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Fall Fashion Preview

1997 MEN'S QUARTERLY
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Of America**
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The Terminator

By Barry Werth

When the French abortion pill soon arrives in America, it will change the course of the nation's most divisive issue. How it got here is a tale of big money and high intrigue

IT WAS THE MOST SHATTERING OF PUBLIC ACTS. A 31-YEAR-old chemical operator, allegedly with a history of abusing his wife and children, walked up to a doctor at a demonstration outside an abortion clinic in Florida and shot him three times in the back, killing him. Instantly, the March 10 slaying of Dr. David Gunn took on biblical endowments: The decades-long acid controversy over abortion rights, the murder seemed to tell us, was slouching toward some form of an apocalypse. It would end—it *must* end—in martyrdom, in blood.

At least that was how it would end on TV, which needs extremism and violence to heat itself up and which devoured, then endlessly regurgitated, the story, just as it would soon in Waco. And yet it is in quieter, less dramatic acts that history is often written: the mutual pressures of competing interests, the pursuit of private ambitions by those in and out of power, the rubbing and bumping of agendas, bureaucratic cunning. The abortion controversy did, in fact, turn momentarily in late winter, but not in Pensacola. It changed in the shadowy world of Washington politics and in the timorous, recession-wracked financial centers of Europe. It changed because enough strange bedfellows came together at last to change it.

The shifting began unremarkably a few months earlier, on December 10, 1992, amid the political ebb tide that followed Bill Clinton's drubbing of George Bush. Dr. David A. Kessler, the Bush-appointed

commissioner of the Food and Drug Administration (FDA), received a letter from Representative Ron Wyden, an up-and-coming critic of the federal health-care bureaucracy who wanted to know what Kessler planned to do about bringing "the French drug RU-486" to the United States.

That the 41-year-old Kessler was presumably a lame duck and that RU-486 was the controversial "abortion pill" heightened Wyden's gamesmanship. The antiabortion Right called the drug the "French death pill" and had made its exclusion a litmus test for the support of federal regulators. Kessler had faithfully enforced the Bush administration's ban on importing the drug—a ban that Clinton promised to overturn as soon as he took office. In other words, Wyden was asking Kessler to repudiate a policy he'd dutifully observed, to defy Bush and to act unilaterally on one of the most controversial issues of the day—all during a time of complete rudderlessness in federal decision-making.

Kessler, unsurprisingly, had other ideas. He was known to want desperately to keep his job with the new administration but had been all but written off within the Beltway: "Toast," one handicapper called him. Nearly obsessively qualified—he is a doctor and a lawyer and has an advanced business degree—he is by most accounts an aggressive, perhaps exceptional, commissioner. But his political baggage is almost as prodigious as his résumé. His Washington mentor is Senator Orrin Hatch (R-Utah), whose rabid skewering of Anita Hill during Supreme Court Justice Clarence Thomas's confirmation hearings practically defined "misogyny" for millions of women. Not immaterially, it was Thomas, forever suspect in all areas of sexual politics, who pressed the Court to uphold the FDA import ban on RU-486 after a pregnant California woman was stopped as she attempted to bring the drug into the country. Though he was a Naderite compared with Bush's laissez-faire minions, Kessler scarcely looked like the pro-choice progressive Clinton was likely to want in one of the most powerful federal regulatory posts.

Kessler had his deputy, Carol Scheman, write back to Wyden. But there was no question that the response was his or that it signaled a major change in the FDA's stance on the drug. Scheman wrote that the FDA was now prepared to consider licensing RU-486 entirely on the basis of European testing (the drug is approved in France, Britain and Sweden and has been used by more than 150,000 women) and that the agency might approve it in as little as four to six months—one third the normal time. Meanwhile, Kessler wrote to Dr. Edouard Sakiz, CEO of Roussel UCLAF, the French manufacturer of the pill, virtually inviting him to submit RU-486 for approval. By any measure, it was an extraordinary reversal.

In an exchange of faxes between Wyden and Scheman, the congressman—who had tried for years to broker just such action through a series of well-publicized hearings—

swiftly seized credit. And yet, there was both more and less to the exchange than either side would have it appear. For instance, the correspondents delicately neglected to mention the overwhelming reason for their careful posturing: abortion. (Scheman, a Kessler hire, came closest, referring to the "interruption of early pregnancy.") Taken in sequence, Wyden's letter seems almost an outline for Scheman's, a stage upon which Kessler's dramatic announcement could be choreographed.

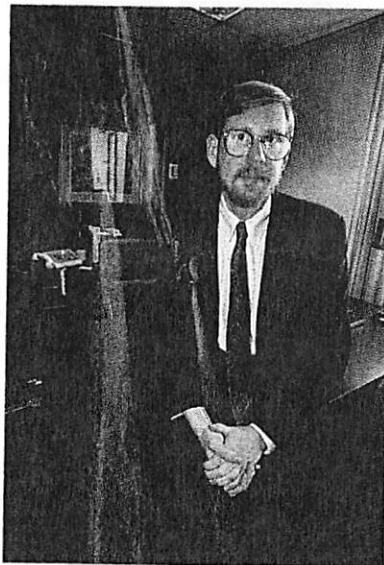
And there was the issue of Roussel. Ominous remarks of a company official in mid-November, shortly after Clinton's election, had prompted Wyden to begin pressuring Kessler. Roussel and its corporate parent, the German chemical giant Hoechst AG, were maintaining a wait-and-see attitude, claiming that the threat of boycotts might prevent them from bringing RU-486 to the United States, *even with a change in federal policy*. Unless Roussel or a proxy could be persuaded to seek FDA approval, RU-486 would remain unavailable as an alternative to the 1.6 million surgical abortions performed annually in this country.

In the end, little had changed procedurally: The companies had always been welcome to file, and the FDA had previously licensed drugs based solely on foreign trials. But in politics, the illusion of change often is a necessary precursor to the real thing, and by this time Wyden and Kessler were outdoing each other in bringing attention to RU-486. "It's almost irrelevant that it's a drug," a longtime pharmaceutical-industry consultant complained. "It's become so much more potent as a cross between a symbol and a weapon."

With scant scientific data, Wyden, a media-smart Oregon Democrat, continued promoting the drug for other uses—such as treatment for everything from benign brain tumors to breast cancer—

downplayed its role as an abortifacient and couched the battle over importation as a test of U.S. primacy in biomedical research. Kessler, meanwhile, began touting the drug with the zeal of a born-again. If a woman's right to an abortion was the underlying social issue behind Clinton's victory, Kessler seemed determined to be its avatar. He made every effort to single out RU-486 in speeches and on TV talk shows. In an effort to survive the change in administrations, he now became the drug's foremost lobbyist and it his lifeline. "He honestly believes that the future to keeping his job is the outcome of RU-486," observed Marie Bass, a lobbyist for women's health issues and for RU-486 in particular. "If he can be the one person who finally, *finally*, makes the drug available, he'll be a hero."

By his words and actions, Clinton clearly viewed RU-486 as pivotal both to the future of abortion and to the bold impression with which he hoped to launch his presidency. Violently schismatic—abortion is either murder or it isn't—abortion politics has long defied compromise, but Clinton



Kessler: anything to keep his job?

was almost compulsively conciliatory. Now that he had been elected in part for what *The New York Times* would describe as his “carefully nuanced” call for “an America where abortion is safe and legal but rare,” the key was to preserve the consensus within the broadest, most acceptable framework: the right to privacy.

America now tentatively seemed to accept that a woman's decision to terminate her pregnancy is her business: inviolable and protectable. RU-486, which allows a woman to end her pregnancy without going to an abortion clinic, theoretically makes abortion a far more private matter. Indeed, it seemed to embody the kind of high-tech, innovative solution that Clinton was trying to establish as a hallmark of his administration. Writing personally within weeks of his election to the drug's codeveloper and chief sponsor, Dr. Etienne-Emile Baulieu, Clinton vowed to order the FDA to treat RU-486, as Baulieu put it, “like any other drug.”

Receiving the letter in his office in a small, modern research building at the Hôpital Bicêtre, an eighteenth-century cloistered maze on the southern lip of Paris, Baulieu was sharply encouraged. For a decade, he had struggled to gain acceptance for RU-486 through a nonstop campaign combining groundbreaking science and relentless advocacy. A passionate and persuasive spokesman, Baulieu more than anyone was responsible for the drug's aura of salvation, the idea that it would efficiently reduce the anguish of abortion to a single painless and guilt-free act. Baulieu hadn't created RU-486, as the media often mistakenly claimed; Roussel's chemists had. But he was its “godfather,” according to Roussel's medical director, Dr. André Ulmann, meaning that Baulieu stood to gain the most from Clinton's endorsement. “Baulieu wants a Nobel prize,” observed Ed van Vlaanderen, a New York City pharmaceutical consultant. “He's not going to get one for an alternative abortion drug of minor significance. . . . Solving the problem of population explosion—that would be something else.” As Baulieu knew better than anyone, the key to enhancing the impact of RU-486 was to pressure Roussel and Hoechst into marketing it, particularly in the U.S., where acceptance of any new drug is not only a financial necessity but a scientific one.

Armed with his letter from the president-elect, Baulieu wrote to Dr. Wolfgang Hilger, chairman of Hoechst, the \$30 billion-a-year drug and chemical giant that owns 55 percent of Roussel's stock. Whatever Hilger's personal feelings—a devout Catholic, he is publicly and militantly anti-

The German firm seemed haunted by the irony of having an abortion pill in its product line.



Wyden: ready to take the credit.

abortion—Baulieu believed the Hoechst-Roussel relationship was “good for the companies, good for France and Germany, good for Europe, good for the world” and that Hilger would see the advantages in complying with Clinton, soon to be the most powerful person on earth.

All drug companies abhor controversy: Constituting perhaps the world's most profitable legal industry, they loathe anything that cuts into their margins. Yet it is probably safe to suggest that, given the issues surrounding RU-486, no CEO of any major pharmaceutical manufacturer could have recoiled more sharply from Baulieu's letter than Hilger did.

For years, Baulieu said, Hoechst had shunned him and his work. The company had “never touched” contraceptive research, much less developed abortifacients, according to Dr. Felicitas Feick, a Hoechst spokesperson.

Indeed, Hoechst had an almost tortured aversion to the drug. As one of the three largest surviving pieces of I.G. Farben, the gruesome German chemical trust that had helped build and run Auschwitz and that had developed the use of Zyklon B, a deadly pesticide, for Hitler's gas chambers, Hoechst seemed particularly haunted by the irony of having an abortion pill in its product line—a pill it had not asked for and that, perhaps worse, had been foisted on it by the contracepting, anti-German French. Primarily a drug and dye company, Hoechst itself had

not been involved in the Nazi genocide. Still, the company has tried hard, as has Germany itself, to atone for its links to barbarism. Company officials bristle at any hint of a connection to it now. Snapped Feick: “It's a different company. It's a different time. It's different people.”

There were other reasons for Hilger's reluctance. Germany has not resolved its own explosive abortion debate; part of the 1989 reunification agreement was that the German government would quickly devise a new abortion law. The former West Germany had had the most-restrictive abortion laws in Europe; the former “Eastern-land,” the most liberal. Though the United States, as a much larger market and the traditional gateway for worldwide distribution of new drugs, was more critical to Hoechst financially, Hilger's demons, it seemed, were all at home. In his one public statement on the matter, Hilger insisted that Roussel wouldn't submit RU-486 for licensing in Germany until the new abortion legislation was in place. “Anything else,” he said, “would mean throwing oil in the fire. . . .”

In the meantime, Hoechst's distinction of being the tar-

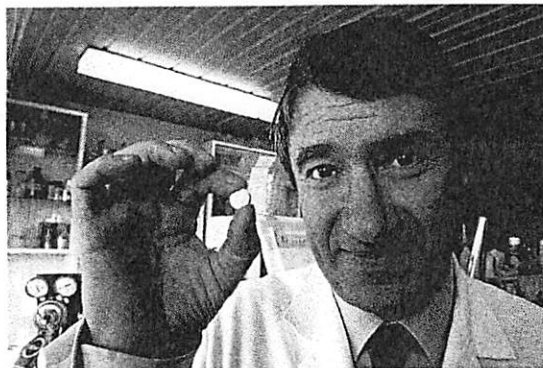
get of long-standing boycott threats in the U.S. by both pro-choice and antiabortion forces gave Hilger more reason to lay low. The National Right to Life Committee (NRLC), which years earlier had organized a boycott of the Upjohn Company over that business's development of a new generation of birth-control pills, threatened similar action against Hoechst and its U.S. subsidiary, Hoechst Celanese. Upjohn's drugs were prostaglandins, which induce menstruation and thus can be used to induce early-stage abortions. The NRLC boycott, erratic and poorly organized, lasted fourteen years and had little economic impact. But Upjohn eventually decided not to market one of the drugs in the U.S., giving the NRLC a claim of victory—a claim it was now, in 1992, reasserting. Writing to the head of Hoechst's health-policy division within days of Clinton's letter to Baulieu, Dr. Wanda Franz, the NRLC's president, warned ominously: "We wish to emphasize that the outcome of the election did not signal an end to the abortion controversy in this country, but, if anything, an intensification." Attacks on abortion clinics increased in the weeks after Clinton's victory.

Meanwhile, the pro-choice Feminist Majority Foundation was raising an equal and opposite obstacle. Founded and led by Eleanor Smeal, former president of the National Organization for Women, the group had recently stepped up its own economic campaign against Roussel and Hoechst, protesting the companies' refusal to market the drug in the United States. The group had targeted specifically Hoechst Celanese, the \$7 billion-a-year chemical manufacturer whose purchase Hilger had proudly engineered and that was one of Hoechst's most profitable divisions. Believing implicitly that Hoechst was not a "different company" from the one it once had been a part of—"Fascism and control of the womb go hand in hand," she said—the feisty, confrontational Smeal organized the multi-fronted so-called Web of Influence campaign. The group has zeroed in on various "pressure points": Celanese products (several lines of synthetic fibers) and the companies that use them (such as Nike) and the stores that sell them (Nordstrom, Lord & Taylor, Bloomingdale's); Celanese bondholders (the New York State Teachers' Retirement System, Met Life); and several unions representing Celanese workers. Like Wyden, Smeal had an almost mystical belief in RU-486's potential for treating a range of illnesses, particularly cancer, which had killed both her parents and her

brother. She also knew that heralding RU-486 as a treatment for breast cancer was good organizational strategy. Like the NRLC's Franz, she was determined to call Roussel and Hoechst to account over the drug.

How Hilger interpreted, much less factored in, these concerns was unknown: He refused to talk about RU-486 publicly. A second-generation chemist who had been with Hoechst for thirty-five years, he was known to be demanding and authoritarian, ruling through fear. The German business press considered him ruthless and cold, noting that he cuts down underlings at meetings so that they come out, as one magazine put it, "a head shorter." Clearly, Hilger would not be bullied, and his hard-line stance seemed to be reflected in letters from Roussel's Sakiz to Wyden and Kessler. Sakiz wrote noncommittally that Roussel was reviewing its position on bringing RU-486 to the American market and hoped to have a decision by the end of January. To Baulieu, Hilger wrote a terse note of thanks. Remarking on Clinton's letter, he said, "Interesting document."

"Hilger," Baulieu observed weeks later, "thinks he is the last wall . . . like the Berlin Wall. He thinks he's the last stone against disaster."



Baulieu: an eye on the Nobel prize.

With drugs, as with people, biology is destiny. RU-486 was born to be controversial because of how it works.

The drug is an anti-progestin: It blocks the hormone progesterone. During the late 1960s, a sudden awareness of the world's exploding population led researchers to seek better methods of birth control. For years, they had suspected that by interfering with progesterone activity, which increases greatly during pregnancy, they could inhibit fertility. But where to intervene? The hormone implants itself primarily in the outer wall of the uterine lining. The scientists believed that by blocking progesterone's cellular receptor—its "socket" on the cell wall, which still hadn't been found—they could bar an embryo from implanting or expel it once implanted.

Anti-progestins, as a concept, had immediate appeal. Theoretically, they would be highly situational, thus safer than the Pill or the IUD. And because these pills could be taken *after* coitus, hundreds of millions of women for whom contraception and surgical abortion were either unavailable or unviable could still use them. Scientifically, if not commercially, anti-progestins seemed to be what drug companies often hope for but seldom find: an ideal drug.

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search for anti-progestins by advising the team that discovered the hormone's receptor. For the next decade, chemists at Roussel and elsewhere tested thousands of compounds to inhibit it, finally producing RU-486, in late 1980. It was an exceptional triumph. Yet the progesterone receptor was not the drug's only—or even chief—target. RU-486 (the drug's laboratory ID number) also blocked a class of gene-regulating hormones made by the adrenal glands. The compound, which Roussel began testing on humans in 1982, could do more than simply control fertility. Discovering what these other effects were and how to manage them would define Roussel's strategy for getting the drug approved and, later, marketing it and making a profit.

In general, pharmaceutical companies welcome such "multi-indication" drugs, but developing them is tricky. From the beginning, Roussel understood that RU-486's strongest application was as an abortifacient: Used by itself, it was successful in 80 percent of cases; with a prostaglandin, which forces the uterus to contract and expel the fetus, the success rate jumped above 95 percent. As an alternative to surgical abortion—which, regardless of what one thinks of it, is breathtakingly violent and increasingly politically inconvenient—this new method seemed safer, easier: more user-friendly. Although some women experience prolonged bleeding (one had a heart attack during early combined testing of RU-486 and a prostaglandin; the prostaglandin was responsible), most report no problems. And yet there is a relatively small and uninviting market for abortion. Even in the United States, the market for RU-486 is estimated at only about \$50 million a year, less spent, for instance, than on even a second-shelf diuretic. During the next decade, Roussel would spend \$100 million trying to develop RU-486—"an enormous amount in view of the return," concedes a company official.

Roussel, which unlike Hoechst was proud of RU-486, did what all drug companies do in such cases: It sponsored a series of tedious clinical trials. It tried RU-486 as a contraceptive (promising, but with little hope of displacing established products); as a once-a-month, menses-inducing "morning-after" pill (also promising); as a cervical softener for childbirth and surgical abortion (extremely promising). Roussel also tested the drug against a range of disorders, from Cushing's syndrome (highly promising) to endometriosis (moderately promising) to glaucoma (faintly promising). Most compelling politically if not scientifically, RU-486 was tested against various tumors, particularly meningioma, a benign brain tumor that can result in blindness and memory loss (anecdotally very promising), and, in two celebrated but ambiguous studies, breast cancer (mildly promising).

To Roussel, these other uses represented potential markets: From a business perspective, the company would analyze whether to pursue them based on the drug's utility

relative to existing therapies. Politically, however, they were something more than that. They were "trapdoors," as Wyden aide Steve Jenning put it.

Strictly as an abortion pill, RU-486 was always a difficult sell in Congress and at the FDA, where support for its importation was vital. Repackaged as an anticancer agent of unknown potential, however, the drug could be expected to have an easier time. Indeed, Wyden seemed to see in the drug's other therapeutic possibilities a way to recast the debate about not only RU-486 but abortion itself. At highly publicized hearings in 1990 and again in 1991 and 1992, Wyden, a casual 44-year-old westerner who first came to Congress at 31, insisted that by banning the importation of RU-486, the Bush administration was standing in the way of an important new drug. Indeed, by forcing Roussel to test RU-486 in other countries, he claimed, the American government was sacrificing U.S. primacy in biomedical research. In Wyden's deft conception, RU-486 became a hostage to the Bush administration's toadying to the pro-life agenda, which was not only antiabortion but antiscience, in some sense even anti-American.

"It's absolutely typical of the way [pro-choice supporters]

handle the abortion issue," complained Dr. Richard Glasow, the NRLC's educational director and a Wyden critic. "They talk about everything but what an abortion is."

Wyden's calls for extensive U.S. testing of the drug echoed a wider politicization of drug research that began with AIDS and was heightened with breast cancer. And yet it also put him in direct conflict with Roussel.

Roussel's main RU-486 breast-cancer trial tested only forty-five women. A quarter of them showed some temporary improvement before all suffered relapses—intriguing results but significantly less so than those of several other drugs already available or in development. Deciding where to put their research dollars, most drug companies would look at such data, consider the cost and logistics of much larger second- and third-phase trials in which the drug being tested must compete with other treatments and quietly shut down the program. However, Wyden—supported loudly by Smeal and others—attacked Roussel for dragging its feet.

"For me, Wyden is not the best-informed person," Roussel's Ulmann said, adding that Wyden "makes more of [his] own publicity than of the truth." Still, with Wyden, Smeal and others pushing the story, a media barrage of features about RU-486's potential as an important new anticancer drug turned up the heat on the company to provide American doctors and patients access to it. Abortion began to seem almost an afterthought, a side effect, and while this may have made antiabortion activists uncomfortable in opposing the drug, it did little to further Roussel's plans. Roussel and Hoechst had already said they would not market the drug on their own in the U.S. but would look for a



Sakiz: "encouraged" to bring the pill to the U.S.

third party that would be less vulnerable to a boycott. But there was no question for either company about the drug's primary use, or on what basis a proxy would have to seek approval: RU-486 was an abortion pill.

Once in office, Clinton wasted no time in bringing abortion center stage. On January 22, two days after his inauguration, he announced in his first major initiative that he would reverse twelve years of Republican edicts on the issue, including ordering the FDA to review the ban on RU-486. Outside the White House, 75,000 antiabortion demonstrators attended the annual March for Life, commemorating the twentieth anniversary of *Roe v. Wade*, the U.S. Supreme Court ruling establishing the constitutional right to an abortion. The symbolism was all too clear. Seven years earlier, at the height of conservative influence in Washington, antiabortion leaders had met with Health and Human Services Secretary Otis Bowen on the day of their march and asked him to investigate RU-486. The meeting set in motion the events that led, several years later, to the FDA ban. Now, with the stroke of a pen, Clinton was initiating a sea change in federal policy—one, he said, that would “go a long way toward protecting vital medical and health decisions from ideological and political debate.” With so many other issues clamoring for his attention, he chose to start his presidency addressing this one.

For the FDA's Kessler, eager to impress Clinton and reassure Roussel, the reversal couldn't have come too soon. Despite Clinton's promise to appoint Republicans to high administration posts, the new president had shown no inclination to waste a choice federal job on someone who hadn't supported him or to whom he didn't owe a favor. The Bush team was all but gone, demoralized. Still, Roussel and Hoechst had long said they wouldn't seek to bring the drug into any country where the political climate was hostile. Officially, at least, that problem no longer existed (unlike in Germany, where the government remained riven). The companies would still be wary about the abortion *controversy*, which showed no similar signs of vanishing, but Kessler was not misspeaking when he indicated to Sakiz that the drug was now strongly welcomed in the U.S. Quietly, he invited Sakiz and Ulmann to Washington to discuss the changing political atmosphere.

No such salutary urges gripped the leaders of the anti-

With the stroke of a pen, Bill Clinton initiated a sea change in federal abortion policy.



Smeal: pressure through boycotts.

abortion movement. It was a grim, desperate time for them, the darkest they'd known in more than a decade. Bush's willingness to veto any pro-choice legislation had been their bulwark, covering their weaknesses, exaggerating their strengths, and now it had been removed. Even many Republicans were blaming Bush's pandering to the right-to-life movement for the party's defeat in November. Friendless, in retreat, the antiabortion movement seemed to have a single goal regarding RU-486: Let the manufacturers know that it had not been vanquished entirely, that it was still a threat.

On the fringes of the movement, pent-up forces continued to swirl. Pro-life extremists vowed to heighten their intimidation campaign against “baby-killers,” a self-styled crusade that included arson, firebombings, drive-by shootings, death threats and blockades. Across the country, they smashed windows in clinics and sprayed doctors' offices with butyric acid, a chemical that causes nausea and vomiting. They harassed doctors with phony malpractice suits, followed the doctors' spouses, taunted their children; doctors responded by wearing bulletproof vests or, more commonly, quitting in fear. “When Clinton came in,” said one of the leaders of Rescue America, a militant antiabortion group involved in the attacks, “we had to stop looking to the president and start looking to God.”

Tensions increased not only in the U.S. but worldwide. In January, Poland, which had had a liberal abortion policy under Communism, was enacting the most-restrictive measures in Eastern Europe. Meanwhile in the U.S., radical pro-choice forces, determined to force Roussel's hand, announced in mid-February that they had brought a Chinese version of RU-486 into the country for testing and that they intended to seek FDA approval for it. Since China doesn't observe international patent conventions, the intent was to force Roussel and Hoechst to respond quickly or lose the American market.

Then David Gunn was killed. Quickly elevated to martyr status by the pro-choice movement and vilified unabashedly, even gleefully, by some militant pro-lifers, Gunn became a symbol of a new *tactical* escalation in abortion politics. Eerily, a few days before the shooting, Randall Terry, founder of Operation Rescue, had announced “We've found the weak link is the doctor.”

Here suddenly was a nerve that had never before been so chillingly exposed, a nerve at the very heart of the

RU-486 controversy. There had been a time, shortly after testing of the drug began in France, in 1982, when proponents speculated (and opponents feared) that by making abortion as simple as taking a pill, RU-486 would eventually eliminate the need for clinics and thus end the abortion controversy altogether. The speculations turned out to be deeply exaggerated on both sides. In fact, many women, given the choice, prefer the swift medical efficiency of a vacuum abortion to the slower, more ambiguous and often psychologically messier experience of an abortion with RU-486.

As currently practiced, a drug-induced abortion requires more visits to a doctor, not fewer, than a surgical one—more medical supervision, not less. A woman in the first seven weeks of her pregnancy takes an RU-486 pill in a doctor's office. She is able to go home and go to work, and within the next forty-eight hours she, in effect, miscarries. She then must go back to her doctor, who gives her prostaglandin, which causes her uterus to contract, flushing the embryo along with her menstrual flow. According to Dr. Elizabeth Aubiny, a leading French gynecologist whose clinic at Paris's Hôpital Broussais has been using RU-486 since 1985 and where many women still choose surgical abortions, "The drug gives a lot of jobs to the woman. For those who say 'I don't want to see anything; I just want it to be over with,' it's not for them."

Nor is the combination of drugs problem-free. RU-486 may be safe, but the accompanying prostaglandin, needed to increase its efficacy, makes a chemical abortion cumbersome, drawn-out and, in a small percentage of cases, dangerous. Besides experiencing heavy and prolonged bleeding, some women also complain of nausea, vomiting and dizziness. Some don't completely expel the fetus, requiring a surgical abortion. Women who are over 40, who smoke heavily or who have kidney, liver or lung problems are excluded from using the drug, as are those who are anemic—a notable complication in poor countries, where RU-486 is a potential alternative to often-botched conventional abortions but where anemia is rampant. All too often, women have been guinea pigs for dangerous drugs and treatments that initially were considered safe: DES, thalidomide, the Dalkon Shield. As a few pro-choice feminists point out, the combination of RU-486 and prostaglandins may yet fall in that group.

In mid-February, confronted with headlines about American doctors' refusing to provide abortions, about the threatened raid against Roussel's patent by the bootleg Chinese drug, about the successful curbs in Poland and about persistent uncertainties within his own Germany, Hoechst's Hilger seemed more intransigent than ever. Even as advocates feared that Roussel would back down,

Hilger stood firm. Indeed, on February 22, the lead story in *The Wall Street Journal* questioned whether he would relent even in the face of U.S. government arm-twisting, which had now reached—with Clinton instructing incoming Health and Human Services Secretary Donna Shalala to "promote the testing, licensing and manufacturing" of RU-486 in the U.S.—a new height, other than in wartime or for otherwise-untreatable lethal diseases.

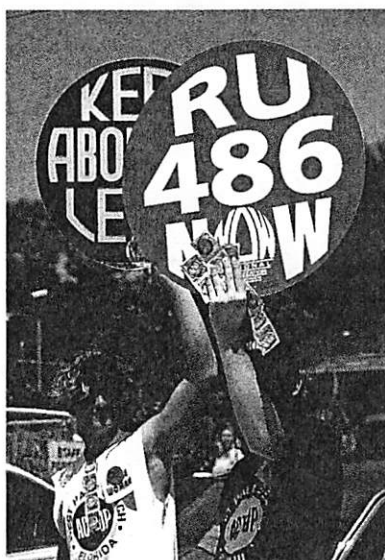
And yet, though Hilger was unwilling to let Roussel export the drug to the U.S., he was equally unwilling to give it up. Wyden had produced the names of several small companies that gladly would have licensed RU-486, but Hoechst disdained the suggestion. Said company spokesperson Feick, "Even if somebody else were to take it over, it's still our responsibility. It's our drug."

Standing alone, the FDA's headquarters, in Rockville, Maryland, towers eighteen stories, is shaped like a giant E and has hundreds of cramped numbered offices situated off endless white hallways. Only on the fourteenth floor, home of the commissioner and his senior staff, does the building concede a human presence. There, behind the commissioner's seal, are modern offices, plush furniture, splashes of color—Oz after Kansas.

Even David Kessler's critics acknowledge he has done much here, restoring confidence and teeth to what had become one of the most ineffectual, demoralized, maligned, misused and scandal-ridden federal agencies. With responsibility for ensuring the safety of products representing fully 25 percent of the nation's consumer spending, the bearded, kinetic, aggressively youthful Kessler clearly imagines himself accomplishing more at the agency.

On February 24, two days after *The Journal's* front-page story on Hoechst's recalcitrance sent stern signals to the business and political worlds, Kessler (apparently unknown to *The Journal's* editors) met finally in his office with Roussel CEO Sakiz and medical director Ulmann. Sakiz, a former biochemist, had long insisted Roussel itself would never market RU-486 in the U.S., and now when Kessler asked if the company would be willing to provide the drug through a third party, the Turkish-born Sakiz said it would. However, Roussel did not want the drug introduced solely on the basis of a European trial, as the FDA had offered in December. Roussel didn't want American doctors handing out the pills before well-controlled procedures were established for the polyglot American style of medicine, which, unlike France's, isn't state-controlled.

Kessler's glee is not hard to fathom; soon afterward, he was on the phone to *The New York Times*, which ran the story on page 1 the following day, with the FDA commissioner as its obvious main source. Equally understandable



Potential victory for pro-choice.

was Sakiz's turnaround. When the CEO of a major foreign drug company doing business in the U.S. and hoping to do more is summoned to the FDA commissioner's office on business apparently of great interest to the president—a president who was beginning to find ample political capital in bashing the drug industry—it behooves him to find a way to comply. Besides, there was an implied threat in Kessler's invitation: If he could speed up a drug's approval, he could also slow one down. If Roussel and Hoechst wanted favorable treatment for subsequent drug applications, where a simple FDA request for more data can quickly add up to tens of millions of dollars in increased development costs and lost revenues, they needed to cooperate.

Harder to figure perhaps was Hilger, who, according to Ulmann, knew about the meeting and allowed Sakiz to attend. "He could not do anything else," Ulmann said. "We have other business in the United States. He in no way could have forbidden us to go." According to this view, Kessler's intercession gave Hilger a much-desired out. For years, he had protested that Hoechst could not challenge a hostile political climate with a controversial drug—a drug that, while it might not be a blockbuster, still might be worth \$60 million to \$90 million a year to the company. Now, the decision had been made for him by forces that even he could not control. "With the people around him," said Ulmann, "Hilger can say 'I've been forced. I had no choice.'"

Hilger had not openly yielded, but he hadn't stood pat. Simply by safeguarding his company's interests, he gave Kessler the prize the FDA chief had been seeking.

On February 27, citing his technical expertise and what some department officials unironically called his "nonpolitical approach to the job," *The New York Times* announced David Kessler's reappointment as commissioner of the FDA, the highest-ranking Bush administration official to keep his job.

What will happen now? In late April, Roussel announced that it would license RU-486 to the New York City-based Population Council, which does contraceptive research, and that the nonprofit organization would be looking for a U.S. manufacturer. (Days earlier, Clinton, alarmed by predictions that the world's population may reach an estimated 15 billion within the next century—mostly in poor, dependent nations—restored federal funding to pro-choice organizations.) In a rare public statement on the matter, Hilger acknowledged that Hoechst had allowed the deal due to pressure from the Clinton administration. With U.S. testing scheduled to begin perhaps as early as this year, the drug is expected to be licensed here by 1995. Germany's own abortion controversy remains

unresolved.

For Roussel, finally successful at bringing RU-486 to the U.S., the question becomes how to market the drug. No doubt it will be extensively tested for other uses, but according to Ulmann, the likeliest follow-up for it is in obstetrics, as a cervix softener. Soon in France it will be standard practice to make the drug available to women who are undergoing surgical abortions; to reduce the risk of injury from sharp implements. The drug may also be marketed as a "morning-after" pill, and later versions, combining RU-486 with a time-released prostaglandin, are promised, bringing the pill closer to the vision of a near-perfect birth-control device that first inspired it. Using the drug as a cancer treatment seems far less of a certainty, though Roussel seems resigned to continue to test the drug's effect on tumors. It may have no choice. Keeping the pressure on the company, the Manhattan-based Abortion Rights Mobilization group announced in early April that it had copied the drug and planned to begin testing it: If Roussel didn't move quickly, the organization implied, someone else would.

Right-to-life groups have repeated their vow to boycott



Gunn's funeral: The movement gets a martyr.

the drug but are so disorganized that such an action would likely only emphasize their weaknesses. In the wake of the Gunn killing, a rift has opened in the antiabortion movement that will be harder to close now that the specter of RU-486 and the threat of liberalization have become fact.

Indeed, it was not long after the nearly simultaneous events of the Gunn slaying and Kessler's meeting with Sakiz that warring

factions in the abortion controversy adjusted themselves to face a new set of common realities. Special-interest politics rises and falls on its symbols, and as a symbol for both pro-choice and antiabortion forces (i.e., as a powerful fund-raising tool), RU-486 was far more potent outlawed than welcomed. With Clinton's ascent, contributions to pro-choice organizations dropped off steeply, as supporters began to feel that the battle had been won. Some groups laid off as many as half their workers, and long-suppressed splits among competing groups resurfaced. What the pro-choice groups did share was a new cause, a new threat: right-wing violence. And they had a made-to-order martyr, a display fixture for full-page fund-raising ads that suddenly cropped up in *The New York Times*: David Gunn.

Gunn had become the new RU-486. One drug-industry insider said cynically, "Gunn's killing was probably an aberrant act, but as a fund-raising issue it's a gold mine. Those people are going to be feeding off that corpse for the next year."

Barry Werth is the author of a forthcoming book about the pharmaceutical industry, to be published by Simon & Schuster.

CHEERLESS TED DANSON

(continued from page 93) than usual. George Wendt barrels in, wearing a Soul Asylum T-shirt. No cries of "Norm!" will ring out today. Kirstie Alley shows up with her infant son and a shaggy dog in tow. Eventually, Ted drifts in, tilting slightly backward, hips first, staring off. Although this is the 274th time he's done this drill, he has a look of dazed wonderment, like "So this is what a soundstage looks like!" Sans toupee, with his California tan and fuzzy white sideburns, he looks as if he could be Sam's funky uncle.

Watching Danson play dense, jocular Sam, you'd never know he and his demons have been going to the mat in real life. He's mastered the bartender's desperate efforts to maintain a cool veneer, and he can lighten up long enough to do some first-rate physical comedy, as when he hears that his old flame Diane Chambers (Shelley Long) is back in town after several years: Instantly panicked, he does a few of his patented manic pivots in the center of the square bar that's caged him all these years, then races around, moving a lot faster than the off-duty Danson ever seems to.

"Ted's even more introspective now," says Long. "More relaxed, wiser. But he still has that incredible comic timing!"

For years, Danson's gone back and forth on whether to keep doing *Cheers*. "I changed my mind so much, Kirstie used to call me Waffle Boy," he says. He actually had to persuade ambivalent cast members to come back for the '92-'93 season; then, in December, he announced it would be his last. The producers, Les and Glen Charles and James Burrows, considered continuing the show without him but decided against it. "This was the way to end with class and dignity," says Burrows. "Because we went out on top."

According to Harrelson, no one was outraged by Danson's decision. "Some people might have felt inconvenienced," he says, "but it's hard to be annoyed at Teddy. He is without guile. And it's hard to get pissed at someone who is doing things for perfectly good reasons. Teddy's got to get rid of some of what was him and start being who he is. This show and everything else is more about what he was."

Perhaps it was time. By the end, the show posed few creative challenges. "I'd sometimes think you could play the theme music, show a still of the bar and have some people tuning in," Danson says. "I know I was a part of something very special, because I can see it in people's faces. I look forward to not doing *Cheers* so I can turn around and see what you've all been looking at."

Danson's finally ready to try living his life without a laugh track. However, making the leap to serious (continued on page 154)



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