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The human rights and patient consequences of Gilead's proposed anti-diversion policies in its tiered-pricing and licensing programs for sofosbuvir, listed by MSF, are quite specific and substance-focused:

1. Access is allowed from a Gilead authorized distributor or a treatment provider only on a named-patient basis, with proof of identification, citizenship and residence required.
2. Each pill bottle will have a QR code printed/engraved on it with embedded information, including the patient's name and address, enabling Gilead or its representatives to track patient information directly to demand tracking information from treatment providers at any time with the right to use such information for any purpose.
3. The patient will have to sign an agreement agreeing to return the empty bottle/s before the next dispensation or sale of the drug is approved or allowed.
4. The medicine will be given to the patient bottle by bottle meaning patients are prohibited from obtaining multiple bottles, which would ease the burden on patients and treatment providers. Before a patient can get a next bottle, the patient must bring back or courier the empty bottle to the distributor only after which will the new bottle be dispensed or couriered to the patient.

Gilead's response on the other hand is vague and process oriented - it promises consultation with no specifics in terms of the concerns raised.

Gilead's proposed anti-diversion program indirectly interferes with patient privacy, confidentiality, and autonomy and it further interferes the doctor-patient and pharmacist-patient relationship. As a general proposition, patients anywhere have a human right to privacy and confidentiality about their treatment choices, subject of course to necessary communications with their health providers. However, it is unprecedented that a commercial supplier of medicines will demand such extensive and continuing access not only to private/confidential patient information, but to have such access for any purpose whatsoever, including in this instance, its commercial interest in avoiding lost sales in high-profit markets. The proposed program infringes on patient autonomy because a patient's decision on how and when to take medicines is a personal choice, subject again to adherence support that might be provided by health workers on a non-coercive basis. Finally, Gilead proposes to insert itself as a corporate "Big Brother" in the doctor-patient and pharmacist-patient relationship, again solely for commercial reasons. Doctors and pharmacists now, instead of a required focus on patient well-being, are being asked to act as commercial informants for a pharmaceutical company, focusing on its profits rather than a patient's best

interests.

The proposed anti-diversion program is also unduly burdensome on patient, particularly patients who are socially marginalized. It is burdensome in the first instance since it demands proof of identity and citizenship that is difficult for many to provide especially migrants and other legal outsiders. In addition, it requires proof of an address, even though many potential patients are functionally homeless. The program is also burdensome because it requires the patient to return bottles and get new bottles on multiple occasions. Instead of making it easy for patients to complete their treatment and avoid treatment default, the mandated procedures impede the human right to health by erecting significant transaction costs and barriers by forcing travel to distant authorized reps or treatment providers. Even the option of using couriers could be burdensome and costly for poor patients and patients in remote regions. Of course, courier service could also result in treatment interruption while empty and full bottles are being transported. Similarly, if for some reason a pill bottle were lost, a patient might be left without, resulting in renewed infection.

The Gilead anti-diversion program contains many human rights and patient rights violations. It needs to be completely revamped to focus on patient interests and rights rather than commercial priorities.