Members:
Rep. Charlie Brown, Chairperson
Rep. Susan Crosby
Rep. Craig Fry
Rep. Vaneta Becker
Rep. Karen Burkhardt
Rep. Phyllis Pond
Sen. Marvin Riegsecker
Sen. Beverly Gard
Sen. Robert Jackman
Sen. Glenn Howard
Sen. Vi Simpson
Sen. Cleo Washington

LSA Staff:

Ann Naughton, Attorney for the Committee
Al Gossard, Fiscal Analyst for the Committee
Ron Sobecki, Fiscal Analyst for the Committee

Authority: ***Legislative Council Resolution 2-1998***

INTERIM STUDY COMMITTEE ON HEALTH ISSUES

Legislative Services Agency
200 West Washington Street, Suite 301
Indianapolis, Indiana 46204-2789
Tel: (317) 232-9588 Fax: (317) 232-2554

MEETING MINUTES

Meeting Date:	September 2, 1998
Meeting Time:	10:00 A.M.
Meeting Place:	State House, 200 W. Washington St., House Chambers
Meeting City:	Indianapolis, Indiana
Meeting Number:	5

Members Present: Rep. Charlie Brown, Chairperson; Rep. Susan Crosby; Rep. Vaneta Becker; Rep. Karen Burkhardt; Rep. Phyllis Pond; Sen. Marvin Riegsecker; Sen. Robert Jackman; Sen. Glenn Howard; Sen. Vi Simpson; Sen. Cleo Washington.

Members Absent: Rep. Craig Fry; Sen. Beverly Gard.

Chairman Brown called the meeting to order at 10:20 A.M. and explained that any action taken on the preliminary drafts discussed during the meeting would need assent by a majority of the members.

Concurrent Resolution Regarding Powdered Latex Gloves[1]
Rep. Brown called for testimony regarding the proposed concurrent resolution on powdered latex gloves. Allison Wharry, Indiana Hospital and Health Association rose in support of the resolution. Adoption of the resolution was moved and seconded and the proposed concurrent resolution was adopted by the Committee by a roll call vote of 9-0.

[1]A copy of the concurrent resolution is on file in the Legislative Information Center, Room 230, State House, Indianapolis, Indiana. The telephone number of the Legislative Information Center, is (317) 232-9856 and the mailing address is 200 W. Washington St., Ste. 301, Indianapolis, Indiana 46204-2789.

PD 3201 - Hospice Licensure[2]
Rep. Brown called for testimony on PD 3201 regarding hospice licensure. Marilyn Cage of the Indiana State Department of Health informed the Committee that the groups involved in the drafting of the proposed legislation are not in complete agreement. Rep. Brown stated that, unless there is agreement on the draft, testimony should not be taken. Rep. Pond made a motion to advance the PD with the knowledge that work will continue on the draft until an agreement is reached. The motion was seconded and carried by a roll call vote of 9-0.

PD 3200 - Generic Drugs[3]
Rep. Brown requested that Sen. Simpson present PD 3200 regarding generic drugs. Sen. Simpson explained that the draft clarifies that only generic substitutions may be made under the generic drugs law. She stated that the draft reinserts language requiring that the customer be informed by the pharmacist when a generic substitution is made.

Rep. Brown requested testimony regarding PD 3200. Bill Keown, Indiana Pharmacists Alliance, rose in support of the draft. In response to questions from Rep. Brown and Rep. Pond, Mr. Keown stated that: 1) he is aware that pharmacists sometimes fill prescriptions with brand name drugs and are only paid for generic drugs because the provider specifies that a brand name drug is necessary, but the patient's insurer will only pay for a generic; 2) he is unaware of any pharmacist substituting generic drugs when the provider has specified that brand name is necessary, regardless of the lower payment; and 3) the draft would require that the pharmacist notify each patient whenever a generic substitution is made.

Grant Monahan, Indiana Retail Council, stated that he had no position on the draft. Mr. Monahan stated that the new provisions in the draft would have no impact on what is currently being done by pharmacists. Mr. Monahan said that he does support the reinsertion of the language requiring the customer to be informed when a substitution is made.

Sen. Simpson explained that the draft is intended to clarify problems with interpretation of the existing law. She stated that most pharmacists do abide by the current law, but the draft is intended to stop misinterpretation by some parties.

Adoption of the draft was moved and seconded and the motion carried on a roll call vote of 9-0.

PD 3172 - Narcotic Treatment Facility Certification[4]
Rep. Brown requested that Bill Soards, Program Management Consultants, discuss PD 3172. Mr. Soards explained that the intent of the draft is to address two issues: 1) allowing input from the public before a narcotic treatment facility is certified; and 2)

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[2]A copy of PD 3201 is on file in the Legislative Information Center (see footnote 1).

[3]A copy of PD 3200 is on file in the Legislative Information Center (see footnote 1).

[4]A copy of PD 3172 is on file in the Legislative Information Center (see footnote 1).

specific criteria which must be considered by the Division of Mental Health when an application is made for certification of a new narcotic treatment facility.

In response to questions from Rep. Brown, Mr. Soards stated that the number of narcotic treatment facilities has tripled in the past 4 years and that public testimony is currently not heard prior to certification. Mr. Soards also discussed what would occur should a contiguous property be a vacant lot. Sen. Howard stated that, based on his experience, he believes that hospitals are a better place for narcotic treatment to take place. Sen. Simpson questioned the breadth of treatments that the definition of "treatment facility" allows and stated that she would want the draft to have limited application to methadone treatment only. Mr. Soards stated that he believes that the draft provides a step toward better control of narcotic treatment facilities.

Lauren Polite, Legislative Liaison, Family and Social Services Administration, and Norma Bradway, Division of Mental Health, spoke regarding several concerns about the content of the draft. Ms. Polite acknowledged that there are more facilities than there were four years ago, but stated that the number has not risen dramatically. She stated that many of the provisions of the draft are already in place including local input, though public input is not currently required. Ms. Polite stated that the public input provision could be addressed through adoption of administrative rules. She explained that quality of services provided by narcotic treatment facilities has not been raised as an issue. She said that the draft would create burdensome requirements such as mailings to individuals, significantly increased documentation by the state, and acquiring the local authority's documentation.

In response to questions from Rep. Brown, Ms. Polite and Ms. Bradway stated that there are four new narcotic treatment facilities with certification pending. Ms. Bradway stated that one of those is in litigation due to neighborhood concerns and another has encountered zoning problems. Ms. Bradway stated that a facility must obtain zoning approval before seeking certification through the Division of Mental Health. Ms. Polite stated that the fiscal impact of the draft would be significant on state and local levels. In response to a question from Sen. Howard, Ms. Polite stated that most current narcotic treatment facilities are for-profit entities. In response to a question from Rep. Pond, Ms. Bradway stated that three currently certified facilities are public facilities and are the only facilities with which the state contracts. She stated that individuals must qualify in order for the state to pay for treatment and that private insurance or the individual pays for treatment for which the state does not pay. In response to a question from Rep. Becker, Ms. Bradway stated that the current certification process starts at the local level with zoning approval. In response to questions from Rep. Brown, Duane O'Neal, Eastside Community Organization/Norton Health Care, explained occurrences in Marion County and in Jeffersonville, Indiana, with regard to zoning approval. Mr. O'Neal stated that Indianapolis/Marion County is the only county that he is aware of that has adopted an ordinance providing for specific locations for methadone clinics.

Rep. Brown requested a motion for action by the Committee. No motion was forthcoming and no action was taken.

PD 3192 - Narrow Therapeutic Index Drugs[5]
Rep. Brown requested that Michael K. Phillips, representing DuPont Pharmaceuticals, explain PD 3192. Mr. Phillips explained the difference between the current draft and the bill heard on this issue during the 1998 legislative session. Mr. Phillips stated that this draft requires that the pharmacist notify the patient and the physician of a substitution, unless the pharmacist refills a prescription with the same drug by the same manufacturer.

In response to questions from Sen. Simpson, Mr. Phillips stated that this draft does not conflict with the generic drugs law, but provides for notification in a particular situation. In response to a question from Rep. Brown, Mr. Phillips explained the action of each drug on the list contained in the draft. He stated that the drugs on the list require finite dosages and proper therapeutic level to properly treat an individual's illness. In response to questions from Sen. Jackman, Rep. Pond, Rep. Brown, Rep. Becker, and Sen. Simpson, Mr. Phillips stated the following: 1) The draft requires that the pharmacist notify the physician and the patient if the pharmacist refills with one generic substitute a prescription originally filled with a different generic substitute; 2) The draft is limited to refills because the drug that the prescription was originally filled with is presumably the drug that the patient was taking at the time of testing for therapeutic levels; 3) The draft does not address testing, but does state that generic substitutions may be made if the physician agrees and the patient is notified; 4) The draft does add an additional responsibility for the pharmacist in filling a prescription for these drugs, but it is the physician's responsibility to determine whether changing manufacturers is appropriate.

Jack Hall, M.D., Practicing Physician, stated that there is usually not that much difference between generic drugs, but that it is important that a patient who is on a certain type and color of drug remain on that specific type and color unless the physician and patient are aware of a change so that accommodations can be made for appropriate treatment. Dr. Hall informed the members that mistakes are more easily made when physicians and patients are not aware of exactly what medication the patient is taking and that color coding by certain manufacturers helps with this.

Sen. Riegsecker stated that he believes that if the pharmacist is required to contact the physician's office when a substitution for one of the listed drugs is made, the physician's office should be required to insert that information in the patient's medical record.

Betty Nelson, Clinical Nurse Coordinator for Anticoagulation, Welborn Hospital, Evansville, Indiana, informed the members that her employment position evolved from a problem encountered at Welborn Hospital in which there was an increased rate of admission of patients on warfarin. She stated that she supports the PD because patients are admitted to the hospital, stabilized on a brand name drug, then sent home on a drug made by a different manufacturer, or the drug is changed to another manufacturer's drug on refill, and stability of therapeutic levels in the patient is compromised by the change, resulting in higher costs of care. In response to questions

[5]A copy of PD 3192 is on file in the Legislative Information Center (see footnote 1).

from Sen. Simpson and Rep. Pond, Ms. Nelson stated that changing from one brand to another should be the physician's decision on a case by case basis, and that the physician should be aware that the substitution is being made, though the physician's staff could insert the information into the patient's medical record.

Randy Prine, DuPont Pharmaceuticals, stated that the intent of the draft is consistency and physician and patient awareness. She stated that confusion arises from pills with different appearances and that incorrect dosing by patients who become confused by the difference is sometimes a result. She went through a list of actions that other states have taken on this issue.

Carol Cox, Barr Laboratories, Inc., rose in opposition to the draft. She responded to the statements made by Ms. Prine regarding other states' actions. Ms. Cox introduced Dr. Marvin Meyer and Ms. Kathleen Jaeger.

Marvin Meyer, Ph.D., Professor, Chair and Associate Dean for Research, College of Pharmacy, University of Tennessee, provided a handout of his testimony.[6] Dr. Meyer discussed the current federal Food and Drug Administration drug approval process, bioequivalence and studies on bioequivalence. He explained the AA, AB, B rating scale used for bioequivalence and concluded that he does not believe that a state law regulating use of this list of drugs is necessary.

Kathleen Jaeger, National Pharmaceutical Alliance, stated that PD 3192 is not necessary. Ms. Jaeger distributed a handout outlining her testimony.[7] She stated that generically equivalent drugs have the same therapeutic benefits and that bioequivalency standards for brand name drugs from lot to lot of that drug are no different than the bioequivalency standards for brand to generic drugs. She informed the Committee that there is no compelling scientific reason for the requirements in the draft. In response to a question from Sen. Washington regarding her statement that restricting generic substitution could cost as much as $19 million annually, Ms. Jaeger stated that random sampling and cost and price differentials were considered in calculation of that figure.

Bill Keown, Indiana Pharmacists Alliance, rose in opposition to the draft. Mr. Keown stated that bioequivalence is established between brand name drugs and generic substitutions. He questioned the manner in which the list of drugs contained in the draft was established and stated that the number of drugs on the list would probably increase over time as more drug companies became involved. Mr. Keown also questioned the review by the Board of Pharmacy and the Medical Licensing Board, which is required by the draft, as those two boards have no authority to approve or change the list. Mr. Keown also stated that the draft adds additional duties for the pharmacist for which no compelling evidence of necessity exists.

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[6]The handout provided by Dr. Meyer is on file in the Legislative Information Center (see footnote 1).

[7]The handout provided by Ms. Jaeger is on file in the Legislative Information Center (see footnote 1).

In response to questions from Rep. Brown and Sen. Simpson, Mr. Keown: 1) acknowledged that the Board of Pharmacy and Medical Licensing Board do have influence via the legislative process; 2) stated that he does not believe that the pharmacist would incur any increased liability as a result of the draft as the pharmacist can meet the requirements of the draft; and 3) explained that the draft does not really give the physician control because it does not state that the physician has to respond to the notice provided for; and 4) stated his belief that the risk of liability from generic substitution of these drugs is low as untoward effects from substitution of these drugs is unlikely.

Rep. Brown asked for a motion for action by the Committee. With no response, no action was taken on the PD.

PD 3195 - State Employee Health Benefits[8]
Rep. Brown informed the Committee that no action would be taken on PD 3195, but that Rep. Dale Grubb would make a statement with regard to the PD. Rep. Grubb stated that the intent of the draft is to improve access to care and improve on problems with the current state employee health benefits program. Rep. Grubb stated that he would like for the parties who had expressed interest in the draft to contact him with suggestions for changes to the draft.

Amendment of July 29, 1998 meeting minutes
Rep. Brown called for consideration of a request for an amendment of the July 29, 1998, minutes concerning the testimony of Dr. Andrew Saxon and Representative Michael Young on latex gloves.[9] After consideration by the Committee, the amendment was adopted by voice vote.

With no further business to discuss, Rep. Brown adjourned the meeting at 12:30 P.M.

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[8]A copy of PD 3195 is on file in the Legislative Information Center (see footnote 1).

[9]A copy of the requested amendment is on file in the Legislative Information Center (see footnote 1).