August 10, 1979

ADAM K. LEVIN, *Director*
Division of Consumer Affairs
1100 Raymond Boulevard
Newark, New Jersey 07102

FORMAL OPINION NO. 17—1979

Dear Director Levin:

You have asked several questions concerning the interpretation and implementation of the New Jersey Prescription Drug Price and Quality Stabilization Act, L. 1977, c. 240, N.J.S.A. 24:6E-1 *et seq.* (hereinafter referred as "the Act"). Each of the questions will be dealt with in order.

I

Your initial inquiry is whether a pharmacist should substitute a generic drug listed on the list of interchangeable drug products (the formulary) in a situation where he has a prescription on a form not imprinted with the two choices: "substitution permissible" and "do not substitute." It is our opinion for the following reasons that a pharmacist should substitute a generic drug listed on the formulary unless the prescriber expressly prohibits substitution.

N.J.S.A. 24:6E-7 provides in pertinent part:

> Every prescription blank shall be imprinted with the words, 'substitution permissible' and 'do not substitute' and shall contain space for the physician's or other authorized prescriber's initials next to the chosen option. Notwithstanding any other law, unless the physician or other authorized prescriber explicitly states that there shall be no substitution when transmitting an oral prescription or, in the case of a written prescription, indicates that there shall be no substitution by initialing the prescription blank next to 'do not substitute' a different brand name or nonbrand name drug product of the same established name shall be dispensed by a pharmacist if such different brand name or nonbrand name drug product shall reflect a lower cost to the consumer and is contained in the latest list of interchangeable drug products published by the council; . . .

N.J.S.A. 24:6E-11 specifies penalties for any violation of the Act, and further provides:

> However, failure of the prescriber to utilize the form of prescription designated in section 8 of this act [N.J.S.A. 24:6E-7] shall not invalidate the prescription as written, if said prescription is otherwise valid.

The question arises whether the words "as written" mean a prescription on a form other than designated by the statute should be followed unless the prescriber expressly permits substitution. An analysis of the

statutory scheme and the underlying legislative history indicates that such an interpretation would be inconsistent with the purposes of the Act.

It is clear from a reading of the statute, N.J.S.A. 24:6E-7 that a prescriber is in each case required to make an express statement that no substitution is permissible. The statute does not require the prescriber to make an express statement that substitution is permissible. An instructive basis for comparison is the New York generic drug law, which states in part:

> (1) A pharmacist shall substitute a less expensive drug product . . . provided that the following conditions are met:
>
> (a) The prescription is written on a form which meets the requirements of subsection six of section sixty-eight hundred ten of this article and the prescriber places his signature above the words 'substitution permissible,' or in the case of oral prescriptions, the prescriber must expressly state that substitution shall be permitted; . . . [N.Y. Educ. Law § 6816a (McKinney).]

Unlike the New York law, the New Jersey law places the burden upon the prescriber to *prohibit* substitution. In the case of an orally transmitted prescription (of necessity not on the required form), the prescriber must explicitly prohibit substitution to prevent it from occurring.

The probable legislative intent expressed in the statutory language is reinforced by the statement on the first version of Assembly Bill No. 2021.

> We must encourage return of doctor-pharmacist health care partnership. Most doctors do not have time, nor facility, to evaluate all drugs they prescribe; pharmacists now make choice under present law, when doctors prescribe generically; a prestigious Drug Research Board's recent resolution urged that physicians be required to delegate product selection to pharmacist *except where doctors explicitly elect to make choice themselves—exactly what this bill provides.* [Emphasis added.]

For these reasons it is our opinion that notwithstanding the actual prescription form used, a pharmacist is required to substitute pursuant to the provisions of the Act unless a prescriber expressly prohibits substitution.

II

You have asked whether a pharmacist may substitute a less expensive generic drug not listed on the formulary without first securing the approval of the prescriber where the prescription specifically indicates "substitution permissible" or "substitute generic." For the following reasons, it is our opinion that a pharmacist must contact and secure the approval of a prescriber prior to substituting a particular drug unless the substituted drug is a less expensive generic equivalent listed on the formulary.

This question turns on the interpretation of N.J.S.A. 24:6E-8, which provides:

> Notwithstanding any other law, where a different brand name or nonbrand name drug product of the same established name shall reflect a lower cost to the consumer and no drug product of such established name is included in the latest list of interchangeable drug products published by the council, or where in the professional judgment of the pharmacist there is no valid proof of efficacy for the drug product prescribed, or the pharmacist's patient profile record discloses drug sensitivity, allergies or adverse reactions to the drug product prescribed, or there exists a more appropriate drug product than the drug product prescribed, a different brand name or nonbrand name drug product shall be dispensed by the pharmacist, provided, however, that such action by a pharmacist shall be authorized only if in each case the pharmacist notifies the prescriber of the drug product to be dispensed and the name of the manufacturer thereof, and receives the approval of the prescriber to substitute such drug product for the drug product prescribed. The pharmacist shall be required to indicate on the prescription the date and time of the prescriber's approval and whether the approval was communicated orally or in writing.

This statutory section was designed to deal with circumstances where a pharmacist desires to substitute a drug which is not listed as equivalent on the formulary. This would be true not only when the intended substitution would be of a lower priced drug but also when a pharmacist determines that a nonequivalent drug should be substituted for medical reasons. In each of these cases, a different drug product "shall be authorized only if in each case the pharmacist notifies the prescriber" of the drug to be dispensed "and receives the approval of the prescriber" to make the substitution.

The specific issue posed here is whether the approval of the prescriber to substitute a drug not listed on the formulary is applicable where a prescriber specifically indicates "substitution permissible" or "substitute generic." An examination of the language of the act and its legislative history indicates that prior approval must be obtained from the prescriber in such cases.

N.J.S.A. 24:6E-8 expressly includes the situation in which:

> a different brand name or nonbrand name drug product of the same established name shall reflect a lower cost to the consumer and no drug product of such established name is included in the latest list of interchangeable drug products. . . .

Where such a situation exists, substitution is "authorized only if *in each case*" the pharmacist first advised the prescriber of the product to be provided, and receives the approval of the prescriber for the specific substitution. It would not be adequate for the prescriber to state in advance "substitution permissible" or "substitute generic," since the prescriber would neither have been advised of nor have approved the actual product being substituted.

An examination of a legislative report reveals an intent to treat equivalent generic drugs not listed on the formulary and nonequivalent drugs recommended by the pharmacist in the same manner. A report prepared by Assemblyman Martin A. Herman (hereinafter referred to as the Herman Report) on Assembly Bill 1257 (an earlier similar version of the bill enacted into law) stated as follows:

> This legislation recognizes that a substantial drug interchange list will not occur overnight. As patents expire, new drugs are manufactured to compete, or a new line of generics appears, there will be a lapse time between this entry into the market place and administrative review.
>
> To meet this problem, and to encourage what should be present good pharmaceutical practices, section (5) requires: that where a doctor prescribes a drug for which there is a lower priced generic equivalent not on the list, or the pharmacist's patient profile record discloses drug sensitivity, allergies or adverse reactions to the drug product prescribed by the patient's physician or for which there is no demonstrated efficacy to the drug prescribed, the pharmacist may substitute the cheaper or more effective drug products, but only with the doctor's prior consent. [Herman Report, p. 7.]

Similarly, the Statement of the Senate Institutions, Health and Welfare Committee accompanying the bill states:

> [A]nother provision of the bill allows the pharmacist to substitute another drug for the prescribed drug, even when the drug to be substituted does not appear on the council's list, *provided* he first obtains the prescriber's approval.

The legislative purpose is clear that a pharmacist is required to obtain the specific approval of a prescriber before substituting a nonequivalent drug for reasons of efficacy, allergies or appropriateness. The legislative intent was to treat such substitutions in precisely the same manner as substitutions of equivalent drugs not listed on the formulary. It is therefore our opinion that unless a substitution is of a less expensive equivalent listed on the formulary, a pharmacist must obtain the approval of the prescriber to substitute such drug product for the product prescribed.

III

You have asked for our opinion as to the treatment of prescriptions written in other states. For the following reasons, you are advised that prescriptions written in other states should be treated under the Act in the same manner as prescriptions written in New Jersey.

Prescriptions written in other states would not generally be set forth in the format called for by the Act. Moreover, a prescriber in another state could not be presumed to have prescribed with the New Jersey Act or formulary in mind. Although the statute expressly provides that such

prescriptions would be valid notwithstanding the failure to utilize the designated form (N.J.S.A. 24:6E-11), the question remains whether such a prescription should be treated in the same manner as a New Jersey prescription with respect to substitution.

One of the policies behind the Act is to require prescribers unfamiliar with available equivalent drug products to make an express choice between the specific product prescribed and a formulary substitution. The presumption is clearly in favor of substitution. This determination having been made, prescriptions written in other states should be treated in the same manner as prescriptions written in New Jersey. The prescriber should be required to expressly prohibit substitution. Since only interchangeable drugs from the formulary may be substituted, unless the prescriber expressly authorizes a specific drug, the public is fully protected.

There are various practical considerations in support of this conclusion. Both the states of New York and Pennsylvania have generic drug laws which require the use of prescription forms containing the words "substitution permissible" or "do not substitute." N.Y. Educ. Law §6816a (1)(a) (McKinney); Pa. Stat. Ann. Tit. 35, §960.3(A) (Purdon). The Pennsylvania statute is similar to the Act in that substitution is mandated unless the prescriber expressly indicates to the contrary. There is a compelling basis for treating Pennsylvania prescriptions in the same manner as those written in New Jersey. Although the New York statute requires a prescriber to expressly authorize substitution, that statute also provides that "in the event a patient chooses to have a prescription filled by an out of state dispenser, the laws of that state shall prevail." N.Y. Educ. Law, §6816a(2). Therefore, in the case of a prescription written in New York State, the laws of that jurisdiction would call for the application of the New Jersey Act.

It is consequently clear that the substantial majority of prescriptions written in other states and received by New Jersey pharmacists will have been written in states whose own laws favor the treatment of those prescriptions in accordance with the New Jersey statute. We cannot assume that the legislature intended a contrary result. It is therefore our opinion that prescriptions written in other states and presented to pharmacists in New Jersey are to be treated in all respects in the same manner as prescriptions written in New Jersey.

IV

You have asked whether a pharmacist should dispense a less expensive generic drug listed on the formulary in a situation where the prescription specifies an inexpensive generic drug by its brand name. It is our opinion for the following reasons that where a pharmacist has a less expensive generic drug listed on the formulary in stock, he is under an obligation to substitute the less expensive generic drug even where the prescription calls for a relatively inexpensive branded generic.

The significance of this inquiry can be illustrated by reference to certain facts before the legislature in its consideration of this enactment. There was a general recognition that many major drug manufacturers who produce branded drugs also produced so-called "branded generics":

> [T]his class of drug is characterized by having a significantly lower price than the long established brand or brands but still bearing the name of a reputable maker. . . . *These drugs cost more than true generics* and acutally represent some drug manufacturer's answer to the increase in generic prescribing by physicians.
>
> . . . .
>
> One would assume that in addition to the extra profit that may be made by establishing a drug product line designated as a 'Branded Generic' are these considerations: . . . that acknowledging among themselves that generically equivalent drugs can be produced at much lower costs, that while they will so promote their product to doctor and pharmacist alike, 'Branded Generic' is another way of still holding out . . . 'that only brand names will do the job . . .'—'*Prescribe generically . . . but not quite generically . . .*' In other words, use our product. *Don't compare price.* We'll do it for you. [Herman Report, pp. 42-44.] [Emphasis added.]

The issue therefore posed is whether a pharmacist must substitute a lower priced generic drug for the prescribed "branded generic" where the branded generic is not the lowest priced product listed on the formulary. The language of the statute as well as the legislative history expressed in the Herman Report indicates that such a substitution should be made. N.J.S.A. 24:6E-7 states that "a different brand name or nonbrand name drug shall be dispensed" by the pharmacist if the product "shall reflect a lower cost to the consumer" and is contained on the formulary. In addition, the Herman Report reflects the understanding that true generics generally are less expensive than branded generics and an implicit purpose to maximize consumer savings. There is no expression of legislative purpose to exempt prescriptions for branded generics from the requirements of the Act where a less expensive equivalent true generic drug is available for sale to the consumer.

It should be parenthetically noted that the Act is designed towards assuring the safety and interchangeability of all drugs listed on the formulary. *See* N.J.S.A. 24:6E-6. Where a pharmacist has a lower priced listed generic equivalent in stock, there would be no reason to deny the consumer the savings of the true generic. Although a consumer may opt for a branded generic, the statute is quite clear that this is a choice to be made by the consumer. *See* N.J.S.A. 24:6E-7. You are therefore advised that where a pharmacist has a less expensive generic drug listed on the formulary in stock, he is under an obligation to substitute the less expensive generic drug, even where the prescription calls for a relatively inexpensive branded generic.

* * *

In summary, you are advised with respect to all of your inquiries as follows: The Act requires substitution of a less expensive generic drug product listed on the formulary for the brand product prescribed, unless the prescriber expressly prohibits substitution. This is true even where a prescription, whether written in New Jersey or out of state, does not use

the form of prescription set forth in the Act. Where a pharmacist desires to substitute a drug product not listed on the formulary including the substitution of a less expensive equivalent drug product, a pharmacist must obtain the specific prior approval of a prescriber even where express general authorization for generic substitution has been given. Finally, substitution is mandated where a prescription calls for a relatively inexpensive branded generic drug and the pharmacist has in stock a less expensive generic drug listed on the formulary.

Very truly yours,
JOHN J. DEGNAN
Attorney General
By: THEODORE A. WINARD
Assistant Attorney General

August 28, 1979

GEORGE H. BARBOUR, *President*
Board of Public Utilities
101 Commerce Street
Newark, New Jersey 07102

FORMAL OPINION NO. 18—1979

Dear President Barbour:

You have inquired as to whether the Hackensack Meadowlands Development Commission (HMDC) can direct the flow of solid waste sought to be disposed of in the Hackensack Meadowlands District (District), to specific waste disposal facilities within said District. It is our opinion that N.J.S.A. 13:17-1 *et seq.* vests such authority in the HMDC.

The HMDC was established in 1968 by the enactment of the Hackensack Meadowlands Reclamation and Development Act, N.J.S.A. 13:17-1 *et seq.* (hereinafter the "Act"), to oversee the orderly, comprehensive reclamation and development of approximately 21,000 acres of marsh and meadowlands which were declared to be a "land resource of incalculable opportunity for new jobs, homes and recreational sites, N.J.S.A. 13:17-1. The Legislature declared that these land resources needed "special protection from air and water pollution and *special* arrangement for the provision of facilities for the disposal of solid waste". *Id.* (Emphasis added.) Thus, solid waste managment in the District was to be one of HMDC's main concerns and the Act vested it with broad authority to deal with this problem. N.J.S.A. 13:17-1 et seq.; *Mun. San. Landfill Auth. v. HMDC,* 120 N.J. Super. 118 (App. Div. 1972); *Kearny v. Jersey City Incinerator Auth.,* 140 N.J. Super. 279 (Ch. Div. 1976).

The Act authorizes the HMDC to formulate a master plan for development in the District. In doing so it must provide disposal facilities for solid waste generated within or brought into the District. N.J.S.A. 13:17-10; N.J.S.A. 13:17-11. The HMDC is also authorized to adopt codes