

Limited Waiver Under the Religious Freedom Restoration Act Regarding Access to Certain Vaccines from Japan

Re: OCR Trans. Nos. [REDACTED], [REDACTED], and [REDACTED]

The Department of Health and Human Services' (HHS) Office for Civil Rights (OCR) received complaints from health care providers and patients who assert that the Food, Drug, and Cosmetic Act's (FDCA) bar on importing certain non-FDA-licensed vaccines for measles, rubella, and hepatitis A substantially burdens their exercise of religion in violation of the Religious Freedom Restoration Act (RFRA). The complainants contend that the bar on importation leaves them with the option of using vaccines derived from cell lines that are the product of abortion, a prospect to which they conscientiously object, or forgoing vaccination against these serious diseases entirely. OCR summarized the complaints for FDA, and FDA provided its views on the complaints.

Following an OCR review of the relevant facts in light of FDA's comments, FDA's prior RFRA importation waiver, and a legal review by the Office of the General Counsel, OCR has determined that a limited waiver of the bar to import is required under RFRA, provided the importation meets the conditions set forth below.

- (1) The Import Vaccines (identified in Exhibit A) are shipped directly from the manufacturer to a State-licensed physician in a manner that does not compromise the integrity of the vaccine;
- (2) The physician importer maintains records of the shipment;
- (3) The physician importer stores the Import Vaccines in an appropriate and secure manner (i.e., uses refrigerators in a secured office setting);
- (4) The physician importer does not resell the Import Vaccines;
- (5) The physician importer obtains reliable, certified translations of the Japanese language labels for the Import Vaccines;
- (6) The physician importer promptly reports any adverse events related to the Import Vaccines and/or any theft of the Import Vaccines to FDA;
- (7) The physician importer provides full disclosure to patients that (a) the Import Vaccines have not been licensed by FDA, (b) the lines on which the Import Vaccines have been manufactured have not been inspected by FDA, (c) that patients who use the Import Vaccines are required to waive any liability against the manufacturers of such products, and (d) that in the event of a vaccine related injury, the patient would not be able to pursue a claim under the Vaccine Injury Compensation Program; and
- (8) That by using the Import Vaccines, patients waive any and all claims against the Federal government, its officers, and employees.

This limited waiver applies to the complainants in OCR Trans. Nos. [REDACTED], [REDACTED], and [REDACTED]. This limited waiver is subject to revocation if the physician importer (1) deviates from the terms of the above, (2) FDA determines from evidence of adverse event reports or published literature that the Import Vaccines are unsafe or ineffective, or (3) an investigational new drug application goes into effect for a non-fetal-tissue-derived vaccine for any of the diseases prevented by the Import Vaccines. Nothing in this limited waiver restricts States from regulating the use or administration of the Import Vaccines.

EXHIBIT A

Import Vaccines

Vaccine	Manufacturer	Diseases
AIK-C-Takahashi vaccine	Daiichi Sankyo/Kitasato	Measles and rubella
Mearubik vaccine	BIKEN	Measles and rubella
Aimmugen vaccine	KM Biologics Co. Ltd.	Hepatitis A