

SIDE BY SIDE OF STUPAK/SMITH LEGISLATION AND ROCHE PLAN

| | Stupak/Smith Legislation | Roche Plan |
|---|---------------------------------|---|
| Mandatory Registry of all Patients, Practitioners, and Pharmacists | YES | YES |
| Education of Practitioners and Pharmacists | YES | YES |
| 30-day prescriptions only | YES | YES |
| Monthly survey for all patients | YES | YES |
| Monthly pregnancy test by accredited laboratory for female patients | YES | YES |
| Prohibition for prescriptions through the phone or Internet | YES | YES |
| Requirement that Accutane be prescribed only for severe recalcitrant nodular acne after conventional treatment including antibiotics have failed | YES | NO |
| Requirement that Accutane be dispensed through Certified Treatment Centers | YES | NO |
| One-year certification for Treatment Centers and yearly evaluation to ensure compliance with program | YES | NO |
| Mandatory quarterly reporting of all adverse reactions and mandatory reporting within 15 days of all patient deaths by manufacturer and provider. | YES | NO. Under current law, drug manufacturers must submit adverse reactions, but reporting by medical providers is voluntary. |
| Patients educated about the risks and required to sign Informed Consent form. | YES | NO. Currently, the patient informed consent form is voluntary. The Roche plan maintains its voluntary status. |