

OSTOMY POUCH DESIGN
AND MANUFACTURERS'
GROUPTHINK

by

Mike ET

A personal and professional
perspective to help elucidate the state
of ostomy pouch manufacturing and
design as it (adversely) affects ostomy
well being.

1960s – 2000s

ABSTRACT

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The needs of the incontinent fecal ostomate are rather straightforward, especially as it relates to the functionality of the external collection pouch necessary to resume a reasonable lifestyle – an effective pouch to comfortably contain the effluent and permit reasonable emptying cycles without undue disruption in lifestyle activities. Since the late 1960s and early 1970s much has been learned, categorized and published to enhance the understanding of the physiology and capacities of bowel and bladder. Paralleling this knowledge has been an increase in the population of traditional or incontinent ostomates. During these same decades a consolidation of ostomy pouch manufacturers has occurred, effectively reducing the dozens of competitors to a handful or two worldwide. Ironically, the evolution of the ostomy pouch has not kept pace with the immutable reality of bowel physiology and capacities and the varied fecal ostomates' range of needs. There has evolved a trend to produce a one-size-fits-all pouch design and limited size choices that are foisted upon the ostomy populace. Groupthink (likemindedness) among the major manufacturers has replaced clear evidence, common sense and sound judgment of the varying needs of the ostomy population. (Word count: 187)

ACKNOWLEDGMENTS

The author wishes to thank the thousands of ostomates and the pouch manufacturers who have contributed so much insight, wittingly and otherwise, into my world of ostomy interaction. Many of my ET colleagues, and in particular Edith Lenneberg and Katherine Jeter, have also been my benefactors while they, personally and through their writings, shared their philosophies and practices of ostomy rehabilitation.

Ultimately, I wish to thank Elizabeth McConnell. She was my first formal ET instructor and mentor. Her comprehensive and pragmatic approach to ostomy management and ET practice truly shaped my lifelong style of ostomy learning, teaching and rehabilitation. Here's to you, Mac!

GLOSSARY

Whimsy, [1] n. 1. Capricious humor or disposition; extravagant, fanciful, or excessively playful expression. 2. An odd or fanciful notion. 3. Anything odd or fanciful; a product of playful or capricious fancy. – Syn. caprice, whim, humor, quirk, vagary. Within the context of this paper, whimsy also refers to the failure to incorporate prima facie arguments into the development, manufacturing, marketing and promotional processes of ostomy pouches.

Groupthink, [2] n. A term coined by psychologist Irving Janis in 1972 to describe one process by which a group can make bad or irrational decisions. In a groupthink situation, each member of the group attempts to conform his or her opinions to what they believe to be the consensus of the group. This results in a situation in which the group ultimately agrees on an action which each member might normally consider to be unwise. Signs of groupthink include:

- Examining few alternatives
- Not seeking expert opinion
- Being highly selective in gathering information (see confirmation bias)
- An illusion of invulnerability
- Strong belief in group's inherent morality
- Rationalizing poor decisions
- Pressure to conform within group; members withhold criticisms
- Overt external or internal pressure to come to a decision
- Pressure to protect group from negative views or information

Confirmation bias, n. A phenomenon whereby, in a variety of settings, decision makers have been shown to notice more, assign more weight to, and actively seek out evidence that confirms their claims and they tend to ignore and not seek that which might discount their claims.

Chapter 1

INTRODUCTION

PERMANENT OSTOMIES

PRIMA FACIE ARGUMENTS – 1

PRIMA FACIE ARGUMENTS - 2

INTRODUCTION

“Adjustment to ostomy can be a lengthy process requiring intense, sensitive rehabilitation contingent upon a well designed, manufactured and implemented pouching system that will efficiently, effectively and comfortably contain the stomal effluent.”[3]

In the 1970s, the expectation for patient care was that, given sufficient time, teaching and opportunity, the patient would achieve a modicum of success with ostomy self care while still hospitalized. Now, fast forward to the 21st century and we have the predicament of fast tracking patients through the hospital phase, with restricted ostomy supply choices, while attempting to relegate rehabilitation goals to the home care phase. Although technical innovations in medicine, drugs and surgery have allowed quicker recuperation response times or shorter hospital stays, the realities of adjusting to ostomy lifestyle have not changed. In short, the mind and body cannot adjust to the altered potty routine as quickly as surgical innovation

and payer driven economics suggest or expect. This disconnect between the expected truncated rehabilitation goals and the reality of time dependent adjustment reactions to ostomy surgery and its aftermath yields a widening chasm between what is hoped for and what fails to occur.

Patients increasingly are asked to adjust more quickly to their ostomies while health care providers are pushed to accomplish the impossible and impractical tasks of rehabilitating them well before they are ready or able to be rehabilitated. I offer up the very simple analogy of potty training an infant – it can not be rushed, no matter how desperate one is to do so. It is even more challenging to potty train one who has to give up what was once learned and replace it with a more complicated process of ostomy adjustment, with all its attendant physical and psycho-social pitfalls. Given this time constrained reality, payers and practitioners are seeking shortcuts to the end goal – whatever it may turn out to be – and calling it a success if the patient is able to do the minimum ostomy potty self care, as defined by a given practitioner at any given time. Along the way the more substantive issues of acceptance and internalization of the ostomy lifestyle are left to the patient's own devices and the vagaries of the ostomy marketplace. It is because of the vagaries of the ostomy marketplace and the arbitrary shenanigans of a manufacturer's pouch size and design change that the impetus for this article arose.

PERMANENT OSTOMIES

Permanent ostomies, whether incontinent or continent, demand lifelong care commitment from all parties responsible for their creation and management. Some ostomates, now approaching and well into their golden years, whose ostomy surgeries occurred during the decades of the 1940s and 1950s, were reborn from their ashes of disease at early ages, especially those with birth defects or in their teens or early adult years. Clearly, by the 1970s the medical literature was beginning to reassert that the average or expected lifespan of an ostomate cured of her underlying disease paralleled that of the normal population.[4] These stalwart ostomates have gone on to live long and productive lives. As they continued with their lives, many of their initial caregivers and products have long passed or changed, and replacement practitioners and products have attempted to meet their ongoing needs. One of the ongoing challenges for ostomates, neophytes and old-timers, and their caregivers is to mesh the equipment expectations of the ostomates with the varied and changing requirements for ongoing practical and effective ostomy management. It is not unreasonable to expect changes over time in stomal behaviors, especially output patterns, for some portion of the ostomy population as they experience changes in their own health, and from the effects of various medicaments or interventions employed to treat a host of illness threats.

Concerning the earliest founders and members of the WOCN, many who are ostomate Enterostomal Therapists (ETs) gracefully fulfilling their lives as they age alongside their non-ostomy peers, the challenge remains for them to continue to assist their younger contemporaries in the art of accommodating the needs and desires of the ostomate. I place myself in this early group of ETs and feel obliged to continue to teach and inform my peers. If I bring more historical context than the reader desires, so be it. It serves us well to place changing circumstances within a meaningful historical context. Given that ostomy is not the sole focus of current WOCN practice, and may only represent twenty percent of ostomy-directed energy expended in many practice settings, the opportunity and time available to learn enough about ostomy management is more difficult to achieve. In this current setting, old time ostomates, ETs and newer WOCN practitioners must work as a team teaching and learning from one another.

PRIMA FACIE ARGUMENTS – 1

Ostomy is an identity crisis of image and function

Prima facie arguments are like prime directives – they supersede all other arguments. To say that having an ostomy is an identity crisis of image and function

is not overstating the tremendous conflicts that arise when one must adapt to and accept all the ramifications that adhere to ostomy surgery and its attendant rehabilitation and lifelong challenges. The table below, while far from a complete representation, succinctly illustrates some of the more salient issues confronting the newly formed ostomate.[5]

| Physiological Changes | Psychological Changes |
|------------------------------------|---|
| Stoma | New toileting (potty crisis anew) |
| Excreta | Color – odor – texture, now more varied and no longer easily hidden |
| Pathology | Ostomy justified? (only time will tell) |
| Surgical technique | Sex and or lifestyle affected? (only time will tell) |
| Amputated / bypassed sphincter | Mourning loss of volitional control and elegant functioning of hidden assets. |
| Pouch as substitute storage device | Loss of elegant and once hidden storage vessel |

Pre-existing factors

Expectations afterward

Pouch capacity is paramount to all other aesthetic needs

While it is appropriate to focus on the issues of loss and change that ostomy incurs, it is also important to understand the quality of the substitute storage vessel that the ostomy pouch represents. It is not until the ostomy pouch is needed that we begin to appreciate how elegant and useful the original storage vessel of the colon or bladder and their respective outlets had been. It is not enough to simply admire the colon and bladder. One must also appreciate how each is constructed, supported and permitted to function. Both organs, in a state of health, contain their respective contents and discharge them as desired or needed. Both organs do their tasks in a very inconspicuous fashion by maintaining a very discrete (i.e., hidden) profile even when full. Both organs retain their essential shapes as they fill and empty because of the suspension systems with which they are supported; their location within the abdominal and pelvic cavities and the make up of their wall tissue – they are not made of flimsy material that bulges out of shape and bangs into adjacent body parts. Any number of medical and surgical texts on anatomy and operative techniques will readily identify and illustrate the structural tissues supporting the bowel and bladder.[6-11] In general, the peritoneum, the various ligamentous

attachments within the abdominal and pelvic cavities and the muscular makeup of the walls of the bowel and bladder act as the suspension mechanisms for maintaining the shape and function of the bowel and bladder.

The ability of the colon and bladder to accommodate a variable volume of content permits one to function reasonably well throughout the day and night without undue anxiety or mishap. Ostomy pouches, by their very necessity should mimic the replaced bowel or bladder as best as possible, even if some compromise to fashion and routine is made.

Function supersedes appearance, or at least it should!

To thwart function at the behest of fashion is likely to invite fashionable disaster. This is brought to bear in the related arena of the bathroom. If you have observed a trend toward smaller toilets and seating surfaces you are not imagining it nor are you alone pondering the rationales for such designs – and this trend is occurring in the face of America’s increasing bariatric population with burgeoning waistlines and buttocks. Just picture a tiny toilet as the bull’s-eye for a huge derriere. Now, try to picture a plump ostomate with a teeny pouch on his belly trying to empty the contents into the disappearing toilet - strains the imagination, does it not. A Wall Street Journal report on sink basins and their quirky styles and sizes points up the paradox and futility of trumping design over practicality.[12] It seems that

marketers of all stripes and in all quarters are more enamored of desire and design than they are of necessity and practicality.

In the very different arena of electronic gizmos like cameras, cell phones, watches, entertainment devices and personal digital assistants (PDAs) we find the trend toward miniaturization brought to its illogical conclusion by making these devices so small that they defy human ergonomics. Whereas before you could use your digits to comfortably input information and complete an action, you now have to use a separate stylus to achieve what the finger was once able to easily do. This push to smaller and smaller for the sake of smaller is flat out insane. Our bodies and related physiologies do not shrink to accommodate someone's desire for discreteness or miniaturization. Of course, the free market allows individuals to make choices, good or bad. However, in the exercise of choosing, bad outcomes may arise and folks will have to live with these consequences or seek remediation as needed. In a similar vein, ostomy manufacturers, who now wield significant oligopoly power, have veered toward smaller pouches and more restrictive choices; leaving the patient with no suitable options and no real voice or venue with which to meet her physiological needs.

Constraining pouch shape & volume choices constrains lifestyle functioning

Among the changes and losses associated with ostomy lifestyle is the less explored and subsequently less appreciated conflict that arises when the natural storage vessel of bowel or bladder is replaced with the man made ostomy pouch or vessel. That which was once invisible is now very visible. In an attempt to minimize the appearance and size of the now external vessel suspended from one's abdomen, manufacturers, practitioners and patients strive to present as innocuous a pouch as possible. Everyone, it seems, strives for a gossamer replacement.

This attempt to minimize the pouch to the degree that has been accomplished to date is a fallacy seriously gone awry. As the ostomate resumes a full return to normal lifestyle, the demands and volume expectations of the effluent or excreta are not diminished. And, in the case of the ileostomate, the lack of an absorptive colon dramatically changes the nature and volume of the output. Volume output needs to be reasonably matched with volume holding capacities of the substitute storage vessel, the ostomy pouch. If you deliberately make the pouch smaller than is practical you invite the necessity of much more frequent emptying cycles. In effect you begin to pervert the return to a normal lifestyle. You begin to shape the ostomate's lifestyle around the pouch more than is desirable or practical. The ostomate is now made a prisoner to the toilet, suffering all the attendant toileting anxieties that a previously dysfunctional bowel or bladder presented. Think of a

person wearing shoes that are too small. Eventually, two things will occur, if permitted. Either the person resorts to properly fitted shoes or continues with the harm wrought by the poorly sized shoes.

Underpinning this pouch size and shape morass are the many divergent and often misguided opinions of many players – the practitioners, patients and pouch manufacturers. Thus, the burden for all ostomy stakeholders is to balance the impossible with the practical. Compromises will have to be made, but they should be useful compromises arising from a well grounded understanding of all factors that make life with an ostomy as satisfying and practical as possible. **Once the normal excretory function is altered by disease, injury, surgery, aging processes or mishap and an incontinent ostomy is created, man's attempt at remediation or repair via the stoma and collecting pouch should at least result in a useful compromise and not some touted goal of discrete pouch sizing or shaping for the sake of some ephemeral ideal.**

PRIMA FACIE ARGUMENTS – 2

Variable ostomy outputs require pouch choices

Any reasonable person can recognize that different sizes of containers exist to fulfill many needs and circumstances. A cook may need a certain amount of an ingredient

to complete a recipe. A motorist fills up her auto with given amounts of petrol to reach her destination. A chemist adds a critical amount of an ingredient to a solution to achieve the desired end product. If all the players were constrained in their ability to add the volume of ingredients they needed they would find their tasks increasingly cumbersome to achieve. If all they were given were a thimble sized container with which to measure and dispense their inputs or contain their outputs it would make for a very frustrating, time consuming and lifestyle altering routine. Imagine being asked to void into a urinal or container that holds much less than what you normally produce at a time. Not a pleasant situation, I suspect.

Similarly, when an ostomate is given a small capacity pouch with which to collect her daily outputs, she is left with increasing burdens or cycles of collection and emptying. To paraphrase the famous acronym GIGO (**G**arbage **I**n and **G**arbage **O**ut), the ostomate who is left with a less than adequate pouch volume capacity or size now has to wrestle with F---GIGO (**F**requent **U**rge to **C**ontrol and **K**eep **G**arbage **I**n and **G**arbage **O**ut). This is not a tenable position and clearly leads to a diminution of lifestyle enjoyment.

Variable body types and lifestyles require pouch choices

Just as we find in the general population, not all ostomates ingest the same quantities and evacuate the same output amounts. Not all ostomates are of a given

age, size or shape configuration. Not all ostomates engage in the exact same work, sleep and play routines. Nor do all ostomates wear the same style of clothing for work or pleasure. Not all ostomates have GI and GU systems that are alike and behave alike. Not all ostomates have the same amount of remaining bowel or the exact same operation – disease and or surgical and therapeutic interventions shape the outcomes greatly. Clearly, there are different strokes for different folks.

How and when did the pouch size become established? What guidelines or standards were followed when designing the first ostomy pouches of the 1920s and 1930s? Truth to tell, not too much science went into the design of these early pouches, especially since not much was known early on about the volume or output capacities of the different types of ostomies. Early pouch designs were predicated upon the particular patient or inventor's notions of adequacy; usually factoring in his particular ostomy and body size. Nevertheless, this seemingly arbitrary approach did lay down the earliest guidelines for pouch design. As more was learned about bowel capacities, and especially as ileostomy output values were measured,[13] a better appreciation of the design capacities and limits of external pouches unfolded. Or, did it? The evolving evidence seems to suggest that manufacturers have failed to integrate these fundamental historical facts into current pouch designs.

Let me state now that my use of early or historical reference works is deliberate and still pertinent. The building blocks of our contemporary understanding of ostomy management rest in large part upon the work of these early investigators and writers. In the intervening decades little has changed in the anatomy or physiology of the intestinal and urinary tracts and the functioning of traditional incontinent ostomies, and subsequent investigations into ileostomy effluent[14] and gas have reaffirmed the obvious basic anatomy and physiology.[15] Often publishers and readers are loathe to accept seemingly outdated references, but it would be foolhardy to dismiss their relevance and utility as it relates to our basic understanding or misunderstanding of current ostomy management issues. Sadly, a good deal of vital and relevant evidence is relegated to the dustbin because some folks judge relevance of facts and references by their newness (age) and not their inherent utility. It would be sadly ironic if the recent quest for evidence-based practices, as it relates to ostomy matters, were to continue to ignore some of the evidence already in place. The fallacy of some forms of progress is to measure the present or future absent the past. To paraphrase an old saw: an old dog can indeed teach a new dog some helpful tricks.

(Hill's 1976) excellent monograph on ileostomy surgery, physiology, and management helped to establish a clear picture of the range of daily stool outputs or ileal discharge to be expected from established ileostomies.[13] This remarkable

text is considered a landmark for all who have an avid interest in ostomy related matters; be they patients, practitioners or manufacturers. Hill succinctly delineates in tabular form the ranges of daily “normal” ileostomy outputs for high and low volume ileostomates or stoolers, as he called them. For the typical low volume stooler, the median output was 401 ml with a standard deviation (SD) of plus or minus 92 ml. For the typical high volume stooler, the median output was 1202 ml with a SD of plus or minus 284 ml.

| Daily Ileostomy Outputs | Typical Low Volume Stooler (ml) | Typical High Volume Stooler (ml) |
|--|---|--|
| Median +/- SD (taken from Hill, 1976) | 401 +/- 92 | 1202 +/- 284 |

Thus far, the consideration of gas in the pouch had not been factored. Fortunately, (Kretschmer, 1978) made the task of assessing stoma gas rather straightforward.[16] Were you to factor in the additional gas or flatus typically found alongside the stool you would arrive at a range of gaseous outputs of 210 ml to 1400 ml. Add the stool and gas together, as is the case in real life, and you achieve a range of daily ileostomy pouch outputs that varies widely from 611ml to 2602 ml.

| Daily Ostomy Outputs of | Typical Low Volume | Typical High Volume |
|-------------------------|---------------------------|----------------------------|
|-------------------------|---------------------------|----------------------------|

| | | |
|---|--------------------------------|---------------------------------|
| stool and gas (incorporating Hill, 1976 & Kretschmer, 1978) | Stool & Gas (ml) 611 ml | Stool & Gas (ml) 2602 ml |
|---|--------------------------------|---------------------------------|

These numbers, I should add, only account for the swallowed air component of gas, which typically represents 70% by volume of the total gas found in the bowel. In this fashion one rules out the variability of bacteria-induced gaseous byproducts associated with colostomies or highly colonized ileostomies. Given these conservative estimates, it should become clear to the reader that volume outputs from ileostomy stomas are quite significant and variable, and that the expectation of volume capacities of pouches should attempt to mirror these demands.

Please appreciate, however, that when a bowel is obstructed or experiences delayed emptying, gaseous and liquid byproducts may well be increased. It is not uncommon for many fecal ostomates to experience periods of delayed output that may arise from adhesions, transient kinks, strictures, medications or bezoars, fecal boli that may arise from indigestible items – a cat hair ball is a classic example of a tricho bezoar while blockage from nuts or corn would constitute a phyto bezoar. When the bowel does open up after a delayed or an obstructive episode there is an increase in effluent volume comprising stool and or gas. Often times this output

can be quite voluminous and rapid and readily overwhelms the capacity of the pouch.

While on this topic of increased outputs secondary to multiple factors and the need to match appliance options accordingly, it may yet come to pass that novel approaches, not targeting external collectors, may address this dilemma. Could a better understanding of the hormonal factors affecting bowel absorption and motility permit better volume output control? I suspect we have yet to see the full scope of human inventiveness targeting this arena. For now the extant focus upon manipulating pouch designs and capacities has been the driving force attempting to meet volume output needs of ostomates, but who is to say what the future for ostomates will be. Remember when plastic was the byword for future progress? It may well be replaced with peptide analogs like Teduglutide for ostomates and those suffering bowel absorption problems. Would such novel strategies let the pouch manufacturers off the hook? Stay tuned!

Chapter 2

MARKET DRIVEN CHOICES SUBSUMED BY...

DIVINING THE MARKET

MARKETING WHIMSY

CONFOUNDED LOYALTIES

QUESTIONS

MARKET DRIVEN CHOICES SUBSUMED BY...

Well grounded patient criteria

Making sense of a marketplace is at best an attempt to measure all the variables that constitute a diverse environment while striving for a reasonable facsimile or interpretation of what was observed. This endeavor to divine the marketplace is fraught with error, misconception and observer bias. Often, the marketer attempts to discern behavioral quirks or differences in order to gain an understanding of his or her product's or service's place in the competitive marketplace. So what is a marketer to do? Stop trying to be all things to all people? Try to understand all the variables that then require you to arrive at a regression to the mean? Focus on the meaningful variables? Fill the identified niche?

There are some things that are immutable, and maybe not always "marketable." Biology and physiology are more constant than toileting behaviors. Behaviors are

complex and often contradictory human expressions or responses to biological and physiological functions. Subsequently, not all human behaviors are consonant with their respective biology or physiology.

Given this apparent contradiction between marketing and reality and between cultural behaviors and bodily functions, how does an ostomy marketer go about meeting the needs in the marketplace? In part, by factoring in well-grounded patient criteria (the evidence) coupled with prima facie arguments – in this case the immutable reality that ostomy effluent volumes may be rather significant and variable.

Informed decisions which factor in all the prima facie arguments

Arriving at fully informed decisions should not be like a court room trial where, while there are opposing points of views, the art of persuasion is more in play than actual fact finding. Rigorous discourse and investigation should be the method employed to ferret out the truth of any endeavor or inquiry. However, many investigators and marketers fail to utilize the requisite time and skills to thoroughly investigate all the factors that make up fully informed decisions.

We have come to rely upon the scientific model as a method to discriminate between useful and useless observations. We come to rely upon the integrity of the peer review process, as applied to published research, to assuage our lack of direct

investigation. Along the way we may become enamored of the validity and constancy of truth assumed in this process. Sadly, there have been shortcomings and deceits in these endeavors- cold fusion research claims come to mind. You may recall that cold fusion was a hot topic in the late 1980s (March 1989, University of Utah) as experimenters attempted to show an inexpensive and potentially limitless source of energy. Plagiarism, fact fudging or gilding and outright fiction have also been implicated in the shortcomings of human behavior applied to scientific and publishing endeavors. Additionally, one person's truth may well be viewed by others as a fantasy of belief. The conclusions of one investigator may well be diametrically opposite the same observed phenomena of another investigator. We call this observer bias. Along with observer bias is the phenomenon of "expectation effects, also known as the Pygmalion effect." [17] This observer-placed bias often times mirrors the placebo effect found in patient expectations of a drug or device or therapeutic modality. Additionally, there is the subjective nature of many lifestyle issues investigated and reported.

It is in this arena of divining the wishes and needs of a particular population's lifestyle that misinterpretations and oversimplifications often arise. When qualitative data bumps up against quantitative data we often incur dissonance. He or she who phrases the questions or develops the survey often obtains the expected

answers (expectation effects) as they seek to unroof the truth or evidence behind the sought after data. There are ways to skirt these pitfalls.

In the case of the ostomate, mimicking the life experiences of the person is a good beginning. For example, the simple act of wearing a pouched filled with facsimiles of stool or urine for extended periods and emptied repeatedly throughout the day and night would lend some meaningful credence to the requirements of a suitable pouch. Lacking this opportunity, an investigator can at least insert herself into the world of the patient for a sufficient length of time to obtain a sense of the ostomate's toileting reality. These kinds of studies, whereby the investigator inserts herself among the population being studied, have been done and reported upon for many decades in many social science disciplines. While they are at risk for observer bias, they nevertheless allow the observer to more fully appreciate many of the issues confronting a patient and allow for a more complete view of the patient's world. However, it is imperative that investigators be armed with all the known physical evidence beforehand in order to make a better and more relevant assessment of the adaptation and adjustment processes an ostomate must undertake. Doing so will often temper observer bias and allow for a more relevant and plausible study. I can tell you that whenever a student or colleague is fully engaged in the trials and tribulations of the ostomy patient, by wearing pouches for lengthy periods of time and doing their best to mirror the life of an ostomate, they have

come away with a much better insight and appreciation of the ostomate's new potty world. Short of becoming an ostomate for the sake of a study, it is a useful approach to take.

For the history buff: during the very early space program, when an option for managing astronauts' effluents was being considered; creating ostomies for the astronauts was very much a considered requirement for potential candidates. As it turned out better management of dietary inputs and other technical options spared the astronauts the risk of ostomy surgery in order to succeed with prolonged manned space explorations. One only wonders: if ostomies had been required for space exploration, what benefits would have derived from such efforts that extended to the larger ostomy community?

While employing a more intense investigation into the life of an ostomate, the investigator also needs to reconcile the laws or facts of biology and physiology with the altered potty world of the ostomate. For both investigators and ostomates the challenge exists to successfully integrate an accurate understanding of physiology, and its attendant limits, with the ostomy lifestyle. This reconciliation has been achieved repeatedly by many well adjusted ostomates as they absorbed the full impact of the changes in their lives and made their lifestyles consonant with the evidence of their altered elimination anatomies and patterns. Reconciling the facts

at hand with the wishes or expectations hoped for goes a long way toward resolving inconsistencies and disappointments.

There are also a number of poorly adjusted ostomates – their failure to adjust may be rooted in physical or psychological shortcomings or may encompass both. Some suffer in silence and others give voice to their distress and seek solutions from practitioners, manufacturers and investigators. Often times, their voices are louder than that of the well adjusted ostomate. It is akin to the squeaky wheel getting the oil or the noisy barrel getting more of the observer's attention. The justification for the noises is sometimes overlooked or misinterpreted in the desire to silence the noises or appease the noisemakers. The challenge for all listeners – marketers, manufacturers and practitioners - is to distinguish the noise from the revealing sounds while attending to the needs and desires of the whole and often silent audience.

Fiduciary duty of health practitioners and manufacturers

There exists a good deal of information or knowledge asymmetry between patients, caretakers and equipment manufacturers. Were it not so, patients would be their own competent caretakers and manufacturers. Those who possess superior knowledge and skills are called upon, and usually for a fee, to exercise their talents helping those who lack this knowledge. Additionally, physicians and nurses

subscribe to, and, hopefully, adhere to oaths of ethical and moral behavior which are enshrined within their respective professional codes.[18] Patients seek the counsel of their physicians and nurses, comforted by the expectations that they will not come to any harm. Similarly, patients, as consumers, seek the products manufactured by others to help restore them to a productive life. “Given that the basis of every personal and corporate relationship is trust,”[19] no one can assert an exception to his or her fiduciary duty. While there is much divergent opinion and discussion about the moral and legal parameters of business toward its shareholders and its stakeholders,[20] there is, however, a unique set of circumstances which places business entities which operate in the patient care arena at a higher threshold of responsibility to its stakeholders or customers. Once you step into the patient’s world you take on a fiduciary burden, whereby your role and relationship is tied very closely to the well being of your client and customer. The concept of fiduciary duty, rooted in the philosophy of John Locke,[21] is well known in the legal, medical, economic and public policy arenas. It need not be fully elaborated upon here, except to make reference to the underlying principles of trust inherent in these theories and practices as they relate to the intersecting roles of patients, practitioners and health related manufacturers.

DIVINING THE MARKET

Constants or prima facie arguments are not market driven

It bears repeating that some essential facts of biology and physiology of the GI and GU tract should not be subject to the whims of man or fashion. Much evidence about ostomy outputs has accrued over the past decades to put to rest any defense manufacturers or practitioners might offer to rationalize their actions when they diverge from the facts at hand. As the legal dictum states: “Ignorance is no excuse.” Over these same decades a cavalcade of marketers has marched through the ostomy world asserting their marketing expertise – comforted in the belief that their marketing skills are quite transparent and portable. Those with the most bravado or bravada assert their talents and expertise unflinchingly as they traverse this ostomy terrain. For them, the challenge is to quickly master the “nuances” of this market and maximize the saturation of their product line and take market share away from their competitors - classic marketing jargon! They are the instruments or warriors on the battlefield and they will not be deterred from meeting their objectives and their commensurate rewards or commissions. Metaphors abound when describing the beliefs and practices of the marketing machine. Every member of this group brings to the table or job a set of talents and expectations shaped by her own past training and experiences.

Self selection biases are inherent

Conversely, every ostomate brings to the marketplace her own set of biases and nowhere is this more evident than at the myriad focus group meetings conjured up by the marketing juggernaut. By their very nature focus groups are not random samples of the populace, hence they are self selecting outcomes loaded with self selection biases inherent within the attendees.

Intimate knowledge required

Recognizing the necessity of using targeted groups for targeted issues, it makes sense to use the audience for whom your product line is intended. The trick is to have a masterful understanding of all the issues inherent in this special marketplace, not just the “nuances.” In fact, it takes a great deal of expertise to successfully nuance the arena one operates within while appearing to casually offer up a fully informed opinion at the drop of a hat. Included within the world of expertise are all the historical building blocks that have shaped the present body of expert knowledge. Eschewing the past for the present is tantamount to practicing tunnel vision – looking only at what is directly in front and ignoring all the peripheral scenery, comprising the past, that helps orient you to a more accurate sense of time and place as well as self. Glossing over the high points or high lights is good for presentations but not for much else. Meaningful effort toward the accumulation and application of knowledge and its skillful implementation is required to achieve a modicum of expertise in any arena of specialized care. All practitioners and manufacturers who specialize have a higher burden of proof to meet before they can assert their title of expert.

MARKETING WHIMSY

Market forces are often whimsical

The use of the term whimsy in connection with marketing, and in particular ostomy marketing, refers to the lack of consideration when designing and manufacturing products that fail to factor in the immutable realities of the physiological needs of ostomates and the requisite prima facie arguments that should always guide product development.

Because of the enduring and pervasive power and influence marketing has over our lives and purchase habits, it is important to continue to focus attention upon some of the strengths and weaknesses involved with marketing outcomes and processes. A clear strength of marketing power is its ability to effectively persuade consumers to buy product B even if it is only a subtle change from product A bought a short while ago. The notion of new & improved is one of the staples of this practice. Consumers do like to feel improved and enhanced as they continue to purchase periodic iterations of the same underlying product or service. The ability to appeal to the frivolous nature of man is an important underpinning of marketing success and whimsy. Mind you, there is nothing inherently wrong with frivolity as long as it is not misconstrued for necessity.

Numbers are quantitative only

Marketing strategies that tout quantity of opinions over quality of opinions is an example of marketing weakness or whimsical processes at work. Quality of opinions, which is very difficult to calibrate or assess, requires more diligent and thoughtful elucidation than mere survey or tally. While surveys can be quite useful for gleaning facts they should not be relied upon as telling the complete story or for validating facts. Often times they act as a stepping stone for further follow-up. At the moment a survey is given the set of circumstances surrounding the survey will often influence the respondent. On any given day one can reply to a question that may well differ when asked at another time and place. It should be taken to heart by marketers and investigators that: “Interviewing few consumers in great depth produces vastly more information than surveying hundreds.”[22]

Conversely, relying upon the wisdom or input from only the supposed upper echelon or familiar sources can also be less productive and useful. There is a parochial tendency to adhere to the counsel of those who are affiliated with familiar

and or prestigious institutions. One should appreciate, however, that prestigious affiliations do not necessarily make for prestigious insights. Among the ranks of unfamiliar or less prestigious affiliates are many talented folks who can shed meaningful insight into the world of ostomy. It is a challenge, indeed, for companies to know where and when to entrust their time, energies and monies soliciting advice and counsel, but it is a burden and responsibility they necessarily must incur if they are to assess the marketplace accurately and well.

As companies continue to plumb the depths of their environment or marketplace they come to rely upon those strategies that tend to work for them. As they achieve dominance in their respective markets they, “usually don’t change unless they’re forced to do so.”[23] And, when a new idea arises “it always needs a champion because it’s so easy to kill ideas.”[23] This notion of belief or idea persistence holds true in many arenas of human endeavor – from religion to politics to science and to marketing. Think back to the brouhaha confronting the established and radical opinions or theories causing peptic ulcer disease. For decades, medicine plodded along with treatments for peptic ulcer disease based upon accepted theories and beliefs that hyperacidity and stress were the primary culprits. Initial attempts to promulgate an alternative theory, later supported by scientific proof, that a certain bacterial strain was primarily responsible were met with firm resistance and scorn by the larger scientific and medical community. More recently, the ongoing challenges exploring Alzheimer’s disease and possible alternative causes are again being met by the first line defense that follows any deviation from the accepted norm – total ridicule and resistance.[24] And, as with any new or different idea, a champion is needed to shepherd the new idea into the light of acceptable scientific scrutiny. These efforts to preserve the status quo are understandable; however they should not be so rigidly adhered to. If history teaches us anything about human

endeavors and behaviors it is that change and challenge to change is a dynamic that will always characterize the turmoil of progress.

A brief discourse on ideas is useful because ideas that are embraced are notoriously enduring and powerful. Without the power and persuasion of ideas man would be worse off than he is today. However, just as ideas are the fuel of innovation, they can also be the yoke that keeps man down or impedes progress. The challenge always confronting society is to know when the idea is useful and when it is destructive. Invariably, however, it takes a good deal of momentum, force or persuasion to displace an established idea, good or bad. Becoming trapped into these types of business behaviors, whereby suspect ideas and ideals prevail, reinforces the whimsical nature of companies as they strive to continue to market their products or services. One can not and should not really take them seriously, yet their dominance and influence accords them a degree of insulation and protection from the follies of their own actions. The burden and responsibility for the health care end user of a company's products or services is to always challenge the status quo to make sure their products and services continue to meet legitimate needs. The object is to convert whimsical products and services to warranted (useful) ones in large measure because medical needs are clearly not of a frivolous nature.

Ex ante decisions are risky – law of unintended consequences

Ostomy manufacturers employ the same economic tools and planning strategies as other industries and entities when they attempt to assess or project the future direction or outcome of their products and processes. They often employ ex ante or forward thinking approaches to answer questions like what will or should happen next when we launch this new product or variant – sort of a prospective or tentative model. In contrast, when one employs a post facto or backward looking approach,

one is asking to assess the facts already in hand – to explain or interpret what has already occurred. Another way to characterize these distinctive approaches is to contrast *ex ante* as a predictive modeling or approach with *ex post* as an identification model or approach. Both approaches have their place in the world at large. The question to consider now is whether or not ostomy pouch manufacturers give sufficient time and energy to employing *post facto* approaches often or soon enough?

One of the serious complications attached to *ex ante* approaches is the law of unintended consequences. How often have you, the reader, experienced an outcome that was not intended or expected when you tried a particular product or service? Most likely you can recall an outcome that was not expected. An allergic reaction or adverse event secondary to a new medication is a classic example of an unintended consequence.

Over the decades there have been episodes of unintended consequences when ostomy products were foisted onto an unsuspecting public. Some of these were of little consequence while others were of immediate concern. Three examples, of many, come immediately to mind.

One concerned a pouch product that was designed to be lower profile and therefore an improvement over the current products. It was a two piece pouch and gasket combination unit that switched from a thicker gauge plastic faceplate to a much thinner one. Shortly after being introduced into the marketplace some ETs saw a handful of stomal laceration complaints and alerted the company to the ongoing serious risk for stomal lacerations from the newer and thinner plastic faceplate. The product was withdrawn from the marketplace.

Another product or improvement centered on a change in the packaging material of a well established and accepted karaya-based washer or seal. Up until this change the product had a stellar reputation for preventing and healing peristomal skin irritation. Out of the blue a rash of complaints began to arise from established users of this product. Queries were sent to the manufacturer and his initial reply was that the problem lay elsewhere, and certainly not with his product. Sadly, it took a lawsuit to persuade the manufacturer to look harder at his manufacturing and packaging processes to ferret out the culprit – a change in the coating on the sheeting material used to separate the wafers during packaging. Between the two, one was a presumed improvement and the other was an unsuspecting and apparently innocuous change in the packaging only. Both however, resulted in an unintended consequence.

The third example of *ex ante* decision making centers on a company who already had a history of success within the ostomy marketplace and was planning to launch a totally new wafer technology. The inventors and research head approached an experienced ET clinician and asked him to assess the merits of this revolutionary product. The clinician pointed out some of the fallacious thinking that prompted its development. The researchers, especially the chemist who invested his strongly held beliefs and energies into bringing this product to market, were not pleased to hear that their ideas and concepts were misguided and likely would not succeed in actual application. In essence, the company was attempting to utilize a hydrophobic wafer material instead of a hydrophilic one around the peristomal site. Without getting into a discussion of stomal plane dynamics (SPD) and barrier properties, suffice it to say that the immediate peristomal zone, the muco-cutaneous (m-c) junction, is a dynamic wet zone that benefits most from a hydrophilic barrier. Nevertheless, a carefully structured and monitored patient trial with the company researchers in attendance was implemented. The results of the trial were as the ET

had predicted – the product failed to perform in the real world, in spite of all the preliminary development efforts and patent applications by the manufacturer. By the way, it should be noted that because something is patented does not mean it is useful or applicable.

In the first case, one can fault the manufacturer for not doing more homework. He clearly failed to understand the risks associated with hard and sharp edges in close proximity to a delicate tissue plane, the stomal surface. One can only speculate what the motivation was for changing the product line that had been so successful for so long. One wonders if he was listening to the siren song of a dissatisfied customer who wished that the appliance was lighter and less conspicuous. Or was he looking for a cheaper alternative for his manufacturing process? Or was he merely trying to improve his product with the best of intentions in hand? Whatever, the reason(s), he failed to fully understand the “nuances” of the market he was serving – he was not sufficiently expert to make safe and meaningful changes.

In the second case, the well established manufacturing and packaging routines were slightly changed and the manufacturer’s expectation was that nothing untoward would arise. This case points up the risk of seemingly innocuous changes resulting in a negative externality or event that was beyond the direct control of the manufacturer but nevertheless threatened his reputation and the well being of his customers.

The third case is more troubling than the first even though the product never made it to market. This was a leading ostomy products manufacturer who had invested a good deal of time, talent and money developing a revolutionary product. The scientists labored at their laboratory benches manipulating scores of chemical processes to arrive at their eureka product. They were so enamored of their product that they assumed it would pass muster with flying colors. Their shortcoming or

sin was one of isolation arrogance. They thought they had all the answers contained within their laboratory setting. Had they done a wee bit of due diligence by learning from the real world before they began their fruitless trek they would have saved a good deal of money and embarrassment. At the very least, they did pause to ask an experienced ET, toiling away at a less than prestigious facility, if they could trial their product, and this after thought did save their hide and reputation. One wonders what would have happened if a lesser talented ET were consulted? Clearly, a lesson learned late in the game is better than none.

Confounded loyalties

For the past decade or so, ostomy product manufacturers have employed the services of ET staff. The major manufacturers in America, or the big three as they are referenced, have enjoyed the privilege of having their own ETs on board aiding and shaping the companies' processes, products and image in the ostomy marketplace. In fairness, it should be pointed out that the smaller companies also have ETs or similarly talented staff on board to aid their efforts in the marketplace. For simplicity sake, the focus will remain upon the big three, especially since they represent the bulk of the marketplace.

It should come as no surprise that as ETs, in order to ensure their professional survival, have ventured into other areas of practice, their energies, foci and skills for ostomy concerns may have diminished somewhat. This is not meant as an indictment, rather an observation that one can not remain up to par or expert if one is diverted from that single-minded focus which allowed them to initially achieve and maintain specialized clinical expertise. Conversely, the manufacturer-based ETs, as in house practitioners, offer both benefit and risk for guiding product development and resolving client concerns. Now out of the normal (community or clinical) practice setting, the ET vision becomes somewhat skewed and hide bound

or isolated and in favor of the companies' goals and objectives. It remains for the manufacturer-based ET to determine whether or not his vision is still as clear as when he was a clinical practitioner, and whether or not his skill sets are as relevant and current. Sadly, it appears that the persistent trend in pouch design and sizing among the big three points to a lapse in the ability of the company-based ETs to properly influence product development.

QUESTIONS

Who decides pouching needs?

Among all the players in the ostomy marketplace, who should decide pouching needs? Should it be the ostomate or practitioner or manufacturer? How about all three working closely together while adhering to a well-grounded understanding of ostomy anatomies and their respective physiology, and related prima facie arguments? This seems like a useful strategy. However, it is worth repeating that listening to a large number of voices may not be as effective as listening very well to a few thoughtful ones.

Manufacturers' criteria for pouching design?

If manufacturers are not adhering to prima facie arguments then what or who are they listening to when designing and promoting ostomy pouches? Are they listening to their own whimsical muses? Are they responding to the din of the noisemakers alluded to earlier? Are they so attached to their own parochial conceits? Well, it seems some have trusted the counsel of their own muses and the cacophonous crowd. Additionally, some have applied marketing survey results to justify their design decisions. And, finally, some have resorted to their own

conceits to justify and defend their actions. The evidence for these behaviors rests with the following case history scenario.

Groupthink or informed understanding?

Presenting a case history of a knowledgeable incontinent ileostomate confronting a manufacturer's pouch size and shape changing strategy[25]

[It is believed that this accurate case history is very illustrative of the underlying themes presented in this article and is the impetus for its writing. The underlying issues regarding groupthink and pouch shape and design shortcomings remain to this day.]

1. In the mid 1990s, a leading ostomy pouch manufacturer changed the size of their standard or adult drainable pouch to a smaller size without alerting its customers. This resulted in the patient having to empty more frequently during the waking hours and, more importantly, previously uninterrupted sleep patterns were now changed because of the need to awaken and empty the smaller pouch of its contents to avoid leaks and bed soiling.
2. The ET-trained ostomy product manager, who recently migrated from another major ostomy competitor, was alerted to this new problem with pouch downsizing. When questioned by the patient the company ET said the downsizing was market driven. The patient was not satisfied with this answer and insisted upon further clarification and justification for this change, and also wished to speak to the company's president. Initial letters to the company president went unanswered. Another company ET informed the patient that the ostomy products division VP would be responding shortly.
3. Below are the VP's verbatim responses to the initial complaint, followed immediately by the patient's questions or replies, which remain unanswered.

- a. VP: “Modification of pouch shape [is] to be more consistent with the shape and size of competitive ostomy pouches.”
 - i. Patient: If you mirror competitive designs how does that accord you a competitive advantage?
 - ii. Does shape similarity offer customers choice or does it, in effect, deny choice?
 - iii. What was the problem with differing shapes that required different users, whether ETs or ostomates, to request a change?
 - iv. Given the notion of shape uniformity as desirable, how does this relate to the dilemma of reduced volume, which prompted my original concern? In other words, why was volume reduced secondary to shape changes?
- b. “Shape and size changes were implemented due to frequent user and ET nurse requests.”
 - i. How do you determine validity of requests?
 - ii. What criteria beyond frequency influence the decision to implement changes?
 - iii. Whose voice(s) carries weight?
- c. “The changes were also implemented due to an overwhelmingly positive market response to the shape and size of the (XYZ) one-

piece and two-piece drainable pouches which were introduced in July of 1994.”

- i. What do you mean by overwhelmingly positive market response?
 - ii. What kind of market analysis was done to ascertain the wishes and needs of the end users?
 - iii. Who constituted your respondent base?
 - iv. Who asked the questions?
 - v. What were the questions?
 - vi. Who, in particular, generated the idea for the pouch shape and volume change?
 - vii. Are you familiar with the concept of ostomy identity crisis of image and function?
 - viii. Are you familiar with the conundrum confronting ostomates regarding their output volumes versus pouch volume capacities?
- d. “The shape modification was made to enhance quality control and reduce complaints.”
- i. How do you define complaints?
 - ii. Are complaints defined as manufacturing outcomes?

- iii. Is complaint the correct term to use for manufacturing outcomes? Or, is it more likely you mean [manufacturing] failure?
 - iv. If complaint is the right term then what is the nature of the complaint?
 - v. What setting or other external variables gave rise to the complaints?
 - vi. Without knowing your manufacturing processes I can only assume that successful weld ratios are shape related. If so, how does this fact relate to pouch volume?
 - vii. For all the years I used your earlier pouch, before the change in volume and shape, I had not experienced any weld seam failures. Was my experience unusual?
- e. “The shape and size changes implemented in 1995 did result in some initial preference complaints. The preference complaint rates have continued to decline and are virtually nonexistent today.”
- i. This statement contradicts what was told to me by your ET representative when I first called him about the pouch volume reduction concern. He told me that almost no complaints were reported to the company.
 - ii. I am disheartened to know that I was misled about the initial negative responses to the changes.

iii. Given that the changes were initially frowned upon, and yet the company persisted in the changes, suggests that a commitment to the decision for change needed to prevail in spite of complaints by the end users. In management parlance, you should be familiar with the concept of escalation of commitment that gets decision-makers into more trouble than is necessary and which can lead to rather disastrous outcomes. The shuttle explosion disaster some years ago was a classic and frightening example of commitment escalation and groupthink that led to a very poor outcome. When the shuttle team was being questioned by the specially appointed scientific panel to explain the events and actions surrounding the disaster no one on the team could clearly and accurately explain why the disaster occurred. Everyone was looking to defend his or her decision using the language of their specialty or focus to explain away their culpability. They all became caught up in their own jargon and literally could not inform the panel or the American public exactly how or why it all happened. Richard Feynman, Nobel Laureate in physics, and a member of the special investigative panel took a Styrofoam cup filled with ice water and placed the rubber O-ring material into it and clearly showed the effects of freezing upon the shuttle's O-ring seals. With one simple and **relevant** example, he demonstrated to all the effect of a freeze event upon the critical seal. The point of all this is that a simple **relevant** explanation is worth more than the entire defensive jargon one can muster to defend a decision. By obfuscating the

panel members, the engineers, technicians and bureaucrats responsible for the shuttle mission dug a deeper hole of culpability than necessary. This type of behavior does not appear to be customer focused as much as it is business as usual focused. The relevance for your company's pouch change is similar. Unless I or anyone else, who rightfully inquires about a change that negatively affects one's life style, is properly and clearly informed then your company is at risk for misrepresenting the truth and rationale of their actions. It harms all parties, and that is very much an undesirable and undeserved consequence.

- f. "The pouch volume change was a reduction from 770 ml to 625 ml using ISO standards of measurement which is based from the center of the skin barrier opening to the point of attachment for the drainable pouch clamp. Since we recommend the pouch be drained when the pouch is $\frac{1}{3}$ to $\frac{1}{2}$ full, the resultant volume change was determined to be acceptable for most users."
 - i. Aside from the gobbledygook about ISO standards, this point is the most troublesome one of them all for you to defend.
 - ii. One pouch design, size and shape does not fit all needs and circumstances.
 - iii. Variable ostomy constructs and outputs demand variable pouch designs, sizes and shapes.
 - iv. At first read these may appear to be rather simplistic statements, but they speak volumes about the breadth and depth of

understanding that differing ostomy types require in pouch capacities.

- v. In fact, your point here almost smacks of hubris on your company's part to suggest it has a better understanding of ostomates' needs than almost every one else.
- vi. 50% (1/2) of 770ml is 385ml and 33 $\frac{1}{3}$ % (1/3) of 770ml is 257ml.
- vii. Conversely, 50% (1/2) of 625ml is 313ml and 33 $\frac{1}{3}$ % (1/3) of 625ml is 208ml.
- viii. The deltas or differences between respective volume percentages are significant, especially in light of the fact that pouch volumes are not static!!! Also, prior pouch volumes were arbitrarily established based upon static criteria.
- ix. Static measurements and opinions are totally misleading and useless when assessing real world experiences of pouch wearers.
- x. A simple question to you, Mr. VP: have you ever worn a pouch, for an extended period of time, filled with liquid effluent while pursuing a full range of activities? This question is akin to Feynman's example of using a simple Styrofoam cup to assess the impact of ice water upon the O-ring. Think carefully about this last question – it is very meaningful and instructive.
- xi. Data and research outcomes are most relevant given the model(s) chosen to assess or test theories or beliefs. From all the input I have received to date from your two ETs and you I do

not see enough understanding or clarity to convince me that your company has made a wise decision regarding the reduction in pouch size and shape changes.

One of the ironic outcomes of this dialogue between the knowledgeable patient and the manufacturer in question was that the other members of the ostomy manufacturing troika have begun to use the same mathematical logic and jargon in their promotional literature and when talking about pouch emptying patterns. This may well have come about because of the inbreeding or cross pollination of staff and ideas that occurs within the ostomy manufacturers' ranks. Direct observation has revealed that employees do jump from one competitor to another and bring their opinions with them. Thus it would appear that the differences between brands A, B, or C are differences in name only. Ultimately, the more relevant and important question to answer is whose interests are to be well served: the patients, the practitioners, the companies? In an idealized world, all are to be well served, and in so doing all benefit – a win-win situation or a state of Pareto optimality is established whereby no one is made worse off by the actions of the other.![26]

Chapter 3

A.S.S. THE TRIUMVIRATE OF GOOD OSTOMY CARE

APPLIANCE – THREE C REQUIREMENTS

INELASTIC SHORTCOMINGS OF OSTOMY

A.S.S.

It is no accident that the basis for understanding successful ostomy care begins with fully internalizing the notion of A.S.S.: Appliance – Skin – Stoma. You can not have an incontinent stoma without having the skin upon which the stoma is created and around which is positioned the appliance or pouch. Nor is it any accident that Appliance comes first in this hierarchy. After all, an ostomy is first and foremost an alteration in the normal function and storage of the bowel and or bladder. Therefore, the appliance or pouch becomes one of the first requirements for successful ostomy lifestyle. When considering appliances or pouches in today's time the differing components that make up the pouching system often are weighted in importance among the manufacturers. It seems that the manufactures still have it *bass akwards* when they ascribe the greater importance to the barrier and not the pouch. Granted the barrier is quite important and should not be relegated to a lesser role. On the other hand, the pouch is also of great importance and should not be given second class status. While some folks can tolerate barrier A better than barrier B all incontinent ostomates need a pouch to contain the effluent. In fact

many patients can do without barriers if they have a stoma and peristomal skin plane that allows for it, but they could not do without the pouch to collect what emanates from the stoma! In the manufacturer's mind the barrier is paramount and everything else that comprises the pouching system may be an afterthought. It is precisely this way of thinking about and characterizing the order or dominance of things that creates the blind spots and promulgates the hubris exhibited by the manufacturers. How does an ostomy patient succeed against such entrenched thinking? Remember, the pouch replaces the loss of the bowel or bladder as a storage vessel, and it is this storage substitute that is the heart of ostomy. When surgeons create alternatives to traditional ostomy they are also striving to preserve as much functional storage capacity as is possible. The operative concept here is storage – storage – storage!!!

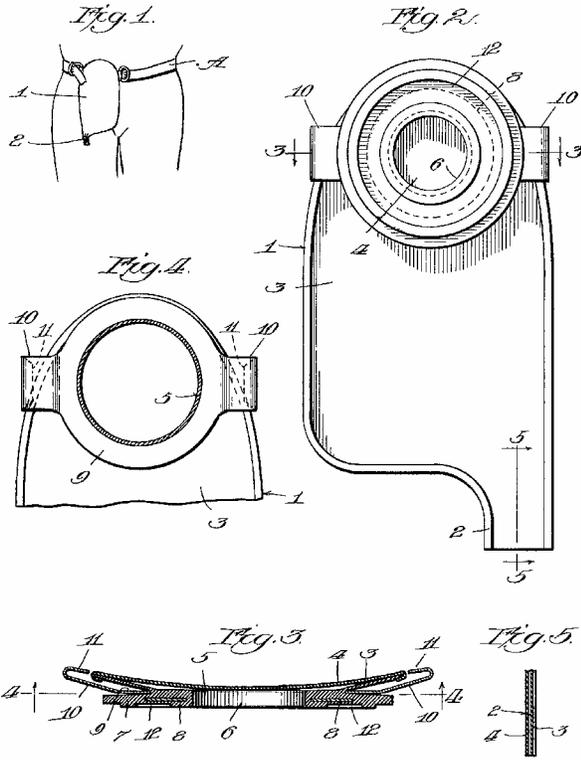
Prior to the widespread use and acceptance of ostomy pouches, few ostomies were recommended or performed.[27] However, once pouches became available for general use, around 1944, the pace of ostomy surgery quickened significantly. Thus, it became self evident that ostomy success was predicated on ostomy appliances or pouches as they are now called. In his book on ulcerative colitis, (Bacon 1958) also references the prototype of today's ostomy pouches, the Koenig pouch. A search of the US Patent Records (#2,048,392)[28] will clearly illustrate this design and its impact on subsequent pouch developments. (Walker 1976, Hill

1976) reinforce Bacon's observations about the plight of the ileostomists prior to two seminal events – the evolution of Koenig ostomy pouches after 1944 and the eversion of the ileostomy stoma by Brooke in 1952.[4, 13] For those who have a flair for history, the Koenig pouch of 1934 morphed into the Strauss-Koenig which morphed into the Strauss-Koenig-Rutzen pouch. Incidentally, the Strauss name belonged to the Chicago surgeon, Alfred Strauss, who in the 1920s conceived the original idea of an adherent rubber bag to collect ileal excreta. Prior to this, patients improvised as best or as poorly as they could with rags, metal & cardboard boxes or other devices to attempt to contain the effluent, even though the skin was suffering from the deleterious effects of the effluent. Strauss, after operating on Henry F. Koenig, an artist, chemist and inventor, pressed him into designing and manufacturing the first practical ileostomy pouch. Rutzen came on board as Koenig's business partner a dozen years after the launch of the Strauss-Koenig pouch and effectively commercialized the bag following Koenig's enforced invalidism secondary to kidney infection. After a while the triple named pouch became known simply as the Rutzen pouch.[27] See figure 1.

July 21, 1936.

H. F. KOENIG
COLOSTOMY APPLIANCE
Filed March 19, 1934

2,048,392



Inventor:
Henry F. Koenig,
by Wm F. Freudenreich, Jr.

Fig. 1

It should be self evident to the reader that this discussion has been about the traditional incontinent ostomy – ileostomy or colostomy or urostomy. It is the historical antecedent to the now popular continent options. Along the way the moniker of “gold standard” passed from the Brooke ostomy to the numerous internal reservoirs and neobladders increasingly popular today. Perhaps one should resist employing the moniker of “gold standard” to any procedure du jour and simply acknowledge that a given procedure is the accepted standard until replaced by another in due time. It sends a false message to patients and practitioners about the durability and desirability of any procedure if it can be so readily replaced by another. To characterize something as a gold standard is to imbue it with a unique and durable standard not easily replaced, and such has not been the case with the evolutionary changes in ostomy related surgeries. An additional problem with ascribing a gold standard to a particular procedure is that when it no longer proves useful it now becomes harder to admit to change and rectify whatever shortcomings derive from that procedure’s continued use. Ultimately, one begins to tarnish the concept of a gold standard when it has little durability or constancy and ironically it begins to take on the characteristics of pyrite or fool’s gold. To date, there are still a great many more incontinent or standard ostomies than there are continent ones. The Grand Design of the small bowel is such that it is suitable for transport and absorption whereas the colon and bladder are primarily suitable for storage. Therefore, it remains to be seen what the long term outcomes of all the internal

pouches or reservoirs will be. A legitimate question to ask is whether or not a significant number of continent pouches, reservoirs or neobladders will be taken down and converted to incontinent ones for a whole host of reasons. Only time will tell. Presently, some continent reservoirs are converted to incontinent ones, however, the numbers involved and the accuracy of reporting such conversions remain unclear and suspect.

Should a large scale conversion from continent to incontinent occur then a significant population bulge of incontinent ostomies will emerge needing external pouching; most likely with additional storage volumes because of surgically shortened storage capacities once the continent pouch is bypassed or removed. Remember too that using up a sizeable portion of limited bowel to construct the internal reservoir places the patient at risk should the pouch fail and be subsequently replaced, removed or bypassed. The risks in this case are those of short bowel syndrome, with its attendant absorption and nutritional risks, and large volume outputs. Anyone who has cared for a person who has converted their continent pouch to an incontinent abdominal stoma can readily agree that the increased volume outputs from the shortened bowel or storage function can be quite challenging.

Thus far only a limited mention of external pouch volumes has occurred in the previously cited case history discussion, in large part because no acknowledgement

or discussion of intestinal and pouch volumes has been offered by the pouch manufacturers to the ostomy and practitioner public.

It would be useful to see updated studies of ostomy output volumes that address the following interrelated issues:

1. underlying diseases or causes for ostomies and their particular types as primary determinants of expected outputs
2. operative interventions at time of initial ostomy and subsequent bowel resections or stomal revisions and related changes in expected and actual outputs
3. lifestyle and other comorbidities and their impact upon outputs
4. output impact upon lifestyle
5. medication or treatment impacts upon outputs
6. output and collection devices (pouch) relationships as they relate to functional or lifestyle effects upon the ostomate – i.e., how pouch design and volume capacity affect the rehabilitation and functioning (ADL) of the ostomate.

Just a few questions to get any interested ostomy researcher started.

Appliance – the Three C Requirements

There is a functional and aesthetic paradox that ostomy pouch manufacturers must deal with when creating the ideal ostomy pouch. Over the decades much iteration of pouch size and shape has occurred by dozens of manufacturers[27, 29, 30] and it is from these early attempts that current manufacturers have and ought to continue to draw lessons to more effectively manage this paradox. Sometimes one does not have to attempt to invent something new, merely tweak what has proven useful in the past (ex post decision making) and make it suitable for the current crop of ostomates. As a point of emphasis, it needs to be restated and internalized that one pouch design, size and shape does not fit all needs and circumstances. Variable ostomy outputs demand variable pouch designs, sizes and shapes. Clearly, there will have to be tradeoffs made to satisfy the needs and desires of the different types of ostomates and the functional limits of their external pouches, especially since no extant pouch material or technology is able to satisfactorily mimic the behavior of the bypassed colon or bladder. The burden of ostomy rehabilitation is to be shared by both patient and provider, be they practitioner or manufacturer. As noted earlier, if one steps into the ostomate's world, he or she had better be prepared to fully understand the interplay of ostomate's needs and desires as they attempt to fulfill their fiduciary duty.

There are three critical requirements for ostomy appliances or pouches, which are listed below.

Containment (storage capacity). First and foremost, a pouch should effectively and efficiently store the outputs in such a way as to not unnecessarily interfere with the ostomate's potty routines and lifestyle. The determinant of pouch capacity should be the well adjusted ostomate and her ostomy output requirements and not the manufacturer's presumed expectations. There exists a state of cognitive dissonance when health care providers and patients struggle with the requirements for a functional protruding stoma and an indistinguishable pouch. How is it that on the one hand a protruding stoma is considered essential and desirable but a functionally sized pouch is not as fully appreciated? Sadly, and too often, has been heard the exclamation by both patients and care providers that the pouch is too big. Perhaps it could just as readily be said that the patient is too small and the care provider too small minded?!

Control (of odor & sound). A pouch should effectively contain, nullify or retard odor permeation from the output and muffle sounds that arise from and within the pouch during the period of use, which can vary from daily to weekly.

Camouflage (discrete shaping). While a distinct property, it is hard to separate camouflage from containment since one property greatly influences the other. A

pouch should not create an unsightly or interfering bulge *as it fills with the effluent* (containment). It should be of a shape and construct, suitable for the type of ostomy involved, which effectively camouflages its appearance against the body *while containing the output*. Ideally, a pouch should be constructed in such a way as to offer a preferred pouch profile (PPP) that flatters the ostomate while offering storage and shape retention utility. There is a close correlation between and among the size and shape of pouch, the material from which it is constructed, and a flattering profile. Misguided attitudes toward pouch sizing can still be found among the ranks of ETs and manufacturers as evidenced by the following observation between a manufacturer sales rep and an ET nurse. A sales rep for company A brought representative samples of their ostomy pouches to the attention of an ET nurse within her sales region. The ET nurse reacted to the newly redesigned adult urostomy pouch by saying: “Oh, it’s too big!” This ET nurse ignored the presence of baffles or welds to prevent the pouch from ballooning out when filling up. The manufacturer’s justified tradeoff with this updated design was found in making the pouch larger overall but utilizing weld baffles to keep the walls of the pouch from ballooning out too much during actual use – thereby providing a pouch with improved useful capacity and sleek profiling or discrete shaping. The lack of thoughtful evaluation by this ET nurse reveals the basis for shortsighted opinions foisted upon patients, other caretakers and manufacturers. By not taking the time to understand the tradeoffs and requirements of adequate containment

within a specific size range, the ET nurse continues to promulgate the knee jerk desire for a discrete, read invisible pouch, and the hell with the problems of frequent emptying and toilet tethering that follows. The reader as well as the manufacturer is cautioned not to jump to the false conclusion that a smaller pouch is more flattering and desirable– in fact just the opposite is true when you factor in the necessity of containing the output without becoming tethered to the toilet.

INELASTIC SHORTCOMINGS OF OSTOMY

Given that an ostomy is not normally a lifestyle choice; some demands for ostomy needs fulfillment are not elastic (easily substituted). In a nutshell, what this means is that having an ostomy is not a simple or multiple choice option. Because it is necessary for maintaining health or life, and not easily replaced with other options, it does not lend itself to easy or readily available competitive substitutes. In economic parlance it is not an elastic or readily substituted need. It is very much an inelastic or very hard to replace or substitute dilemma, and pricing pressure will not readily affect the ongoing need. The patient is subject to the restraints and limitations of non competitive ostomy experiences and these place her at a unique disadvantage, subservient to the forces and whims of the product supplier and providers of care. In general, most folks would agree that health is not an elastic option, especially since the alternative – ill health or death - is very undesirable.

When an ostomate confronts such an inelastic need, he or she is subject to bizarre exacerbations should something go awry with her management. For example, if pouch A fails to perform well then easily switching to pouch B may not be feasible, especially if pouch B is inappropriate for A's use. If ostomate A suffers short bowel syndrome and needs to use pouch A, a high output drainable pouch, she can not successfully utilize closed end or small sized pouch B intended for ostomate B, who has a sigmoid colostomy that is well regulated and does not drain liquid stool. If an ostomate encounters a medical or surgical complication or mishap, necessitating further bowel resection, she can not continue to maintain the same quality of life and ostomy management routine that her previous small volume capacity pouch offered her. If the peristomal skin breaks down secondary to either stool leakage or product irritation, she can not simply ignore the use of a pouch and expect her life to be acceptable. Clearly, urgent remedies will be sought. When no good or easy alternatives exist to continue to manage one's life with relative ease, then one must bite the proverbial bullet and make do with whatever limited options (inelastic setting) are available. One can not easily undo the surgical mishap or permanent ostomy or return excised bowel or replace diseased colon with another off the shelf part, can one? In effect, the ostomate is behind the proverbial eight ball when it comes to choices. Either good options exist or they don't. The ostomate is normally not in a position to create her own options. She is very much dependent upon the vagaries and good will of the medical marketplace and the few

players who still troll the ostomy arena. In a sense, the ostomate almost becomes powerless or subservient to the medical and manufacturing hierarchy or oligarchy. This lopsided relationship begs for good governance or fiduciary accountability. The tremendous imbalance that exists between the patient and her providers should be self evident to the most casual reader and observer. If the patient can not fully and easily control her destiny, who then contributes to her well being? The medical and economic providers are the linchpins to her self care success. The medical provider encompasses all entities involved in her health care management and the economic provider consists of all those entities who contribute directly or indirectly to underwriting her health care costs.

While this article has addressed several interrelated issues of ostomy pouch design and capacities and marketing concepts and potential pitfalls, it also has pointed out some areas that may benefit from further research. The hope of the writer for the reader is that he or she will take the time and exert the mental effort to fully understand the myriad intersecting needs of the incontinent ostomate and integrate them into more coherent and practical strategies of long term care and pouching choices for the varied ostomy population while also remaining reasonably skeptical of manufacturing claims and concepts.

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