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HEADLINE: A **warning** that must not be ignored;
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BODY:

THE numbers and full facts are not yet known, and I can only guess at the confusion and anxiety facing the couples involved in these cases.

But most of us would agree that even one healthy and wanted baby being terminated because of failures in genetic testing is horrifying. We cannot let these disturbing cases be a harbinger of what is to come as screening becomes widespread, and as the number of diseases for which people are screened grows.

If we want to prevent such mistakes being repeated, there is much to do. In the US, there is more government oversight of the colouring used in M&Ms than there is for genetic tests that can have untold physical and emotional consequences, and the same is true in many other countries.

Genetic testing should offer families the chance to get the information they need to guide their healthcare and reproductive decisions. If conducted properly, the tests can do just that. But the current system has two fundamental flaws.

First, the players involved in genetic testing are linked to one another in a one-way pathway. An error or confusion at any step in the process will affect the rest of those in the chain including, most importantly, the patient. There is no reliable system of checks and balances within the system so that errors at one point can be detected and corrected at others.

Secondly, the mechanisms for regulating genetic testing are fragmentary and inadequate. Each government agency involved is only concerned with a single narrow slice of the entire process.

Like similar agencies elsewhere, the US Food and Drug Administration regulates commercially produced test kits as medical devices. However, many laboratories that perform genetic testing do not use commercial kits but instead develop their own tests. The FDA regulates neither the safety nor the effectiveness of these "home brew" tests, and has so far limited its oversight to a subset of the components laboratories use to generate tests.

In July 2000, a US government advisory committee made several recommendations for increasing

government oversight, including that the FDA should regulate all new genetic tests that have moved beyond the research phase. That has not happened.

As for the laboratories that carry out the tests, in 1998 Congress passed the Clinical Laboratory Improvement Amendments and charged the Center for Medicare and Medicaid Services with improving clinical laboratory practice. But the agencies responsible for implementing the amendments have largely stayed out of genetic testing. In May 2000, the Centers for Disease Control acknowledged that improvements were needed in oversight of genetic testing laboratories, but there has been no action since then.

Even if all the various agencies involved meticulously oversaw their particular slice, the problem would still not be resolved because no one would be addressing all parts of the issue. The end result is that the poor patients are left with no assurance that the information they are being given is accurate.

Cystic fibrosis is the first genetic test to be routinely offered to prospective parents in the US, and the cracks in the system are already painfully plain. Reflect on what is likely to happen when the many other genetic tests in the pipeline come through.

We have our canary-in-the-mineshaft warning of the dangers of genetic screening. The physical and emotional stakes, not to mention the legal implications, are too high to ignore it.

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