



Welcome to the Webinar:

**NON-MANUFACTURER SELLERS OF MEDICAL
PRODUCTS:
HELPING OR HURTING THE DEFENSE**



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Today's webinar: Non-Manufacturer Seller (NMS)

- General overview of the laws affecting the NMS
- How can a NMS **conduct** its business
 - to maximize common law and statutory **protection** from product liability
 - to achieve **indemnity** from the manufacturers under common law and statutes of the applicable States

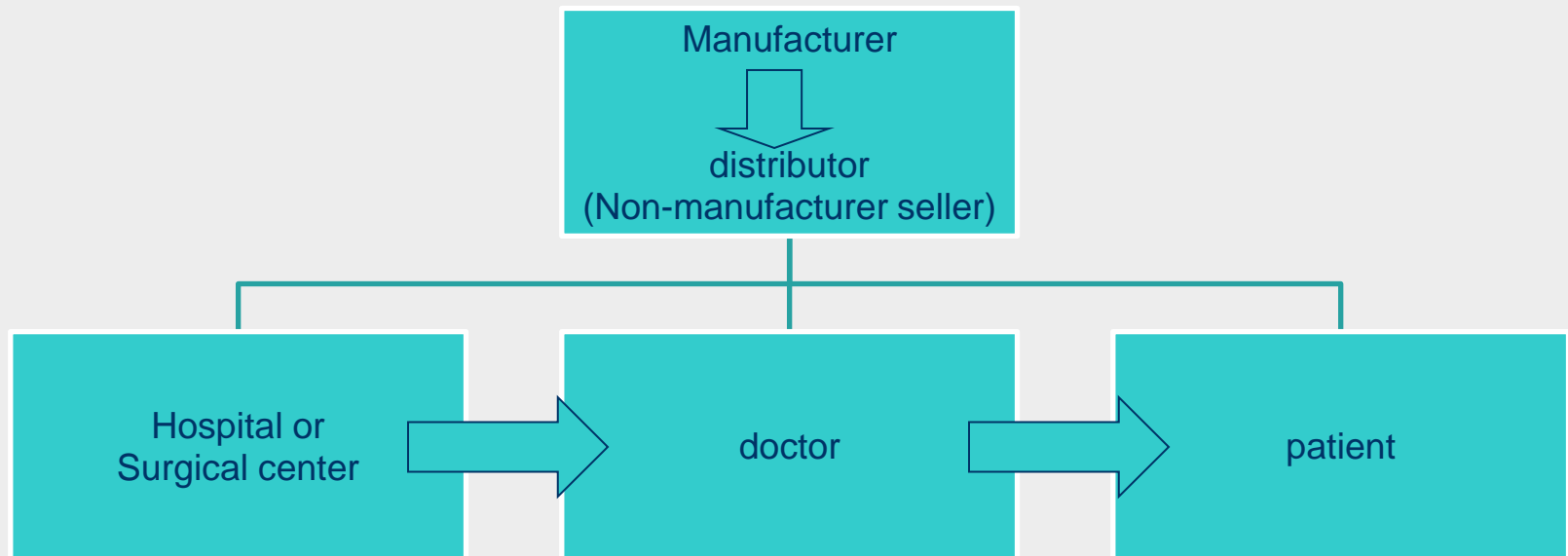


Who are NMS-distributors? How are they set up?

- Independent distributors
- Box movers
- distributors contracted with manufacturers
- Buyers of products who then rent the medical products and may reuse them
- Distributors of medical products to hospitals or other HCP
- Distributors of medical products without a prescription or under a prescription or with prescription, but used by the patient
- Distributors of over-the-counter products and home health
- Distributors of products for surgical insertion in the OR



Distribution of medical products





Why does the plaintiff sue the NMS when NMS **does not** make the product?

- Patient/doctor has NMS's name and address
- NMS is local and subject to the jurisdiction for suit
- Local defendant defeats diversity for removal to federal court
- Potential independent liability for the NMS
- In some states, the NMS is liable regardless of whether innocent.



States have different laws as to ..

- **Liability** for the NMS of a product under strict liability, negligence and warranties
 - Statutes affecting the NMS: “innocent seller” or passive seller” or “sealed package”: Ex. TX, ID, KS, KY, LA, MD , WA, OH, NM
 - Common law limiting NMS liability
- Basis of **indemnification** as between manufacturer and NMS
 - Common law implied indemnity: Ex. WV, OK, NM, KS
 - Contract between the parties
 - State statutes: ex. TX, ID, CA, OK, OH, ND, MS



American Law Firm Association Compendium
email me for a copy

**2009 COMPENDIUM OF
PRODUCT LIABILITY
LAW ISSUES**

ADMISSIBILITY OF PLAINTIFF EXPERT TESTIMONY
LIABILITY OF COMPONENT PART MANUFACTURERS
LIABILITY FOR LEGACY EQUIPMENT
MANUFACTURER INDEMNIFICATION OF
NON-MANUFACTURING SELLER

PRESENTED BY THE
PRODUCT LIABILITY PRACTICE GROUP

ALFA INTERNATIONAL
THE GLOBAL LEGAL NETWORK



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Generally NMS of medical products are subject to strict liability:..

- Restatement of Torts 402A: one who sells any product in a defective condition unreasonably dangerous to the user or consumer or his property is subject to liability for physical harm thereby caused to the ultimate user or consumer or to his property...
- Based on doctrine of innocent injured party and placing the liability on the entity who placed the defective product in the stream of commerce
- Courts have expanded the doctrine to those in the distribution chain including the NMS



Protection under some State common law or statutes for NMS, unless NMS

1. Exercises control over a warning or instruction
 - NMS instruction sheet or instructions
 - What NMS representatives say to doctors, nurses, patients
 - Need to comply with what the manufacturer says and don't add your own
2. Expresses a factual representation about the product that caused the injury
 - “Use it as long as you want” “it can't hurt you”
3. NMS knew or should have known of a defect to the product
 - Failure to inspect when it would have been apparent
 - Complaints to NMS give notice of defect – report to manufacturer
4. NMS participated in the design of the product
 - Parameters given to a manufacturer in China



Other reasons NMS can be strictly liable under state law ...

5. NMS altered or modified the product
 - Just a little change or use with accessories from other manufacturer or instructions or warnings
6. There is no recourse against the manufacturer by judgment
7. Manufacturer not subject to service of process in the state
8. Manufacturer is insolvent
9. NMS made the product its own
 - Avoid putting your own labeling on the product
10. NMS installed the product or a part on the product
11. NMS negligence
12. NMS intentional misrepresentation or concealment



So, the NMS is potentially liable... Can NMS still have indemnity from the manufacturer?

- Potential basis of indemnification as between manufacturer and NMS
 - Contracts between the parties
 - Common law
 - State statutes



Contracts between the manufacturer and the NMS

- Law of contracts are usually strictly enforced in the states
- Usually strictly construed against the party seeking indemnity
- Clear and unequivocal language that the manufacturer is indemnifying the NMS for its own acts of negligence in order to enforce the indemnity
- Mutuality of indemnity may not give “indemnity” depending on the state law
- Success in enforcing depends on the state law and the specific contract terms
- Some parties are negotiating to be an additional insured on the manufacturer’s policy



Indemnity of NMS by manufacturer under common law and statutes of some states...

- Equitable doctrine to shift the burden to the most responsible party, i.e. the party that created the risk
- Some states have statutes or an implied indemnity to protect the “innocent seller”, if NMS:
 - Did not contribute to the defect in the product
 - No knowledge of the defect
 - No opportunity to inspect superior to the user
 - Not use own trade name in selling the product
 - No negligence or fault on NMS
 - Seller did not modify product
 - Not participate in or exercise control over the design, warnings, testing, labeling



But no indemnity for the NMS if...

- No jurisdiction over the manufacturer or it is insolvent or not likely to satisfy judgment
- NMS is owned by the manufacturer
- Negligent assembly of the product by NMS
- NMS failed to provide the manufacturer's warnings to the user
- **NMS not able to ID the manufacturer**
- Breach of express or implied warranty by NMS
- Look at ALFA compendium for details as to States

Caution on indemnity:

- Some states find that if the NMS settles the cause of action, then they may not seek indemnity
- Some states require NOTICE to the manufacturer before indemnity with deadlines related to litigation
- Not allow indemnity if NMS has taken a position adverse to the manufacturer at trial.
Ex. Oklahoma



Other basis of liability for NMS even if no duty to warn

- Gratuitous assumption of a duty or negligent undertaking
 - Even through there is no duty to warn
 - If distributor undertakes to warn
 - NMS does not use reasonable care
 - Patient relied upon it
 - And the warning increased the risk to the patient



Based on the law, how does the NMS conduct business..

- Product ID
- Contacts with the user and patient
- Documenting calls and Complaints
- Documenting return of product
- Documenting reported injuries



Product ID

- Selling/renting similar product where the NMS handles products for more than one manufacturer



Cold therapy: which manufacturer? Product: rented/returned/no complaint





Prescription for polar care

Telephone (512) _____ DEA #BP _____
FOOT SPECIALISTS
. D.P.M.
San Marcos, TX 78666

Name _____ Date 12/20/06
Address _____

Rx

Polar Care with
foot pad

~~Dx: Slp Bunionectomy
(735.0)~~

Label
Refill - 0 - 1 - 2 - 3 - 4 - PRN

_____, D.P.M. _____, D.P.M.
Product Selection Permitted Dispense As Written



“Polar care” is like “Kleenex”: generic

Date	Document	Description	Case Number	Amount
Previous Balance:				0.00
Patient:		Chart #: GOMMA000		
Case Description: 2006SELF		Last Payment Received:		Amount: 0.00
12/20/2006	0701110000	COLD THERAPY UNIT	16589	20.00
12/20/2006	0701110000	Misc item <i>Polar Care Foot wrap</i>	16589	40.00
This is your balance due for the polar care unit with foot wrap you received on 12/20/06 for a two day rental. Thank you.				
Paid Due 20 Days		Paid Due 60 Days		Balance Due
0.00		0.00		60.00

FOR BILLING QUESTIONS, CALL

Misc item *Polar Care Foot wrap* 16589



DISTRIBUTOR

Page: 1

5/14/2008

Patient:

Chart #: GOMMA000

Case #: 16589

Date	Description	Procedure	Modify	Dx 1	Dx 2	Dx 3	Dx 4	Units	Charge
12/20/2006	COLD THERAPY UNIT	E0236	RR RT	735.0				2	20.00
12/20/2006	MISC PROCEDURE	E1399	NURT	735.0				1	40.00
1/11/2007	COMMENT	COMMENT						1	0.00
2/28/2007	COMMENT	COMMENT						1	0.00
2/28/2007	CHECK PAYMENT	PTCHECK						1	-60.00

COLD THERAPY UNIT

E0236

MISC PROCEDURE

E1399

Provider Information

Provider Name:
License:
Insurance PIN:
SSN or EIN:

Total Charges: \$ 60.00
Total Payments: -\$ 60.00
Total Adjustments: \$ 0.00
Total Due This Visit: \$ 0.00
Total Account Balance: \$ 0.00



Statement Date Chart Number Page

1/11/2007	GOMMA000	1
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AMOUNT ENCLOSED: \$ _____
 PAYMENT METHOD:
 CHECK
 CREDIT CARD:
 M/C _____ EXP: _____
 VISA _____ EXP: _____
 DISCOVER _____ EXP: _____
 AM EX _____ EXP: _____

DETACH HERE AND RETURN THIS PORTION WITH YOUR PAYMENT.

Date	Document	Description	Case Number	Amount
Previous Balance:				0.00
Patient:		Chart #: GOMMA000		
Case Description: 2006SELF		Last Payment Received:		Amount: 0.00
12/20/2008	0781110000	COLD THERAPY UNIT		20.00
12/20/2008	0701110000	Misc item <i>Polar Care Foot wrap</i>		40.00

This is your balance due for the polar care unit with foot wrap you received on 12/20/08 for a two day rental. Thank you.

COLD THERAPY UNIT

Misc item *Polar Care Foot wrap*

Past Due 30 Days	Past Due 60 Days	Past Due 90 Days	Balance Due
0.00	0.00	0.00	60.00

FOR BILLING QUESTIONS, CALL



DISTRIBUTOR

Statement Date	Chart Number	Page
03/06/2009	GOMMA000	1

Final Statement

PATIENT NAME

PHYSICIAN

prescribed the below product(s) to you.

Patient: Chart Number: GOMMA000 Previous Balance 0.00
 Case: 2006SELF Date of Last Payment: Amount: 0.00

Product	Charge	Paid By	Adjustments	Balance
		Guarantor		
12/20/06 COLD THERAPY	20.00			20.00
12/20/06 MISC	40.00			40.00

This is your balance due for the polar care unit with foot wrap you received on 12/20/06 for a two day rental. Thank you.

COLD THERAPY 20.00

Amount Due
60.00



Discovery required to determine product ID...

- Interrogatories and requests for production to plaintiff asking for pictures of the product
- 5 + depositions with subpoena of pictures of plaintiff and unit
- Depositions of her family, doctor and his staff...
- JPG of pictures produced of Christmas that left out some pictures in the numbering of the JPG
- Motion to Compel pictures and request for a forensic examination of plaintiff's computer by a computer and camera expert.

Cold therapy: which manufacturer?



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12/23/2007

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Product ID

- Selling/renting similar product with more than one manufacturer
 - Generic names, like Kleenex or polar care
 - If the product is not available at time of suit, patient may not have the best description and distributor may sell several
 - Need a system to ID product
- Billing codes do not identify the manufacturer
- Notes may be inconsistent in what manufacturer's product was sold or rented between order form, billing and documents
- Which model was sold or rented **does** make a difference since warnings and literature change



Special considerations for rented/multiuse medical products

- Upon return, document condition, complaints and comments of the patient/family
- Document what changes were made to the product before rented again
- HIPPA and preservation of information:
Where a product has a computer that patient information, remove/retain information about a patient before sending out in the field:



NMS direct contact with user

- Have the patient sign a receipt upon delivery of the product and instructions
- Document calls and complaints including question of the patient and a description of what happened: story may change over time...



Deposition testimony by plaintiff: what a NMS rep said & did on delivery of the product...

Q. What did the representative look like?

A. He was somewhat tall. He was Caucasian, had kind of spikish hair, slender. He was skinny.

Q. What do you recall about your conversation with him?

A. He just came and he told us that he was in a hurry, so he was going to explain real quick the instructions because he had a dinner date with his wife and she was going to be mad if he didn't make it back in time because he had to go back to Austin. And then he just said, "You're going to wrap the Polar Care around your foot, and then you can leave it on as long as you want and as cold as you want as long as the –you know, as long as the pain goes away, as cold as you want."

Q. Did the gentleman leave you a card or any information?

A. No, ma'am.

Q. And what did he leave you?

A. Just the ice machine, the Polar Care.



Testimony continued...

Q. Did he leave you a pad to use with the Polar Care?

A. Yes, ma'am.

Q. Did the gentleman leave you a card or any information?

A. No, ma'am.

Q. And what did he leave you?

A. Just the ice machine, the Polar Care.

Q. Did he leave you a pad to use with the Polar Care?

A. Yes, ma'am.

Q. Did not come wrapped in any kind of plastic container or anything of that sort?

A. No. No, ma'am.



Documenting calls/complaints



- Calls may lead to other issues
- What did the patient ask; get a description of what happened; story changes over time
..especially after patient calls a lawyer
- Refer questions to the manufacturer or doctor
- Do not try to answer medical questions



System of receiving returned products to the manufacturer due to malfunction

- Spoliation: separate cause of action or evidentiary claim
- When did the duty to preserve the evidence arise?
- Was there intentional destruction of evidence or only negligence?
- Is the other party prejudiced by the destruction?
- Preserve the product: no injury quickly turns into an expensive lawsuit



EQUIPMENT INCIDENT REPORT

NOTE: This document is to be treated as confidential information.

Patient Name: _____ A.1

Date of Incident: 9/2/08 Location: at home

Type of Equipment: walker Mfg: _____

Model No.: _____ Serial No. _____

Nature of Problem: Front left leg broke off

Maintenance Data on This Item: N/A

Delivery and Training: blcm

Date Item was Delivered: 8/22/07 By Whom: Front left leg broke off

Set-up and Training By: ZG

Present-Other Than Patient: Spouse

Retrieval of Item: _____

Date of Retrieval: 9/2/08 By Whom: ZG

Data Provided by Patient or Family Members at Retrieval:
Pt tried walking and fell straight down on floor when leg of walker broke

Other Comments:
Pt understands - atypical flaw in construct of walker - no injury stated

Manufacturer/Supplier Notified: Yes No

FDA notified: _____

Completed By: Pt understands - atypical flaw in construct of walker - no injury stated

Signature: _____

JCAHO-2005



System of receiving returned products to the manufacturer due to malfunction

- Before sending back to the manufacturer, take pictures and document: the product may not be preserved by the manufacturer
- If patient will not give you the product, take pictures and document



NMS can adversely affect liability through..

- Frustrating product ID
 - Model, brand, serial number, lot #, (makes a difference in warnings likely given) and/or NMS serial #
- Warnings and learned intermediary defense
 - Adding NMS's own warnings or not encouraging doctor instructions to be followed by the patient
- Spoliation
 - Failing to preserve the alleged defective product
- Failing to document complaints or problems



Be careful who you do business with..

- Insolvent manufacturer
- Manufacturer with poor warnings, instructions or research
 - Bad sign if NMS thinks it has to supplement with own instructions
- Manufacturer that is not subject to the jurisdiction of the court
- Report issues/injuries to manufacturer or subject to allegation that knew or should have known of defect



What the future holds for NMS:

- Credentialing of NMS representative, especially in the OR
 - Criminal background checks, privacy issues, reps asked to sign agreements with the hospitals
- NMS policy for contacts with HCP and patients
- If you have a policy, follow it!
- Dear Doctor letter
 - If you received it, and the doctor does not then you have superior knowledge
 - may have a duty to convey information to doctors



The future is now...

- Busy HCP tendency to rely on NMS reps to inform the patient about the product
- Advertising and contact with the patient may lead to a duty directly to the consumer



For further inquiry please use the contact information below

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