CARL T.C. GUTIERREZ
GOVERNOR OF GUAM

OFFICE OF THE SPEAKER
Date: 9/16/96
Time: 2:10pm
Received By: Daumabm
Print Name: Cheryl Daumabm

SEP 16 1996

The Honorable Don Parkinson
Speaker
Twenty-Third Guam Legislature
424 West O'Brien Drive
Julale Center - Suite 222
Agana, Guam 96910

Dear Speaker Parkinson:

Enclosed please find a copy of Substitute Bill No. 174 (LS), "AN ACT TO AMEND §12617.1 OF CHAPTER 12, TITLE 10, GUAM CODE ANNOTATED, TO REQUIRE ALL PHARMACIES TO PROVIDE A PRESCRIPTION INFORMATION SHEET FOR EACH PRESCRIPTION INCLUDING THE NAME OF MEDICATION, THE INGREDIENTS OF THE MEDICATION, AND A LISTING OF THE SIDE EFFECTS THAT THE MEDICATION OR ANY OF ITS INGREDIENTS MAY HAVE ON THE PATIENT FOR WHOM THE DRUGS WERE PRESCRIBED", vetoed and overridden by the Legislature on September 9, 1996, which I have designated as **Public Law 23-123.**

Very truly yours,

Carl T. C. Gutierrez

Attachment
231464

OFFICE OF THE LEGISLATIVE SECRETARY
ACKNOWLEDGMENT RECEIPT
Received By: Jdbarrett
Time: 4:46 pm.
Date: 9-16-96

TWENTY-THIRD GUAM LEGISLATURE
1996 (SECOND) Regular Session

CERTIFICATION OF PASSAGE OF AN ACT TO THE GOVERNOR

This is to certify that Substitute Bill No. 174 (LS), "AN ACT TO AMEND §12617.1 OF CHAPTER 12, TITLE 10, GUAM CODE ANNOTATED, TO REQUIRE ALL PHARMACIES TO PROVIDE A PRESCRIPTION INFORMATION SHEET FOR EACH PRESCRIPTION INCLUDING THE NAME OF MEDICATION, THE INGREDIENTS OF THE MEDICATION, AND A LISTING OF THE SIDE EFFECTS THAT THE MEDICATION OR ANY OF ITS INGREDIENTS MAY HAVE ON THE PATIENT FOR WHOM THE DRUGS WERE PRESCRIBED," returned to the Legislature without approval of the Governor, was reconsidered by the Legislature and after such reconsideration, the Legislature did, on the 9th day of September, 1996, agree to pass said bill notwithstanding the objection of the Governor by a vote of eighteen (18) members.

DON PARKINSON
Speaker

Attested:

JUDITH WON PAT-BORJA
Senator and Legislative Secretary

This Act was received by the Governor this 12th day of September, 1996, at 4:45 o'clock P.M.

Assistant Staff Officer
Governor's Office

Public Law No. 23-123

TWENTY-THIRD GUAM LEGISLATURE
1995 (FIRST) REGULAR SESSION

Bill No. 174 (LS)
As substituted by the
Committee on Health, Welfare
& Senior Citizens

Introduced by:

D. Parkinson
S. L. Orsini
F. E. Santos
F. P. Camacho
A. C. Blaz
J. T. San Agustin
M. C. Charfauros
T. S. Nelson
A. C. Lamorena V
H. A. Cristobal
T. C. Ada
L. Leon Guerrero
A. L. G. Santos
J. Won Pat-Borja
C. Leon Guerrero
J. P. Aguon
E. Barrett-Anderson
J. M. S. Brown
M. Forbes
V. C. Pangelinan
A. R. Unpingco

AN ACT TO AMEND §12617.1 OF CHAPTER 12, TITLE 10, GUAM CODE ANNOTATED, TO REQUIRE ALL PHARMACIES TO PROVIDE A PRESCRIPTION INFORMATION SHEET FOR EACH PRESCRIPTION INCLUDING THE NAME OF MEDICATION, THE INGREDIENTS OF THE MEDICATION, AND A LISTING OF THE SIDE EFFECTS THAT THE MEDICATION OR ANY OF ITS INGREDIENTS MAY

HAVE ON THE PATIENT FOR WHOM THE DRUGS WERE PRESCRIBED.

BE IT ENACTED BY THE PEOPLE OF THE TERRITORY OF GUAM:

Section 1. Legislative findings and intent. The Guam Legislature finds that when medical prescriptions are dispensed, required written information is listed on the medication label only. Many pharmacists do provide additional information, but most times, it is verbal. Many patients, especially the elderly, hear and understand the verbal instructions and information while in the pharmacy but forget or become confused when they arrive home. It is the intent of the Legislature that, upon the request of the patient, all medical prescriptions provided by pharmacies, medical clinics or doctors include a description of the contents of the medicine provided in the prescription. This breakdown will be in the form of a printed information sheet or label giving the name of the drug or drugs, what ailment the drug or drugs are being used to treat, and some of the more common side effects that the drug or drugs are known to cause, how to recognize them, and what to do when they occur.

Section 2. §12617.1 of Chapter 12, Title 10, Guam Code Annotated, is amended to read:

"**§12617.1. Prescription Label Requirements.** (a) All dangerous drugs dispensed by a pharmacy pursuant to a prescription shall be properly labeled and contain the following information:

(1) The name, address and phone number of the dispensing pharmacy;

(2) The number under which the prescription is filed in the pharmacy;

(3) The prescribing physician's name;

(4) The name of the person for whom the drug was prescribed;

(5) The date filled;

(6) The name (generic or proprietary) of the medication;

(7) The directions for use;

(8) The date of expiration of the effectiveness of the drug if this information is required on the original label of the manufacturer.

(b) Each initial prescription filled by a pharmacy, medical clinic or doctor will contain a printed prescription information sheet giving the name of the drug or drugs, what aliment the drug or drugs are being used to treat, contraindications of the drug, drug interactions and a list of the most common or significant side effects that the drug or drugs are known to cause.

(c) A Patient shall be informed by the pharmacy, medical clinic, or doctor of his/her right to receive a printed prescription information sheet.

Section 3. Notwithstanding any other provisions of law, this Act becomes effective 30 days after enactment.

TWENTY-THIRD GUAM LEGISLATURE

1996 (SECOND) Regular Session

Date: 9/9/96

VOTING SHEET

✓ Bill No. 174
Resolution No.
Question: Shall vetoed Bill 174 be enacted into law notwithstanding the Governor's objection?

NAME	YEAS	NAYS	NOT VOTING/ ABSTAINED	ABSENT/ OUT DURING ROLL CALL
ADA, Thomas C.	✓			
AGUON, John P.	✓			
BARRETT-ANDERSON, Elizabeth		✓		
BLAZ, Anthony C.	✓			
BROWN, Joanne S.	✓			
CAMACHO, Felix P.	✓			
CHARFAUROS, Mark C				✓
CRISTOBAL, Hope A.	✓			
FORBES, MARK	✓			
LAMORENA, Alberto C., V	✓			
LEON GUERRERO, Carlotta	✓			
LEON GUERRERO, Lou	✓			
NELSON, Ted S.	✓			
ORSINI, Sonny L.	✓			
PANGELINAN, Vicente C	✓			
PARKINSON, Don	✓			
SAN AGUSTIN, Joe T.	✓			
SANTOS, Angel L. G.	✓			
SANTOS, Francis E.	✓			
UNPINGCO, Antonio R.		✓		
WONPAT-BORJA, Judith	✓			
TOTAL	18	2	0	1

CERTIFIED TRUE AND CORRECT:

Recording Secretary

CARL T.C. GUTIERREZ
GOVERNOR OF GUAM

JUL 29 1996

OFFICE OF THE LEGISLATIVE SECRETARY
ACKNOWLEDGMENT RECEIPT
Received By
Time 10:02 a.m.
Date 7/29/96

The Honorable Judith Won-Pat Borja
Acting Lt. Governor and Acting Speaker
Twenty-Third Guam Legislature
Guam Legislature Temporary Building
155 Hesler Street
Agana, Guam 96910

Dear Speaker Won-Pat Borja:

Enclosed please find Substitute Bill No. 174 (LS), "AN ACT TO AMEND §12617.1 OF CHAPTER 12, TITLE 10, GUAM CODE ANNOTATED, TO REQUIRE ALL PHARMACIES TO PROVIDE A PRESCRIPTION INFORMATION SHEET FOR EACH PRESCRIPTION INCLUDING THE NAME OF MEDICATION, THE INGREDIENTS OF THE MEDICATION, AND A LISTING OF THE SIDE EFFECTS THAT THE MEDICATION OR ANY OF ITS INGREDIENTS MAY HAVE ON THE PATIENT FOR WHOM THE DRUGS WERE PRESCRIBED", which I have **vetoed.**

Although this bill has a positive intent, the persons who are professionals in the field, the pharmacists of Guam, are against the passage of this bill. I am sure that the author of the bill intended to improve communication between pharmacist and patient, however, the method prescribed is burdensome and may actually lead to some harm to patients.

According to the provisions of this legislation, a pharmacy would have to devise and print up written descriptions for all of the items its dispenses, including name of the drug, ailment it is being used to treat, contraindications of the drug, drug interactions, and a list of the most common or significant side effects.

A pharmacy cannot responsibly use the literature already pre-printed by manufacturers. This information is meant for medical professionals, and includes information that an individual physician may specifically not want to communicate to a patient. An example of this is the case where a

particular patient is susceptable to suggestion and if given manufacturer's literature will then imagine that he or she is experiencing every side effect listed. Another example is the case where a drug is prescribed because the physician has read certain medical literature and knows a drug is valuable in treatment of conditions not listed in the manufacturer's literature.

If a pharmacy cannot use pre-printed manufacturer's literature, the pharmacy must prepare and print its own literature. Although desireable, this is quite burdensome for small businesses.

Drugs dispensed by pharmacies already have labels printed on them. The labels tell the name of the drug and how to take it. It is not likely that a separate printed description of a drug and all of its side effects and uses will clear up any confusion which may arise. Working with such patients on a person-to-person and face-to-face basis is the best approach.

A copy of Governor's message and the bill has also been delivered to the Office of the Legislative Secretary.

Very truly yours,

Carl T. C. Gutierrez
Governor of Guam

Attachment
231371

23-123

CARL T.C. GUTIERREZ
GOVERNOR OF GUAM

JUL 29 1996

The Honorable Sonny L. Orsini
Acting Legislative Secretary
Twenty-Third Guam Legislature
Guam Legislature Temporary Building
155 Hesler Street
Agana, Guam 96910

Dear Mr. Legislative Secretary:

Enclosed please find a copy of Governor's message and copy of Substitute Bill No. 174 (LS), "AN ACT TO AMEND §12617.1 OF CHAPTER 12, TITLE 10, GUAM CODE ANNOTATED, TO REQUIRE ALL PHARMACIES TO PROVIDE A PRESCRIPTION INFORMATION SHEET FOR EACH PRESCRIPTION INCLUDING THE NAME OF MEDICATION, THE INGREDIENTS OF THE MEDICATION, AND A LISTING OF THE SIDE EFFECTS THAT THE MEDICATION OR ANY OF ITS INGREDIENTS MAY HAVE ON THE PATIENT FOR WHOM THE DRUGS WERE PRESCRIBED", which I have **vetoed.**

A copy has also been delivered to the Office of the Speaker.

Very truly yours,

Carl T. C. Gutierrez
Governor of Guam

Attachments

231372

Post Office Box 2950, Agana, Guam 96910 ▪ (671)472-8931 ▪ Fax: (671)477-GUAM

CARL T.C. GUTIERREZ
GOVERNOR OF GUAM

OFFICE OF THE LEGISLATIVE SECRETARY
ACKNOWLEDGMENT RECEIPT
Received By ceg
Time 3:26 pm.
Date 30 July 96

JUL 29 1996

The Honorable Sonny L. Orsini
Acting Legislative Secretary
Twenty-Third Guam Legislature
Guam Legislature Temporary Building
155 Hesler Street
Agana, Guam 96910

Dear Mr. Legislative Secretary:

Enclosed please find a copy of Governor's message and copy of Substitute Bill No. 174 (LS), "AN ACT TO AMEND §12617.1 OF CHAPTER 12, TITLE 10, GUAM CODE ANNOTATED, TO REQUIRE ALL PHARMACIES TO PROVIDE A PRESCRIPTION INFORMATION SHEET FOR EACH PRESCRIPTION INCLUDING THE NAME OF MEDICATION, THE INGREDIENTS OF THE MEDICATION, AND A LISTING OF THE SIDE EFFECTS THAT THE MEDICATION OR ANY OF ITS INGREDIENTS MAY HAVE ON THE PATIENT FOR WHOM THE DRUGS WERE PRESCRIBED", which I have **vetoed.**

A copy has also been delivered to the Office of the Speaker.

Very truly yours,

Carl T. C. Gutierrez
Governor of Guam

Attachments
231390

Post Office Box 2950, Agana, Guam 96910 • (671)472-8931 • Fax: (671)477-GUAM

TWENTY-THIRD GUAM LEGISLATURE

1996 (SECOND) Regular Session

Date: 7/16/96

VOTING SHEET

Bill No. 174
Resolution No. _____
Question: _____

NAME	YEAS	NAYS	NOT VOTING/ ABSTAINED	ABSENT/ OUT DURING ROLL CALL
ADA, Thomas C.				✓
AGUON, John P.	✓			
BARRETT-ANDERSON, Elizabeth	X	✓		
BLAZ, Anthony C.	✓			
BROWN, Joanne S.				✓
CAMACHO, Felix P.	✓			X
CHARFAUROS, Mark C	✓			
CRISTOBAL, Hope A.	✓			
FORBES, MARK	✓			
LAMORENA, Alberto C., V	✓			
LEON GUERRERO, Carlotta	✓			
LEON GUERRERO, Lou	✓			
NELSON, Ted S.	✓			
ORSINI, Sonny L.	✓			
PANGELINAN, Vicente C	✓			
PARKINSON, Don	✓			
SAN AGUSTIN, Joe T.	✓			
SANTOS, Angel L. G.	✓ ✓			X
SANTOS, Francis E.	✓			
UNPINGCO, Antonio R. III		✓		
WONPAT-BORJA, Judith	✓			
TOTAL	16	2	0	3

CERTIFIED TRUE AND CORRECT:

_____
Recording Secretary

* Three proxies = No vote.
Before announcement ESA changed to "no"

TWENTY-THIRD
GUAM LEGISLATURE
324 W. SOLEDAD AVENUE
AGAÑA, GUAM 96910
TEL: (671) 472-3543/44/45
FAX: (671) 472-3832

SENATOR LOU LEON GUERRERO, *RN, MPH*
CHAIRPERSON
COMMITTEE ON HEALTH, WELFARE, AND SENIOR CITIZENS

16 January 1996

The Honorable
Don Parkinson
Speaker, 23rd Guam Legislature
Agana, Guam

via: Committee on Rules

Dear Mr. Speaker:

The Committee on Health, Welfare & Senior Citizens to which was referred Bill No. 174- **"AN ACT TO AMEND SECTION 12617.1, CHAPTER 12, 10 GUAM ANNOTATED TO REQUIRE ALL PHARMACIES TO PROVIDE A PRESCRIPTION INFORMATION SHEET OR A PRINTOUT OF EACH PRESCRIPTION INCLUDING THE NAME OF THE MEDICATION AND A LISTING OF THE SIDE EFFECTS THAT THE MEDICATION OR ANY OF IT'S INGREDIENTS MAY HAVE ON THE PATIENT FOR WHOM THE DRUGS WERE PRESCRIBED."** has had the same under consideration and reports, **To Do Pass As Subsituted.**

Votes of committee members are as follows:

- 12 To Pass
- 0 Not To Pass
- 0 To The Inactive File
- 0 Abstained
- 0 Off-Island
- 0 Not Available

Sincerely,

Lou Leon Guerrero, RN, MPH
attachments

Committee On Health, Welfare, And Senior Citizens
VOTE SHEET

on

Substitute Bill No. 174- **"AN ACT TO AMEND SECTION 12617.1, CHAPTER 12, 10 GUAM ANNOTATED TO REQUIRE ALL PHARMACIES TO PROVIDE A PRESCRIPTION INFORMATION SHEET OR A PRINTOUT OF EACH PRESCRIPTION INCLUDING THE NAME OF THE MEDICATION AND A LISTING OF THE SIDE EFFECTS THAT THE MEDICATION OR ANY OF IT'S INGREDIENTS MAY HAVE ON THE PATIENT FOR WHOM THE DRUGS WERE PRESCRIBED."**

COMMITTEE MEMBER	TO PASS	NOT TO PASS	ABSTAIN	INACTIVE FILE
Sen. Lou Leon Guerrero, RN, MPH, Chair	✓			
Sen. Ben C. Pangelinan, Vice Chair	✓			
Sen. Tom C. Ada, member	✓			
Sen. Mark C. Charfauros, member	✓			
Sen. Hope A. Cristobal, member	✓			
Vice Speaker Ted S. Nelson, member	✓			
Sen. Angel L.G. Santos, member	✓			
Sen. Judith Won Pat-Borja, member	✓			
Sen. Anthony C. Blaz, member	✓			
Sen Felix P. Camacho, member	✓			
Sen. Alberto Lamorena V, member	✓			
Sen. Carlotta Leon Guerrero, member	✓			

COMMITTEE REPORT
HEALTH, WELFARE & SENIOR CITIZENS

Bill No. 174- **"AN ACT TO AMEND SECTION 12617.1, CHAPTER 12, 10 GUAM ANNOTATED TO REQUIRE ALL PHARMACIES TO PROVIDE A PRESCRIPTION INFORMATION SHEET OR A PRINTOUT OF EACH PRESCRIPTION INCLUDING THE NAME OF THE MEDICATION AND A LISTING OF THE SIDE EFFECTS THAT THE MEDICATION OR ANY OF IT'S INGREDIENTS MAY HAVE ON THE PATIENT FOR WHOM THE DRUGS WERE PRESCRIBED."**

PUBLIC HEARING

The Health, Welfare & Senior Citizens Committee held a public hearing on Friday, August 18, 1995 at 9:00 a.m. to hear testimonies on Bill No. 174- **"AN ACT TO AMEND SECTION 12617.1, CHAPTER 12, 10 GUAM ANNOTATED TO REQUIRE ALL PHARMACIES TO PROVIDE A PRESCRIPTION INFORMATION SHEET OR A PRINTOUT OF EACH PRESCRIPTION INCLUDING THE NAME OF THE MEDICATION AND A LISTING OF THE SIDE EFFECTS THAT THE MEDICATION OR ANY OF IT'S INGREDIENTS MAY HAVE ON THE PATIENT FOR WHOM THE DRUGS WERE PRESCRIBED."** The public hearing was held in the Legislative Public Hearing Room.

The hearing was called to order by the H,W&SC Chairperson, Senator Lou Leon Guerrero. Present were Co-Chair Senator Ben Pangelinan, Senator Hope Cristobal and Senator Carlotta Leon Guerrero.

PURPOSE

Currently, when medical prescriptions are dispensed required written information is listed on the medication label only. (FDA requires patient information leaflets for drugs that pose a serious and significant public health concern.) (Pharmacists are required by federal law to verbally counsel Medicare patients when medications are dispensed.) Many pharmacists do provide additional information, but most times, it is verbal. Many patients, especially the elderly, hear and understand the verbal instructions and information while in the pharmacy but forget or become confused when they arrive home.

The intent of this bill is to provide written information for the patient to refer to after leaving the pharmacy. It would require that a printed written sheet be given to the patient that details the name of the drug, the ailment the drug is intended to treat and the most common or significant side effects. It also

requires that the patient be informed of his/her right to receive a copy of the drug manufacturer's original information sheet.

BACKGROUND

Section 12617.1, Chapter 12, 10 GCA states:

> **Prescription Label Requirements.** All dangerous drugs dispensed by a pharmacy pursuant to a prescription shall be properly labeled and contain the following information:
>
> (1) The name, address and phone number of the dispensing pharmacy
> (2) The number under which the prescription is filled in the pharmacy
> (3) The prescribing physician's name
> (4) The name of the person for whom the drug was prescribed
> (5) The date filled
> (6) The name (generic or proprietary) of the medication
> (7) The directions for use
> (8) The date of expiration of the effectiveness of the drug if this information is required on the original label of the manufacturer.

The proposed legislation, amends Section 12617.1, to require written information in addition to the information required on the medication label.

TESTIMONY

Presenting written and oral testimony:

Sarah M. Thomas-Nededog for Cynthia J. Torres , President-Guam Association of Retired Persons
Mrs. Torres supports Bill 174. She stated that patients should be educated about the drugs they are taking and need to be empowered to be more responsible for their medication, their health and their lives. She also believes that a requirement should be added to the bill for information on what other prescriptions or over-the-counter drugs should be avoided while taking medication to prevent increased or serious side effects.

Daniel J. Thoene, Pharm. D.,RPh, President-Guam Pharmaceutical Association
The Guam Pharmaceutical Association opposes Bill 174. The opposition is to the language of the bill and not the intent. Mr. Thoene stated that the requirement to provide a package insert to the patient is inappropriate as it is intended for the health care provider and some manufacturers specifically instruct that it be removed before dispensing the medicine. He also feels that manufacturer information could lead to increased hospitalizations as a result of non-compliance. He indicated that a more appropriate source would be patient information written in lay language. He agreed that written

information can augment good patient care, but that oral counseling can easily be tailored to each patient.

The Association believes that requirements such as those covered in this bill should be handled through the Pharmacy Board and the rules governing the professional practice of pharmacy.

Mildred G. Arceo, RPh, Chairman-Guam Board of Examiners for Pharmacy
The Guam Board of Examiners for Pharmacy opposes Bill 174. Ms. Arceo feels that changes should not be mandated under statute but under the rules and regulations of the Pharmacy Board. She said new proposed rules and regulations require oral patient counseling. Many pharmacies are not computerized and are not equipped to provide a written printout. She discussed a federal mandate that would require both oral and written counseling by the turn of the century and thus Bill 174 is redundant.

Ms. Arceo stated that manufacturers' inserts are intended for pharmacists and not for patients.

Frederick Jestrab, RPh, MBA, Guam Memorial Hospital Authority
Mr. Jestrab supports the intent of Bill 174 but expressed concern about implementing written information especially where software is not available. He discussed the 1990 OBRA Act which requires oral patient counseling on prescription drugs for Medicare patients. Compliance includes giving the name, strength and directions for use. Patients are encouraged to ask for additional information before leaving the pharmacy. He believes that the risk-benefit issue of drug use should be accessed by the professional community not the lay public. He also believes any changes should be by regulation and not by law.

Joseph C. Quinata, RPh, Perezville Pharmacy
Mr. Quinata is concerned with the requirement to provide the manufacturer's insert. This information is intended for prescribers or health professionals and can cause more harm than good for patients. More information may be provided to a patient than a physician may want for the patient to have.

Presenting written testimony:

Dennis G. Rodriguez, Director-Public Health & Social Services
PH & SS agrees with the intent of Bill 174. However, he wrote, a printed sheet of information cannot and should not substitute for verbal communication between the patient and the provider.

Presenting oral testimony:

Antonia Duenas, GovGuam Association of Retired Persons
Mrs. Duenas supports Bill 174. She said she doesn't always know the side effects of her medications.

Gary Goldberg, Pharmacist-FHP
Mr. Goldberg believes that the manufacturers' insert is intended for the health care professional and not for the public. He stated that it is "high tech info in small print". He suggests that manuals, such as "Advice for the Patients", are more appropriate. FHP has such manuals available in the pharmacy for patient reference. He also advocates that any requirements be channeled through the Pharmacy Board in the rules and regulations and not by statue.

Aurelio Espinola, M.D.- Chief Medical Examiner
Dr. Espinola believes that if patients are given all side effects many will be scared to take the prescribed medication. He feels the physician should be the one responsible for determining if the side effect fears outweigh the benefits of the medication.

George Macris, M.D.
Dr. Macris feels that the intent of Bill 174 is good but not practical. Once the NET is available and information is uniform and consistent it will be practical. Until then, compliance should be voluntary. He said that there is no evidence to show that written information helps that, in fact, it scares many patients.

Michael Cruz, M.D.
Dr. Cruz agrees with the intent of Bill 174. He stated that there are multiple questions to be addressed. He would like to see a task force formed to further discuss this issue.

Sarah M. Thomas-Nededog, SPIMA
Ms. Thomas-Nededog asked that the consumer not be forgotten. Education and helping people understand what is happening to them is important. Oral information is good but more is needed. Many times, if a patient has side effects they don't tell the doctor but will discuss with the pharmacist.

FINDINGS

Based on requests by several of those testifying, Senator Lou Leon Guerrero committed to the formation of a task force to include pharmacists, consumers and physicians.

The task force met on Tuesday, October 24, 1995. It was the general consensus of the group that providing a copy of the original manufacturers'

information sheet is not appropriate as it provides details not easily understood by the lay person.

The group discussed the recently released proposed FDA program that would give patients more and better information about the prescription drugs they use. It establishes specific goals and standards that would significantly increase the distribution and quality of written information about prescription drugs. The first goal of the proposal is that by the year 2000 at least 75 percent of consumers who have new prescriptions filled will receive written, adequate and useful information about their medication. The information would have to meet quality standards for both content and format, which are to be established by the FDA in close cooperation with health care professionals and consumer organizations. Several task force members representing local pharmacies currently have computer hardware and software and provide written information routinely or upon request.

At the request of the task force a survey was taken of local pharmacies to determine how many currently provide written information and, if not, how many would support such a requirement. Out of 18 pharmacies surveyed 5 routinely provide written information, 6 provide written information upon request, and 7 do not provide written information. Of the 7 pharmacies that do not provide written information, only 2 are in support of a requirement for written information.

The recommendations of the task force are:

1. Do not require that a copy of the original manufacturers' information sheet be provided to the patient;
2. Do not require written information. The local pharmacist group could publish a listing of pharmacies that do provide written information and patients could then patronize these pharmacies;
3. Any new requirements or changes in current requirements should be made by rules and regulation and not by statute.

After reviewing the recommendations of the task force, the Committee agrees that requiring a copy of the original manufacturers' information sheet is not appropriate. However, in the interests of the consumer, written information should be available, upon request and needs to be required by statute to insure compliance.

COMMITTEE RECOMMENDATION

On Bill 174-**"AN ACT TO AMEND SECTION 12617.1, CHAPTER 12, 10 GUAM CODE ANNOTATED TO REQUIRE ALL PHARMACIES TO PROVIDE A PRESCRIPTION INFORMATION SHEET OR A PRINTOUT OF EACH PRESCRIPTION INCLUDING THE NAME OF THE MEDICATION, THE INGREDIENTS OF THE MEDICATION AND A LISTING OF THE SIDE**

EFFECTS THAT THE MEDICATION OR ANY OF ITS INGREDIENTS MAY HAVE ON THE PATIENT FOR WHOM THE DRUGS WERE PRESCRIBED", the Committee on Health, Welfare & Senior Citizens hereby recommends, on **Bill 174 TO DO PASS AS SUBSTITUTED.**

TWENTY-THIRD GUAM LEGISLATURE
1995 (FIRST) REGULAR SESSION

Bill No. 174
As Substituted by the Committee on Health, Welfare & Senior Citizens

D. Parkinson

AN ACT TO AMEND SECTION 12617.1, CHAPTER 12, 10 GUAM CODE ANNOTATED TO REQUIRE, UPON REQUEST OF THE PATIENT, ALL PHARMACIES TO PROVIDE A PRESCRIPTION INFORMATION SHEET OR A PRINT OUT OF EACH PRESCRIPTION INCLUDING THE NAME OF MEDICATION, THE INGREDIENTS OF THE MEDICATION AND A LISTING OF THE SIDE EFFECTS THAT THE MEDICATION OR ANY OF ITS INGREDIENTS MAY HAVE ON THE PATIENT FOR WHOM THE DRUGS WERE PRESCRIBED

BE IT ENACTED BY THE PEOPLE OF THE TERRITORY OF GUAM:

SECTION 1. LEGISLATIVE FINDINGS AND INTENT. The Guam Legislature finds that when medical prescriptions are dispensed required written information is listed on the medication label only. Many pharmacists do provide additional information, but most times, it is verbal. Many patients, especially the elderly, hear and understand the verbal instructions and information while in the pharmacy but forget or become confused when they arrive home. It is the intent of the Legislature that, upon the request of the patient, all medical prescriptions provided by pharmacies, medical clinics or doctors include a description of the contents of the medicine provided in the prescription. This break down will be in the form of a printed information sheet or label giving the name of the drug or drugs, what ailment the drug or drugs are being used to treat, and some of the more common side effects that the drug or drugs are known to cause, how to recognize them, and what to do when they occur.

SECTION 2. Section 12617.1, Chapter 12, 10 Guam Code Annotated is amended to read:

"Section 12617.1. **Prescription Label Requirements.** All dangerous drugs dispensed by a pharmacy pursuant to a prescription shall be properly labeled and contain the following information:

a. (1) The name, address and phone number of the dispensing pharmacy

(2) The number under which the prescription is filed in the pharmacy

(3) The prescribing physician's name

(4) The name of the person for whom the drug was prescribed

(5) The date filled

(6) The name (generic or proprietary) of the medication

(7) The directions for use

(8) The date of expiration of the effectiveness of the drug if this information is required on the original label of the manufacturer.

b. Upon patient request, each prescription filled by a pharmacy, medical clinic or doctor will contain a printed sheet giving the name of the drug or drugs, what ailment the drug or drugs are being used to treat, and a list of the most common or significant side effects that the drug or drugs are known to cause."

SECTION 3. Not withstanding any other provisions of law, this Act becomes effective 30 days after enactment.

COMMITTEE ON RULES

Twenty-Third Guam Legislature
155 Hesler St., Agana, Guam 96910

March 22, 1995

MEMORANDUM

TO: Chairperson, Committee on Health, Welfare and Senior Citizens

FROM: Chairman, Committee on Rules

SUBJECT: Referral - Bill No. 174

The above Bill is referred to your Committee as the principal committee. Please note that the referral is subject to ratification by the Committee on Rules at its next meeting. It is recommended you schedule a public hearing at your earliest convenience.

SONNY LUJAN ORSINI

Attachment

I.L.G.

TWENTY-THIRD GUAM LEGISLATURE
1995 (FIRST) REGULAR SESSION

Bill No. 174
Introduced By: D. Parkinson

AN ACT TO AMEND SECTION 12617.1, CHAPTER 12, 10 GUAM CODE ANNOTATED TO REQUIRE ALL PHARMACIES TO PROVIDE A PRESCRIPTION INFORMATION SHEET OR A PRINT-OUT OF EACH PRESCRIPTION INCLUDING THE NAME OF THE MEDICATION, THE INGREDIENTS OF THE MEDICATION AND A LISTING OF THE SIDE AFFECTS THAT THE MEDICATION OR ANY OF ITS INGREDIENTS MAY HAVE ON THE PATIENT FOR WHOM THE DRUGS WERE PRESCRIBED

BE IT ENACTED BY THE PEOPLE OF THE TERRITORY OF GUAM:

SECTION 1. LEGISLATIVE FINDINGS AND INTENT. The Guam Legislature finds that most if not all medical prescriptions are written and given to the patient without a complete description of the medication included in the prescription, or its side affects. It is the intent of the Legislature that all medical prescriptions provided by pharmacies, medical clinics or doctors include a description of the contents of the medicine provided in the prescription. This break down will be in the form of a printed information sheet or label giving the name of the drug or drugs, what ailment the drug or drugs are being used to treat, and some of the more common side affects that the drug or drugs are known to cause, how to recognize them, and what to do when they occur. In addition, the pharmacist shall upon request make available to the patient a copy of the original information sheet provided by the drug manufacture.

SECTION 2. Section 12617.1, Chapter 12, 10 Guam Code Annotated is amended to read:

"Section 12617.1. **Prescription Label Requirements.** All dangerous drugs dispensed by a pharmacy pursuant to a prescription shall be properly labeled and contain the following information:

a. (1) The name, address and phone number of the dispensing pharmacy

(2) The number under which the prescription is filed in the pharmacy

(3) The prescribing physician's name

(4) The name of the person for whom the drug was prescribed

(5) The date filled

(6) The name (generic or proprietary) of the medication

(7) The directions for use

(8) The date of expiration of the effectiveness of the drug if this information is required on the original label of the manufacturer.

(9) In addition to the above, the patient shall be informed of his right to have a copy of the drug manufacturer's original information sheet.

b. Each prescription filled by a pharmacy, medical clinic or doctor will contain a printed sheet giving the name of the drug or drugs, what ailment the drug or drugs are being used to treat, and a list of the most common or significant side affects that the drug or drugs are known to cause."

Section 3. Not withstanding any other provisions of law, this Act becomes effective 30 days after enactment.

F:\23\Bills\Medlabel.bil\sh

FISCAL NOTE
BUREAU OF BUDGET AND MANAGEMENT RESEARCH

BBMR-F7

SEP 01 1995

SEP 06 1995

Bill No. 174
Amendatory Bill YES XX NO

Date Received 8/10/95
Date Reviewed 8/30/95

Department/Agency Affected: Public Health, Mental Health, Guam Memorial Hospital, & other Health Related Entities
Department/Agency Head: PH&SS/Dennis Rodriguez
Total FY Appropriation to Date: $73,991,582

Bill Title (preamble): An act to amend section 12617.1, Chapter 12, 10 GCA to require all pharmacies to provide a prescription information sheet or a print-out of each prescription including the name of the medication, the ingredients of the medication and a listing of the side affects that the medication or any of its ingredients may have on the patient for whom the drugs were prescribed.

Change in Law: Amend section 12617.1, Chapter 12, 10 GCA

Bill's Impact on Present Program Funding:
X Increase ___Decrease ___Reallocation ___No Change

Bill is for: X Operations ___Capital Improvement ___Other (_____)

FINANCIAL/PROGRAM IMPACT

ESTIMATED SINGLE-YEAR FUND REQUIREMENTS (Per Bill)

PROGRAM CATEGORY	GENERAL FUND	OTHER	TOTAL
Public Health & Welfare	1/		

ESTIMATED MULTI-YEAR FUND REQUIREMENTS (Per Bill)

FUND	1st	2nd	3rd	4th	5th	TOTAL
GENERAL FUND						
OTHER						
TOTAL						

FUNDS ADEQUATE TO COVER INTENT OF THE BILL? YES/NO-IF NO, ADD'L AMOUNT REQUIRED $_____
AGENCY/PERSON/DATE CONTACTED: _____/_____/_____

ESTIMATED POTENTIAL MULTI-YEAR REVENUES

FUND	1st	2nd	3rd	4th	5th	TOTAL
GENERAL FUND						
OTHER						
TOTAL						

ANALYST Christine D. Flores DATE 8/31/95 DIRECTOR Joseph E. Rivera DATE SEP 01 1995
Acting Director, BBMR

FOOTNOTES: 1/ Please See Comments

The proposed legislation will have a financial impact on the general fund relative to agencies operating a pharmacy. The proposed legislation provides each patient an optional copy of the drug manufacturer's original informational sheet as well a printed sheet accompanying each prescription giving the name of the drug or drugs, what ailment the drug or drugs are being used to treat, and a list of the most common or significant side affects that the drug or drugs are known to cause.

AGENDA

COMMITTEE ON
HEALTH, WELFARE & SENIOR CITIZENS

PUBLIC HEARING
Legislature Public Hearing Room
Friday, August 18, 1995 from 9 a.m.

Bill 174, AN ACT TO AMEND SECTION 12617.1, CHAPTER 12, 10 GUAM CODE ANNOTATED TO REQUIRE ALL PHARMACIES TO PROVIDE A PRESCRIPTION INFORMATION SHEET OR A PRINTOUT OF EACH PRESCRIPTION INCLUDING THE NAME OF THE MEDICATION AND A LISTING OF THE SIDE AFFECTS THAT THE MEDICATION OR ANY OF ITS INGREDIENTS MAY HAVE ON THE PATIENT FOR WHOM THE DRUGS WERE PRESCRIBED.

Bill 254, AN ACT TO AMEND §2912.1 OF TITLE 10, GUAM CODE ANNOTATED, RELATIVE TO WAIVER OF LIMITATION ON MAXIMUM COVERAGE FOR CATASTROPHIC ILLNESS PROGRAM.

COMMITTEE ON HEALTH, WELFARE & SENIOR CITIZENS

Sen. Lou Leon Guerrero, RN, MPH, Chairperson
Sen. Ben C. Pangelinan, Vice Chair

Sen. Tom C. Ada, member
Sen. Mark C. Charfauros, member
Sen. Hope A. Cristobal, member
Vice Speaker Ted S. Nelson, member
Sen. Angel L.G. Santos, member
Sen. Judith Won Pat-Borja, member
Sen. Anthony C. Blaz, member
Sen. Felix P. Camacho, member
Sen. Alberto Lamorena V, member
Sen. Carlotta Leon Guerrero, member

The undersigned have appeared and/or submitted testimony to the Committee on Health, Welfare & Senior Citizens on Bill 174, AN ACT TO AMEND SECTION 12617.1, CHAPTER 12, 10 GUAM CODE ANNOTATED TO REQUIRE ALL PHARMACIES TO PROVIDE A PRESCRIPTION INFORMATION SHEET OR A PRINTOUT OF EACH PRESCRIPTION INCLUDING THE NAME OF THE MEDICATION AND A LISTING OF THE SIDE AFFECTS THAT THE MEDICATION OR ANY OF ITS INGREDIENTS MAY HAVE ON THE PATIENT FOR WHOM THE DRUGS WERE PRESCRIBED.

Name Sarah M. Thomas - Written for Cynthia J. Torres
Representing Gov Guam Assoc. of Retired Persons
Address/Phone 477-9014

Name Antonia Duenas
Representing Gov Guam Assoc. of Retired Persons
Address/Phone 477-9014

Name Gary H. Goldberg Pharmacist
Representing FHP
Address/Phone Tamuning 646-5825 X282

Name AURELIO A. ESPINOLA, M.D.
Representing MEDICAL EXAMINER'S OFFICE
Address/Phone 325 DUENAS DRIVE
TAM. 96911 - 646-9363

Name NEIL EGURROLA
Representing SEN. T. C. ADA
Address/Phone ADA'S COMMERCIAL PLAZA, AGANA
472-3426

Name Daniel J. Thoene (Tape)
Representing Guam Pharmaceutical Association
Address/Phone POB 9352 Dededo GUAM
96912

Name MILDRED G. ARCEO
Representing GUAM BOARD OF PHARMACY
Address/Phone P.O. BOX 2816
AGANA, GUAM 96910

Name Norma Rodriguez
Representing
Address/Phone

The undersigned have appeared and/or submitted testimony to the Committee on Health, Welfare & Senior Citizens on Bill 174, AN ACT TO AMEND SECTION 12617.1, CHAPTER 12, 10 GUAM CODE ANNOTATED TO REQUIRE ALL PHARMACIES TO PROVIDE A PRESCRIPTION INFORMATION SHEET OR A PRINTOUT OF EACH PRESCRIPTION INCLUDING THE NAME OF THE MEDICATION AND A LISTING OF THE SIDE AFFECTS THAT THE MEDICATION OR ANY OF ITS INGREDIENTS MAY HAVE ON THE PATIENT FOR WHOM THE DRUGS WERE PRESCRIBED.

Name FRED JESTRAB
Representing GUAM MEMORIAL HOSPITAL
Address/Phone 850 CAMPUS ROAD TAMUNING, GU 96911

Name Joseph C Quinata, RPh
Representing Perezville Pharmacy
Address/Phone The Doctor's Clinic 649-9400

Name George Urasaki MD
Representing private practice
Address/Phone 2214-B A'Ili Guam 96912 637-1772

Name
Representing
Address/Phone

Name
Representing
Address/Phone

Name
Representing
Address/Phone

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Representing
Address/Phone

Name
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Guam Association of Retired Persons

Servicio Para I ManAmko
P. O. Box 3057 - Agana, GU 96910
Retirement Bldg, Maite, Guam
(671) 472-2188 477-9014/1156 472-6632 Fax: 477-9015

August 17, 1995

Honorable Lou Leon Guerrero
Chairperson, Committee on Health, Welfare and Senior Citizens
23rd Guam Legislature
Agana, Guam

Dear Chairperson Leon Guerrero and Members of the Committee;

The GovGuam Association of Retired Persons presents this attached written testimony in ***support of Bill 174*** introduced by Speaker Don Parkinson and other members of the Guam Legislature.

If you need additional information, please let me know.

Sincerely,

CYNTHIA J. TORRES
President

TESTIMONY IN SUPPORT OF
BILL 174
by the
GOVGUAM ASSOCIATION OF RETIRED PERSONS

The GovGuam Association of Retired Persons is in support of Bill 174 which has been introduced by Speaker Don Parkinson and other members of the 23rd Guam Legislature.

If passed, Bill 174 would mandate all pharmacies to do two things - inform patients of their right to have a copy of the drug manufacturer's original information sheet and to provide with prescriptions a printed information listing the use of the drug and the most common side affects.

It seems as though these two simple things are so simple that it would be appear to be unnecessary. Quite the contrary. These simple things can do quite a bit in not only educating patients about the drugs they are taking, but to empower them to be even more responsible for their medications, their health and their lives.

Patients will then know clearly what and why they are taking medications and what they should expect to happen to them in terms of the affects of the drug. Now knowing this, patients can make wiser decisions about how these drugs will affect their lives for the first few days or during the entire period of use and how they can adapt to such. An example is if the patient is aware that they may become drowsy, they may plan not to drive or to stay home if possible for a few days until their bodies adjust to the new medication. Also, there should be information on what other prescriptions or over-the-counter drugs should be avoided while taking that medication to prevent increased or serious side affects.

All patients would certainly benefit from the passage of this bill. In addition, we feel strongly that senior citizens and their families would surely gain from Bill 174 becoming law. Most elderly take prescribed drugs on an every day basis and may be taking many different drugs several times a day. They and their families often do not know what the drugs are for and what kinds of sensations they may be experiencing. Often drugs affect the moods and personalities of patients. The man'amko, upon being educated about their medication, can refer to the information sheet from time to time, especially if they forget or want to be reminded. We can also expect that the elderly and their families will be more patient and understanding should they be susceptible to certain affects such as being irritable, or constantly fatigued.

In closing, we would like to thank you for your kind consideration of this important bill and encourage your support for its expeditious passage.

GUAM PHARMACEUTICAL ASSOCIATION

P.O. Box 9352
Dededo, Guam 96912

TESTIMONY

BILL 174 AN ACT TO REQUIRE ALL PHARMACIES TO PROVIDE WITH PRESCRIPTION MEDICINES A PRINTED INFORMATION SHEET OR LABEL GIVING THE NAME OF DRUG, THE AILMENT THE DRUG IS USED TO TREAT, THE MORE COMMON SIDE EFFECTS, AND HOW TO RECOGNIZE THEM AND WHAT TO DO IF SUCH SIDE EFFECTS OCCUR. IN ADDITION, THE PHARMACIST SHALL UPON REQUEST PROVIDE THE PATIENT WITH A COPY OF THE ORIGINAL INFORMATION SHEET PROVIDED BY THE DRUG MANUFACTURER.

Chairperson and members of the Committee on Health, Welfare and Senior Citizens. The consensus among the Guam Pharmaceutical Association members is to oppose BILL 174. We feel that this bill as it is writtten, would be detrimental to health care as is currently provided on Guam.

The Pharmaceutical Association members disagree with the language of BILL 174 and not its presumed intent to benefit the people of Guam. In the interest of Healthcare on Guam the Pharmacy Association makes the following statements.

1. In our opinion, it does not appear that pharmacist input was sought in the writing of this legislation.

2. The Legislation appears to have been introduced in March 1995, although the majority of pharmacists have only been made aware of this legislation in the past 48 hours.

3. a.) We feel that manufacturer information (i.e. package insert) could lead to increased hospitalizations as a result of medication non-compliance when patients are presented with inappropriate information.

   b.) Package inserts (see attachment A) in general are for healthcare providers, and some manufacturers clearly instruct the pharmacist to remove the package insert before dispensing the medicine. As well, we feel that most physicians would oppose our giving their patients package inserts.

4. We feel there are more appropriate sources for patient information, which are specifically written in lay language (see attachment B).

5. In our opinion, patients are best served by oral counseling, which can be easily tailored to each patient. Although, we agree that writtten information can certainly augment good patient care.

6. The Pharmacy Association agrees that all rules governing the professional practice of pharmacy should be made in conjunction with the Pharmacy Board.

7. The Association recommends that the Committee on Health, Welfare and Senior Citizens, create a task force to get further input before pursuing BILL 174 and that such a task force include someone from each of the following groups: Pharmacy Board, Pharmacy Association, Medical Board, Medical Association and a consumer group.

8. We ask that item #9 on page 2 be deleted in its entirety as currently written.

We agree with the intent of BILL 174, but oppose it as written in the interest of providing better health care to the people of Guam.

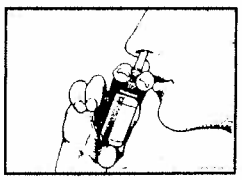
We thank you for your time in hearing our concerns. We trust that you will take more time to work with the Pharmacy profession in improving the island's health care.

Daniel J Thoene, Pharm.D., RPh

Daniel J. Thoene, Pharm.D., RPh
President, Guam Pharmaceutical Association
August 18, 1995

Attachment A

Samples of package inserts



3. Holding the Unit as shown, place your index and second finger on either side of the Finger Rests and your thumb underneath the Unit.

4. Press the Finger Rests down firmly and allow to return *until* a single spray is delivered. It is only necessary to do this the first time you use the Unit.

5. Place the Tip into one nostril and inhale deeply as you press the Finger Rests down firmly. This will release one dose of medication. NOTE: Dose only as directed by your physician.

6. Repeat the process in your other nostril.

7. Replace Dust Cap and Safety Clip before storing.

Special Tips

1. Clear nasal passages before using your NASALMATIC Unit. Your doctor will instruct you if any other medication is required.

2. Keep out of the reach of children.

The NASALMATIC Unit is manufactured for:

FISONS
Pharmaceuticals
Fisons Corporation
Rochester, NY 14623 U.S.A.

By: Valois S.A.
Le Neubourg, France

Rev. 10/94
RF037D
317-1-153

PHARMACIST—DETACH HERE AND GIVE INSTRUCTIONS TO PATIENT

ADVERSE REACTIONS

Gastrointestinal: anorexia, epigastric distress, **nausea, vomiting,** diarrhea, bulky loose stools, **stomatitis, sore throat,** glossitis, black hairy tongue, **dysphagia,** hoarseness, enterocolitis, and **inflammatory lesions** (with candidal overgrowth) in the **anogenital region,** including proctitis and **pruritus ani. These** reactions have been caused by both the oral and parenteral administration of tetracyclines but are less frequent after parenteral use.

Skin: maculopapular and erythematous rashes. Exfoliative dermatitis has been reported but is uncommon. Onycholysis and discoloration of the nails have been reported rarely. Photosensitivity has occurred (see **WARNINGS**).

Renal toxicity: rise in BUN has been reported and is apparently dose-related (see **WARNINGS**).

Hepatic cholestasis has been reported rarely, and is usually associated with high dosage levels of tetracycline.

Hypersensitivity reactions: urticaria, angioneurotic edema, anaphylaxis, anaphylactoid purpura, pericarditis, exacerbation of systemic lupus erythematosus, and serum sickness-like reactions, as fever, rash, and arthralgia.

When given over prolonged periods, tetracyclines have been reported to produce brown-black microscopic discoloration of thyroid glands. No abnormalities of thyroid function studies are known to occur.

Bulging fontanels have been reported in young infants following full therapeutic dosage. This sign disappeared rapidly when the drug was discontinued.

Blood: anemia, hemolytic anemia, thrombocytopenia, thrombocytopenic purpura, neutropenia and eosinophilia have been reported.

Dizziness and headache have been reported.

INDICATIONS

1. *Endocrine disorders:*
   Primary or secondary adrenocortical insufficiency (hydrocortisone or cortisone is the first choice; synthetic analogs may be used in conjunction with mineralocorticoids where applicable; in infancy mineralocorticoid supplementation is of particular importance).
   Congenital adrenal hyperplasia
   Nonsuppurative thyroiditis
   Hypercalcemia associated with cancer
2. *Rheumatic disorders:*
   As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in:
   Psoriatic arthritis
   Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy)
   Ankylosing spondylitis
   Acute and subacute bursitis
   Acute nonspecific tenosynovitis
   Acute gouty arthritis
   Post-traumatic osteoarthritis
   Synovitis of osteoarthritis
   Epicondylitis
3. *Collagen diseases:*
   During an exacerbation or as maintenance therapy in selected cases of:
   Systemic lupus erythematosus
   Acute rheumatic carditis
4. *Dermatologic diseases:*
   Pemphigus
   Bullous dermatitis herpetiformis
   Severe erythema multiforme (Stevens-Johnson syndrome)
   Exfoliative dermatitis
   Mycosis fungoides
   Severe psoriasis
   Severe seborrheic dermatitis
5. *Allergic states:*
   Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment.
   Seasonal or perennial allergic rhinitis
   Serum sickness
   Bronchial asthma
   Contact dermatitis
   Atopic dermatitis
   Drug hypersensitivity reactions
6. *Ophthalmic diseases:*
   Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as:
   Allergic conjunctivitis
   Keratitis
   Allergic corneal marginal ulcers
   Herpes zoster ophthalmicus
   Iritis and iridocyclitis
   Chorioretinitis
   Anterior segment inflammation
   Diffuse posterior uveitis and choroiditis
   Optic neuritis
   Sympathetic ophthalmia
7. *Respiratory Diseases:*
   Symptomatic sarcoidosis
   Loeffler's syndrome not manageable by other means
   Berylliosis
   Fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate antituberculous chemotherapy.
   Aspiration pneumonitis
8. *Hematologic disorders:*
   Idiopathic thrombocytopenic purpura in adults
   Secondary thrombocytopenia in adults
   Acquired (autoimmune) hemolytic anemia
   Erythroblastopenia (RBC anemia)
   Congenital (erythroid) hypoplastic anemia
9. *Neoplastic disease:*
   For palliative management of:
   Leukemias and lymphomas in adults
   Acute leukemia of childhood
10. *Edematous states:*
    To induce a diuresis or remission of proteinuria in the nephrotic syndrome, without uremia, of the idiopathic type or that due to lupus erythematosus.
11. *Gastrointestinal diseases:*
    To tide the patient over a critical period of the disease in:
    Ulcerative colitis
    Regional enteritis
12. *Miscellaneous:*
    Tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate antituberculous chemotherapy.
    Trichinosis with neurologic or myocardial involvement.
    In addition to the above indications, prednisone is indicated for systemic dermatomyositis (polymyositis).

CONTRAINDICATIONS

Systemic fungal infections.

WARNINGS

In patients on corticosteroid therapy subjected to unusual stress, increased dosage of rapidly acting corticosteroids before, during, and after the stressful situation is indicated.

Corticosteroids may mask some signs of infection, and new infections may appear during their use. There may be decreased resistance and inability to localize infection when corticosteroids are used.

Prolonged use of corticosteroids may produce posterior subcapsular cataracts, glaucoma with possible damage to the optic nerves, and may enhance the establishment of secondary ocular infections due to fungi or viruses.

USAGE IN PREGNANCY: Since adequate human reproduction studies have not been done with corticosteroids, the use of these drugs in pregnancy, nursing mothers or women of childbearing potential requires that the possible benefits of the drug be weighed against the potential hazards to the mother and embryo or fetus. Infants born of mothers who have received substantial doses of corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalism.

Attachment B

Side Effects:

Every drug is capable of producing side effects. Many tetracycline users experience no, or minor, side effects. The frequency and severity of side effects depend on many factors including dose, duration of therapy and individual susceptibility. Possible side effects include:

Diabetes Insipidus (demeclocycline): Weakness; excessive urination; excessive thirst.

Digestive Tract: Nausea; vomiting; appetite loss; diarrhea; stomach ache.

Skin: Rash; hives; sensitivity to sunlight.

Other: Fever; joint pain; anemia; decreased platelets; difficult breathing; abnormal liver or kidney function tests and blood counts; mouth sores; teeth staining (children); headache; lightheadedness (minocycline).

Guidelines for Use:

- If a dose is missed, take it as soon as possible. If several hours have passed or if it is nearing time for the next dose, do not double the dose in order to "catch up" (unless advised to do so by your doctor). If more than one dose is missed, or it is necessary to establish a new dosage schedule, contact your doctor or pharmacist. Use exactly as prescribed.
- Continue use until all the prescribed drug has been taken. Failure to take a full course of therapy may prevent complete elimination of bacteria, causing a relapse of the infection. Continue the antibiotic for a few days after a fever or other symptoms disappear.
- Do not use during pregnancy.
- Do not use in children under 8 unless other drugs are not likely to be effective or are inadvisable. Use during tooth development may cause permanent discoloration and inadequate hardening of baby and permanent teeth.
- Take on an empty stomach at least 1 hour before or 2 hours after a meal (exceptions: Doxycycline and minocycline are not affected by food or milk).
- Take with a full glass of water or other fluid.
- *Oral suspension*—Store in refrigerator. Do not freeze. Shake well before using. Check expiration date.
- Avoid use of tetracyclines with antacids, laxatives, dairy products (milk, cheese) or iron-containing products. If an antacid must be taken, take 2 to 3 hours before or after tetracyclines.
- *Sensitivity to light:* May cause photosensitivity (sensitivity to sunlight). Avoid prolonged exposure to the sun and other ultraviolet light. Use sunscreens and wear protective clothing until tolerance is determined.
- *Do not use outdated tetracyclines.* Outdated tetracyclines are highly toxic to the kidneys.
- *Minocycline* may cause lightheadedness, dizziness and vertigo (feeling of whirling motion). Use caution while driving or performing other tasks requiring alertness.
- Doses vary depending on factors such as age, disease and other risk factors.

If you have questions concerning tetracyclines, consult your pharmacist or doctor.

pharmacology of The ESTROGEN in LOESTRIN and/or TAGAMET when taken together might be altered as follows:
PLASMA LEVEL OF LOESTRIN MAY BE INCREASED.
HEPATIC METABOLISM OF LOESTRIN MAY BE DECREASED BY TAGAMET
NO SPECIAL PRECAUTIONS OR DOSAGE ADJUSTMENT APPEAR NECESSARY.
ONSET : RAPID SEVERITY : MINOR DOCUMENTATION : POSSIBLE

RX # : 506948
DATE : 07/31/95
PATIENT :
DOCTOR : HAUGHTON,DANA
DRUG : TAGAMET 300MG TAB

PEREZVILLE PHARMACY
P.O.BOX 8016
TAMUNING, GUAM 96911
(671)649-9400

DRUG CONSULTATION INFORMATION

Why is it prescribed ?
USED TO TREAT AND PREVENT THE RECURRENCE OF ULCERS AND TO TREAT CONDITIONS CAUSED BY TOO MUCH ACID IN THE STOMACH.

How should it be taken ?
FOLLOW THE DOSAGE INSTRUCTIONS ON YOUR PRESCRIPTION LABEL. DON'T TAKE ANTACIDS WITHIN 1 HR OF TAKING THIS MEDICINE.

How should it be stored ?
KEEP IN ORIGINAL TIGHTLY CLOSED CONTAINER IN A DARK, COOL, AND DRY PLACE OUT OF REACH OF CHILDREN.

Are there any side effects ?
DIARRHEA, MUSCLE PAIN, HEADACHE, DIZZINESS, SKIN RASH, BREAST ENLARGEMENT AND SORENESS, DROWSINESS, MENTAL CONFUSION.

Other Precautions ?
DO NOT SMOKE CIGARETTES. TELL YOUR DOCTOR IF YOU'RE PRE GNANT OR NURSING OR IF YOU HAV E KIDNEY OR LIVER DISEASE.

What If I Miss a dose?
IF YOU MISS A DOSE,OMIT MISSED DOSE COMPLETELY; RESUME REGULAR SCHEDULE. NO DOUBLE DOSES.

GUAM BOARD OF EXAMINERS FOR PHARMACY

Department of Public Health & Social Services
Government of Guam
P.O. Box 2816
Agana, Guam 96910

TESTIMONY

BILL 174, AN ACT TO AMEND SECTION 12617.1, CHAPTER 12, 10 GUAM CODE ANNOTATED TO REQUIRE ALL PHARMACIES TO PROVIDE A PRESCRIPTION INFORMATION SHEET OR A PRINTOUT OF EACH PRESCRIPTION INCLUDING THE NAME OF THE MEDICATION AND A LISTING OF THE SIDE AFFECTS THAT THE MEDICATION OR ANY OF ITS INGREDIENTS MAY HAVE ON THE PATIENT FOR WHOM THE DRUGS WERE PRESCRIBED.

Madame Chairman and members of the Committee on Health, Welfare and Senior Citizens. With the consensus of the Board the Guam Board of Examiners for Pharmacy is in opposition to Bill 174 to require all pharmacies to provide a prescription information sheet or a printout of each prescription listing the side affects that the medication may have on the patient.

The Board believes that the intent of the bill is to benefit the people of Guam. With that in mind the Board would like to make the following statements.

1. The information about the medication should be available to patients, but it should not be mandated under statute.

2. The Board is not opposed to counseling the patient per se; in fact the new proposed rules and regulations for Guam Board of Examiners for Pharmacy (GBEP) require oral patient counseling. However, requiring a printout of just the above information does not reflect the total medication healthcare of the patient.

3. How would the legislation be enforced? Currently, there are no inspectors for pharmacies other than those from Environmental Health who enforce the handling of controlled substances as a courtesy to the GBEP.

4. "Printout" should not replace oral counseling which should start with the physician. Oral counseling is not mentioned in the proposed legislation.

5. All pharmacies are not computerized and are not equipped to provide a "printout".

6. Manufacturers' inserts are intended for pharmacists, not for patients.

7. What about unlabeled uses of drugs? Doctors use drugs in some ways that are effective, but are not listed on the manufacturers' inserts.

8. Will this proposed legislation apply to refills? That will be very impractical as some people use the same medication for several years.

9. What about starter samples dispensed by physicians?

10. Federal guidelines under OBRA 90 require oral or written patient counseling on all drugs.

11. Oral counseling is not addressed in the proposed legislation.

Thank you for the opportunity to provide input regarding Bill 174 and we hope to continue to work together regarding healthcare issues.

Mildred G. Arceo, R. Ph.

Mildred G. Arceo, RPh
Chairman
August 17, 1995

GUAM MEMORIAL HOSPITAL AUTHORITY

850 GOV. CARLOS G. CAMACHO ROAD
OKA, TAMUNING, GUAM 96911
TEL: 646-5801 thru 5; 646-8710 thru 19
FAX: (671) 649-0145

To: Assistant Administrator, Professional Services

From: Director of Pharmacy

Date: August 16, 1995

Subject: Comments on Bill 174

1. The Pharmacy Department will be out of compliance with this proposed law until the new Hospital Information System is installed. Currently, pharmacy has no computer system software or xerox machine to get the required printed information about side effects to a patient.

2. The 1990 OBRA act requires patient counseling of prescription drugs. The pharmacy department complies with this law in giving the name, strength and directions for use. Patients are encouraged to ask for additional information about drug use before leaving the Pharmacy area including side effects.

3. The legislature should let the Guam Board of Pharmacy Examiners promulgate this regulation. This should be a regulation and not a law.

4. The medical community should provide input on this issue. Most doctor offices will be out of compliance and unable to comply with the law as written. In the past medical organizations have opposed this type of legislation due to patient confidentiality.

5. The intent of the law should be questioned. The law will provide more patient education of drug use which is good, but will not increase the compliance of taking drugs; probably will decrease compliance. Patients have problems in understanding directions for use. If they read about the side effects, the average patient might not take a drug. The risk-benefit issue of drug use should be accessed by the professional community not lay public.

6. There are no studies that I am aware of that by giving written material to patients about side effects is going to increase patient understanding of drug use. Most of the information will not be read or understood if read. Some side effects are not known before a drug comes on the market.

Sincerely,

Frederick Jestrab

Frederick Jestrab, RPh MBA

91-18-057 (Order 191B), recodified as § 246-869-200, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 87-08-031 (Order 205), § 360-16-245, filed 3/27/87; Order 120, § 360-16-245, filed 3/11/74.]

WAC 246-869-210 Prescription labeling. To every prescription container, there shall be fixed a label or labels bearing the following information:

(1) All information as required by RCW 18.64.246, provided that in determining an appropriate period of time for which a prescription drug may be retained by a patient after its dispensing, the dispenser shall take the following factors into account:

(a) The nature of the drug;

(b) The container in which it was packaged by the manufacturer and the expiration date thereon;

(c) The characteristics of the patient's container, if the drug is repackaged for dispensing;

(d) The expected conditions to which the article may be exposed;

(e) The expected length of time of the course of therapy; and

(f) Any other relevant factors.

The dispenser shall, on taking into account the foregoing, place on the label of a multiple unit container a suitable beyond-use date or discard by date to limit the patient's use of the drug. In no case may this date be later than the original expiration date determined by the manufacturer.

(2) The quantity of drug dispensed, for example the volume or number of dosage units.

(3) The following statement, "Warning: State or federal law prohibits transfer of this drug to any person other than the person for whom it was prescribed."

(4) The information contained on the label shall be supplemented by oral or written information as required by WAC 246-869-220. [Statutory Authority: RCW 18-.64.005. 92-12-035 (Order 277B), § 246-869-210, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-869-210, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.246. 85-06-010 (Order 193), § 360-16-255, filed 2/22/85. Statutory Authority: RCW 18.64.005. 84-22-027 (Order 191), § 360-16-255, filed 11/1/84.]

WAC 246-869-220 Patient information required. Except in those cases when the prescriber has advised that the patient is not to receive specified information regarding the medication:

(1) In order to assure the proper utilization of the medication or device prescribed, with each new prescription dispensed by the pharmacist, in addition to labeling the prescription in accordance with the requirements of RCW 18.64.245 and WAC 246-869-210, the pharmacist must:

(a) Orally explain to the patient or the patient's agent the directions for use and any additional information, in writing if necessary, for those prescriptions delivered inside the confines of the pharmacy; or

(b) Explain by telephone or in writing for those prescriptions delivered outside the confines of the pharmacy.

(2) In those instances where it is appropriate, when dispensing refill prescriptions, the pharmacist shall communicate with the patient or the patient's agent, by the procedure outlined in subsection (1)(a) or (b) of this section or the patient's physician regarding adverse effects, over or under utilization, or drug interaction with respect to the use of medications.

(3) Subsections (1) and (2) of this section shall not apply to those prescriptions for inpatients in hospitals or institutions where the medication is to be administered by a nurse or other individual authorized to administer medications.

(4) In the place of written statements regarding medications, the pharmacist may use abstracts of the Patient USP DI 1992 edition, or comparable information. [Statutory Authority: RCW 18.64.005. 92-12-035 (Order 277B), § 246-869-220, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-869-220, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 89-04-016 (Order 223), § 360-16-265, filed 1/23/89.]

WAC 246-869-230 Child-resistant containers. (1) All legend drugs shall be dispensed in a child-resistant container as required by federal law or regulation, including CFR Part 1700 of Title 16, unless:

(a) Authorization is received from the prescriber to dispense in a container that is not child-resistant.

(b) Authorization is obtained from the patient or a representative of the patient to dispense in a container that is not child-resistant.

(2) Authorization from the patient to the pharmacist to use a regular container (nonchild-resistant) shall be verified in one of the following ways:

(a) The patient or his agent may sign a statement on the back of the prescription requesting a container that is not child-resistant.

(b) The patient or his agent may sign a statement on a patient medication record requesting containers that are not child-resistant.

(c) The patient or his agent may sign a statement on any other permanent record requesting containers that are not child-resistant.

(3) No pharmacist or pharmacy employee may designate himself or herself as the patient's agent. [Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-869-230, filed 8/30/91, effective 9/30/91; Order 126, § 360-16-270, filed 5/21/75.]

WAC 246-869-240 Pharmacist's professional responsibilities. (1) A pharmacist shall not delegate the following professional responsibilities:

(a) Receipt of a verbal prescription other than refill authorization from a prescriber.

(b) Consultation with the patient regarding the prescription, both prior to and after the prescription filling

COMMENTS ON BILL 174 :

The following are my comments on Bill 174:

SECTION 1. LEGISLATIVE FINDINGS AND INTENT

I AGGREE WITH MOST OF THE FINDINGS AND INTENT OF THE LEGISLATURE. HOWEVER, I DO NOT AGGREE THAT THE PHARMACIST BE REQUIRED TO PROVIDE THE PATIENT A COPY OF THE ORIGINAL MANUFACTURER'S LITERATURE AS THE INFORMATION PROVIDED IN THIS "INSERT" ARE INTENDED FOR THE PRESCRIBING PHYSICIAN AND OTHER HEALTH PROFESSIONALS(PHARMACIST, NURSES ETC.). DRUG MANUFACTURER'S PROVIDE ONLY ONE(1) INSERT PER CONTAINER FOR ALL LEGEND OR PRESCRIPTION DRUGS. SHOULD FEDERAL GUIDELINE REQUIRE ADDITIONAL INFORMATION FOR PATIENTS, THESE INSERTS WILL BE PRINTED IN A FORMAT THAT A PATIENT CAN READILY UNDERSTAND.

SECTION 2.

I AGGREE WITH ALL OF THIS SECTION EXCEPT FOR No.9 letter "a". To PROVIDE A PATIENT WITH A DRUG MANUFACTURER'S INSERT INTENDED FOR PRESCRIBERS OR HEALTH PROFESSIONAL USE CAN CAUSE MORE HARM THAN GOOD FOR PATIENTS.

GENERAL COMMENTS ON BILL 174

THE BILL AS WRITTEN HAS GOOD MERITS. HOWEVER, THE REQUIREMENT ON PHARMACIST TO PROVIDE MORE INFORMATION THAN WHAT PHYSICIANS MAY WANT FOR A PATIENT TO RECEIVE FROM PHARMACISTS MUST BE CONSIDERED. I FEEL PHYSICIANS MUST BE PROVIDED AN OPPORTUNITY TO COMMENT ON THIS BILL. THE SHORT NOTICE THAT MOST OF US RECEIVE ON THIS BILL MAY BE CONSIDERED AND PERHAPS ANOTHER HEARING WILL PROVIDE THE LEGISLATORS MORE INFORMATION TO ACT ON THE BILL RESPONSIBLY AND CARRY OUT THE INTENT IN PROVIDING BETTER HEALTH CARE FOR ALL PATIENTS.

THANKYOU

Joseph C. Quinata,RPh
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DEPARTMENT OF PUBLIC HEALTH & SOCIAL SERVICES
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COMMENTS ON BILL 174, AN ACT TO AMEND SECTION 12617.1, CHAPTER 12, 10 GUAM CODE ANNOTATED TO REQUIRE ALL PHARMACIES TO PROVIDE A PRESCRIPTION INCLUDING THE NAME OF THE MEDICATION AND A LISTING OF THE SIDE AFFECTS THAT THE MEDICATION OR ANY OF ITS INGREDIENTS MAY HAVE ON THE PATIENT FOR WHOM THE DRUGS WERE PRESCRIBED.

The Department agrees with the intent of Bill 174. At the same time, we recognize that handing out a printed sheet of information cannot and should not substitute for verbal communication between the provider and patient. The National Council on Patient Information and Education theme in 1993 was "Talk about Prescriptions". The concept includes talking to patients every time a medicine is prescribed or dispensed and at other teachable moments.

Pre-printed color labels are available for pharmacies to use that highlight certain precautions when taking a certain drug. These precautionary labels are not only for possible "adverse side effects" but may emphasize when and how to take the medication. Can these labels be used in lieu of handing out a printed sheet?

Prescriptions are given to treat a condition. Disease and illness will continue when patients do not follow their treatment **as prescribed.** Therefore, the patient must fully understand the benefit of treatment as well.

DENNIS G. RODRIGUEZ
Director
Date AUG 18 1995

Introduced

MAR 13 1995

TWENTY-THIRD GUAM LEGISLATURE
1995 (FIRST) REGULAR SESSION

Bill No. 174(LS)
Introduced By: D. Parkinson

AN ACT TO AMEND SECTION 12617.1, CHAPTER 12, 10 GUAM CODE ANNOTATED TO REQUIRE ALL PHARMACIES TO PROVIDE A PRESCRIPTION INFORMATION SHEET OR A PRINT-OUT OF EACH PRESCRIPTION INCLUDING THE NAME OF THE MEDICATION, THE INGREDIENTS OF THE MEDICATION AND A LISTING OF THE SIDE AFFECTS THAT THE MEDICATION OR ANY OF ITS INGREDIENTS MAY HAVE ON THE PATIENT FOR WHOM THE DRUGS WERE PRESCRIBED

BE IT ENACTED BY THE PEOPLE OF THE TERRITORY OF GUAM:

SECTION 1. LEGISLATIVE FINDINGS AND INTENT. The Guam Legislature finds that most if not all medical prescriptions are written and given to the patient without a complete description of the medication included in the prescription, or its side affects. It is the intent of the Legislature that all medical prescriptions provided by pharmacies, medical clinics or doctors include a description of the contents of the medicine provided in the prescription. This break down will be in the form of a printed information sheet or label giving the name of the drug or drugs, what ailment the drug or drugs are being used to treat, and some of the more common side affects that the drug or drugs are known to cause, how to recognize them, and what to do when they occur. In addition, the pharmacist shall upon request make available to the patient a copy of the original information sheet provided by the drug manufacture.

SECTION 2. Section 12617.1, Chapter 12, 10 Guam Code Annotated is amended to read:

"Section 12617.1. **Prescription Label Requirements.** All dangerous drugs dispensed by a pharmacy pursuant to a prescription shall be properly labeled and contain the following information:

a. (1) The name, address and phone number of the dispensing pharmacy

(2) The number under which the prescription is filed in the pharmacy

(3) The prescribing physician's name

(4) The name of the person for whom the drug was prescribed

(5) The date filled

(6) The name (generic or proprietary) of the medication

(7) The directions for use

(8) The date of expiration of the effectiveness of the drug if this information is required on the original label of the manufacturer.

(9) In addition to the above, the patient shall be informed of his right to have a copy of the drug manufacturer's original information sheet.

b. Each prescription filled by a pharmacy, medical clinic or doctor will contain a printed sheet giving the name of the drug or drugs, what ailment the drug or drugs are being used to treat, and a list of the most common or significant side affects that the drug or drugs are known to cause."

Section 3. Not withstanding any other provisions of law, this Act becomes effective 30 days after enactment.

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