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COVER STORY

Who Is Mary J. Ruwart?

Mary J. Ruwart, Ph.D. is a former pharmaceutical research scientist and Assistant Professor of Surgery. She has worked extensively with the disadvantaged in low-income housing. Her scientific, political and community activities have been profiled in several prestigious biographical works, including American Men and Women of Sciences, World's Who's Who of Women International Leaders in Achievement and Community Leaders of America.

Dr. Ruwart is the author of *Healing Our World: The Other Piece Of The Puzzle*, hailed by *Visions Magazine* as "what may be the most important book of the decade." This book applies win-win strategies to the political realm, "bridging the gap between conservatives and liberals, special interests and the common good with practical solutions to our economic, environmental and societal woes" (Ron Paul, U.S. Congressman [R-TX] and 1988 Libertarian Party Presidential Nominee).

Dr. Ruwart has written extensively about what is wrong with the FDA and has proposed practical ways of fixing the agency. The following excerpts from Dr. Ruwart's application for Commissioner explain some of the ways she proposes to reform the FDA:



For almost 20 years, I was a research scientist at a major pharmaceutical company and understand the impact of regulatory delays. Former FDA Commissioner, Alexander Schmidt, once remarked, "The failure to approve an important new drug can be as detrimental to the public health as the approval of a potentially bad drug." As your appointee, I would pursue a more cooperative approach with pharmaceutical firms in order to speed the delivery of new, life-saving medications to the American public.

Doctors often prescribe approved medications for off-label uses in order to give their patients the best health care options. However, the FDA discourages drug companies from sharing information that would educate physicians about these choices for their patients. As your appointee, I would make this valuable knowledge on off-label use available to our dedicated health care practitioners.

Health care professionals who utilize non-traditional methods of treatment are often subjected to prejudicial treatment by the FDA, even in the absence of patient complaints. As your appointee, I would intervene only when patients were at risk, thereby broadening our health care choices.

Whenever Congress considered giving the FDA more control over nutritional supplements, voters inundated their representatives with protests. The American public clearly wants the freedom to choose what vitamins and minerals to take. As your appointee, I would honor the choice of my fellow Americans.

FDA examiners are in a no-win situation. If they delay approving a drug with life-saving potential, many Americans, especially those with terminal diseases, die needlessly. If the FDA approves a drug and unpredictable side effects occur, the FDA is blamed.

As your appointee, I will alleviate this situation by allowing terminally ill patients to "opt-out" of the approval process. They will then have access to potentially life-saving medications which are not yet through FDA review.

In 1999, a Federal Appellate Court ruled 11-0 that the FDA must abide by the First Amendment of the U.S. Constitution and permit truthful health claims for antioxidants, fiber, folic acid and omega-3 fatty acids (Pearson vs. Shalala). The FDA ignored this decision and in February of this year was censured by the court for its failure to comply. As your appointee, I would make sure that the FDA abides by our Constitution, the law of the land.

As your appointee, my goal will be to facilitate the conversion of the FDA from a bureaucratic regulatory regime into a market-oriented support system that maximizes our access to life-savings medications. Of course, only a team effort will achieve this dramatic shift. Win-win strategies, such as the ones described above, can help create alignment among groups who may sometimes be at odds with each other. I believe that I have the experience and the skills to create such an environment.

I hope that you will seriously consider moving the FDA in a direction that will stimulate innovative drug development. After all, before we are politicians or special interest groups, we are human beings. Whether we enjoy a long life or a short one will largely depend on the availability of life-saving medications. I would be honored, as your appointee, to help the American people—and yourself—achieve the longest, most productive life possible.

If you want to help change today's flawed healthcare system, we encourage you to contact The White House and voice your support for Mary J. Ruwart as the next FDA Commissioner. The following page describes the different ways you can communicate with President Bush's staff.

Let Your Voice Be Heard At The White House
It's easier than you think!

We live in a democratic society, yet few Americans take the time to let their elected officials know what is really important.

In the case of the FDA, severe problems have been repeatedly identified, but a politically palatable solution has never been conveyed to the President of the United States. Since the President will be appointing a new FDA commissioner soon, it's time to speak out. If we fail to point out an obvious way of reforming the FDA, it's hard to complain later about the agency's continuing inadequacies.

For the first time in history, a qualified individual has emerged with a specific plan to turn the FDA into an organization that will facilitate, rather than impede, the development of new therapies to eradicate disease.

It is now up to those of us who understand the FDA problem to convey the solution to the President. Our message to President Bush is simple: Dr. Mary J. Ruwart is the best qualified individual to lead the FDA out of the medical dark ages.

History has shown us that FDA Commissioners are primarily concerned with maintaining the status quo, rather than resolving serious problems within the agency. This lack of vision is why Americans continue to suffer and die in the FDA's "waiting room."

Dr. Ruwart has proposed meaningful reforms within the FDA. For those depending on scientific breakthroughs to stay alive, it is critical for the next Commissioner to have the vision to tear down the FDA's barriers against medical innovation. Dr. Ruwart has emerged as the most viable candidate to implement these life-saving changes.

The White House is set up to receive suggestions and comments from the public. The following are several ways to let your voice be heard.

Mail your letters to:

President George W. Bush
The White House
Washington, D.C. 20500

Fax your letters to The White House Comments Line Fax: 1-202-456-2461

To discuss these issues with The White House staff, call: 1-202-456-1111

To read more about Mary J. Ruwart, Ph.D. check out her website at www.ruwart.com.

Read Dr. Ruwart's Curriculum Vitae [here](#).

[Click here to e-mail the President about supporting Dr. Ruwart's application for FDA Commissioner.](#)

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