDER
- 8124 ARTHRODESIS OF ELBOW
- 8125 CARPORADIAL FUSION
- 8126 METACARPOCARPAL FUSION
- 8127 METACARPOPHALANGEAL FUSION
- 8128 INTERPHALANGEAL FUSION
- 8129 ARTHRODESIS OF SPECIFIED JOINT
- 8151 TOTAL HIP REPLACEMENT
- 8152 PARTIAL HIP REPLACEMENT
- 8154 TOTAL KNEE REPLACEMENT
- 8156 TOTAL ANKLE REPLACEMENT
- 8157 REPLACEMENT OF JOINT OF FOOT & TOE
- 8171 ARTHROPLASTY OF METACARPALANGEAL &
INTERPHALANGEAL JOINT WITH IMPLANT
- 8173 TOTAL WRIST REPLACEMENT
- 8174 ARTHROPLASTY OF CARPOCARPAL OR CARPOMETACARFAL
JOINT WITH IMPLANT
- 8180 TOTAL SHOULDER REPLACEMENT
- 8181 PARTIAL SHOULDER REPLACEMENT
- 8184 TOTAL ELBOW REPLACEMENT
- 8261 SURGICAL CONSTRUCTION OF THUMB FROM PORTION OF
INDEX FINGER
- 8269 RECONSTRUCTION OF THUMB
- 8272 PLASTIC OPERATION ON HAND WITH GRAFT OF MUSCLE OR
FASCIA
- 8279 PLASTIC OPERATION ON HAND WITH GRAFT OR IMPLANT
- 8375 TENDON TRANSFER/TRANSPLANT
- 8377 MUSCLE TRANSFER/TRANSPLANT
- 8381 TENDON GRAFT
- 8382 MUSCLE/FASCIA GRAFT
- 8392 INSERTION/REPLACEMENT OF SKELETAL MUSCLE
STIMULATOR
- 8440 IMPLANTATION/FITTING OF PROSTHETIC LIMB DEVICE,
UNSPECIFIED
- 8441 FITTING OF PROSTHESIS OF UPPER ARM & SHOULDER
- 8442 FITTING OF PROSTHESIS OF LOWER ARM & HAND
- 8443 FITTING OF PROSTHESIS OF ARM, UNSPECIFIED

- 8444 IMPLANTATION OF PROSTHETIC DEVICE OF ARM
- 8445 FITTING OF PROSTHESIS ABOVE KNEE
- 8446 FITTING OF PROSTHESIS BELOW KNEE
- 8447 FITTING OF PROSTHESIS OF LEG, UNSPECIFIED
- 8448 IMPLANTATION OF PROSTHETIC DEVICE OF LEG

SKIN

- 8533 UNILATERAL SUBCUTANEOUS MAMMECTOMY WITH SYNCHRONOUS IMPLANT
- 8535 BILATERAL SUBCUTANEOUS MAMMECTOMY WITH SYNCHRONOUS IMPLANT
- 8550 AUGMENTATION MAMMOPLASTY, UNSPECIFIED
- 8551 UNILATERAL INJECTION INTO BREAST FOR AUGMENTATION
- 8552 BILATERAL INJECTION INTO BREAST FOR AUGMENTATION
- 8553 UNILATERAL BREAST IMPLANT (for Augmentation)
- 8554 BILATERAL BREAST IMPLANT (for Augmentation)
- 8570 TOTAL RECONSTRUCTION OF BREAST
- 8582 SPLIT-THICKNESS GRAFT TO BREAST
- 8583 FULL-THICKNESS GRAFT TO BREAST
- 8584 PEDICLE GRAFT TO BREAST
- 8585 MUSCLE FLAP GRAFT TO BREAST
- 8595 INSERTION OF BREAST TISSUE EXPANDER
- 8606 INSERTION OF TOTALLY IMPLANTABLE INFUSION PUMP
- 8607 INSERTION OF TOTALLY IMPLANTABLE VASCULAR ACCESS DEVICE (VAD)
- 8660 FREE SKIN GRAFT, UNSPECIFIED
- 8661 FULL-THICKNESS SKIN GRAFT TO HAND
- 8662 SKIN GRAFT TO HAND
- 8663 FULL-THICKNESS SKIN GRAFT
- 8664 HAIR TRANSPLANT
- 8665 HETEROGRAFT TO SKIN
- 8666 HOMOGRAFT TO SKIN
- 8669 SKIN GRAFT
- 8670 PEDICLE FLAP/GRAFT, UNSPECIFIED
- 8671 CUTTING & PREPARATION OF PEDICLE FLAP/GRAFT
- 8672 ADVANCEMENT OF PEDICLE GRAFT
- 8673 ATTACHMENT OF PEDICLE FLAP/GRAFT TO HAND
- 8674 ATTACHMENT OF PEDICLE FLAP/GRAFT
- 8693 INSERTION OF TISSUE EXPANDER

IN THE MATTER OF

THE WINNING COMBINATION, INC., ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF
SECS. 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT*Docket C-3398. Complaint, Aug. 24, 1992--Decision, Aug. 24, 1992*

This consent order prohibits, among other things, a California corporation and its officer from misrepresenting the efficacy of Essential Factors with Oxy-Energizer, a food supplement, or any similar product; from making certain representations unless they possess competent and reliable scientific evidence to substantiate the representations; and from representing that any such product has been accepted by the U.S. Government as effective for relieving fatigue or providing extra energy.

Appearances

For the Commission: *Michael Milgrom and Brinley H. Williams.*
For the respondents: *Pro se.*

COMPLAINT

The Federal Trade Commission, having reason to believe that The Winning Combination, Inc., a corporation, and Andrew Lessman, individually and as an officer of said corporation ("respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, alleges:

PARAGRAPH 1. Respondent The Winning Combination, Inc., is a corporation organized, existing and doing business under and by virtue of the laws of the State of California, with its office or principal place of business located at 1661 19th Street, Santa Monica, California.

Respondent Andrew Lessman is an officer of the corporate respondent named herein. He formulates, directs and controls the acts and practices of said corporate respondent, including the acts and