

Republic of the Philippines Supreme Court Manila

SECOND DIVISION

REPUBLIC OF THE PHILIPPINES, represented by the BUREAU OF FOOD AND DRUGS (now FOOD AND DRUG

Petitioner,

- versus -

ADMINISTRATION),

DRUGMAKER'S LABORATORIES, INC. and TERRAMEDIC, INC.,

Respondents.

G.R. No. 190837

Present:

CARPIO, *J.*, Acting Chief Justice,*
Chairperson,

BRION, DEL CASTILLO, PEREZ, and

PERLAS-BERNABE, JJ.

Promulgated:

MAR 0 5 2014 dl Walcabaliag Porfectio

DECISION

PERLAS-BERNABE, J.:

This is a direct recourse to the Court from the Regional Trial Court of Muntinlupa City, Branch 256 (RTC), through a petition for review on certiorari, raising a pure question of law. In particular, petitioner Republic of the Philippines, represented by the Bureau of Food and Drugs (BFAD), now Food and Drug Administration (FDA), assails the Order dated December 18, 2009 of the RTC in Civil Case No. 08-124 which: (a) declared BFAD Circular Nos. 1 and 8, series of 1997 (Circular Nos. 1 and 8, s. 1997) null and void; (b) ordered the issuance of writs of permanent injunction and prohibition against the FDA in implementing the aforesaid circulars; and (c) directed the FDA to issue Certificates of Product Registration (CPR) in favor of respondents Drugmaker's Laboratories, Inc. and Terramedic, Inc. (respondents).

Designated Acting Chief Justice per Special Order No. 1644 dated February 25, 2014.

Rollo, pp. 9-70.

Id. at 71-98. Penned by Acting Presiding Judge Romulo SG. Villanueva.

The Facts

The FDA³ was created pursuant to Republic Act No. (RA) 3720,⁴ otherwise known as the "Food, Drug, and Cosmetic Act," primarily in order "to establish safety or efficacy standards and quality measures for foods, drugs and devices, and cosmetic product[s]."5 On March 15, 1989, the Department of Health (DOH), thru then-Secretary Alfredo R.A. Bengzon, issued Administrative Order No. (AO) 67, s. 1989, entitled "Revised Rules and Regulations on Registration of Pharmaceutical Products." Among others, it required drug manufacturers to register certain drug and medicine products with the FDA before they may release the same to the market for sale. In this relation, a satisfactory bioavailability⁶/bioequivalence⁷ (BA/BE) test is needed for a manufacturer to secure a CPR for these products. However, the implementation of the BA/BE testing requirement was put on hold because there was no local facility capable of conducting the same. The issuance of Circular No. 1, s. 19978 resumed the FDA's implementation of the BA/BE testing requirement with the establishment of BA/BE testing facilities in the country. Thereafter, the FDA issued Circular No. 8, s. 1997⁹ which provided additional implementation details concerning the BA/BE testing requirement on drug products.¹⁰

Respondents manufacture and trade a "multisource pharmaceutical product" with the generic name of *rifampicin*¹² – branded as "*Refam 200mg/5mL Suspension*" (*Refam*) – for the treatment of adults and children

Executive Order No. 851 (1982) abolished the FDA and created the BFAD in its stead. However, with the enactment of RA 9711, otherwise known as the "Food and Drug [FDA] Act of 2009," the BFAD was renamed back to the FDA.

⁵ http://www.fda.gov.ph/about-food-and-drug-administration (visited January 28, 2014).

⁴ Entitled "An Act to Ensure the Safety and Purity of Foods, Drugs, and Cosmetics Being Made Available to the Public by Creating the Food and Drug Administration which shall Administer and Enforce the Laws Pertaining Thereto."

⁶ "Bioavailability" means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action. (Section 10[z] of RA 3720, as amended by Section 9 of RA 9711.)

[&]quot;Bioequivalence" means the rate and extent of absorption to which the drugs do not show a significant difference from the rate and extent of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses. Bioequivalence shall also refer to the absence of a significant difference on the rate and extent to which the active ingredient(s) of the sample and reference drug becomes available at the site of drug action when administered under the same molar dose and under similar conditions. (Section 10[aa] of RA 3720, as amended by Section 9 of RA 9711.)

Entitled "Enforcement of the Requirement for Bio-Availability Studies for Registration of Products included in the List B' (Prime) under DOH – Administrative Order 67 Series of 1989."

Entitled "IMPLEMENTATION DETAILS OF BFAD CIRCULAR NO. 1 s. 1997."

¹⁰ *Rollo*, pp. 260-267.

[&]quot;Multisource pharmaceutical products" refers to pharmaceutically equivalent or pharmaceutically alternative products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable. (Section 4[h] of RA 9502, otherwise known as the "Universally Accessible Cheaper and Quality Medicines Act of 2008.")

Rifampicin is a medicine which is used in certain types of bacterial infections and tuberculosis. http://www.nhs.uk/medicineguides/pages/MedicineOverview.aspx?condition=Tuberculosis&medicine=Rifampicin (visited January 28, 2014).

suffering from pulmonary and extra-pulmonary tuberculosis.¹³ On November 15, 1996, respondents applied for and were issued a CPR for such drug, valid for five (5) years, or until November 15, 2001.¹⁴ At the time of the CPR's issuance, *Refam* did not undergo BA/BE testing since there was still no facility capable of conducting BA/BE testing. Sometime in 2001, respondents applied for and were granted numerous yearly renewals of their CPR for *Refam*, which lasted until November 15, 2006, albeit with the condition that they submit satisfactory BA/BE test results for said drug.¹⁵

Accordingly, respondents engaged the services of the University of the Philippines' (Manila) Department of Pharmacology and Toxicology, College of Medicine to conduct BA/BE testing on *Refam*, the results of which were submitted to the FDA.¹⁶ In turn, the FDA sent a letter dated July 31, 2006 to respondents, stating that *Refam* is "not bioequivalent with the reference drug." This notwithstanding, the FDA still revalidated respondents' CPR for *Refam* two (2) more times, effective until November 15, 2008, the second of which came with a warning that no more further revalidations shall be granted until respondents submit satisfactory BA/BE test results for *Refam*.¹⁸

Instead of submitting satisfactory BA/BE test results for *Refam*, respondents filed a petition for prohibition and annulment of Circular Nos. 1 and 8, s. 1997 before the RTC, alleging that it is the DOH, and not the FDA, which was granted the authority to issue and implement rules concerning RA 3720. As such, the issuance of the aforesaid circulars and the manner of their promulgation contravened the law and the Constitution.¹⁹ They further averred that that the non-renewal of the CPR due to failure to submit satisfactory BA/BE test results would not only affect *Refam*, but their other products as well.²⁰

During the pendency of the case, RA 9711,²¹ otherwise known as the "Food and Drug Administration [FDA] Act of 2009," was enacted into law.

¹³ *Rollo*, p. 268.

¹⁴ Id. at 268 and 336-337.

¹⁵ Id. at 269 and 337-338.

¹⁶ Id. at 268-269 and 341-342.

¹⁷ Id. at 269-270 and 342.

¹⁸ Id. at 270-271, 338, and 344-345.

¹⁹ Id. at 71.

Such as: (a) Metoprolol Tartrate 50mg Tablet; (b) Atenolol (Aloten) 50mg Tablet; (c) Pyrazinamide (Pyramin)125mg/5mL Suspension, (d) Metformin Hydrochloride 500mg Tablet; (e) Nifedipine 10mg Capsule; (f) Gliclazide 80mg Tablet; (g) Diltiazem Hydrochloride 90mg Capsule; and (h) Theophylline 200mg Tablet. (Id. at 335.)

Entitled "An Act Strengthening and Rationalizing the Regulatory Capacity of the Bureau of Food and Drugs (BFAD) by Establishing Adequate Testing Laboratories and Field Offices, Upgrading its Equipment, Augmenting its Human Resource Complement, Giving Authority to Retain its Income, Renaming it the Food and Drug Administration (FDA), Amending Certain Sections of Republic Act No. 3720, As Amended, and Appropriating Funds Thereof."

The RTC Ruling

In an Order²² dated December 18, 2009, the RTC ruled in favor of respondents, and thereby declared Circular Nos. 1 and 8, s. 1997 null and void, ordered the issuance of writs of permanent injunction and prohibition against the FDA in implementing the aforesaid circulars, and directed the FDA to issue CPRs in favor of respondents' products.

The RTC held that there is nothing in RA 3720 which granted either the FDA the authority to issue and implement the subject circulars, or the Secretary of Health the authority to delegate his powers to the FDA. For these reasons, it concluded that the issuance of Circular Nos. 1 and 8, s. 1997 constituted an illegal exercise of legislative and administrative powers and, hence, must be struck down.²³

Accordingly, the RTC issued a Writ of Permanent Injunction²⁴ dated January 19, 2010, enjoining the FDA and all persons acting for and under it from enforcing Circular Nos. 1 and 8, s. 1997 and directing them to approve the renewal and revalidation of respondents' products without submitting satisfactory BA/BE test results.

Aggrieved, the FDA sought direct recourse to the Court through the instant petition with an urgent prayer for the immediate issuance of a temporary restraining order and/or a writ of preliminary injunction against the implementation of the RTC's Order dated December 18, 2009 and Writ of Permanent Injunction dated January 19, 2010.²⁵ The Court granted FDA's application and issued a Temporary Restraining Order²⁶ dated February 24, 2010, effective immediately and continuing until further orders.

The Issue Before the Court

The primordial issue in this case is whether or not the FDA may validly issue and implement Circular Nos. 1 and 8, s. 1997. In resolving this issue, there is a need to determine whether or not the aforesaid circulars partake of administrative rules and regulations and, as such, must comply with the requirements of the law for its issuance.

The FDA contends that it has the authority to issue Circular Nos. 1 and 8, s. 1997 as it is the agency mandated by law to administer and enforce

²² *Rollo*, pp. 71-98.

²³ Id. at 91-98.

²⁴ Id. at 100.

²⁵ Id. at 9-69.

²⁶ Id. at 103-105.

laws, including rules and regulations issued by the DOH, that pertain to the registration of pharmaceutical products.²⁷

For their part, respondents maintain that under RA 3720, the power to make rules to implement the law is lodged with the Secretary of Health, not with the FDA.²⁸ They also argue that the assailed circulars are void for lack of prior hearing, consultation, and publication.²⁹

The Court's Ruling

The petition is meritorious.

Administrative agencies may exercise quasi-legislative or rule-making powers only if there exists a law which delegates these powers to them. Accordingly, the rules so promulgated must be within the confines of the granting statute and must involve no discretion as to what the law shall be, but merely the authority to fix the details in the execution or enforcement of the policy set out in the law itself, so as to conform with the doctrine of separation of powers and, as an adjunct, the doctrine of non-delegability of legislative power. ³⁰

An administrative regulation may be classified as a legislative rule, an interpretative rule, or a contingent rule. **Legislative rules** are in the nature of subordinate legislation and designed to implement a primary legislation by providing the details thereof.³¹ They usually implement existing law, imposing general, extra-statutory obligations pursuant to authority properly delegated by Congress³² and effect a change in existing law or policy which affects individual rights and obligations.³³ Meanwhile, **interpretative rules** are intended to interpret, clarify or explain existing statutory regulations under which the administrative body operates. Their purpose or objective is merely to construe the statute being administered and purport to do no more than interpret the statute. Simply, they try to say what the statute means and refer to no single person or party in particular but concern all those belonging to the same class which may be covered by the said rules.³⁴ Finally, **contingent rules** are those issued by an administrative authority

See FDA's Memorandum dated February 8, 2011; id. at 275-291.

²⁸ See respondents' Memorandum dated March 2, 2011; id. at 381-408.

²⁹ Id. at 408-412.

See *Holy Spirit Homeowners Association v. Sec. Defensor*, 529 Phil. 573, 585 (2006) and Nachura, Antonio E. B., *Outline Reviewer in Political Law* (2009), p. 415.

Commissioner of Internal Revenue v. Court of Appeals, 329 Phil. 987, 1007 (1996), citing Misamis Oriental Association of Coco Traders, Inc. v. Department of Finance Secretary, G.R. No. 108524, November 10, 1994, 238 SCRA 63, 69.

First National Bank of Lexington, Tennessee v. Sanders, 946 F. 2d 1185 (1991).

³³ Animal Legal Defense Fund v. Quigg and Verity, 932 F. 2d 920, 18 USPQ. 2d 1677 (1991).

Commissioner of Internal Revenue v. CA, supra note 31, see Separate Opinion of Associate Justice Josue Bellosillo, at 1018.

based on the existence of certain facts or things upon which the enforcement of the law depends.³⁵

In general, an administrative regulation needs to comply with the requirements laid down by Executive Order No. 292, s. 1987, otherwise known as the "Administrative Code of 1987," on prior notice, hearing, and publication in order to be valid and binding, except when the same is merely an interpretative rule. This is because "[w]hen an administrative rule is merely interpretative in nature, its applicability needs nothing further than its bare issuance, for it gives no real consequence more than what the law itself has already prescribed. When, on the other hand, the administrative rule goes beyond merely providing for the means that can facilitate or render least cumbersome the implementation of the law but substantially increases the burden of those governed, it behooves the agency to accord at least to those directly affected a chance to be heard, and thereafter to be duly informed, before that new issuance is given the force and effect of law."³⁶

In the case at bar, it is undisputed that RA 3720, as amended by Executive Order No. 175, s. 1987³⁷ prohibits, *inter alia*, the manufacture and sale of pharmaceutical products without obtaining the proper CPR from the FDA.³⁸ In this regard, the FDA has been deputized by the same law to accept applications for registration of pharmaceuticals and, after due course, grant or reject such applications.³⁹ To this end, the said law expressly authorized

Section 11. The following acts and the causing thereof are hereby prohibited:

XXXX

(j) The manufacture, importation, exportation, sale, offering for sale, distribution, or transfer of any drug or device which is not registered with the Bureau pursuant to this Act.

Section 21-B. No drugs or device shall be manufactured, sold, offered for sale, imported, exported, distributed or transferred, unless registered by the manufacturer, importer or distributor thereof in accordance with rules and regulations promulgated by the Secretary pursuant to this Act. The provisions of Section 21 (b), (d) and (e), to the extent applicable, shall govern the registration of such drugs and devices.

³⁹ Section 4(a), (c), and (e) of RA 3720, provides:

Section 4. To carry out the provisions of this Act, there is hereby created an office to be called the Food and Drug Administration in the Department of Health. Said Administration shall be under the Office of the Secretary and shall have the following functions, powers, and duties:

(a) To administer and supervise the implementation of this Act and of the rules and regulations issued pursuant to the same.

Nachura, Antonio E. B., Outline Reviewer in Political Law (2009), p. 416, citing Cruz v. Youngberg, 56 Phil. 234 (1931). See also ABAKADA GURO Party List (formerly AASJS) v. Hon. Purisima, 584 Phil. 246, 282-283 (2008).

Commissioner of Customs v. Hypermix Feeds Corporation, G.R. No. 179579, February 1, 2012, 664 SCRA 666, 675, citing Commissioner of Internal Revenue v. Michel J. Lhuiller Pawnshop, Inc., 453 Phil. 1043, 1058 (2003).

Entitled "Further Amending Republic Act No. 3720, entitled 'An Act to Ensure the Safety and Purity of Foods, Drugs, and Cosmetics Being Made Available to the Public by Creating the Food and Drug Administration which shall Administer and Enforce the Laws Pertaining Thereto,' As Amended, and For Other Purposes."

Sections 11(j) and 21-B of RA 3720, as amended, provide:

the Secretary of Health, upon the recommendation of the FDA Director, to issue rules and regulations that pertain to the registration of pharmaceutical products.⁴⁰

In accordance with his rule-making power under RA 3720, the Secretary of Health issued AO 67, s. 1989 in order to provide a comprehensive set of guidelines covering the registration of pharmaceutical products. AO 67, s. 1989, required, among others, that certain

X X X X

(c) To analyze and inspect food, drug and cosmetic in connection with the implementation of this Act.

 $\mathbf{X} \ \mathbf{X} \ \mathbf{X} \ \mathbf{X}$

(e) To issue certificate of compliance with technical requirements to serve as basis for the issuance of license and spot-check for compliance with regulations regarding operation of food, drug and cosmetic manufacturers and establishments.

Section 21of RA 3720, as amended, provides:

Section 21. (a) No person shall manufacture, sell, offer for sale, import, export, distribute or transfer any drug or device, unless an application filed pursuant to subsection (b) hereof is effective with respect to such drug or device. (b) Any person may file with the Secretary, through the Bureau, an application under oath with respect to any drug or device subject to the provisions of subsection (a) hereof. Such persons shall submit to the Secretary through the Bureau: (1) full reports of investigations which have been made to show whether or not such drug or device is safe, efficacious and of good quality for use based on clinical studies conducted in the Philippines; (2) a full list of the articles used as components of such drug or device; (3) a full statement of the composition of such drug or device; (4) a full description of the methods used in and the facilities and controls used for the manufacture of such drug or device; (5) such samples of such drug or device and of the articles used as components thereof as the Secretary may require; (6) specimens of the labeling proposed to be used for such drug or device; and (7) such other requirements as may be prescribed by regulations to ensure the safety, efficacy and good quality of such drug or device.

x x x x

- b. If the Secretary finds, after due notice to the applicant and giving him an opportunity for a hearing, that (1) the reports of the investigations which are required to be submitted to the Secretary pursuant to subsection (b) hereof, do not include adequate tests by all methods reasonably applicable to show whether or not such drug or device is safe, efficacious and of good quality for use under the conditions prescribed, recommended, or suggested in the proposed labelling thereof; x x x he shall issue an order disapproving the application.
- c. The effectiveness of an application with respect to any drug or device shall, after due notice and opportunity for hearing to the applicant, by order of the Secretary be suspended if the Secretary finds [sic] that clinical experience, tests by new methods, or tests by methods not deemed reasonably applicable when such application became effective show that such drug or device is unsafe or ineffective for use under the conditions used upon the basis of which the application contains any untrue statement of a material fact. The order shall state the findings upon which it is based.

x x x x

Section 26(a) of RA 3720, as amended, provides:

Section 26. (a) Except as otherwise provided in this section, the Secretary of Health shall, upon recommendation of the Director, issue rules and regulations as may be necessary to enforce effectively the provisions of this Act. The rules and regulations shall provide for, among others, the banning, recalling or withdrawing from the market drugs and devices which are not registered, unsafe, inefficacious or of doubtful therapeutic value, the adoption of an official National Drug Formulary, and the use of generic names in the labeling of drugs.

pharmaceutical products undergo BA/BE testing prior to the issuance of CPR, contrary to respondents' assertion that it was Circular Nos. 1 and 8, s. 1997 that required such tests.⁴¹

Despite the fact that the BA/BE testing requirement was already in place as early as the date of effectivity of AO 67, s. 1989, its implementation was indefinitely shelved due to lack of facilities capable of conducting the same. It was only sometime in 1997 when technological advances in the country paved the way for the establishment of BA/BE testing facilities, thus allowing the rule's enforcement. Owing to these developments, the FDA (then, the BFAD) issued Circular No. 1, s. 1997, the full text of which reads:

In Annex 1 of A.O. 67 s. 1989 which is entitled Requirement for Registration provides that "Bioavailability/Bioequivalence study for certain drugs as determined by BFAD" is required for [(i)] Tried and Tested Drug, (ii) Established Drug, and (iii) Pharmaceutical Innovation of Tried and Tested or Established Drug.

Drugs requiring strict precaution in prescribing and dispensing contained in the List-B (Prime) were the drugs identified by BFAD in the process registration be of that will required "Bioavailability/Bioequivalence" studies. However, due supervening factor that there had yet been no bioavailability testing unit in the country when the A.O. 67 s. 1989 became effective, the Bureau did not strictly enforce the said requirement.

The supervening factor no longer exist [sic] as of date. As a matter of fact, one of the registered products tested by the Bioavailability Testing Unit at the University of Sto. Tomas under the NDP Cooperation Project of the Philippines and Australia failed to meet the standard of bioavailability. This finding brings forth the fact that there may be registered products which do not or may no longer meet bioavailability standard.

Wherefore, all drugs manufacturers, traders, distributor-importers of products contained or identified in the list b' (prime) provided for by BFAD, a copy of which is made part of this circular, are advised that all pending initial and renewal registration of the products aforementioned, as well as all applications for initial and renewal registration of the same, shall henceforth be required to submit bioavailability test with satisfactory results on the products sought to be registered or renewed conducted by any bioavailability testing units here or abroad, duly recognized by the BFAD under the Dept. of Health. (Emphases and underscoring supplied)

The FDA then issued Circular No. 8, s. 1997 to supplement Circular No. 1, s. 1997 in that it reiterates the importance of the BA/BE testing requirement originally provided for by AO 67, s. 1989.

See Annex I, Specific Requirements 3.2 and 5.2, and Annex II of AO 67 (1989).

A careful scrutiny of the foregoing issuances would reveal that AO 67, s. 1989 is actually the rule that originally introduced the BA/BE testing requirement as a component of applications for the issuance of CPRs covering certain pharmaceutical products. As such, it is considered an administrative regulation – a legislative rule to be exact – issued by the Secretary of Health in consonance with the express authority granted to him by RA 3720 to implement the statutory mandate that all drugs and devices should first be registered with the FDA prior to their manufacture and sale. Considering that neither party contested the validity of its issuance, the Court deems that AO 67, s. 1989 complied with the requirements of prior hearing, notice, and publication pursuant to the presumption of regularity accorded to the government in the exercise of its official duties.⁴²

On the other hand, Circular Nos. 1 and 8, s. 1997 cannot be considered as administrative regulations because they do not: (a) implement a primary legislation by providing the details thereof; (b) interpret, clarify, or explain existing statutory regulations under which the FDA operates; and/or (c) ascertain the existence of certain facts or things upon which the enforcement of RA 3720 depends. In fact, the only purpose of these circulars is for the FDA to administer and supervise the implementation of the provisions of AO 67, s. 1989, including those covering the BA/BE testing requirement, consistent with and pursuant to RA 3720. Therefore, the FDA has sufficient authority to issue the said circulars and since they would not affect the substantive rights of the parties that they seek to govern – as they are not, strictly speaking, administrative regulations in the first place – no prior hearing, consultation, and publication are needed for their validity.

In sum, the Court holds that Circular Nos. 1 and 8, s. 1997 are valid issuances and binding to all concerned parties, including the respondents in this case.

As a final note, while the proliferation of generic drugs and medicines is indeed a welcome development as it effectively ensures access to affordable quality drugs and medicines for all through their lower prices, the State, through the FDA, which is the government instrumentality tasked on this matter, must nevertheless be vigilant in ensuring that the generic drugs and medicines released to the market are safe and effective for use.

WHEREFORE, the petition is GRANTED. The Order dated December 18, 2009 and the Writ of Permanent Injunction dated January 19, 2010 of the Regional Trial Court of Muntinlupa City, Branch 256 in Civil Case No. 08-124 are hereby SET ASIDE. BFAD Circular Nos. 1 and 8,

See Section 3(m), Rule 131 of the Rules of Court.

⁴³ See Section 4 of RA 3720.

series of 1997 are declared **VALID**. Accordingly, the Court's Temporary Restraining Order dated February 24, 2010 is hereby made **PERMANENT**.

SO ORDERED.

ESTELA M. HERLAS-BERNABE

Associate Justice

WE CONCUR:

ANTONIO T. CARPIO

Acting Chief Justice Chairperson

ARTURO D. BRION

Associate Justice

MARIANO C. DEL CASTILLO

Associate Justice

JOSE PORTUGAL PEREZ

Associate Justice

CERTIFICATION

Pursuant to Section 13, Article VIII of the Constitution, I certify that the conclusions in the above Decision had been reached in consultation before the case was assigned to the writer of the opinion of the Court's Division.

ANTONIO T. CARPIO Acting Chief Justice