EUROPEAN COURT OF HUMAN RIGHTS
COUR EUROPÉENNE DES DROITS DE L'HOMME

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Spanish authorities failed to protect woman who had undergone a medical procedure without her informed consent

In today's **Chamber** judgment[1] in the case of S.O. v. Spain (application no. 5742/22) the European Court of Human Rights held, unanimously, that there had been:

a violation of Article 8 (right to respect for private and family life) of the European Convention on Human Rights.

The case concerned the removal of Ms S.O.'s nipple and areola, allegedly carried out without her consent, during an operation to save her breasts from cancer, and subsequent court proceedings.

The Court found in particular that the Spanish authorities had failed to examine whether the doctors had informed her of the specific possibility of the nipple and areola being removed. The Spanish authorities had not responded adequately to S.O.'s claim concerning the absence of valid informed consent. They had failed to implement the existing legal framework correctly and sufficiently to protect her autonomy, in violation of Article 8.

Principal facts

The applicant, S.O., is a Venezuelan national who was born in 1956 and lives in Madrid.

In 2016 S.O. was diagnosed with breast cancer for the second time, this time in her right breast. In January 2017 the Gómez Ulla Hospital in Madrid proposed to her that she undergo breast-conserving surgery. She signed an informed-consent form.

In February of that year S.O. was operated on. Two samples of breast tissue were immediately analysed, and the decision was made to lower the incision and to remove the nipple and the areola.

S.O. complained to the Health Department of the Madrid Autonomous Community in September 2017. She claimed 100,000 euros in compensation, asserting that her nipple and areola had been removed although no cancer had been present there, and that she had given informed consent only to the breast-conserving surgery and the removal of lymph nodes.

In the absence of a reply to her administrative complaint, she took the case to the Spanish courts. However, the Madrid High Court of Justice in September 2020 considered that the consent she had given had been adequate, noting, in particular, that "oncological safety" (*seguridad oncológica*) had been the primary objective and that the possibility of varying the surgical technique had been included in the information given to S.O.

Complaints, procedure and composition of the Court

Relying on Article 8 (right to respect for private and family life), Ms S.O. complained that she had not given valid consent to the removal of her nipple-areola complex.

The application was lodged with the European Court of Human Rights on 21 January 2022.

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1. Under Articles 43 and 44 of the Convention, this Chamber judgment is not final. During the three-month period following its delivery, any party may request that the case be referred to the Grand Chamber of the Court. If such a request is made, a panel of five judges considers whether the case deserves further examination. In that event, the Grand Chamber will hear the case and deliver a final judgment. If the referral request is refused, the Chamber judgment will become final on that day.
Once a judgment becomes final, it is transmitted to the Committee of Ministers of the Council of Europe for supervision of its execution. Further information about the execution process can be found here: www.coe.int/t/dghl/monitoring/execution.

Judgment was given by a Chamber of seven judges, composed as follows:

Kateřina **Šimáčková** (the Czech Republic), *President*,
María **Elósegui** (Spain),
Gilberto **Felici** (San Marino),
Andreas **Zünd** (Switzerland),
Diana **Sârcu** (the Republic of Moldova),
Mykola **Gnatovskyy** (Ukraine),
Vahe **Grigoryan** (Armenia),

and also Martina **Keller**, *Deputy Section Registrar.*

Decision of the Court

The Court noted, firstly, that the procedure performed by the hospital had potentially significant impacts on a woman's physical and mental wellbeing, her image and self-esteem, and her sexual life. This particular case and the issue of consent therefore came under Article 8. The Court was satisfied that the legal framework in place in Spain around medical consent was adequate.

In this case, S.O.'s consent had been sought and given concerning the intervention in general, albeit without specific discussion around the risk of removal of the nipple and areola as part of the overall aim of removing the cancer. It noted that the High Court had considered this to have been adequate.

Regarding the consent form the Court held that it had not been sufficiently clear for a person with no medical knowledge which of the surgeries included on it could be considered as a modification of surgical technique covered by the informed-consent form, in particular that signing it meant accepting the removal of the nipple and areola as a possibility. The Court reiterated that, under Spanish law, where written consent was required, the consent form had to contain sufficient information regarding the procedure and its risks to enable the patient to make an informed decision.

The High Court had not examined whether the doctors had informed her of the specific possibility of the nipple and areola being removed. The Court held that given the nature and purpose of breast-conserving surgery, the general risks and consequences associated with it and with incomplete removal of a tumour, and S.O.'s specific circumstances, the doctors had been required to inform her beforehand about the possibility of a removal of her areola and nipple. The Spanish courts should have been aware of the repercussions to S.O.'s self-image and sexual life and should have addressed that in proceedings.

Overall, the Spanish authorities had not responded adequately to S.O.'s claim concerning the absence of valid informed consent. They had failed to implement the existing legal framework correctly and sufficiently to protect her autonomy, in violation of Article 8.

The judgment is available only in English.

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The European Court of Human Rights was set up in Strasbourg by the Council of Europe member States in 1959 to deal with alleged violations of the 1950 European Convention on Human Rights.