ABSTRACT

HAILEY, KATHLEEN MCKENZIE. Identification of the Major Cost Drivers within a Medical Nonwovens Pipeline (under the direction of Dr. George Hodge, Dr. Michelle Jones, and Dr. Robert Handfield)

The objective of this research was to gain a better understanding of a medical nonwoven pipeline in terms of the specific cost drivers associated with it. This was achieved by mapping the pipeline, identifying the processes and components, and finally, identifying the cost drivers associated with the pipeline. Interviews with academic and industry experts revealed that the medical nonwovens industry is very complex. There are many players within the pipeline, consisting of roll goods manufacturers, converters, distributors/wholesalers, and end customers.

The results prove to contribute to the body of knowledge in that they offer an in depth look at the pipeline structure, the major cost drivers and their interrelationship to one another, and the overall structure and shape of the medical nonwovens industry. Included in the results are a medical nonwovens pipline map, which contains the key elements and processes within the pipeline, and the cost drivers associated with them.

In addition to the findings of this research, recommendations for future research are made concerning the topics of cost modeling, data extraction, nonwovens processing and materials, testing standards, supply chain management, medical nonwovens in North Carolina, and sourcing decisions for converters.

IDENTIFICATION OF THE MAJOR COST DRIVERS WITHIN A MEDICAL NONWOVENS PIPELINE

By

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BIOGRAPHY

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1.0 Introduction

As the textile industry in the United States struggles, due to heavy competition from global sources, the nonwovens industry is growing and prospering. The nonwovens industry in the United States is a fairly new industry, as compared to wovens and knits, and is proving to be a sustainable industry. Known as the triple bottom line, sustainability is a key ingredient to a product's success and companies in the US nonwovens industry appear to demonstrate all three levels in that it offers economically viable and environmentally responsible products, as well as serve a social need (Chapas, 2002). This success is a result of the nonwovens' industry offering many growth opportunities, at a time when textiles in the United States is on a downward spiral, in terms of profitability. These opportunities are mainly found in the areas of product design, new material innovations, and machinery innovations (Chapas, 2002; M. Sommerfeld, personal communication, May 22, 2003).

Nonwovens, as a product, bring many benefits to multiple industrial and consumer markets, such as within the cosmetic industry, hygiene industry, and most importantly, for this study, the medical industry. Nonwovens provide many necessary and practical properties for the medical industry in terms of disposability, protection, and cost.

So, why study nonwovens? Nonwovens represent a relatively new area of textiles that has not been explored to its full potential. While there exists a plethora of research on the fibers used (e.g., cotton, polyester, polypropylene), many strides have yet to be made in the area of research and development. In particular, exploration into the pipeline or supply chain of activities associated with the manufacturing of nonwovens is lacking. In order to remain competitive today, it is necessary to understand all activities within a supply chain and the cost drivers associated with them. Competitiveness stems first from understanding

the activities of the pipeline, then secondly, further steps can be taken to minimize the costs associated with them. Gaining a better understanding of the nonwovens pipeline and the costs associated with it will allow managers to make more efficient and effective decisions in order to remain competitive.

2.0 Literature Review

2.1 Overview of Nonwovens Industry

According to the Association of Nonwovens Fabric Industry (INDA), a nonwoven is defined as:

> "A sheet or web structure bonded together by entangling fiber or filaments (and by perforating films) mechanically, thermally or chemically. They are flat, porous sheets that are made directly from separate fibers or from molten plastic or plastic film. They are not made by weaving or knitting and do not require converting the fibers to yarn" (INDA, 2003).

Nonwoven fabrics are fabrics that can be engineered to have a limited life, be a single-use fabric, or a very durable fabric can, provide specific functions (e.g., absorbency, liquid repellency, resilience, stretch, softness, strength, flame retardancy, washability, cushioning, filtering, bacterial barrier, sterility) (INDA, 2003). These properties associated with nonwovens are often combined to produce fabrics for specific jobs, while providing a balance between product use and cost. Nonwovens cab be engineered to look and perform like woven and knit fabrics (INDA, 2003). By using nonwovens, in conjunction with other materials, manufacturers can provide a wide variety of products with diverse properties such as for apparel, home furnishings, health care, engineering uses, and industrial and consumer goods.

A list of types of nonwovens is shown in Table 1:

Table 1: Nonwoven Applications

Personal Products
• disposable diapers • sanitary napkins & tampons
Medical
• sterile wraps, caps, gowns, masks and drapings used in the medical field
Industrial and Home Applications
• household and personal wipes • laundry aids (fabric dryer-sheets) • apparel interlining • carpeting and upholstery fabrics, padding and backing • wall coverings • agricultural coverings and seed strips • automotive headliners and upholstery • filters • envelopes • tags • labels • insulation • house wraps • roofing products • civil engineering fabrics/geotextiles

Source: (INDA, 2003)

Early nonwovens begain as concepts based on basic technologies and equipment for textile, paper, and plastic production process. For example, early nonwovens producers used textile carding machinery, modified the equipment to fit their need, and added chemical bonding to the fibers. From there, the product was dried and cure with heated rollers that came from a manufacturing line previously used in printed goods, or other paper products (Holliday, 1997). The major obstacle that nonwovens faced then was the acceptance, by both industrial and consumer-customers, of these products being just as effective in as many uses as wovens or knits. Overall, customers were unsure of the properties of nonwovens, as well

as whether or not they could withstand the processing associated with their manufacturing processes (Holliday, 1997). For manufacturers of nonwovens, every market that they attempted to penetrate they faced similar resistance. Geotextiles, roofing, coating/laminating, flooring, healthcare, filtration, and home furnishings were among the industries most doubtful of the nonwoven's ability to perform (Holliday, 1997). The expectation of the nonwoven fabric, by all industries, was that it should be cheaper and perform better than the material that the industry was currently using (Holliday, 1997). The good news for nonwovens was that in most cases they were and are cheaper and perform just as well, if not better, than a woven or a knitted fabric. Today, equipment manufacturers are producing a variety of machines especially for the production of nonwovens. In addition, nonwovens today are recognized as viable replacements to certain wovens and knits (Holliday, 1997).

Nonwovens are proving themselves to be sustainable products. In 2002, Chapas studied nonwovens and determined the characteristics of a sustainable product. As mentioned, nonwovens are proving to possess all qualities of a truly sustainable product: they are environmentally responsible, economically viable, and serve a social need (Chapas, 2002). Manufacturers of nonwovens and other disposables have made significant strides toward becoming sustainable products. Processing technology in the nonwovens industry has greatly improved over the past few years and has revolutionized the industry. The ability to automate to conversion of raw materials into fibrous structures has reduced labor and energy usage, reduced waste, and created product design opportunities. In addition, bonding technologies and polymer development have also contributed to the increase of design options, allowing for functionality to drive process choices (Chapas, 2002). Also, the machinery used to produce nonwovens are becoming cheaper, making the nonwovens

industry appealing to entrepreneurs worldwide. Engineering expertise has become intrinsic to the technology, greatly diminishing the need for a large support staff (Chapas, 2002). As a result, many developing countries are experiencing lower barriers to entry in terms of nonwovens production.

In terms of the characteristics of nonwovens, innovation is critical. Improvements in environmental performance, product design, new material technologies, and societal impacts are all dependant on innovation (Chapas, 2002). Environmental performance has improved due to significant reductions in material usage. This results from the use of high performance materials or new processing technologies. Also, the industry has reported no history of pollution problems in terms of air pollution. Product design also continues to improve, which has a significant impact of environmental performance. The most evident societal impact from nonwovens is the significant improvements in hygiene and medical applications worldwide. This will continue to improve as nonwovens become more innovative in terms of production and overall product characteristics (Chapas, 2002). Innovation is the key for medical nonwovens producers to stay competitive in today's market (M. Sommerfeld, personal communication, May 22, 2003). Possible improvements may include improved barrier protection, improved strength and comfort, and improved production speed of medical nonwovens.

The most noted challenges that the nonwovens industry is currently facing are:

- **Disposability of the products** – disposable nonwovens are not reusable and must be thrown away, which contributes to the increase in the levels of trash in community landfills. Products need to be disposable and biodegradable.

- **Dependency on petroleum** – most nonwovens are made from synthetic fibers, which are composed of petroleum based fibers, which may become a concern during any oil crisis, when oil prices increase as a result of war or other political instability in petroleum producing countries.
- **Societal dislocations of wovens as they are replaced by nonwovens** – is society ready to replace woven products with nonwoven products. This shift to nonwoven production will affect the employment that exists for woven and knitted goods. Also, research and development costs may be high in order to improve current woven and knitted goods (Chapas, 2002).

In addition to the above challenges, the nonwovens industry is only producing for the top five percent of the world's population. This represents a great opportunity for the industry in that there is much larger market out there that the nonwovens industry is not currently addressing. However, the nonwovens industry, being fairly new, has not produced the business models to move forward. The success of the industry depends on several factors: local entrepreneurs, new delivery modes, product design, and compatible manufacturing methodology (Chapas, 2002).

As reported in the Chapas study, local entrepreneurs are critical because they know the needs of the local markets (Chapas, 2002). New delivery forms should include new packaging methods and logistics, and most importantly, design innovation is necessary, with the target being simplicity. From a global perspective, the design must be compatible with a developing country's population, manufacturing systems, and infrastructure (Chapas, 2002).

There are many reasons that nonwovens, and more specifically, nonwovens with synthetic fibers have grown in use over the past few years. These contributing factors, as reported by Dobson (2001) reported are:

- Population growth – increased demand as population increases
- Growth in gross national product per capita and level of disposable income
- Increases in trade as the result of trade accords
- Replacement of other textiles and other commodities with nonwovens
- Introduction of new, more efficient, and more economical processing technologies

In terms of population growth, nonwovens play a large role in the production of diapers and, at the other end of the spectrum, adult incontinence products. Thus, an assumption would be that as the population grows due to births, diaper consumption increases, and as people are leading longer lives due to technologies in medicine and a higher standard of living, adult incontinence products consumption also increases. It is projected by the year 2050, the average life expectancy will be 83.9 years and the fertility rate will grow to 2,219,000 births per year (US Census Bureau, 2003). Overall, these two nonwoven products, adult and children's diapers, represent a significant portion of the nonwovens industry (Dobson, 2001). The increase in the gross national product per capita and the increase in the level of income affect the consumption of nonwovens as well. As disposable income increases, people can afford to buy diapers, medical nonwovens, feminine hygiene products, nonwoven-based household goods, and nonwoven vehicle consumer textiles. As global trade becomes easier due to trade agreements, the nonwovens industry will continue to grow outside of the United States, in terms of exporting and manufacturing. Representing further growth is the ability of nonwovens to replace other textiles, such as wovens and knits, based on cost and overall fabric performance. Finally, the introduction of new, more

efficient, and economical processing technologies is making the production of nonwovens very cost effective and more appealing for entrepreneurs to get involved (Chapas, 2002). Future trends in the nonwovens industry include: innovations in process technology, innovations in material technology, and multifunctional composites (Chapas, 2002).

2.1.1 Nonwovens in the US and North Carolina

The US is the largest market for nonwovens production. The US industry is composed of over 550 firms with employment totals of 160,000+ and annual sales of over $40 billion (Pourdeyhimi, 2003). US firms are typically small with the median employment being 75 people and annual sales of $7.5 million (Pourdeyhimi, 2003).

Core nonwovens firms are located primarily in 32 states and the District of Columbia. However, North Carolina has the largest number of core nonwovens firms in the US. Forty of North Carolina's 100 counties have at least one commercial nonwoven related facility located in them (Pourdeyhimi, 2003).

Table 2: Core US Nonwovens Producers

State	Number of Firms
North Carolina	29
Massachusetts	17
Georgia	12
New York	12
South Carolina	10
New Jersey	8
Michigan	6
Virginia	3

Source: B. Pourdeyhimi, 2003

2.1.2 Nonwovens Production and Consumption

At present, the worldwide nonwovens industry is dominated by manmade fibers. This nonwovens industry seems to be dominated by polypropylene and polyester, with these fibers representing the majority of nonwoven's fiber consumption. Overall, all fiber type consumption for the production of nonwovens is expected to increase over the next few years (I. Butler, personal communication, May 19, 2003; M. Sommerfeld, personal communication, May 22, 2003).

Nonwovens are consumed globally, but mainly in the United States, as represented by the data in the table below. This, however, will change as developing countries become more and more developed and will have the capability to produce nonwovens and at a price they can afford. As this occurs, developing countries will have access to more nonwovens products.

Table 3: Fiber and Resin Consumption in Nonwovens (Millions of tons)

Staple Fibers	**2001**	**2006**
Polypropylene	870	1180
Polyester	560	770
Rayon	230	310
Bico, Fiberglass, and Other Synthetics	280	370
Cotton	60	70
Wood Pulp	390	760
Other Natural Fibers	<20	<30
Total Fibers	2410	3490
SpunMelt Resins		
Polypropylene	1180	1930
Polyester	270	360
Nylon, Polyethylene, Bico, Others	120	150
Total Resins	1570	2440

Source: INDA, 2002

Table 4: Nonwovens Consumption by Region 1983-2007 (% of total)

Year	USA	West Europe	Japan	China	Rest of World
1983	52	31	8	unknown	9
1988	48	30	9	2	11
1995	38	30	9	6	17
1998	35	30	10	8	17
1999	34	30	9	10	18
2000	33	30	9	11	18
2005	31	31	9	11	18
2007	30	30	9	12	19

Source: Dobson, 2001

Nonwovens production is found worldwide, but is mainly focused in North America, Europe, and Japan. This trend is likely to change as developing countries become more and more developed in terms of technology and more production will be seen in Latin America, Asia-Pacific, and the Middle East. In terms of nonwovens roll goods production, production has increased since 1991 and is expected to increase over the next few years.

Table 5: Nonwovens Production by Region (000,000 tons)

Region	1991	1996	2001	2006	Growth Rate 1991-2001	Growth Rate 2001-2006
N. America, Europe, Japan	1.5	1.8	2.6	3.6	6.4%	6.2%
Latin America	.09	.17	.24	0.4	10.3%	8.5%
Asia-Pacific	.22	.46	.64	1.1	11.2%	10.7%
Middle East	.04	.08	.17	.4	15.6%	15.0%
Rest of World	.06	.11	.16	0.3	10.5%	11.3%
Total	1.9	2.6	3.9	5.6	7.5%	7.6%

Source: INDA, 2002

Table 6: Nonwovens Roll Goods Production

Quantity	1991	1996	2001	2006	Growth Rate 1991-2001	Growth Rate 2001-2006
Dollars (billions)	8.2	10.8	14.1	20.2	5.5%	7.5%
Square Meters (billions)	41.0	61.0	93.0	140.0	8.6%	8.5%
Tons (millions)	1.86	2.63	3.85	5.63	7.5%	7.6%

Source: INDA, 2002

2.2 Medical Textiles

2.2.1 Definition

Medical textiles, also known as biomedical textiles, are textile products and constructions, for medical and biological uses used for first aid, clinical, or hygienic purposes ("What are Medical," 2003). Examples of their applications include:

- **"Protective and healthcare textiles**: surgeons' wear, operating drapes, and gowns
- **External devices**: wound dressings, bandages, pressure garments, prosthetics
- **Implantable materials**: sutures, vascular grafts, artificial ligaments
- **Hygiene products**: incontinence pads, nappies, tampons, sanitary towels
- **Extracorporeal devices**: artificial liver, artificial kidney, artificial lung"

("What are Medical," 2003).

The design of a biomedical textile is driven by its end use. These main factors include:

- **"Function**: the textile needs to fulfill the purpose for which it was designed
- **Biocompatibility**: this refers to the reaction of the textile with blood and an implantable material has more potential for reaction than an external material and therefore has tighter regulations.

- **Cost**: this will depend on the raw materials and manufacturing process
- **Product approval**: each country has its own regulations and standards for the approval of biomedical textiles" ("What are Medical," 2003).

2.2.2 Applications

Medical textile uses are wide ranging. Medical textiles can be anything from implantable devices used in surgery to simple bandages used for cuts and scrapes. Medical textiles represent a very diverse market in terms of uses, as well as production. Because the products and uses are so different, the methods of manufacturing are varied as well. In addition, the materials used vary a great deal. Materials used can be basic cotton to complex synthetics. All production and material decisions are driven by the end use of the textile.

2.2.3 Reusable Versus Disposable

A key decision in deciding which type of medical textile is chosen is whether or not the structure will be reusable or disposable. In the case of surgical gowns, reusable textiles represent 50% of the total product category (Rodie, 2001). "The advances have made reusables [nonwoven products] more viable from a clinical perspective, as well as they cost much less per use than disposables, as laundering costs are less than costs of acquiring comparable disposables" (Rodie, 2001). In addition, the effective liquid barrier protection and comfort afforded by reusable fabrics are appreciated by healthcare professionals and patients alike (ARTA, n.d.) Also, a decrease in the quantity of toxic pollution generated by the disposal of healthcare waste and sent into the environment means an increase in the quality of the air breathed (ARTA, n.d.).

According to the American Reusable Textile Association (ARTA), reusables are less costly. Dr. C. Everett Koop, former United States Surgeon General, states that disposable

products are a major cause of rising healthcare costs. Koop continues to say, "…because they are disposable, our society thinks they must be cheap. They [disposable products] are extraordinarily expensive" (ARTA, n.d.). Helen M. French, a clinical nurse at the University of Virginia Health Sciences Center, states that approximately 3.2 million tons of medical waste is generated annually by American hospitals. This amounts to quite a bit of expense at 50 cents per pound to incinerate or dump. This totals $480 million a year to dispose of its infectious discards (ARTA, n.d.).

In terms of product performance, the Occupational Safety and Health Administration's (OSHA) rule on effective barrier performance clothing is that garments be designed to protect healthcare professionals against harm from exposure to blood born pathogens. OSHA further considers disposable incontinence-care products to be bio-hazard waste. This, however, is not a problem with reusables. As mentioned, advances in technology for superior barrier protection in reusables is continuing, making reusables a competitive option for medical textile applications (ARTA, n.d.).

When describing the battle between reusable and disposable medical textiles, it can almost be completely interchanged with woven/knit versus nonwovens. In terms of significance, nonwoven's disposability property is one of the main reasons hospitals and operating rooms prefer nonwovens over woven fabrics (Frei, 1999). Disposables used in a hospital offer a freshness quality that reusable textiles cannot offer. Reusable textiles, even after washing, can retain stains (Frei, 1999). Other manufacturers feel nonwovens offer more possibilities than wovens, allowing them to better adjust their product lines to potential customers (Frei, 1999). However, the conversion of wovens to nonwovens has been slower than anticipated due to corporate red tape, along with the time needed for R&D, lab and

clinical trials, and FDA approvals (Frei, 1999). A critical focus for medical disposables producers is pollution due to an increase in the amount of waste associated these disposable products (Frei, 1999).

2.3 Medical Textiles and Nonwovens

Medical textiles use all types of textile facbrications, including knits, wovens, and nonwovens. Each type of construction offers unique properties that are useful to various medical applications. Woven fabrics are most useful in reusable medical textiles applications, such as reusable gowns, bedding, and towels. In addition, woven structures can be found in applications such as polyester vascular and cardiovascular grafts. Some woven devices have a leno structure which reduces fraying and holds sutures better than other woven structures (Rodie, 2001).

Knits are also prevalent players in the medical textile field. These fabrics offer superior flexibility for such applications as grafts and good support for applications, such as support hosiery. Knits also offer greater control over such properties as elasticity (Rodie, 2001).

Nonwovens are also a major player in the medical textiles field. Nonwovens are beginning to take the place of wovens and knits as they offer disposability at a time when fear of disease contraction is at its height (Rodie, 2001).

Medical textiles are proving to be just as important as the medicines that are used today. These textile products act in the same capacity as they treat and prevent medical problems with patients. Businesses and scientists are combining efforts to develop new medical textiles that optimize biocompatibility, sterility, leak resistance, and wear of medical products ("Wear and Care," Textile Month, 2001). The use of nonwoven fabrics in medical

textiles has grown over the past 25 years. The main growth area is single use disposable medical products. The acceptability of these products has resulted from the significant improvements made in the properties and cost of the materials ("Wear and Care," Textile Month, 2001).

Nonwoven fabrics have brought "better medicine" to healthcare in terms of improved wound care, lower patient infection rate, better staff/worker protection, cost/benefit improvements, and sterility assurance (McDowell, 1991). With the widely accepted use of these nonwovens materials comes the definite concern, which has already been discussed: disposability. The chief concerns with the disposal of these single use products are fear of AIDS, environmental pollution, decreasing numbers of landfills, increasing costs, and regulatory/legislative actions (McDowell, 1991).

As seen in Table 7, medical textiles can be intended for surgical or general use applications. Surgical applications include operating room drapes, OR gowns, head coverings, face masks, scrub apparel, CSR wrap, and shoe coverings. More than three quarters of the fabrics used in these applications are nonwovens. General care applications include uniforms and bed linens. These are mainly reusable textiles.

Table 7: Applications of Medical Textiles

	Definition/Use	Material Composition	Examples
Implantable	Devices that are implanted inside the body that are porous enough to allow tissue to grow on and enclose them	Biodegradable and non-biodegradable fibers are used Biodegradable: collagen, alginate, polyacide, polyglicolide, polyamine, and polyurethanes Non-Biodegradable: polytetrafluoroethylene (PTFE), polyester, polypropylene, carbon	**Sutures** Synthetic skin Bone-setting materials Vascular grafts Ligaments Heart valve components Hernia mesh Adhesion barriers
Dressings/Bandages	Dressings and bandages protect wounds from infection, as well as further injury	Cotton Polyester Antimicrobial products Cosmocial CQ polyhexamethylene biguandine (PHMB)	**Bandages** **Gauze** **Wound dressings** **Sponges**
Support Systems	Support systems help hold blood vessels or bones in place during healing and help restore normal function by providing pressure and/or a rigid framework around an affected area	Nylon Elastene	Surgical stockings Pantyhose Compression hose Braces Casts
Protective Covering	Protective covering consists of surgical apparel and accessories, breathable membranes, and barrier products. These must be fluid proof and comfortable and provide freedom of movement.	Knitted, woven, and nonwoven cotton, polyester, polypropylene, polyethylene, viscose, or glass fiber. Barrier protection is enhanced by the addition of coatings and laminations.	**Surgical gowns** **Surgical drapes** **Face masks** **Shoe coverings** **Head coverings**
Hygiene	Products used to aid in incontinence, general cleanliness, and menstrual uses	Polyester Cotton Vinyl Polyurethane Rayon	**Incontinence pads** **Feminine napkins** Tampons **Nappies** **Sanitary towels**

Source: Rodie, 2003 **(All examples in bold are potential nonwoven products.)**

The desired properties for medical nonwoven products are as follows:

- Repellant vs. breathable comfortable
- Strong vs. lightweight
- Laser and electrocautery safe
- Low lint/abrasion resistant vs. softness
- Environmentally compatible
- Fluid control
- Antimicrobial activity
- Sterility assurance
- Non-toxic
- Non-allergic
- Non-carcinogenic
- Antistatic in nature
- Optimum fatigue endurance
- Flame proof
- Dyes must be fast and non-irritant (McDowell, 1991)

The US demand for medical textiles is expected to increase over the next few years. Global sales are expected to rise to $4.1 billion in 2005, which will account for 12% of the overall technical textiles market. Sales in 2000 were $478 million in the US. 2.3% growth is expected per year for medical textiles ("USA: Medical Textiles," Asia Africa Intelligence, 2003).

2.3.1 Medical Nonwovens Producers

There are a few main competitors in the medical nonwovens industry as seen in Table 8 (Noonan, 1992).

Table 8: Major Medical Nonwovens Producers

Company	Medical Products Produced	Total Sales for 2002 (in millions $)	Percent Sales Medical Nonwoven
Johnson & Johnson	Wound dressings, surgical devices	36,298	52%
Kimberly-Clark	Surgical drapes and gowns, medical devices, sterilization wrap,	13,566	33%
3M	Dressings, surgical tapes and wraps, bandages	16,332	Data not available
Freudenberg	Medical nonwovens	4,007	3%
Polymer Group International	Operating and emergency room products, wound care, specialty prodcuts	757	Data not available

Source: Hoover's Online

2.4 Cost Principles

In general, the cost assumed by a producer is the total dollar amount invested by the manufacturer (Glock & Kunz, 1990). Manufacturing costs have a major effect on a firm's profit and need to be identified and managed. All manufacturing processes have costs that are unique, but overall, can be categorized into several main types of costs. Three main categories are: raw materials, direct labor, and factory overhead (Glock & Kunz, 1990). Raw materials, such as fabric, fiber, thread, and trim are examples of direct variable costs. Variable costs are costs that change depending on the amount of production that occurs. If production increases, variable costs increase and vice versa (Glock & Kunz, 1990). Direct labor costs include wages of employees that work on an incentive, piece rate, or an hourly wage basis, such as cutters, sewers, and finishers (Glock & Kunz, 1990). Factory overhead consists of both variable and nonvariable indirect manufacturing costs. These costs are

unique to each plant, but are generally subdivided into indirect labor, factory occupancy costs, and other overhead. Indirect labor includes service personnel, quality control, material handlers, mechanics, and maintenance workers, industrial engineers, and security (Glock & Kunz, 1990). The work of these individuals is essential to the completion of a product, but none of them work directly with the product. Nonvariable factory occupancy costs include rent, depreciation, insurance, property taxes, and security (Glock & Kunz, 1990). Variable factory costs include machine parts and repairs, marker paper, and needles. Other overhead costs are materials management, machinery and equipment costs, and cost of compliance with regulations (Glock & Kunz, 1990).

Another type of cost is the general operating expense or the administrative overhead. These are indirect costs the include the costs of operating the general offices and departments, such as accounting, computer programming, management information systems, secretarial and clerical staff, personnel office, design and merchandising, marketing and sales, and management salaries (Glock & Gunz, 1990). Other costs to be considered in the manufacturing of a product are logistics, sourcing costs, inventory costs, storage, and additional processing such as finishing.

2.5 Mapping and Modeling

Business processing models or maps provide a systematic approach for understanding processes and information flows (DAMA, n.d.). By documenting these processes within a manufacturing pipeline, managers can begin to understand and identify who the players are within the pipeline and how they interact together. On a more detailed level, mapping a pipeline allows for managers to easily identify the key activities within and the cost drivers

associated with them. Mapping is useful in many ways. Not only does a map allow for easy identification of activities, it produces a map from which improvements and education can occur. Developing an "as-is" model of an enterprise or company establishes a base from which you can begin to re-engineer the business (DAMA, n.d.). Also, a model can enable your business to communicate business rules and critical data interchanges among partners (DAMA, n.d.). Finally, business models can be used as an excellent way for the employee to be introduced to how business processes are related to the employee's area of responsibility (DAMA, n.d.).

The primary reasons for modeling are as follows:

- "To provide a means for completely understanding and analyzing an organization's data resources
- To provide a common means of representing and communicating the complexity of data
- To provide a method for presenting an overall view of the data require to run an enterprise
- To provide a means for defining an application-independent view of data which can be validated by users and transformed into a physical database design
- To provide a method for deriving an integrated data definition from existing data resources" (Joao, 2002)

DAMA, the Demand Activated Manufacturing Architecture, began in 1992, and is one of the first organizations to map a textile process. The DAMA project's goal was to understand how a product moves through the textile pipeline, as it is transformed from fiber to apparel over a 55-week period. The project has completely modeled the production of men's cotton slacks through the textile complex (Hodge, 1997).

This study recognizes that cost is a critical factor that impacts all the players within a pipeline. The medical nonwoven pipeline map, developed from this research, will establish a framework in which costs can be identified and examined

3.0 Objectives of Research

3.1 Research Question

The focus of this study is to determine what a medical nonwovens pipeline looks like. Specifically, addressing the following questions:

1) Who are some of the key players in the production of medical nonwovens?
    a) Who are the leading manufacturers of medical nonwoven textile products
    b) What types of products do they manufacture?
2) What does the medical nonwoven cost structure look like?
    a) What are the raw material inputs?
    b) What are the processes that are used to manufacture medical nonwovens?
    c) What are the cost drivers?
    d) What are the interrelationships between cost drivers and the pipeline members?
3) Can the medical nonwoven's pipleline be depicted graphically?
    a) How do academic nonwovens experts view the medical textiles pipeline?
    b) How do industry experts view the medical textiles pipeline?
    c) How does the manufacturing route change based on various products?
4) What are the general characteristics of the medical nonwovens industry?

3.2 Research Objectives

The purpose of this research is to enhance the understanding of a medical nonwoven's production pipleline by mapping a product pipeline from the manufacturing of the product to the end customer. The purpose of mapping the pipeline is to provide a graphical representation or a "road map" which can be used to identify and quantify the key cost drivers associated with the production of the product. Pipeline analysis is one technique

developed under the Demand Activated Manufacturing Architecture (DAMA) Project. The goal of their analysis is to strengthen the competitiveness of the complex, including the fiber, textile, apparel, and fabricated product sectors. DAMA's purpose was to increase competitiveness of the textile industry in the US, resulting in the recapture of the global marketplace (DAMA, n.d.). The mapping and modeling methodologies of the DAMA project, as mentioned in section 2.5, will be used to gain a better understanding of a nonwoven medical product's pipeline.

The first step in the DAMA methodology was to map the "As Is" pipeline associated with a specific product – what does the pipeline look like today. A similar methodology will be followed in this study. The goal of DAMA was to determine where changes in a "link" in the supply chain or where changes in interrelationships among links will result in reduced product throughput time, lead time, and stock-outs and where non-value added activities can be reduced or eliminated. The "As Is" pipeline will provide a "road map" to follow for identifying costs within the pipeline. Pipeline analysis starts at the business function level (information flow, inbound and outbound logistics, production, customer service, etc.) for each link in the supply chain.

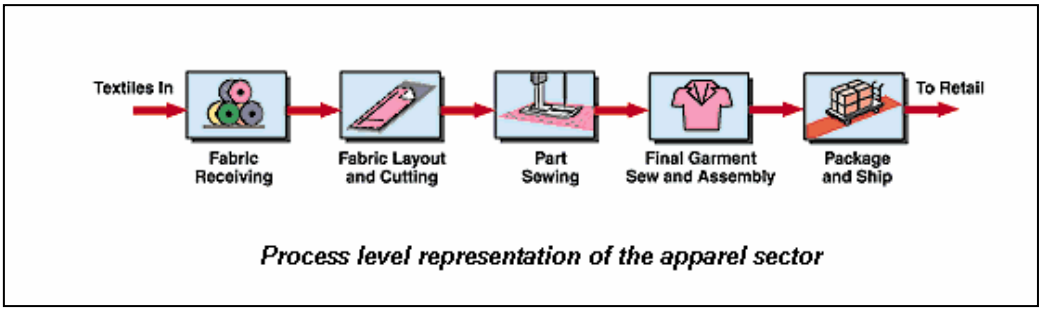

Figure 1: DAMA Apparel Pipeline , Source: DAMA

For this study, key cost drivers will be identified through interviews with medical nonwovens producers. These interviews will be used to produce a graphical representation of a medical

nonwoven's pipeline, which will be used as a "roadmap" to identify the key cost drivers within the pipeline.

3.3 Research Methodology

3.3.1 Perform case studies on 2 to 3 nonwovens manufacturers.

The companies selected must be large producers of at least one type of medical textile. Because the medical nonwovens industry is fairly new, data surrounding the pipeline is limited if not available. As a result, case studies with specific companies will be performed in order to gain timely and accurate data. In addition, because the topic is very specific in nature, statistically based sampling will not provide specific enough information. At least one contact will be spoken to at each manufacturer's location. If more contacts are available, they will be spoken with as well.

Specific interview questions will be created and reviewed by at least 2 textile experts here at the NC State College of Textiles. The questions will cover the remaining research objectives. The interview will be performed in person or telephone, with all follow up correspondence be completed by telephone or email.

3.3.2 Map the activities within the medical nonwoven's pipeline.

By using the interviews and research performed with 2 to 3 companies, a pipeline map illustrating all of their components from the raw material to the end user will be created. Pipeline mapping includes diagramming the activities of a pipleline by using either flow charting or other diagramming capabilities in the order in which the activities occur. Other activities that have used mapping are business projects in which inventories must be identified and this can only occur when a map of the pipeline is created. Without knowing the activities involved in a supply chain or pipeline, inventories cannot be located and in the

case of this project, cost drivers cannot be identified. Supply chain and pipeline mapping provides an organized way to illustrate the activities with a supply chain or pipeline so further research can be performed.

3.3.3 Using the pipeline activity map, identify all key cost drivers.

A cost driver, in the sense of this project, includes all activities within the pipeline, which cost the company money. Examples of cost drivers include machinery, logistics, sourcing decisions, raw materials, medical standards inspections, etc. Key cost drivers are considered to be cost drivers that are specifically found in the medical nonwovens industry. They are the cost drivers that differentiate the medical nonwovens industry from all other industries. By identifying the key cost drivers associated with a medical nonwovens pipeline, doors will be opened for further research on how to minimize these costs and better manage the pipeline.

3.3.4 Analysis of Results - Compare the significance of the cost drivers relative to one another.

Basically, this objective will analyze all results and identify which cost drivers are the most significant in terms of dollar amounts within a medical nonwovens pipeline. Further, why are these cost drivers costing more than others – what are the factors influencing this – red tape, labor, standards (federal standards), time, etc.

4.0 Results

4.1 Medical Nonwoven Road Map

Preliminary results of the interviews revealed that the medical nonwoven production pipeline had a very basic structure, which is represented by a basic road map. This roadmap, for a medical nonwoven, consists of five major steps: raw materials, web formation, bonding, finishing, and conversion. Most any medical nonwoven can be made choosing one or more components of each major step.

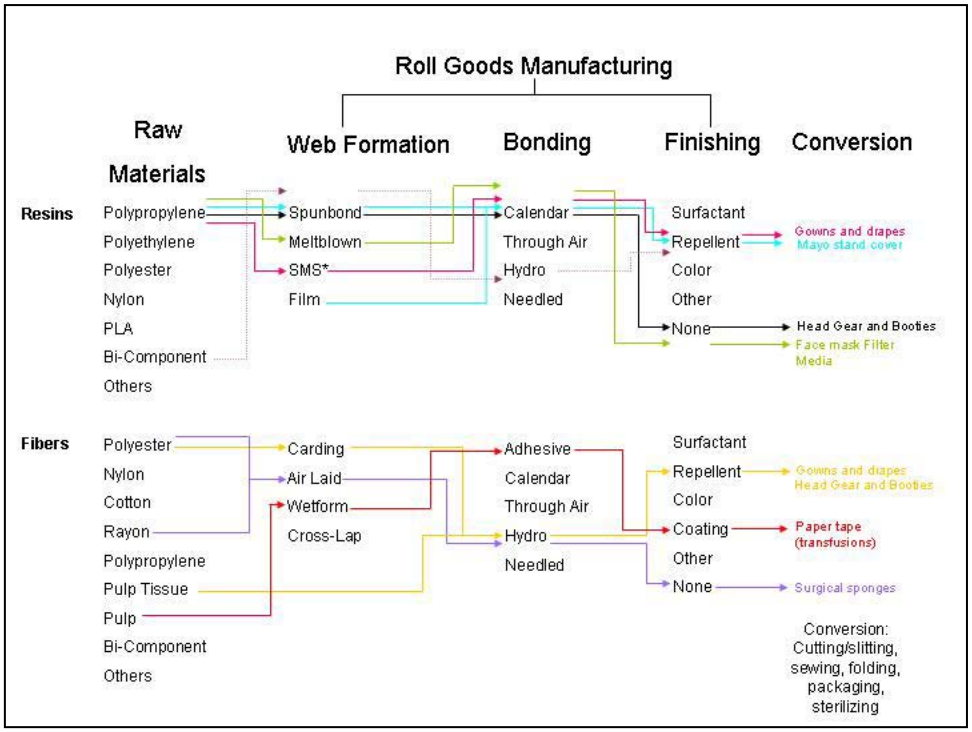

Figure 2: Nonwoven Production Road Map

4.2 Medical Nonwoven Production and Pipeline

The medical nonwoven pipeline is very complex and segmented and is dominated by many companies,which are involved in the production of the final product. It is true that the nonwoven industry is dominated by a few key players, producing about 70% of the total

market (M. Sommerfeld, personal communication, May 22, 2003). However, the production of medical nonwovens cannot be that simply defined. As seen in the Section 4.1, the Medical Nonwoven Road Map, it is clear that the pipeline is composed of raw materials providers, roll goods manufacturers, converters, distributors, and the final customer. The large nonwovens producers do manufacturer medical roll goods nonwovens, as seen in Section 2.3.1, but they are not responsible for the entire manufacturing process. The medical nonwoven industry is also dominated by many converters. These converters are responsible for cutting or slitting, sewing, and coating, which are procedures that prepare the roll goods for its final end uses. Converters are just as important as the roll goods manufacturer. There are major players in the converting business. For example, of the almost 800,000,000 drapes and gowns produced per year, one company is responsible for converting about 75% of the volume for gowns and drapes, making them a dominant player in the conversion of drapes and gowns (M. Sommerfeld, personal communication, May 22, 2003). Upon the completion of conversion, most medical nonwovens are shipped to another converter for further processing, to a distributor to be allocated out, or to the end customer, such as hospitals, drug stores, etc. It is safe to say that the medical nonwovens roll goods industry is dominated by a few key players, as well as the conversion process is dominated by a few key players. Overall, the industry cannot be dominated by single companies. There are many players that contribute to the manufacturing and finishing of a medical nonwoven.

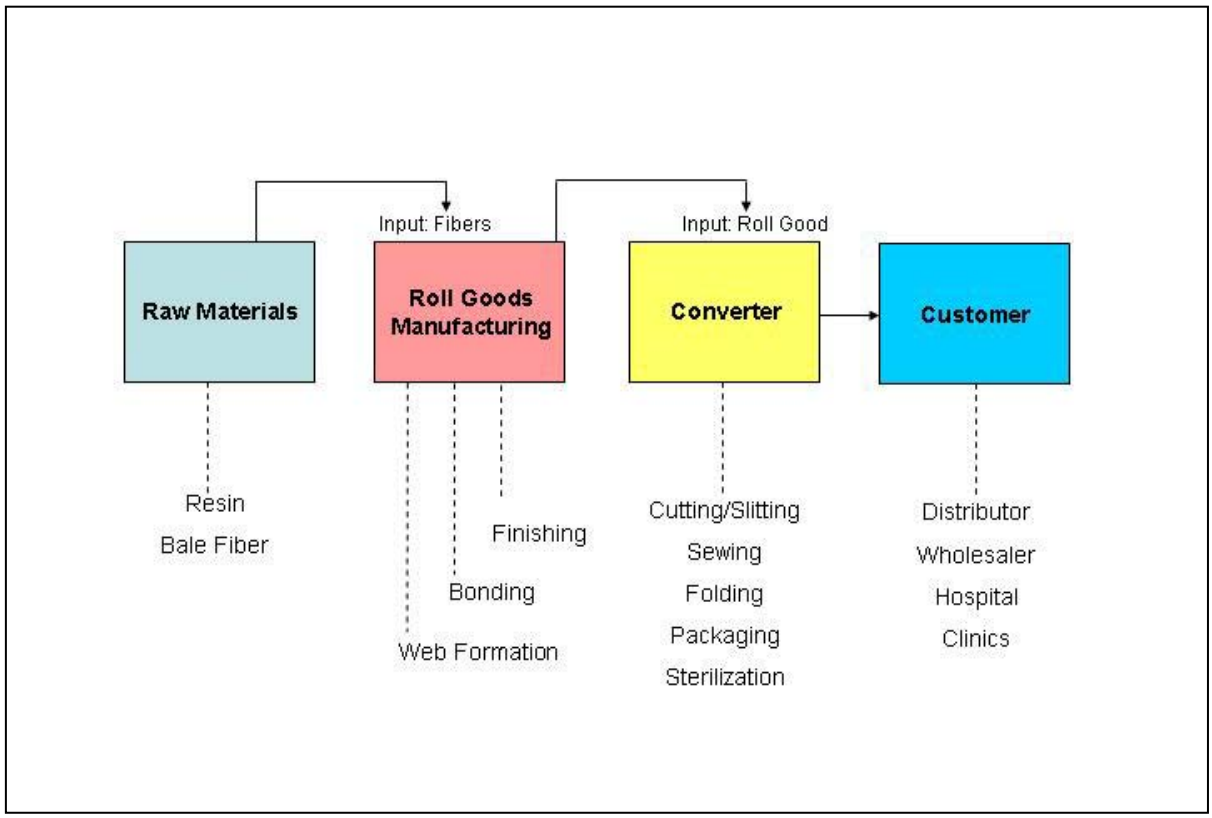

Figure 3: Medical Nonwoven Production Pipeline

.2.1 Raw Material Inputs

There are many types of fibers used in the production of medical nonwovens, but the manufacturing of these goods is dominated by synthetic fibers and resins. Although it was anticipated that compliance with US Federal Standards would be a significant cost driver, about 50-70% of the final cost of a medical nonwoven consists of raw materials (i.e., unprocessed fibers) (I. Butler, personal communication, May 19, 2003; M. Sommerfeld, personal communication, May 23, 2003; R. Holmes, personal communication, May 4, 2003). Thus, the acquisition of the fiber makes it the number one cost driver within a medical nonwovens' pipeline. The costs that are associated with the production and processing of fibers for medical nonwovens are considered to be insignificant cost drivers relative to the cost of fibers. Table 9 identifies the major types of resins and fibers being used today in the

production of medical nonwovens. For example, there are steps of preparation that can occur before web formation, either for baled fibers or synthetic resins. Baled fibers must be opened and blended and most resins have to be dried. Some polyester fibers need to be crystallized, and most fibers need to be humidified before being processed. In addition, all carded fibers must be finished using a three level finishing bath.

The results from the interviews indicate that the federal standards placed on raw materials are not clearly defined. For example, the level of cleanliness for fibers was defined broadly as needing to be "clean and sanitary," and without regard to specific tolerances of trash content. In addition, the results revealed no existing federal sterilization standards for the machinery used to process these fibers. The machinery must, however, be "clean and sanitary" (R. Holmes, personal communication, May 4, 2003).

Table 9: Examples of Fiber Types and Prices (Bales and Resins)

Resins	**Prices ($)/kg**
Polypropylene	0.86
Polyethylene	0.97
Polyester	1.34
Nylon	2.09
PLA	1.76
PVA	6.60
Bales of Fibers	
Polyester	1.54
Nylon	2.20
Bleached Cotton	2.31
Rayon	1.98
Polypropylene	1.54
Pulp	0.55
Fluff Pulp	0.57
Bi-Component	2.31

Source: Holmes, 03

In terms of the most popular fiber types used in the production of medical nonwovens, synthetic fibers dominate the industry. Polypropylene is the number one fiber used in roll goods production, followed by polyester, and then polyethylene, which offers

superior softness qualities (K. Solomita, personal communication, May 26, 2003; M. Sommerfeld, personal communication, May 22, 2003).

4.2.2 Processes Used to Manufacture Roll Goods: Web Formation, Bonding, and Finishing

Web formation, bonding, and finishing all occur at the roll goods manufacturer. There are several methods used to form a web of fibers which is the first step in forming a nonwoven. These methods vary based upon the fiber type and end product use. Below is a list of the primary methods of web formation:

- **"Spunbond** – Filaments are extruded, drawn, and laid on a moving screen to form a web. Often interchanged with "spunlaid."
- **Meltblown** – Molten polymer resins are heated, extruded, and drawn with high velocity air to form fine filaments. The filaments are cooled and collected as a web onto a moving screen.
- **Spunbond/Meltblown/Spunbond** – A web formed by layered webs of spunbond and meltblown processing.
- **Carding** – A process for making fibrous webs in which the fibers are aligned either parallel or randomly in the direction that the carding machine produces the web.
- **Air Laid** – Web forming process that disperses fibers into a fast moving air stream and condenses them onto a moving screen by means of pressure or vacuum.
- **Wetform** – The web is produced by filtering an aqueous suspension of fiber onto a screen conveyor belt or perforated drum.
- **Cross-Lap** – Process of layering a carded web on a conveyor, moving at right angles so the fibers are oriented in the cross direction increasing the cross directional strength of the fabric and the web weight." (INDA, 2002)

Spunbond/Meltblown/Spunbond (SMS) is the most popular method of web formation used today in the production of medical nonwovens roll goods (I. Butler, personal communication, May 19, 2003; M. Sommerfeld, personal communication, May 22, 2003). SMS offers an excellent fiber barrier, by layering a spunbond web, followed by a meltblown

web, and then another spunbond web, creating a "sandwich." Also, SMS offers superior softness qualities and is considered to be the most competitive web formation process (M. Sommerfeld, personal communication, May 22, 2003). SMS can also offer increased production speeds as additional spunbond and meltblown stations are added to the line. A typical SMS line configuration could look like SS/MM/SSS/MM (I. Butler, personal communication, May 19, 2003).

Following web formation, the web must be bonded. Bonding occurs within the continuous process of producing a roll good.

> "Bonding is the process of combining a fibrous web into a nonwoven fabric by means of resins (e.g., adhesives or solvent) or physical (e.g., mechanical entanglement or thermal adherence). The bonding may be all over or restricted to predetermined, discrete sites" (INDA, 2002).

There are several types of bonding used for nonwovens production. These bonding methods are:

- **"Calendaring** – Thermally bonding a web of loose fibers by passing them through the nip of a pair of calendar rolls, of which one or both are heated. Plain or patterned rollers may be used.
- **Hydro** – A bonding system that uses high temperature air to fuse the web's fibers. There are two basic systems: blowing hot air through the web in a conveyor oven or passing heated air through the web on a rotating drum.
- **Needled** – Mechanically binding a web to form a fabric by penetrating the web with an array of barbed needles that carry tufts of the web's own fibers in a vertical direction through the web.
- **Through air** – Hot air is blown through the fiber web, causing the thermoplastic fibers to melt and bond.
- **Adhesive** – The use of an adhesive to bond the web's fibers together" (INDA, 2002)

The bonding methods above represent both types of bonding: mechanical and chemical. Mechanical bonding consists of calendaring, hydro, and needling. Chemical bonding

consists of adhevises, coatings, resins, and films that are added to a fiber web to hold the web together. The most popular types of bonding for medical nonwovens are mechanical methods, calendaring and through air (M. Sommerfeld, personal communication, May 22, 2003).

After a fiber web has been formed and bonded, the nonwoven is then finished. Finishing consists of preparing the nonwoven fabric's surface for its specific end use. Finishing can occur in many forms:

- **"Surfactant** – A chemical additive that changes the surface attraction between two liquids, or between a liquid and a solid, by changing the surface energy of one or both components.
- **Repellent** – A chemical additive that grants the fabric the ability to resist wetting and staining by materials or soils.
- **Color** – Adding color to a nonwoven fabric.
- **Coating** – Application of a liquid material to one or both surfaces of a fabric, which is followed by drying or curing.
- **Printing** – Adding designs to a fabric surface by using a printing method." (INDA, 2002)

The type of finishing that occurs ultimately depends on the end use of the medical nonwoven.

4.2.3 Nonwovens Conversion

After the rolls of nonwoven fabric are manufactured at the roll goods facility, conversion may occur at the same facility as the roll goods are manufactured or at a different facilities, called the converter. Conversion consists of taking a roll goods material and processing it into the final product. Some common converter processes are cutting and slitting, folding, and sewing, and coating (M. Sommerfeld, personal contact, May 22, 2003). It is at the point of conversion that a nonwoven final product is formed. In addition to

producing the final nonwoven material, the converter is also responsible for submitting the paperwork regarding any FDA regulations that a medical nonwoven must meet. Medical nonwovens are inspected for meeting federal standards throughout the pipeline, but the converter is the only component of the pipeline that produces the final documentation of a medical nonwoven complying to federal standards. The form, which details all FDA testing requirements for a medical nonwoven, is called a 510K form. It is key to note that if any process throughout the pipeline changes, the 510K form must be resubmitted to account for any changes which are also required to meet federal inspection standards.

Each member firm in the medical nonwovens pipeline is responsible for complying with all federal standards. Thus, as the product moves through the pipeline, the proof of inspection and approval should move as well. By not following this best practice, medical nonwovens producers can increase the cost of the final product due to loss of time or possible compliance failures which can lead to reworks or waste.

It should be noted that in many cases converters do not own the material that they are converting. The roll goods manufacturer still owns the fabric until it is shipped to the distributor or the final customer. Converting costs can be very high as some medical nonwovens must travel to several converters before becoming a finished good (M. Sommerfeld, personal communication, May 22, 2003). The task of converting can be very complex and is an entirely different business as compared to roll goods production, and has a varying cost model, which will be reviewed in Section 4.3.

4.2.4 Testing Methods for Medical Nonwovens

As mentioned, testing occurs throughout the production pipeline, not just at the converter. However, the converter is the only party responsible for documenting the testing.

There are several test methods that can be used when testing medical nonwovens before being converted. The most common are:

- **Weight test**
- **Mullen Burst Tests**
- **Tensile Testing**
- **Hydrophobicity** (I. Butler, personal communication, May 19, 2003)

These tests are not FDA tests, they are purely completed to make sure the product meets the customer's specification requirements. However, the following tests are completed after the fabric has been converted and before being sent to the final customer. These tests are included in FDA standards and must be passed before the product is approved to be sold. These are:

- **"Spray impact test** – 500 ml of water is sprayed on fabric to test the amount of water penetration, results are typically > 1 gram
- **Hydrostatic pressure test** – water is loaded onto surface of fabric at 60mbar/min, results are typically 25 – 75 cm
- **Synthetic blood penetration test** – fabric is placed in fixture with synthetic blood, pressure is applied and any evidence of synthetic blood penetration is a failure, results are pass/fail
- **Viral barrier test** – bacteriophage is applied to fabric in a nutrient broth, pressure is applied, opposite surface is washed with sterile broth, and incubated, any evidence of bacteriophage is a failure, results are pass/fail" (R. Holmes, personal communication, May 4, 2003)

AAMI (Association for the Advancement of Medical Instrumentation) Classifications (Level 4 is best)

Level 1: < 4.5 gm spray impact
Level 2: < 1.0 gm spray impact, > 20 cm hydro head
Level 3: < 1.0 gm spray impact, > 50 cm hydro head
Level 4: Penetration – pass, viral barrier – pass

AAMI is the primary resource for the industry, the professions, and government for national and international standards, with regards to medical devices. AAMI has several services:

- "AAMI is the primary source of consensus and timely information on medical instrumentation and technology
- AAMI is the primary resource for the industry, the professions, and government for national and international standards.
- AAMI provides multidisciplinary leadership and programs that enhance the ability of the professions, health care institutions, and industry to understand, develop, manage, and use medical instrumentation and related technologies safely and effectively" (AAMI, 2003)

- **Classifications in Europe**

Although the governing body was not located during this study, through a personal interview, the testing standards for Europe were reviewed:

Gown
Level 1: > 20 cm hydro head, impervious
Level 2: Impervious

Drape
Level 1: >30 cm hydro head
Level 2: Impervious (R. Holmes, personal communication, May 4, 2003)

Based on academic and industry experts, both groups agreed that the cost of testing a medical nonwoven is insignificant, in terms of the percentage of the final cost of the fabric. The costs incurred deal with testing machinery and the labor involved in running the machines. The cost of testing is incurred and labeled as overhead when itemized in the cost of the final product, and will be reviewed in Section 4.3.

4.2.5 510K Form

A 510K form must be completed by any nonwovens company trying to produce a medical device. The 510K form is filled out by each component of the production pipeline and must be approved by the FDA.

> "Section 510(k) of the Food, Drug and Cosmetic Act requires those device manufacturers who must register to notify FDA, at least 90 days in advance, of their intent to market a medical device. This is known as Premarket Notification – also called PMN or 510(k). It allows FDA to determine whether the device is equivalent to a device already placed into one of the three classification categories. Thus, "new" devices (not in commercial distribution prior to May 28, 1976) that have not been classified can be properly identified.
>
> Specifically, medical device manufacturers are required to submit a premarket notification if they intend to introduce a device into commercial distribution for the first time or reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected. Such change or modification could relate to the design, material, chemical composition, energy source, manufacturing process, or intended use." (FDA , 2003)

A 510K form typically includes the following information:

- "Indications for Use
- Summary
- Proposed Labeling
- Description of the Device
- Results from Laboratory & Animal Studies
- Results from Biocompatibility Studies
- Sterilization Information
- Comparison To Predicate Device" (Engineering Reference.com, 2002)

Also, a 510K form requires specific actions of the company trying to produce a medical device:

- "Assess basis of substantial equivalence (prepare a comparison table; determine how technological differences will be addressed)
- Determine what testing needs to be completed (performance such as bench, animal and or clinical; biocompatibility; etc.)
- Draft labeling (unit labels, box labels, instructions for use, etc.)

- Description Information (photos, engineering drawings, narrative, etc.)
- Sterilization information" (Engineering Reference.com, 2002)

Finally, once the 510K form has been prepared, the company must follow a submission process:

- "Three identical, paginated copies of the 510K in a format compliant with 21CFR807 are assembled.
- Two copies sent to FDA, one stays as reference copy.
- When received, submission is logged in and receives a document number; submitter also receives acknowledgment letter
- Submission is sent to appropriate reviewing division within ODE (one of five)
- Submission is checked against a "Refuse to Accept" checklist. A recommendation is then made to the division supervision ('Refuse to Accept' or 'Accept')
- If accepted, submission is assigned a reviewer and checked for "tier status" (I, II, or III)
- Technical review is conducted and results in either a request for more information or a recommendation to the division director.
- ODE checks with OC for compliance status.
- Decision letter" (Engineering Reference.com, 2002)

4.2.6 Labor Involved in the Production of a Medical Nonwoven

As compared to other types of fabric production, such as weaving or knitting, the overall percentage of labor is low. The cost of labor in terms of the final cost of the product represents 5-7% of the total cost, as compared to 35% for a woven good (R. Holmes, personal communication, May 4, 2003). The production of nonwoven fabrics is not very labor intensive. "Nonwovens are manufactured by high-speed, low-cost processes – large volume, low cost," with the majority of the cost being represented by raw materials and machinery (Pourdeyhimi, 2003). Overall, the investment for machinery is dependent on how many processes of the production pipeline the company would like to assume.

4.2.7 Storage and Packaging of Medical Nonwovens

The key concept that needs to be achieved by a package for a medical nonwoven is sterility. The package must be able to provide a sterile barrier for the product inside. In addition, the sterilizing of the product occurs after packaging, so the package has to allow the method of sterilization inside the package, and let it out, leaving the product sterilized. Some types of sterile packaging include paper and Tyvek. There are several types of sterilization methods used today for medical nonwovens:

- **"Gamma -** Cobalt-60, a radioactive compound that emits gamma radiation while it decays into non radioactive nickel. Gamma radiation is a form of electromagnetic energy comparable to sunlight or microwaves. an electrical machine producing electrons that have been accelerated in electrical field. Cobalt 60 is the cheapest method to use, but the most expensive to build. In addition, the rules and regulations that go along with a gamma source are very stringent. ($0.03/yard)
- **Plasma** – Hydrogen peroxide plasma (gas) pressurized, gas oxidizes all bacteria, mold, fungus, etc. Small volume process.
- **Ethylene (ETO)** – Pressurized gas, slight odor ($0.08/yard)"

  (R. Holmes, personal communication, May 4, 2003)

The major aspect that needs to be considered when choosing a sterilization method is that the fabric should be able to withstand that specific sterilization method (M. Sommerfeld, personal communication, May 22, 2003). The sterilizing of the fabric should not degrade the product in any way.

4.3 Basic Components of a Nonwoven (Roll Good) Cost Structure

The basic cost model components for a nonwoven product can be broken down into 4 major categories:

- Raw materials
- Labor
- Variable overhead

- Non-variable overhead

4.3.1 Raw Materials

Raw materials can be defined as the basic ingredients of the product. This includes all waste. Types of raw material inputs for medical nonwovens can be reviewed in Section 4.2.1. Raw materials make up between 50-70% of the final product's cost (I. Butler, personal communication, May 19, 2003; K. Solomita, personal communication, May 26, 2003; M. Sommerfeld, personal communication, May 22, 2003). It is the most significant cost driver within a medical nonwovens pipeline.

4.3.2 Labor

Labor is the human input in the development of an intermediate or final product and includes direct labor, indirect labor, and benefits for the employees. Direct labor includes the personnel assigned to the actual production process whose payroll expenditures can be directly tracked to the cost of the goods produced. Indirect labor is conversely identified as the personnel assigned to tasks which are not directly linked to the production of the product and cannot be traced to the actual cost of the good sold. Labor benefits for employees include healthcare, worker's compensation, social security, and dental plans (Dictionary of Small Business, 2003). As mentioned in Section 4.2.6, labor is not a significant part of the medical nonwoven production pipeline. Labor represents less than 20% of the final cost of a medical nonwoven (I. Butler, personal communication, May 19, 2003; K. Solomita, personal communication, May 26, 2003).

4.3.3 Variable and Non-Variable Overhead

Variable overhead consists of utilities, maintenance, and operating repair materials. Utilities consist of "the basic services needed to function in the modern world, such as water,

sewer, gas, electricity, and telephone" (Dictionary of Small Business, 2003). In addition, variable overhead includes maintenance for the production facility. Maintenance is considered to be "the care and work necessary to keep something in the usual operating condition for productive use." (Dictionary of Small Business, 2003) Finally, operating repair materials are part of variable overhead.

Non-variable overhead costs consist of depreciation, utilities, and allocated overhead.

- Depreciation – An accounting term for the cost recovery of real property and personal property; the expense deduction on an income statement allowing for gradual wear out of a fixed asset; amortization of a fixed asset. The duration of the depreciation period approximates the useful life of the asset. (Dictionary of Small Business, 2003)
- Utilities
- Allocated overhead – Plant management, human resources, engineering, and finance.

For the production of any nonwoven, depreciation is a huge cost because so much of the manufacturing costs is tied up machinery. Overall, overhead is going to include the above factors, in addition to testing (M. Sommerfeld, personal communication, May 22, 2003). However, overhead is a fairly insignificant cost driver, representing around less than 10% of the costs at the roll goods manufacturer.

4.4 Converter Cost Structure

Overall, a converter has the same cost drivers as the roll goods manufacturer. The raw material coming in, the roll goods, still represents about 50-70% of their cost, but can decrease to less than 60% in some cases. However, the major difference between the roll goods and converter cost structure is the labor cost. Labor can be greater than 20% based on the processes that occur at the converter. In most cases, labor represents a higher percentage

at the converter (M. Sommerfeld, personal contact, May 22, 2003). Overhead remains about the same and may be a little lower at the converter.

4.5 Cost Breakdown Example

During an interview with Ian Butler at INDA, based on the percentages that he felt like were representative of the industry, Table 10 was derived. By knowing the cost of raw materials per kilogram (polypropylene), how many grams of material went into gown (67 gsm or 14.9 g/km)) and the percentages gained from industry interviews, the labor, overhead, selling, general, and administrative expenses were estimated. The total cost of the roll of nonwoven fabric per .16 square meter would cost $2.35 to make.

Table 10: Cost Breakdown

Roll Good Producers:			
Variable Costs:			
Direct Labour	$0.038		
Raw Materials	1.105		
Variable O/H	0.083		
Total Variable Cost		1.226	
Fixed Cost:			
Incremental O/H	0.087		
Depreciation	0.480		
Total Fixed Cost		0.567	
Total Product Cost (0.12 / sq. meter) (1.793/14.9)			1.793
Selling General &Administration Expenses		.561	
Total Cost at Roll Goods ($0.16 / sq. meter)			$2.354

Using the example of a surgical gown requiring 4.25 meters at $.16 per square meter, the cost of conversion and waste is added to the raw materials cost to arrive at the cost for the converter. In this example, the total cost of raw materials at the converter can be calculated by:

$$[4.25\ m^2/\text{gown} \times (\$.16/m^2 + \$.05/m^2 \text{ in conversion cost})] + 5\% \text{ waste} = \$.94/\text{gown}$$

According to Butler, the finishing process (e.g., coating, repellant, surfactant) would add approximately $.04-.06 per square meter to the final cost of the product. Therefore the total cost to the convertor is about 0.21 per square meter. (I. Butler, personal communication, May 19, 2003).

Table 11: Converter Cost Breakdown

Converter Cost Build-up:			
Direct Costs:			
Direct Labour	$0.50-0.70		
Raw Materials (4.25 meters x $.21+5% waste)	0.94		
Direct Overhead	0.35-0.50		
Fixed Costs:			
Fixed Overheads (Depreciation)	0.20-0.25		
Total Cost		2.15	
Selling General &Administration Expenses		0.65	
Selling Price Surgical Gown			$2.80

4.6 Manufacturing Routes and Time Involved

The production of a medical nonwoven varies based on its end use. All medical nonwovens begin at a roll goods manufacturer, but what happens after that changes based on what type of medical nonwoven the roll good will become. As mentioned, after the roll goods are produced, the roll is sent to a converter. This converter may only complete one stage of the conversion that needs to be completed for this product. If this is true, the fabric must then be sent to another converter and continue until conversion is finished. This can add additional time to the pipeline. Upon the completion of conversion, the fabric may be sent to a distributor or shipped directly to an end customer. This can either add or subtract to the time needed for the completion of the product. Overall, the basic route for a medical nonwoven consists of roll goods to converter to distributor/wholesaler or end customer. The variance of this route depends on how complex the conversion process is (how many converters are involved) and whether or not the product is shipped to distributor or not. The basic timeline for the completion of a medical nonwoven is as follows:

Table 11: Medical Nonwoven Pipeline Timeline

Process	Time
Order material	2 weeks
Inventory as roll goods	1 week
Time in conversion	Average 3 weeks/converter
Total time in pipeline	7 weeks+

Source: Sommerfeld, Solomita, 2003

As compared to an apparel pipeline, lasting up to 66 weeks, the medical nonwoven pipeline is relatively short. Less time in the pipeline equates to savings overall on costs, such as logistics and inventory.

4.7 State of Medical Nonwovens Industry

Overall, the medical nonwovens industry is a very competitive and complex industry with few players dominating the industry at present. The medical nonwovens industry is not clearly defined in terms of all the key players, but can definitely be labeled a classic oligopoly (M. Sommefeld, personal communication, May 22, 2003). An oligopoly is "a market dominated by a small number of participants who are able to collectively exert control over supply and market prices" (Investorwords.com, 2003). Directly related to its stiff competitive traits, the medical nonwovens industry is a tough market to enter as a new company. Some key barriers to entry are the fact that the industry is an oligopoly, economies of scale, and the industry is also dominated by small companies fulfilling specific niche markets (M. Sommerfeld, personal communication, May 22, 2003). In addition to its high barriers to entry, the medical nonwoven's market side is very difficult to assess. It is hard for companies to truly assess what the market needs today because it (the market) is flooded with so many products and medicine and medicinal techniques change rapidly (M. Sommerfeld, personal communication, May 22, 2003). Another important barrier is patent concerns. Patents are being developed daily and it is a very risky business when dealing with patents because patent infringement is serious trouble for companies. Companies must be sure to research all current patents before developing a new product. Patent research also costs money and time, things that a new company may not possess.

The best way for companies to remain competitive in the medical nonwoven's industry is to continue to be innovative (M. Sommerfeld, personal communication, May 22, 2003). Innovation in material properties, product uses, comfort, and costs are critical factors

that medical nonwovens' manufacturers and converters must keep in mind when trying to remain competitive.

5.0 Conclusions and Future Research

The objective of this research was to gain a better understanding of a medical nonwoven pipeline in terms of the specific cost drivers associated with it. This was achieved by mapping the pipeline, identifying the processes and players, and finally, identifying the cost drivers associated with the pipeline. Interviews with academic and industry experts reveal that the medical nonwovens industry is very complex. There are many components within the pipeline, consisting of roll goods manufacturers, converters, distributors/wholesalers, and end customers. The basic pipeline representation can be seen in Section 4.1. The complexity and length of the pipeline depends on how many converters are involved and whether or not the product is shipped directly to the end customer or a middleman. The major costs within the pipeline consist of:

- Raw Materials (50-70% for both roll goods and converters)
- Labor (<20% for roll goods, >20% for converters)
- Overhead (<10% for roll goods and converter)

The medical nonwovens industry is a very competitive industry, which is dominated by a few large roll goods producers and converters, and several smaller niche market roll goods producers and converters. The medical nonwovens industry is a very difficult industry to enter due to its high barriers to entry. In addition, the medical nonwovens industry is very focused on innovation as a major key to success.

Based on the interviews and the review of existing literature, the following is an assessment of the strengths and weaknesses of the products and companies, as well the external opportunities and threats existing in the medical nonwovens industry:

Strengths

- Commodity products
- Opportunity for specialization of products and processes (manufacturing and conversion)
- Short pipeline – shorter lead times, less inventory, quick response opps
- Potential for high mark-up
- Patent opportunities (machine, process, fiber, product)
- Easy to produce
- Disposability

Weaknesses

- Capital intensive
- High barriers to entry
- Market hard to assess
- Dependence on petroleum
- Dependency on suppliers
- Lack of a standardized supplier network

Opportunities outside of company or in market

- Increase in population
- Advancement in medicinal technique and procedures
- Substitutability of knits and wovens
-

Threats

- Wars which are centered around petroleum producing nations
- Lack of knowledge by general consumers and industrial users of nonwoven properties

In terms of the significance of the findings of this research, the results prove to be significant in that they offer an in depth look at the pipeline structure, the cost drivers and their significance as related to one another, and the overall structure and shape of the medical nonwovens industry. Anyone looking to enter the medical nonwovens market needs to know this kind of information before making the decision to enter the market. In addition, the medical nonwovens industry may not have a clear idea of what the industry, as a whole, looks like and which cost drivers are truly driving the industry. If this information is known,

better decisions can be made as to how to manage the pipeline's structure and costs associated with it. As better management decisions are made, the competitiveness of firms can increase.

5.1 Recommendations for Future Research

There are several topics of this research that offers possible areas for future research. The first area deals with the development of a more detailed cost model for a medical nonwoven product. The basic objectives of the cost model would be to aid in the optimization of product cost, as well in the design of the product. In addition, this research would include how a medical nonwoven's cost structure differs from a more traditional textile good, such as a woven or knitted good. This model could be used to calculate the costs of various medical nonwoven goods based on a basic cost structure.

The next area of possible future research consists of examining the medical nonwoven pipeline as a supply chain. In looking at the pipeline in terms of supply chain, partnerships, supplier relationships, sourcing decisions, supply base optimization, inventory management, and overall supply chain management topics can be reviewed. The basic idea of supply chain management is to better understand the supply chain so better decisions can be made. As a result, companies can achieve increased profitability and competitiveness.

As this research was being compiled, it became very clear that there were few articles or research directly related to medical nonwovens. At present, medical nonwovens data is embedded in general nonwoven data. This data includes major companies, data statistics, and the overall structure of a medical nonwovens pipeline. A possible point of future research could be the separation of medical nonwoven textile data from the general

nonwoven data. In addition, an in depth analysis of the differing factors separating a regular nonwoven from a medical nonwoven would be performed.

As mentioned, testing standards are a key part of the medical nonwoven production pipeline. Testing occurs, in some form, at every component of the pipeline. A possible topic for future research would include an analysis of the testing methods, standards, tolerances, and costs associated with those specific tests associated with the medical nonwovens industry. In addition, how can testing standards change as goods are being shipped out of the United States and how can standards be used as methods of controlling trade internationally?

As mentioned in Section 2.1.1, nonwovens play a large part of North Carolina's textile industry. However, for further research, what type of impact do medical nonwovens have on North Carolina's economy? This study would include which companies in North Carolina produce medical nonwovens, sales, and overall impact on the economy. In addition, the sustainability of the US textile industry will be reviewed in terms of the possible replacement of traditional (woven/knit) medical textiles with medical nonwoven products and how this will affect North Carolina's industry. The basic objectives for this future research would be to perform a market analysis of the medical nonwovens industry in North Carolina and identify any opportunities North Carolina may have in this area. This can be achieved through extensive data collection including the research of statistics concerning medical textiles and conducting interviews with academic and industry experts.

A final point for future research includes the research of the sourcing decisions concerning the conversion of medical nonwovens. Where is conversion mainly being done? US or global? What are the factors driving the sourcing decision of where to convert medical nonwovens?

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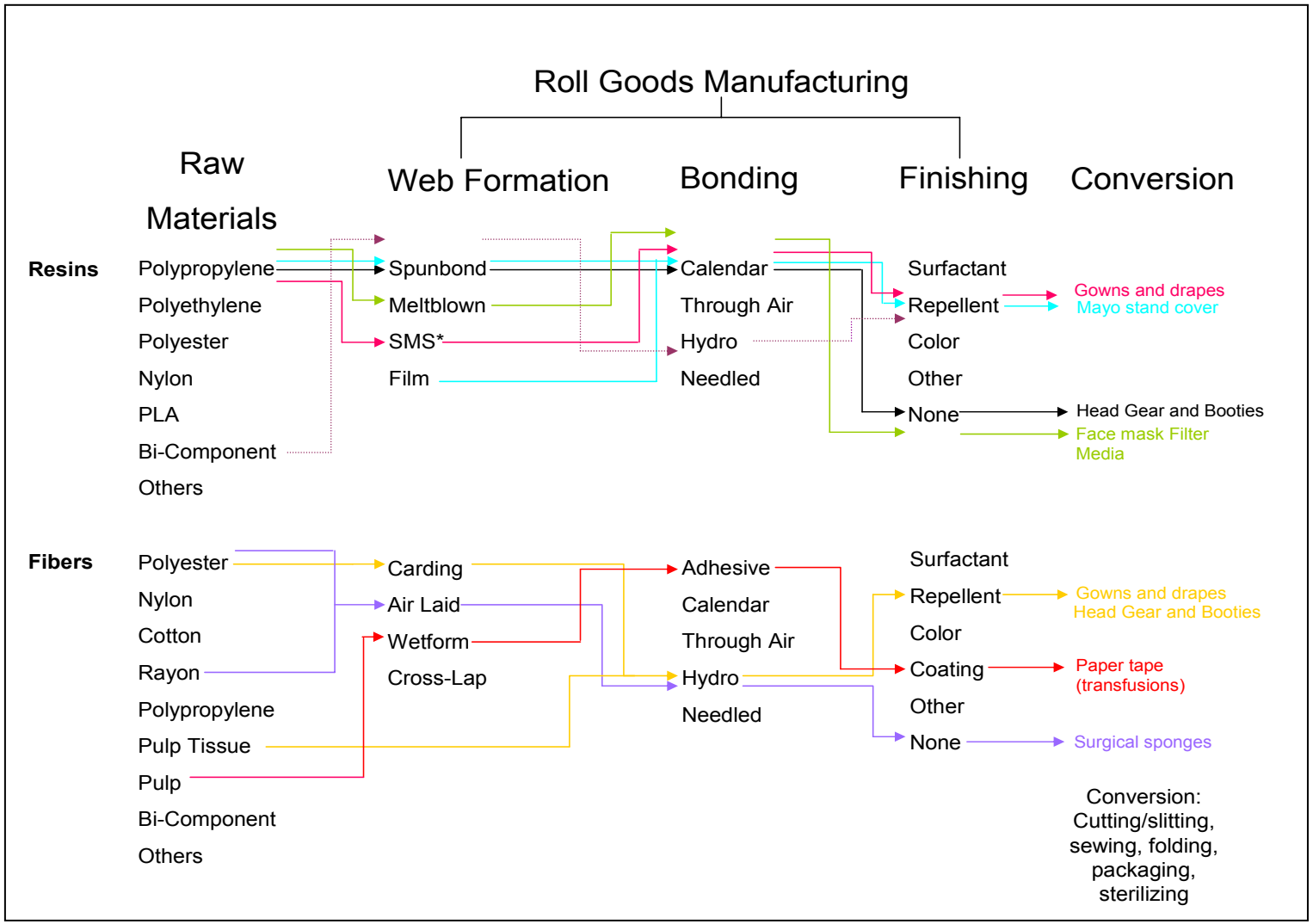
7.0 Appendix

Appendix A: Medical Nonwoven Production Road Map



Appendix B: Medical Nonwoven Production Pipeline