793 Phil. 831

SECOND DIVISION

[G.R. No. 217872, August 24, 2016]

ALLIANCE FOR THE FAMILY FOUNDATION, PHILIPPINES, INC. (ALFI) AND ATTY. MARIA CONCEPCION S. NOCHE, IN HER OWN BEHALF AND AS PRESIDENT OF ALFI, JOSE S. SANDEJAS, ROSIE B. LUISTRO, ELENITA S.A. SANDEJAS, EMILY R. LAWS, EILEEN Z. ARANETA, SALVACION C. MONTIERO, MARIETTA C. GORREZ, ROLANDO M. BAUTISTA, RUBEN T. UMALI AND MILDRED C. CASTOR, PETITIONERS, VS. HON. JANETTE L. GARIN, SECRETARY-DESIGNATE OF THE DEPARTMENT OF HEALTH, NICOLAS B. LUTERO III, ASSISTANT SECRETARY OF HEALTH, OFFICER-IN-CHARGE, FOOD AND DRUG ADMINISTRATION, AND MARIA LOURDES C. SANTIAGO, OFFICER-IN-CHARGE, CENTER FOR DRUG REGULATION AND RESEARCH, RESPONDENTS.

[G.R. No. 221866]

MARIA CONCEPCION S. NOCHE, IN HER OWN BEHALF AND AS COUNSEL OF PETITIONERS, JOSE S. SANDEJAS, ROSIE B. LUISTRO, ELENITA S.A. SANDEJAS, EMILY R. LAWS, EILEEN Z. ARANETA, SALVACION C. MONTIERO, MARIETTA C. GORREZ, ROLANDO M. BAUTISTA, RUBEN T. UMALI AND MILDRED C. CASTOR, PETITIONERS, VS. HON. JANETTE L. GARIN, SECRETARY-DESIGNATE OF THE DEPARTMENT OF HEALTH, NICOLAS B. LUTERO III, ASSISTANT SECRETARY OF HEALTH, OFFICER-IN-CHARGE, FOOD AND DRUG ADMINISTRATION, AND MARIA LOURDES C. SANTIAGO, OFFICER-IN-CHARGE, CENTER FOR DRUG REGULATION AND RESEARCH, RESPONDENTS.

D E C I S I O N

MENDOZA, J.:

Subjects of this disposition are the: [1] Petition for *Certiorari*, Prohibition, Mandamus - with Prayer for Issuance of a Temporary Restraining Order and/or Writ of Preliminary Prohibitory and Mandatory Injunction (G.R. No. 217872); and the [2] Petition for Contempt of Court (G.R. No. 221866).

The subject petitions sprouted from *Imbong v. Ochoa* and other cases[1] (*Imbong*) where the Court declared Republic Act No. 10354 (*RH Law*) and its Implementing Rules and Regulations (*RH-IRR*) as not unconstitutional, save for several provisions which were declared as violative of the Constitution. The decretal portion of *Imbong* reads:

> WHEREFORE, the petitions are PARTIALLY GRANTED. Accordingly, the Court declares R.A. No. 10354 as NOT UNCONSTITUTIONAL except with

respect to the following provisions which are declared UNCONSTITUTIONAL:

1] Section 7 and the corresponding provision in the RH-IRR insofar as they: a) require private health facilities and non-maternity specialty hospitals and hospitals owned and operated by a religious group to refer patients, not in an emergency or life-threatening case, as defined under Republic Act No. 8344, to another health facility which is conveniently accessible; and b) allow minor-parents or minors who have suffered a miscarriage access to modem methods of family planning without written consent from their parents or guardian/s;

2) Section 23(a)(1) and the corresponding provision in the RH-IRR, particularly Section 5.24 thereof, insofar as they punish any healthcare service provider who fails and or refuses to disseminate information regarding programs and services on reproductive health regardless of his or her religious beliefs;

3) Section 23(a)(2)(i) and the corresponding provision in the RH-IRR insofar as they allow a married individual, not in an emergency or life-threatening case, as defined under Republic Act No. 8344, to undergo reproductive health procedures without the consent of the spouse;

4) Section 23(a)(2)(ii) and the corresponding provision in the RH-IRR insofar as they limit the requirement of parental consent only to elective surgical procedures;

5] Section 23(a)(3) and the corresponding provision in the RH-IRR, particularly Section 5.24 thereof, insofar as they punish any healthcare service provider who fails and/or refuses to refer a patient not in an emergency or life-threatening case, as defined under Republic Act No. 8344, to another health care service provider within the same facility or one which is conveniently accessible regardless of his or her religious beliefs;

6] Section 23(b) and the corresponding provision in the RH-IRR, particularly Section 5.24 thereof, insofar as they punish any public officer who refuses to support reproductive health programs or shall do any act that hinders the full implementation of a reproductive health program, regardless of his or her religious beliefs;

7] Section 17 and the corresponding provision in the RH-IRR regarding the rendering of pro bona reproductive health service in so far as they affect the conscientious objector in securing PhilHealth accreditation; and 8] Section 3.01(a) and Section 3.01(g) of the RH-IRR, which added the qualifier "primarily" in defining abortifacients and contraceptives, as they are *ultra vires* and, therefore, null and void for contravening Section 4(a) of the RH Law and violating Section 12, Article II of the Constitution.

The Status Quo Ante Order issued by the Court on March 19, 2013 as extended by its Order, dated July 16, 2013, is hereby LIFTED, insofar as the provisions of R.A. No. 10354 which have been herein declared as constitutional.

G.R. No. 217872

On May 28, 2014, barely two (2) months after the promulgation of the Court's decision in *Imbong*, the petitioners, who were among those against the constitutionality of the RH Law, wrote a letter[2] addressed to the Food and Drug Administration (*FDA*), inquiring about the steps that the agency might have taken to carry out the decision of the Court. In reply[3] to this letter, the Office of the Solicitor General (*OSG*) assured the petitioners that both the Department of Health (*DOH*) and the FDA were taking steps to comply with the decision of the Court and that it would inform them of any developments. The petitioners claimed that, as of the date of filing, they had not heard anything anymore from the OSG.

Controversy began in September 2014, when petitioner Rosie B. Luistro chanced upon the FDA's Notice[4] inviting Marketing Authorization Holders (*MAH*) of fifty (50) contraceptive drugs to apply for re-evaluation/re-certification of their contraceptive products and directed "all concerned to give their written comments to said applications on or before October 8, 2014."

Petitioner Alliance for the Family Foundation, Inc. (*ALFI*) believed that the contraceptives enumerated in the Notice fell within the definition of "abortifacient" under Section 4(a) of the RH Law because of their "secondary mechanism of action which induces abortion or destruction of the fetus inside the mother's womb or the prevention of the fertilized ovum to reach and be implanted in the mother's womb."[5] For said reason, ALFI, through its president, Maria Concepcion S. Noche (*Noche*), filed its preliminary opposition, dated October 8, 2014,[6] to all 50 applications with the FDA. The same opposition also questioned some twenty-seven (27) other contraceptive drugs and devices that had existing FDA registrations that were not subjects of any application for re-evaluation/re-certification.[7]

On November 24, 2014, ALFI filed its main opposition to all seventy-seven (77) contraceptive drugs.[8]

On November 27, 2014, notwithstanding the pending opposition of the petitioners to the re-evaluation/re-certification of these contraceptive products, the FDA issued two (2) certificates of product registration[9] for the hormonal contraceptives, "Implanon" and "Implanon NXT."[10]

On March 19, 2015, ALFI wrote another letter[11] to the DOH and the FDA, reiterating its opposition to the applications for re-evaluation/re-certification. It requested, among others, that the agencies shed light on the status of their earlier opposition and that it schedule hearings and consultations regarding the applications for re-evaluation/re-certification.

The petitioners claimed that their requests had remained unanswered.

Hence, the petitioners instituted the subject petition for *certiorari*, contending that the FDA committed grave abuse of discretion, not only for violating the Court's pronouncements in *Imbong*, but also for failing to act on their opposition.

The petitioners also contend that due to lack of any procedure, rules and regulations and consultations for re-evaluation/re-certification of contraceptive drugs and devices, the FDA had also violated the rudimentary requirements of due process.[12] Invoking the Court's power under Section 5(5), Article VIII of the Constitution,[13] they seek that the Court "promulgate rules and/or disapprove (or approve) rules of procedure in order to adequately protect and enforce the constitutional right to life of the unborn."[14]

As for the certificates of product registration for the hormonal contraceptives, "Implanon" and "Implanon NXT," the petitioners contend that these certificates of product registration were issued *in haste* because they were released just three (3) days after the Senate Committee on Finance required FDA certifications for contraceptives as conditions for government funding for family planning commodities.[15]

The petitioners further aver that even before the issuance of these certificates, the DOH, as early as February 2015, had been administering Implanon in Cebu City. Pointing to a news article in the Panay News,[16] they claim that respondent Health Secretary Janette L. Garin (*Secretary Garin*) even defended the decisions of the DOH to administer these contraceptives. The petitioners add that photographs of several tarpaulins[17] show that the DOH has undertaken the distribution of contraceptives as early as March 25, 2015.

The petitioners allege that despite the Court's declaration that several portions of the RH Law and the RH-IRR are unconstitutional, the DOH has not effected any amendment in the RH-IRR to conform with the Court's judgment. They claim that the RH-IRR posted on the DOH website still contain the provisions which were declared by the Court to be unconstitutional.[18]

Thus, the petitioners assert that absent any compliant rule of procedure issued by the FDA, or consultation regarding its re-evaluation/re-certification, or consideration of their opposition, the approval, procurement, distribution, administration, advertisement, and promotion of contraceptive use by the FDA and the DOH should be enjoined as they are tainted with grave abuse of discretion.[19]

In support of their prayer for the issuance of a Temporary Restraining Order and/or Writ of Preliminary Prohibitory and Mandatory Injunction, the petitioners assert that the actions of the FDA and the DOH violate the right to life of the unborn and, thus, must be restrained to ensure their protection.[20]

On June 17, 2015, the Court issued the Temporary Restraining Order (*TRO*)[21] enjoining the respondents from: [1] granting any and all pending applications for reproductive products and supplies, including contraceptive drugs and devices; and [2] procuring, selling, distributing, dispensing or administering, advertising, and promoting the hormonal contraceptives, "Implanon" and "Implanon NXT."

Comment of the Respondents

In their Comment,[22] the respondents, through the OSG, argued that petitioners failed to establish not only the direct injury that they had suffered, or would suffer,

but also the transcendental importance of the issues raised as a result of [1] the issuance of certificates of registration and the re-certification of contraceptive drugs and devices; and [2] the purchase of Implanon and Implanon NXT.

The OSG also contended that the petitioners violated the doctrine of hierarchy of courts for failing to allege any special and compelling reasons to justify their direct resort to the Court. For the OSG, the Court's concurrent jurisdiction with the lower courts to issue writs of *certiorari*, prohibition and mandamus did not give the petitioners the unrestrained freedom to file a Rule 65 petition directly before the Court.

The OSG further argued that the re-certification of contraceptive drugs and devices involved the scientific determination of fact and that it was conducted by the FDA in the exercise of its regulatory power. Thus, the OSG explained that the re-certification process conducted and the conclusions arrived at by the FDA [1] lay outside the ambit of a Rule 65 petition; [2] did not require any notice and hearing; and [3] need not comply with the standard of substantial evidence required in quasi-judicial proceedings. For the OSG, the FDA might even use extraneous and credible scientific data and was not limited by the evidence submitted by those seeking re-certification considering that Republic Act (*R.A.*) No. 3720[23] mandated that the FDA utilize "the latest medical knowledge."[24]

Finally, the OSG dismissed the petitioners' call for the Court to promulgate the necessary rules of procedure for re-certification, arguing that the rule-making power of the Court was confined to promulgating, approving or disapproving rules of procedure of courts and quasi-judicial bodies, and not to bodies like the FDA. The OSG asserted that the re-certification process undertaken by the FDA was not without basis, as the FDA was guided not only by the RH-IRR Law, but also by Bureau Circular (*BC*) No. 5, series of 1997, Administrative Order (*AO*) No. 2013-0021, AO No. 67, series of 1989, AO No. 2006-2021, AO No. 2005-0030, BC No. 2006-005, BC No. 2006-007, among many others.

In their Reply,[25] the petitioners pointed out that the Court sanitized the RH-IRR, dated March 15, 2013, by declaring Section 3.01 (a) and Section 3.01(j) thereof as unconstitutional. For this reason and the acknowledged constitutional right to life of the unborn from fertilization, the mandate of the FDA was understood to necessarily include the duty to recertify certain contraceptives that had already been approved and registered and had been made available to the public, but this time using the constitutional yardsticks and standards expounded by the Court in its decision. In this process of registration and/or re-certification, the FDA had to ensure that only contraceptives that were non-abortifacient and safe would be purchased and distributed to the public.

The petitioners stated that the re-certification was not automatic and that there had to be an actual re-examination and re-testing of all contraceptives to ensure that they were compliant, not with the old standards utilized by the DOH and the FDA which, the Court had determined could open the floodgates to abortion, but with the new standards it laid out that aimed to ensure protection of the life of the unborn from injury or death starting from fertilization to implantation in the mother's womb.

The registration and/or re-certification of drugs are in the exercise of the quasi-