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Court ruling could prompt congressional interest in soap chemical

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ALBANY, N.Y. (Reuters) - A new ruling by a panel of the U.S. 2nd Circuit Court of Appeals could spur renewed congressional interest in how the Federal Drug Administration regulates a chemical used in hand soap, toys and other consumer products, lawyers said.

On Friday, the panel ruled that the Natural Resources Defense Council could pursue a lawsuit to force the FDA to finalize its review and regulation of the chemical, triclosan, under Over-the-Counter Drug Review regulations.

The decision reversed the district court, which had found in 2011 that the NRDC lacked standing to sue the FDA over triclosan.

Representative Ed Markey (D-Mass.) has sought to compel the FDA to ban triclosan, a chemical he has argued can damage the endocrine system and increase antibiotic resistance, according to a statement. In a letter to the FDA in 2010, Rep. Louise Slaughter (D-N.Y.) also asked the FDA to ban the chemical, stating that traces had been found in surface water in the United States.

Neither lawmaker returned calls for comment.

In its ruling, the three-judge panel found that the Natural Resources Defense Council had adequately shown that triclosan is potentially dangerous and the FDA had failed to complete a review of the chemical despite decades of research.

The court said the FDA in 1978 and 1994 had released tentative reviews of triclosan and similar chemicals and had proposed the eventual elimination of triclosan from hospital scrubs and hand soaps, but those reviews had never been finalized.

Sending the case back to the district court, the panel wrote, "NRDC's evidence shows that triclosan may be harmful, that the FDA is unable to determine whether it is, and that FDA's failure to regulate allows triclosan to enter the market without its safety having been confirmed."

The three members of the panel were Circuit Judges Rosemary Pooler and Gerard Lynch and District Court Judge Brian Cogan of the Eastern District of New York, who sat by designation.

Mae Wu, an NRDC attorney who worked on the case, said the group wants the district court to give FDA a hard deadline for completing its triclosan review. "This is clearly an agency that, absent any kind of legislative or court-ordered mandate, is not going to do what it is supposed to do," she said.

The FDA declined to comment on the ruling. In a statement, a spokeswoman said the agency "is actively engaged in a scientific and regulatory review of triclosan."

RISKS OF TRICLOSAN

The NRDC had sued the FDA in 2010 on behalf of two of its members, a veterinary technician and a physician, who claimed their employers purchased soaps that included triclosan and with which they washed their hands dozens of times each day. The lawsuit said the chemical put NRDC members at risk.

U.S. District Court Judge Alvin Hellerstein of the Southern District of New York in 2011 granted the FDA summary judgment, finding that the NRDC did not have standing because its members could avoid exposure by purchasing triclosan-free soap for use at work.

The 2nd Circuit on Friday disagreed, finding that if the members had purchased their own soap, even that trivial cost would have counted as an injury and given the NRDC members grounds to sue.

The court relied on its decision in a 2003 case, *Baur v. Veneman*, in which it found that the exposure to potentially harmful products may constitute an injury-in-fact for the purposes of establishing standing.

The FDA had argued in the triclosan case that the NRDC had no standing because the likelihood of its members being harmed by triclosan was uncertain. Under *Baur*, the court said, the NRDC had proven the credible threat

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