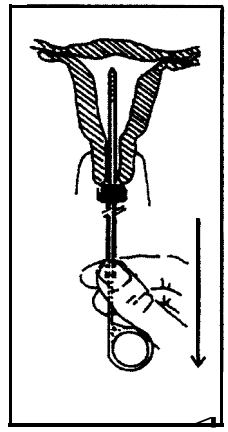
DICKINSON'S FDA Review
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'Deceptions' alleged in FDA attack on quinacrine

An internal FDA health hazard evaluation of the unapproved use of quinacrine pellets to non-surgically sterilize women contains "an unmistakable pattern of deceptions, of ignoring available scientific evidence," charged Center for Research on Population and Security president **Stephen D. Mumford** in a 12/9 letter to FDA ombudsman **Amanda B. Norton.**

Mumford's nine-page letter challenged the basis of a recent FDA regulatory action to stop him from trans-shipping generic, Indian-made pellets of the former Sanofi-Winthrop branded Atabrine drug for giardiasis and malaria. Atabrine was voluntarily withdrawn from the market for unrelated reasons in 1993 and the company says there are no plans to revive it.



Seven quinacrine ,pelets are deposited from simple inserter into Fallopian tubes, where they dissolve and scar the tube lining until passage of eggs is permanently blocked

FDA's action, a 10/14 Warning Letter arising from a 4/8 inspection, was launched on the eve of a sympathetic 10/18 CBS 60 Minutes segment on his privately-funded efforts to provide cheap and easy sterilization to women in the Third World.

In a 14-page, 11/4 response to the Warning Letter, Mumford complained that FDA had taken extraordinary steps ("a journalistic coup") to disseminate its letter to the producers of 60 Minutes before the program aired and to a *Wall Street Journal* writer who opposes the quinacrine method of sterilization. (Mumford told ***FDA Review*** an FDA field officer drove 70 miles to his Research Triangle Park, NC home to hand-deliver the letter at 7:00 PM so it could be released to the media the next day.) Mumford's response also accused FDA of basing its action on unsubstantiated World Health Organi-



Mumford (left) and colleague Elton Kessel, MD, as they appeared on CBS' 60 Minutes l0/18

zation statements challenging quinacrine's lack of toxicology, genotoxicity and carcinogenicity testing — statements the British medical journal *The Lancet* investigated and called "reprehensible."

'abuse of power' ...

In his letter to Norton, Mumford said FDA's actions against him and a colleague, Oregon Health Sciences University clinical professor **Elton Kessel,** MD, "are clear examples of abuse of power." He targeted the internal hazard analysis document on quinacrine — which Warning Letter author **Brad Williams,** CDER director of labeling and nonprescription drug compliance, told ***FDA Review*** was a basis for FDA's regulatory concern.

Prepared by CDER medical officer ***Susan Allen,*** *MD, of the Division of Reproductive and Urologic Drug Products, this four-page, 8/26 document "contains so many misrepresentations and omissions that one must conclude its intent is to deceive," Mumford told Norton.*

Mumford listed 37 faults in Allen's analysis, the most significant of which were her failure to credit updated experiential information about quinacrine's use that answer earlier published concerns. For example, Mumford said:

- ***Alien reported a 100 mg-200 mg daily dosage of quinacrine in U.S. soldiers to combat malaria during World War II, and other uses, all of which were strengths too low to assess safety when used in non-surgical sterilization. Mumford said this "grossly understates" the soldiers' prophylactic exposures cumulatively as high as 52,000 mg yearly for up to four years, far greater than the sterilization procedure's 252 mg deposited in the uterus only twice.***
- ***Allen cited a sterilization failure rate as high as 10 per 100 woman-years of use, but Mumford said "this is spurious. This should read 10 per 1,000 years of use.."***
- ***Allen said the dosing regimen has yet to be standardized but Mumford said it was standardized in 1994.***
- ***Allen called quinacrine studies poorly controlled with incomplete follow-up and "not comparable due to differences in formulation, dose, dosing regimen and adjuvant therapies used." Mumford said follow-up has been 85%-100% at three to five years "or more" and 99% of 100,000 studied cases used the same pellet formulation (252 mg).***
- ***Allen cited studies finding cancer in quinacrine-treated women, but Mumford said she omitted other citations that the findings were later ruled to be either meaningless or not statistically significant — "a grossly deceptive statement."***
- ***Allen cited data showing "severe uterine bleeding post-administration at an incidence less than 1 % ." Mum ford said the incidence "is more like less than 1:15,000 cases. Using 'less than 1%' misleads the reader into thinking the incidence is far greater than it really is."***
- ***Allen "really steps over the line," Mumford alleged when she stated that quinacrine has "known mutagenicity and probable carcinogenicity" but then gave examples that had nothing to do with either "'Probably' grossly overstates the odds that this drug causes cancer at the dose recommended.."***

Mumford said Allen's "extraordinary lists of short-term and long-term safety risks reveal her to have wiped the scientific slate clean, concluding, and informing the reader, that nothing has been learned from the 100,000 or more cases of quinacrine sterilization performed thus far . . . Something is terribly wrong here."

EDITOR'S NOTE. There is a political overlay to the quinacrine controversy. No government has approved this sterilization procedure (although some have funded trials), and Mumford's Center for Research on Population and Security is accused by some Third World commentators of being a white, U.S. effort to suppress the Third World (non-white) birthrate and thus help save the U.S. from future unwanted immigrants. Mumford, who admits to concern about immigration, sees a clandestine Vatican connection in WHO'S undocumented statements about quinacrine.