

SECOND DIVISION

[G.R. No. 190837, March 05, 2014]

**REPUBLIC OF THE PHILIPPINES, REPRESENTED BY THE BUREAU
OF FOOD AND DRUGS (NOW FOOD AND DRUG
ADMINISTRATION), PETITIONER, VS. DRUGMAKER'S
LABORATORIES, INC. AND TERRAMEDIC, INC., RESPONDENTS.**

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*,^[1] 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^[2] 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).

The Facts

The FDA^[3] 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 bioavailability^[6]/bioequivalence^[7] (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. 1997^[8] 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. 1997^[9] which provided additional implementation details concerning the BA/BE testing requirement on drug products.^[10]

Respondents manufacture and trade a "multisource pharmaceutical product"^[11]

with the generic name of *rifampicin*^[12] – branded as "*Refam 200mg/5mL Suspension*" (*Refam*) – for the treatment of adults and children 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."^[17] 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.

The RTC Ruling

In an Order^[22] 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 Injunction^[24] 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 Order^[26] 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 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 Congress^[32] 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 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. 1987^[37] 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 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 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 of registration that will be required "Bioavailability/Bioequivalence" studies. **However, due to the 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.

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